



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

DIVISION OF
CORPORATION FINANCE

March 7, 2018

Victor Goldfeld
Wachtell, Lipton, Rosen & Katz
vgoldfeld@wlrk.com

Re: Mallinckrodt plc

Dear Mr. Goldfeld:

This letter is in regard to your correspondence dated March 6, 2018 concerning the shareholder proposal (the "Proposal") submitted to Mallinckrodt plc (the "Company") by Mercy Investment Services, Inc. et al. (the "Proponents") for inclusion in the Company's proxy materials for its upcoming annual meeting of security holders. Your letter indicates that the Proponents have withdrawn the Proposal and that the Company therefore withdraws its January 12, 2018 request for a no-action letter from the Division. Because the matter is now moot, we will have no further comment.

Copies of all of the correspondence related to this matter will be made available on our website at <http://www.sec.gov/divisions/corpfin/cf-noaction/14a-8.shtml>. For your reference, a brief discussion of the Division's informal procedures regarding shareholder proposals is also available at the same website address.

Sincerely,

Kasey L. Robinson
Attorney-Adviser

cc: Donna Meyer
Mercy Investment Services, Inc.
dmeyer@mercyinvestments.org

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March 6, 2018

VIA EMAIL (SHAREHOLDERPROPOSALS@SEC.GOV)

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

Re: *Withdrawal of Shareholder Proposal to Mallinckrodt plc by Mercy Investment Services, Inc., Providence Trust and Catholic Health Initiatives*

Ladies and Gentlemen:

In a letter dated January 12, 2018 and a subsequent supplemental letter dated March 6, 2018 (together, the “No-Action Request”), each of which we submitted on behalf of our client, Mallinckrodt plc, an Irish public limited company (“Mallinckrodt”), we requested that the Staff of the Division of Corporation Finance (the “Staff”) of the U.S. Securities and Exchange Commission concur that Mallinckrodt could exclude from its proxy statement and form of proxy for its 2018 Annual General Meeting of Shareholders (collectively, the “2018 Proxy Materials”) a shareholder proposal (the “Proposal”) and the statement in support thereof

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received from Mercy Investment Services, Inc., Providence Trust, and Catholic Health Initiatives (collectively, the "Proponents") for proposed inclusion in the 2018 Proxy Materials.

Enclosed as Exhibit A is a letter dated March 6, 2018 from Ms. Donna Meyer of Mercy Investment Services, Inc. formally withdrawing the Proposal on behalf of the Proponents. In reliance on this letter, we hereby withdraw the No-Action Request and ask that the Staff give no further consideration to this matter. A copy of this letter is being sent simultaneously to the Proponents as notification of Mallinckrodt's withdrawal of the No-Action Request.

If we can be of any further assistance in this matter, please do not hesitate to contact me at (212) 403-1005 or by email to VGoldfeld@wlrk.com.

Very truly yours,

A handwritten signature in black ink that reads "Victor Goldfeld". The signature is written in a cursive, flowing style.

Victor Goldfeld

Enclosures

cc: Mark Casey, Mallinckrodt plc
Stephanie D. Miller, Mallinckrodt plc

Exhibit A



March 6, 2018

Stephanie D. Miller
Vice President, Corporate Secretary and International Legal
Mallinckrodt
675 McDonnell Boulevard
Hazelwood, MO 630242 USA

Dear Ms. Miller:

Thank you for your mail dated March 5, 2018, which informed shareholder proponents that Mallinckrodt Pharmaceuticals is proposing to dispose of its opioid manufacturing business. This intent was further confirmed by the letter today from Andrew Kenny with Wachtell, Lipton, Rosen & Katz.

Based on this information, proponent shareholders, including Mercy Investment Services, Inc., Providence Trust, and Catholic Health Initiatives would like to withdraw the resolution requesting that the board of directors of Mallinckrodt (MNK) prepare a report to shareholders by September 30, 2018, on measures MNK has taken to mitigate business risks related to its opioid business. We agree that the pending divestiture of MNK's opioid manufacturing business substantially undermines the relevance of the requested report to MNK's business and its shareholders. We hope you will withdraw your SEC no-action request.

As shareholders, we will continue to be interested in the long-term success of our Company. We thank staff and independent board members for their concern about the opioid epidemic in the U.S. and their willingness to engage with shareholders about this issue.

Sincerely,

A handwritten signature in cursive script, appearing to read "Donna Meyer".

Donna Meyer, PhD

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March 6, 2018

VIA EMAIL (SHAREHOLDERPROPOSALS@SEC.GOV)

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

Re: *Shareholder Proposal to Mallinckrodt plc by Mercy Investment Services, Inc.,
Providence Trust and Catholic Health Initiatives*

Ladies and Gentlemen:

On behalf of our client, Mallinckrodt plc, an Irish public limited company (“Mallinckrodt” or the “Company”), we write to supplement the no-action request letter dated January 12, 2018 that we submitted on behalf of Mallinckrodt (the “Initial Request Letter”) regarding the shareholder proposal (the “Proposal”) and the statement in support thereof received from Mercy Investment Services, Inc., Providence Trust, and Catholic Health Initiatives (collectively, the “Proponents”) for proposed inclusion in Mallinckrodt’s proxy statement and

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form of proxy for its 2018 Annual General Meeting of Shareholders (collectively, the “2018 Proxy Materials”).

We are submitting this letter on behalf of Mallinckrodt to provide information regarding an update to the Company’s business plans since the date of the Initial Request Letter and to address certain aspects of the letter dated February 9, 2018 submitted by the Proponents (the “Proponents’ Response Letter”) to the Staff of the Division of Corporation Finance (the “Staff”) of the U.S. Securities and Exchange Commission (the “Commission”), a copy of which is attached hereto as Exhibit A.

Pursuant to Rule 14a-8(j) under the Exchange Act, we have:

- transmitted this letter by email to the Staff at shareholderproposals@sec.gov; and
- concurrently sent copies of this letter, together with its attachments, to the Proponents at the email addresses they have provided.

As counsel to the Company, we continue to request confirmation that the Staff will not recommend enforcement action if the Company excludes the Proposal from the 2018 Proxy Materials for the reasons set forth in the Initial Request Letter and this letter. This letter supplements, and does not replace, the Initial Request Letter.

CHANGE IN THE COMPANY’S BUSINESS PLANS

Since the submission of the Initial Request Letter and the Proponent’s Response Letter, as announced by the Company on February 27, 2018, the Company has reclassified its Specialty Generics business segment as discontinued operations, effective as of December 29, 2017. Mallinckrodt plans to dispose of these businesses, which include the Company’s opioid manufacturing business, because they do not align with Mallinckrodt’s strategic vision of becoming a brands-focused innovation-driven specialty pharmaceutical growth company. The Company continues to believe that the Proposal is excludable from the 2018 Proxy Materials for the reasons set forth in the Initial Request Letter. We will not repeat those reasons here. But the pending divestiture of the Company’s opioid manufacturing business substantially undermines the purported relevance, if any, of the proposed report to the Company’s business and its shareholders. As noted on page 11 of the Initial Response Letter, “[o]pioid products [already] account for only a small portion—less than 10%—of Mallinckrodt’s total revenues.” Following the pending divestiture, those revenues will fall to zero.

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THE PROPONENTS' RESPONSE LETTER

The Proponent's Response Letter cites a variety of recent articles and reports related to the opioid crisis, including various reports regarding perceived or alleged governance failures by companies other than Mallinckrodt, and in particular Purdue Pharma L.P., a privately held company that manufactures opioid products. These facts (and/or allegations), whatever their validity, are not relevant to the Company's governance procedures in general or its historical role in combating the opioid crisis in particular, or to the question of whether the proposal transcends the Company's ordinary business operations or has the necessary nexus to the Company. The mere fact that the Company operates in the same industry is not sufficient to demonstrate that the Proposal is required to be included in the Company's Proxy Materials.

The Proponents also reference the Staff's recent determination that a similar proposal was not excludable by AmerisourceBergen, asserting that "[i]f the nexus is strong enough for a distributor, manufacturers, who are blamed equally, if not more, for opioid misuse, must have a sufficiently strong nexus." This conclusory assertion is made with no support, and it is not supportable. As explained in the Initial Request Letter, Mallinckrodt does not market or promote its opioid products directly to physicians or patients. The Proponents' attempt to paint all manufacturers and distributors with the same broad brush likewise fails to demonstrate that their proposal transcends the Company's ordinary business operations or has the necessary nexus to the Company.

Separately, on page 9, the Proponent's Response Letter refers to the section of the Initial Request Letter explaining that there is not a sufficient nexus between the nature of the Proposal and the Company, because (among other reasons) opioid products constitute only a small portion of Mallinckrodt's revenues (which, as noted above, are now expected to be reduced to zero). The Response Letter asserts that "an argument like this one about nexus should be part of a submission reflecting the board's consideration of the Proposal's subject in the context of the company's business" as contemplated by Staff Legal Bulletin No. 14I, which announced a new Staff policy regarding the application of Rule 14a-8(i)(7). However, the Initial Request Letter states expressly on page 8 that "[t]he Nominating and Governance Committee (the "Governance Committee") of the Board reviewed the Proposal and Supporting Statement in consultation with management, and the discussion herein reflects the review and analyses of the Governance Committee, which was subsequently approved by the full Board, as well as the Company's management."

REQUEST FOR EXCLUSION

The Company respectfully requests that the Staff concur in its view that the Proposal and the Supporting Statement may be excluded from the 2018 Proxy Materials pursuant to (i) Rule 14a-8(i)(7), because the Proposal involves matters that relate to the ordinary business

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operations of the Company and/or (ii) Rule 14a-8(i)(10), because the Company has already substantially implemented the Proposal.

CONCLUSION

Based on the foregoing and the reasons set forth in the Initial Request Letter, the Company respectfully requests the Staff's concurrence with the Company's view or, alternatively, that the Staff confirm that it will not recommend any enforcement action if the Company excludes the Proposal and the Supporting Statement from the 2018 Proxy Materials.

If we can be of any further assistance in this matter, please do not hesitate to call the undersigned at (212) 403-1005. If the Staff is unable to concur with the Company's conclusions without additional information or discussions, the Company respectfully requests the opportunity to confer with members of the Staff prior to the issuance of any written response to this letter. In accordance with Staff Legal Bulletin No. 14F, Part F (Oct. 18, 2011), please send your response to this letter and in the Initial Request Letter by email to VGoldfeld@wlrk.com.

Very truly yours,

A handwritten signature in black ink that reads "Victor Goldfeld". The signature is written in a cursive, slightly slanted style.

Victor Goldfeld

Enclosures

cc: Mark Casey, Mallinckrodt plc
Stephanie D. Miller, Mallinckrodt plc

Exhibit A



February 9, 2018

[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 Mallinckrodt plc to omit proposal submitted by Mercy Investment Services, Providence Trust and co-filers

Ladies and Gentlemen,

Pursuant to Rule 14a-8 under the Securities Exchange Act of 1934, Mercy Investment Services Inc., Providence Trust and Catholic Health Initiatives (together, the "Proponents") submitted a shareholder proposal (the "Proposal") to Mallinckrodt plc ("Mallinckrodt" or the "Company"). The Proposal asks Mallinckrodt's board to report to shareholders on governance measures ABC has implemented since 2012 to more effectively monitor and manage financial and reputational risks related to the opioid crisis in the U.S.

In a letter to the Division dated January 12, 2018 (the "No-Action Request"), Mallinckrodt stated that it intends to omit the Proposal from its proxy materials to be distributed to shareholders in connection with the Company's 2018 annual meeting of shareholders. Mallinckrodt argues that it is entitled to exclude the Proposal in reliance on Rule 14a-8(i)(7), as relating to Mallinckrodt's ordinary business operations; and Rule 14a-8(i)(10), on the ground that Mallinckrodt has substantially implemented the Proposal. As discussed more fully below, Mallinckrodt has not met its burden of proving its entitlement to rely on either exclusion; accordingly, the Proponents respectfully ask that the Company's request for relief be denied.

The Proposal

The Proposal states:

"RESOLVED, that shareholders of Mallinckrodt plc ("Mallinckrodt") urge the Board of Directors (the "Board") to report to shareholders by September 30, 2018 on the governance measures Mallinckrodt has implemented since 2012 to more effectively monitor and manage financial and reputational risks related to the opioid crisis in the U.S., given Mallinckrodt's sale of opioid medications and active

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pharmaceutical ingredients in opioid medications, including whether Mallinckrodt has assigned responsibility for such monitoring to the Board or one or more Board committees, revised senior executive compensation metrics or policies, adopted or changed mechanisms for obtaining input from stakeholders, or altered policies or processes regarding company political activities.

The report should be prepared at reasonable cost and should omit confidential and proprietary information.”

Ordinary Business

Mallinckrodt argues that it is entitled to omit the Proposal in reliance on Rule 14a-8(i)(7), which allows exclusion of proposals related to a company’s ordinary business operations. Specifically, Mallinckrodt urges that the Proposal’s subject is the “manufacture and sale of products” or the Company’s compliance program and that the Proposal does not deal with a significant social policy issue with a nexus to Mallinckrodt. Mallinckrodt also claims the Proposal would micromanage the Company.

As discussed below, Mallinckrodt has not met its burden of establishing that the Proposal relates to its ordinary business operations. The Proposal addresses a significant social policy issue with which opioid manufacturers have a strong connection. The Proposal asks for disclosure of governance measures, not a specific policy change or detailed reporting about operations, and thus cannot be said to micromanage Mallinckrodt. Accordingly, the Proponents ask that Mallinckrodt’s request for relief be denied.

The Opioid Crisis Is a Significant Social Policy Issue and a Strong Nexus to Opioid Manufacturers Exists

The opioid epidemic is undoubtedly a “sustained” and “consistent topic of widespread public debate,” the standard the Staff has applied in determining whether a proposal deals with a significant social policy issue.¹

According to the Center for Disease Control and Prevention (“CDC”), the number of opioid painkillers dispensed in the U.S. quadrupled from 1999 to 2010, despite no change in reported pain levels.² In 2015, opioid overdoses killed more than 33,000 Americans, and that number is expected to be up significantly when official data for 2016 are released.³ Opioid addiction alone has lowered U.S. average life expectancy by 2.5 months.⁴

The sheer volume of national media coverage, expressions of public sentiment and legislative and regulatory initiatives spawned by the opioid epidemic precludes an exhaustive list. Some key examples are:

¹ See Exchange Act Release No. 40018 (May 21, 1998); Comcast Corp. (Mar. 4, 2011); Verizon Communications Inc. (Feb. 13, 2012).

² <https://www.cdc.gov/drugoverdose/epidemic/index.html>.

³ Centers for Disease Control and Prevention data on 2015 deaths (<https://www.cdc.gov/drugoverdose/>); Lenny Bernstein, “Deaths from Drug Overdoses Soared in the First Nine Months of 2016,” *The Washington Post*, Aug. 8, 2017 (<https://www.washingtonpost.com/news/to-your-health/wp/2017/08/08/deaths-from-drug-overdoses-soared-in-the-first-nine-months-of-2016/>) (“Given available state data and anecdotal information, many experts are expecting a big increase in deaths in 2016, driven by the worsening crisis in overdoses from opioids, especially fentanyl and heroin”).

⁴ <http://www.chicagotribune.com/news/nationworld/ct-opioids-life-expectancy-20170920-story.html>

- President Trump declared the opioid epidemic a public health emergency in October 2017.⁵ He has empaneled a Presidential Commission on Combating Addiction and the Opioid Crisis to make recommendations on the federal response.⁶
- During the 2016 Presidential election campaign, addressing the opioid crisis ranked as the most important issue for voters in some areas.⁷ Candidates discussed the opioid epidemic on the campaign trail in both the primaries⁸ and general election.⁹
- Continuous coverage of the epidemic over the past several years in national publications, including The New York Times,¹⁰ The Washington Post,¹¹ The Wall Street Journal¹² and USA Today.¹³
- Seventy-three bills dealing with opioids have been introduced in the 115th Congress, including the Effective Opioid Enforcement Act, the DEA Opioid Enforcement Restoration Act, the Opioid Addiction Prevention Act and the Combating the Opioid Epidemic Act.¹⁴
- Concerns over the effect of cuts in Medicaid and resulting loss of access to opioid addiction treatment featured prominently in the debate over repeal of the Affordable Care Act.¹⁵
- Local budgets are being strained by the increase in opioid overdoses and hikes in the price of overdose reversal drug naloxone.¹⁶
- The opioid epidemic is taxing child welfare and foster care systems: Between 2013 and 2016, the number of children removed from their parents' care grew by 40%, driven mainly by opioid

⁵ <http://www.cnn.com/2017/10/26/politics/donald-trump-opioid-epidemic/index.html>

⁶ <https://www.whitehouse.gov/the-press-office/2017/03/30/presidential-executive-order-establishing-presidents-commission>

⁷ <https://www.wsj.com/articles/drug-deaths-becoming-a-2016-presidential-election-issue-1446596075>

⁸ E.g., <https://www.wsj.com/articles/drug-deaths-becoming-a-2016-presidential-election-issue-1446596075>; <http://www.cnn.com/2016/02/06/politics/donald-trump-new-hampshire-drug-epidemic/index.html>

⁹ E.g., <https://web.archive.org/web/20170504001021/https://www.donaldjtrump.com/press-releases/donald-j.-trump-remarks-in-portsmouth-nh>

¹⁰ E.g., <https://www.nytimes.com/2017/01/06/us/opioid-crisis-epidemic.html>;

<https://www.nytimes.com/2017/10/26/us/opioid-crisis-public-health-emergency.html>;

<https://www.nytimes.com/2017/08/21/health/hospitals-opioid-epidemic-patients.html>;

<https://www.nytimes.com/2016/02/22/us/politics/governors-devise-bipartisan-effort-to-reduce-opioid-abuse.html>;

<https://www.nytimes.com/2014/06/18/us/governors-unite-to-fight-heroin-in-new-england.html>;

<https://www.nytimes.com/2015/01/13/us/after-stabilizing-overdose-deaths-rose-in-2013-.html>.

¹¹ E.g., https://www.washingtonpost.com/graphics/2017/investigations/dea-drug-industry-congress/?tid=a_inl&utm_term=.84592cf7ad5d; https://www.washingtonpost.com/national/health-science/no-longer-mayberry-a-small-ohio-city-fights-an-epidemic-of-self-destruction/2016/12/29/a95076f2-9a01-11e6-b3c9-f662adaa0048_story.html?tid=sm_fb&utm_term=.91264e23e0fa; https://www.washingtonpost.com/news/to-your-health/wp/2017/03/?utm_term=.c6d46b0eeefe.

¹² E.g., <http://www.wsj.com/graphics/toll-of-opioids/>; <https://www.wsj.com/articles/opioid-addiction-diagnoses-up-nearly-500-in-past-seven-years-study-shows-1498737603>; <https://www.wsj.com/articles/colleges-take-action-on-opioid-epidemic-1494158403?tesla=y>; <https://www.wsj.com/articles/the-children-of-the-opioid-crisis-1481816178>.

¹³ <https://www.usatoday.com/story/news/politics/2017/10/23/fda-chief-supports-opioid-prescription-limits-regrets-agencys-prior-inaction/774007001/>; <https://www.usatoday.com/story/news/2017/11/08/its-far-more-than-overdoses-iv-opioid-users-diseases-overwhelm-hospitals/821693001/>;

<https://www.usatoday.com/story/news/nation/2016/09/25/drug-addiction-treatment-insurance-heroin/91079496/>;

¹⁴ Data as of November 20, 2017 from Carol Nolan Drake, President and CEO, Carlow Consulting LLC (private correspondence dated November 20, 2017).

¹⁵ E.g., <http://www.latimes.com/politics/la-na-pol-obamacare-repeal-opioids-20170621-story.html>;

<http://www.nejm.org/doi/full/10.1056/NEJMp1700834#t=article>

¹⁶ <https://www.cnn.com/2017/01/04/as-opioid-epidemic-worsens-the-cost-of-waking-up-from-an-overdose-soars.html>; https://www.washingtonpost.com/world/as-opioid-overdoses-exact-a-higher-price-communities-ponder-who-should-be-saved/2017/07/15/1ea91890-67f3-11e7-8eb5-cbcc2e7bfbf_story.html?utm_term=.adb4f9214ba6.

addiction.¹⁷ Several Ohio counties asked voters to approve ballot initiatives providing additional funding for family services in November 2017 due to opioid addiction.¹⁸

- Opioid use has been identified as a possible reason working-age men's participation in the labor force has been low.¹⁹
- The hospital costs associated with treating addicted newborns rose to \$1.5 billion in 2013, from \$732 million in 2009, according to a study in the Journal of Perinatology.²⁰ Stories like the one about James Schenk, born addicted to opioids, illustrate the difficulties of weaning these babies after birth.²¹

Mallinckrodt claims that manufacturers are too remote from physicians and patients to have a sufficiently strong nexus to the opioid crisis. But manufacturers of opioid medication have played an important role in creating and perpetuating the opioid crisis, and they are facing efforts to hold them accountable for their behavior, both legally and otherwise.

Numerous large cities, including Chicago, New York, Philadelphia and Seattle, and countless more small municipalities,²² have sued opioid manufacturers in the past few years.²³ States²⁴ and counties²⁵ have done the same. Suits claim that manufacturers made misleading marketing claims, downplaying the risk of addiction and the efficacy of opioids for chronic pain, leading to opioid abuse and associated costs.²⁶ More than 250 cases have been consolidated in Ohio, where they are being overseen by Judge Dan Polster. Judge Polster has convened not only the parties in these cases, but others such as addiction experts, representatives of insurance companies, and officials of the FDA and DEA, with the goal of producing a settlement.²⁷

¹⁷ <https://www.wsj.com/articles/the-children-of-the-opioid-crisis-1481816178>

¹⁸ <https://www.nytimes.com/aponline/2017/11/06/us/ap-us-opioid-crisis-children.html>

¹⁹ <https://nypost.com/2017/07/23/yellen-links-opioid-crisis-to-low-workforce-participation/>

²⁰ <https://www.nytimes.com/2016/12/12/health/rise-in-infant-drug-dependence-in-us-is-felt-most-in-rural-areas.html>

²¹ http://host.madison.com/wsj/news/local/health-med-fit/babies-dependent-on-opioids-wisconsin-sees-surge-in-infants-born/article_1da6faee-827d-5435-aada-23a1d5fc8024.html

²² <http://hot96.com/news/articles/2018/feb/07/city-of-evansville-suing-opioid-manufacturers/>

²³ <https://www.citylab.com/life/2017/10/the-cities-suing-big-pharma-over-opioids/542484/>; J. David Goodman & William Neuman, "New York City Sues Drug Companies Over Opioid Crisis," The New York Times, Jan. 23, 2018 (<https://www.nytimes.com/2018/01/23/nyregion/nyc-de-blasio-opioid-lawsuit.html>)

²⁴ <https://www.theatlantic.com/business/archive/2017/06/lawsuit-pharmaceutical-companies-opioids/529020/>; <https://www.nbcphiladelphia.com/news/local/New-Jersey-Sues-Evil-Painkiller-Company-449651983.html>; http://www.theadvocate.com/baton_rouge/news/crime_police/article_7c667572-02f8-11e8-ba90-53c92cef1f7c.html; https://www.google.com/search?q=opioid+manufacturers&ei=T_l8WtCKGYOO5wKyi5LgCw&start=30&sa=N&biw=1352&bih=693

²⁵ E.g., <https://www.lohud.com/story/news/health/2018/02/06/westchester-targets-pharma-heroin-opioid-crisis-taxpayers/307951002/>; <http://www.islandpacket.com/news/local/article198598909.html>; <http://www.baltimoresun.com/news/maryland/baltimore-city/bs-md-ci-city-opioid-suit-20180131-story.html>; http://www.syracuse.com/news/index.ssf/2018/01/onondaga_county_sues_drug_companies_over_opioid_crisis.html; <http://www.gainesville.com/news/20180208/alachua-osceola-counties-take-aim-at-opioid-manufacturers>

²⁶ J. David Goodman & William Neuman, "New York City Sues Drug Companies Over Opioid Crisis," The New York Times, Jan. 23, 2018 (<https://www.nytimes.com/2018/01/23/nyregion/nyc-de-blasio-opioid-lawsuit.html>); see also Rebecca L. Haffajee & Michelle M. Mello, "Drug Companies' Liability for the Opioid Epidemic," New England Journal of Medicine, Dec. 14, 2017 (<http://www.nejm.org/doi/full/10.1056/NEJMp1710756>)

²⁷ <https://www.usnews.com/news/news/articles/2018-01-30/federal-judge-wants-opioid-lawsuits-to-end-in-settlement>

Whether opioid manufacturers are ultimately held legally liable for various costs associated with the opioid crisis, they are being held responsible in the broader public debate about appropriate public policy responses and measures to deter opioid abuse. One article on the opioid crisis summed up this view as follows: “Managing pain, specifically chronic pain, is an essential part of any doctor’s practice. It is terrible to see people suffer and whenever possible and prudent, pain should be treated. And some of the players in this story were driven by real concern for patients’ quality of life. But others, specifically the manufacturers, were driven by crasser motives: the realization that they could make a fortune by pushing for wider use of prescription opioids.”²⁸

More specifically, drug manufacturers have been attacked for their promotion of opioid medications, both directly and indirectly. Materials provided to patients claimed that addiction was a “myth” and “rarely” occurred when opioids were prescribed for chronic pain. The PainKnowledge.com website, sponsored by Endo, made similar claims.²⁹ The study often cited in support of these assertions was very small, only 38 patients, and its author no longer stands behind it.³⁰

The American Pain Foundation (“APF”), described in a 2011 ProPublica investigation as an “influential champion” for opioids, came under scrutiny early in the opioid crisis. The ProPublica investigation, published in the Washington Post,³¹ revealed that the APF garnered nearly 90% of its funding in 2010 from the drug and medical device industry.³² It also unearthed financial relationships between opioid manufacturers and APF board members.³³ Critics charged that it was serving as an ostensibly “patient-oriented” mouthpiece for opioid makers. The APF’s publications were charged with being misleading and inappropriately downplaying the risks associated with opioids.³⁴ For example, the APF put out a publication sponsored by OxyContin manufacturer Purdue Pharma, asserting that only 1% of children prescribed opioids become addicted.³⁵

In 2012, the Senate Finance Committee, as part of an investigation into drug manufacturers’ responsibility for the opioid epidemic, wrote to the APF requesting information about funding of the APF by opioid manufacturers, collaborations between the APF and those funders and distribution of any publications written by opioid manufacturers.³⁶ The same day the letter was sent, the APF announced that it was immediately dissolving.³⁷

A 2016 investigation by the Associated Press and Center for Public Integrity described a “pro-painkiller echo chamber” in Washington DC created by the Pain Care Forum (“PCF”), a “loose coalition of

²⁸http://www.slate.com/articles/health_and_science/medical_examiner/2016/06/prince_s_death_reveals_how_wrong_our_over_reliance_on_dangerous_opioids.html

²⁹ <https://www.vox.com/policy-and-politics/2017/6/7/15724054/opioid-companies-epidemic-lawsuits>

³⁰

http://www.slate.com/articles/health_and_science/medical_examiner/2016/06/prince_s_death_reveals_how_wrong_our_over_reliance_on_dangerous_opioids.html

<https://www.wsj.com/articles/SB10001424127887324478304578173342657044604> (interview with study author Dr. Russell Portenoy)

³¹ https://www.washingtonpost.com/national/health-science/patient-advocacy-group-funded-by-success-of-painkiller-drugs-probe-finds/2011/12/20/gIQAgvczDP_story.html?utm_term=.1c1e597c5206

³² <https://www.propublica.org/article/the-champion-of-painkillers>

³³ <https://www.propublica.org/article/two-leaders-in-pain-treatment-have-long-ties-to-drug-industry>

³⁴ <https://www.propublica.org/article/the-champion-of-painkillers>

³⁵ <https://www.vox.com/policy-and-politics/2017/6/7/15724054/opioid-companies-epidemic-lawsuits>

³⁶ <https://www.documentcloud.org/documents/354941-opioid-investigation-letter-to-american-pain.html>

³⁷ <https://www.propublica.org/article/senate-panel-investigates-drug-company-ties-to-pain-groups>

drugmakers, trade groups and dozens of nonprofits supported by industry funding.”³⁸ It was founded by the Washington lobbyists for Purdue Pharma, the OxyContin manufacturer that in 2007 settled claims of deceptive promotion of that drug. The investigation found that PCF participants spent massive amounts on lobbying, including on opioid-related matters, and political contributions.³⁹ The APF was “one of the [PCF’s] principal members.”⁴⁰ The PCF played a role in watering down the FDA’s risk management plan around opioids, generating thousands of public comments.⁴¹ Senator Ron Wyden raised concerns last year about the participation of industry-financed groups in an FDA workshop on opioid prescribing.⁴²

Opioid manufacturers also influenced physicians through medical groups such as the American Pain Society (“APS”) and the American Academy of Pain Medicine. Many fault these groups’ increased emphasis on eliminating pain for contributing to the opioid crisis and trace the origin of that shift to the keynote address of the 1996 annual conference of the APS, which coined the phrase “the fifth vital sign” to encourage physicians to take pain management more seriously.⁴³ Purdue Pharma contributed funding to the APS during this time.⁴⁴

Purdue also funded programs of the Joint Commission (formerly known as the Joint Commission on Accreditation of Healthcare Organizations) for complying with standards regarding pain management; the Joint Commission’s 1999 pain policy stated that “Some clinicians have inaccurate and exaggerated concerns about addiction, tolerance and risk of death . . . despite the fact there is no evidence that addiction is a significant issue when persons are given opioids for pain control.”⁴⁵ A CNN story from 2016 reported that the Joint Commission produced a book for use in continuing medical education, funded by Purdue, calling physician worries about opioid addiction “inaccurate and exaggerated.”⁴⁶

Similarly, a Purdue executive helped draft a 1998 policy from the Federation of State Medical Boards aimed at alleviating physician anxieties that they would be pursued by regulators for prescribing opioids; the Federation published an industry-funded book about the policy, pocketing the proceeds.⁴⁷

Reviewing the history of the opioid abuse crisis, an article in the Cleveland Clinic Journal of Medicine explained the role of manufacturers: “Opportunistically, or perhaps wielding inappropriate and

³⁸ <https://www.apnews.com/3d257452c24a410f98e8e5a4d9d448a7>

³⁹ <https://www.apnews.com/3d257452c24a410f98e8e5a4d9d448a7>

⁴⁰ <https://www.apnews.com/3d257452c24a410f98e8e5a4d9d448a7>

⁴¹ <https://www.apnews.com/3d257452c24a410f98e8e5a4d9d448a7>

⁴²

<https://www.finance.senate.gov/imo/media/doc/050517%20Senator%20Wyden%20to%20Secretary%20Price%20re%20FDA%20Opioid%20Prescriber%20Working%20Group.pdf>

<http://www.modernhealthcare.com/article/20170508/NEWS/170509883>

⁴³ <https://www.vox.com/2017/6/5/15111936/opioid-crisis-pain-west-virginia>;

http://www.slate.com/articles/health_and_science/medical_examiner/2016/06/prince_s_death_reveals_how_wrong_or_over_reliance_on_dangerous_opioids.html

⁴⁴ <https://www.vox.com/2017/6/5/15111936/opioid-crisis-pain-west-virginia>

⁴⁵

http://www.slate.com/articles/health_and_science/medical_examiner/2016/06/prince_s_death_reveals_how_wrong_or_over_reliance_on_dangerous_opioids.html

⁴⁶ <https://www.cnn.com/2016/05/12/health/opioid-addiction-history/>

⁴⁷ <https://www.wsj.com/articles/SB10001424127887324478304578173342657044604>

sketchy influence, some drug manufacturers in the early 2000s funded publications and physician presentations to encourage the expanded use of opioids and other medications for pain control.”⁴⁸

In September 2017, forty-one attorneys general wrote to America’s Health Insurance Plans (“AHIP”), the trade association for health insurers, asking it to “encourage [its] members to review their payment and coverage policies . . . to encourage healthcare providers to prioritize non-opioid pain management options over opioid prescriptions for the treatment of chronic, non-cancer pain.”⁴⁹ AHIP launched the Safe, Transparent Opioid Prescribing (“STOP”) Initiative, which is “designed to support widespread adoption of clinical guidelines for pain care and opioid prescribing,” a month later.⁵⁰ As part of STOP, AHIP released the STOP Measure, which allows plans to compare physician prescribing practices to the Centers for Disease Control (“CDC”) Guideline for Prescribing Opioids for Chronic Pain.⁵¹

The CDC Guideline was released in March 2016, after a notice and comment process, to help physicians decide whether to prescribe opioids and to provide advice on “medication selection, dosage, duration and discontinuation of treatment.”⁵² An article in *JAMA Internal Medicine* reviewed the comments submitted on the Guideline and found that, among the 150 organizations that submitted comments, opposition to the Guideline was associated with having received funding from opioid manufacturers, as was opposition specifically to the recommendations about dosing and duration of treatment.⁵³

The Senate’s Homeland Security and Governmental Affairs Committee opened an investigation in Mar. 2017 into the makers of the five opioid medications with the highest sales.⁵⁴ The investigation sought to determine “whether pharmaceutical manufacturers—at the head of the opioids pipeline—have contributed to opioid over-utilization and over-prescription”⁵⁵ Senator Claire McCaskill, in her letter to the manufacturers, who did not include Mallinckrodt, opined that the opioid epidemic “is the direct result of a calculated sales and marketing strategy major opioid manufacturers have allegedly pursued over the past 20 years to expand their market share and increase dependency on powerful — and often deadly — painkillers.”⁵⁶ Specifically, she wrote, manufacturers “downplay[ed] the risk of addition”

In sum, the opioid abuse crisis is one of the most urgent social problems facing the U.S., with major effects on health, prosperity and well-being. Significant attention and criticism have focused on opioid manufacturers for deceptively promoting opioids, inappropriately intervening the legislative and political process and influencing physician prescribing, both directly and indirectly, through trade associations and other groups. Accordingly, the subject of the Proposal—how Mallinckrodt has changed its corporate

⁴⁸ <https://www.mdedge.com/ccjm/article/109138/drug-therapy/fifth-vital-sign-complex-story-politics-and-patient-care>

⁴⁹ [http://myfloridalegal.com/webfiles.nsf/WF/JMAR-ARCKCD/\\$file/NAAG-Opioid-Letter-to-AHIP.pdf](http://myfloridalegal.com/webfiles.nsf/WF/JMAR-ARCKCD/$file/NAAG-Opioid-Letter-to-AHIP.pdf)

⁵⁰ <https://www.ahip.org/health-plans-launch-new-stop-initiative-to-help-battle-opioid-crisis-in-america/>

⁵¹ <https://www.ahip.org/health-plans-launch-new-stop-initiative-to-help-battle-opioid-crisis-in-america/>

⁵² <https://www.cdc.gov/media/releases/2016/p0315-prescribing-opioids-guidelines.html>

⁵³ <https://jamanetwork.com/journals/jamainternalmedicine/article-abstract/2598092?redirect=true>

⁵⁴ Dan Mangan, “Opioid Epidemic: Senate Committee Opens Probe of Five Big Painkiller Makers,” CNBC, Mar. 28, 2017 (<https://www.cnbc.com/2017/03/28/senate-committee-opens-probe-of-five-big-opioid-makers.html>); <https://www.motherjones.com/politics/2017/03/opioid-investigation-mccaskill-pharmaceutical-companies/>

⁵⁵ Dan Mangan, “Opioid Epidemic: Senate Committee Opens Probe of Five Big Painkiller Makers,” CNBC, Mar. 28, 2017 (<https://www.cnbc.com/2017/03/28/senate-committee-opens-probe-of-five-big-opioid-makers.html>)

⁵⁶ Dan Mangan, “Opioid Epidemic: Senate Committee Opens Probe of Five Big Painkiller Makers,” CNBC, Mar. 28, 2017 (<https://www.cnbc.com/2017/03/28/senate-committee-opens-probe-of-five-big-opioid-makers.html>)

governance to monitor and manage opioid-related risks—is a significant social policy issue with a strong connection to Mallinckrodt.

The “Sale of Products” Determinations Do Not Apply Because the Proposal Deals with a Significant Social Policy Issue

Mallinckrodt rests its argument on previous determinations in which the Staff permitted companies that sold or distributed products to exclude proposals related to those products on ordinary business grounds. The proposals in those determinations, which fall into three categories, differ from the Proposal in important ways. Mallinckrodt also neglected to mention a recent determination declining to allow exclusion on ordinary business grounds of a proposal nearly identical to the Proposal submitted at a pharmaceutical distributor.

First, Mallinckrodt points to proposals submitted last year to AbbVie⁵⁷ and Johnson & Johnson,⁵⁸ which asked those companies to report on their policies for safe disposal of prescription drugs to prevent water pollution and possible options to address that problem, including the endorsement or funding of industry take-back programs. Both AbbVie and Johnson & Johnson argued, among other things, that the proposals dealt with their ordinary business operations, urging that they addressed customer disposal and misuse of their products. The Staff concurred with the companies’ positions, stating simply that the proposals related to the companies’ ordinary business operations.

The Staff thus implicitly rejected the proponents’ claims that the proposals dealt with a significant social policy issue. In opposing the Johnson & Johnson no-action request, the proponent had argued that the proposals addressed “the significant public policy issue of reducing water pollution caused by disposal of used pharmaceuticals.” In responding to both requests, the proponents had attempted to tie the take-back issue to the larger problem of the opioid crisis.

The AbbVie and Johnson & Johnson determinations are not dispositive here, however, because the connection to the opioid crisis was more remote in those proposals. Both proposals’ supporting statements addressed concerns over water pollution in addition to the possibility of poisoning or opioid misuse resulting from the lack of safe disposal options for leftover opioid medications. The public debate described in the Johnson & Johnson no-action response related almost entirely to take-back programs.

The AbbVie and Johnson & Johnson proposals’ supporting statements also discussed the mechanics and funding of take-back programs for prescription drugs and other hazardous products. In that way, the AbbVie and Johnson & Johnson proposals were much more operationally focused than the Proposal, which confines its scope to governance measures aimed at better managing opioid-related risks. Unlike the proposals in AbbVie and Johnson & Johnson, the Proposal does not concern itself with specific product-related practices.

The second group of determinations on which Mallinckrodt relies involve proposals submitted to distributors or retailers, but not manufacturers, addressing risks related to the sale or distribution of controversial products such as tobacco, firearms and products tested on animals, which were deemed excludable on ordinary business grounds.⁵⁹ Although the reasoning for those determinations is not provided, it is possible to infer that the Staff believed that the proposal subjects did not qualify as significant

⁵⁷ AbbVie Inc. (Mar. 16, 2017)

⁵⁸ Johnson & Johnson (Jan. 30, 2017)

⁵⁹ See determinations cited on pages 4-6 of the No-Action Request.

social policy issues or that a sufficient nexus did not exist between the companies, whose involvement with the products was essentially passive, and the policy issues associated with the products themselves.

Mallinckrodt also cites two determinations allowing omission of proposals at drug manufacturers Pfizer⁶⁰ (drugs used in executions) and Eli Lilly⁶¹ (price increases on specific drugs). As with the proposals described above, it appears likely that the Staff did not view the issues raised by the proposals as significant social policy issues, given that the nexus between the companies and issues was strong.

The Staff's recent determination in AmerisourceBergen Corporation,⁶² on a proposal nearly identical to the Proposal, supports our contention that the opioid crisis is a significant social policy issue and was not mentioned by Mallinckrodt. In that determination, the Staff rejected a drug distributor's argument that the required nexus between the opioid crisis and the company's activities as a distributor did not exist. If the nexus is strong enough for a distributor, manufacturers, who are blamed equally, if not more, for opioid misuse, must have a sufficiently strong nexus.

Mallinckrodt's protestation that "[o]pioid products account for only a small portion—less than 10%—of Mallinckrodt's total revenues" does not undermine the strength of the nexus. Companies sometimes use a "rule of thumb" that a misstatement or omission is material if it involves 5% or more of revenues, though the Staff has indicated that solely using a numeric threshold is inappropriate.⁶³ As well, under the recent Staff Legal Bulletin 14I,⁶⁴ an argument like this one about nexus should be part of a submission reflecting the board's consideration of the Proposal's subject in the context of the company's business. The absence of such a submission substantially weakens Mallinckrodt's argument.

The Proposal's Subject is Not Mallinckrodt's Compliance Program

Mallinckrodt also contends that the Proposal's topic is the Company's compliance program, citing determinations that have permitted omission on ordinary business grounds of proposals addressing legal compliance. That claim is inconsistent with the actual language of the Proposal and ignores the fact that the Proposal deals with a significant social policy issue.

Unlike the numerous determinations discussed on page six of the No-Action Request, the Proposal does not ask for reporting on how Mallinckrodt is ensuring compliance with a specific law or adoption of a new policy aimed at improving compliance. Potential liability stemming from culpability in the opioid crisis forms the backdrop for the Proposal, but is not the Proposal's primary thrust. Instead, the Proposal focuses on governance measures to manage risk going forward.

It is worth noting that even a proposal focused more directly on compliance is not excludable if the subject qualifies as a significant social policy issue. For example, the Commission has stated that "significant employment discrimination matters," which by their nature involve legal compliance, are a significant social policy issue.⁶⁵ Here, given that the opioid crisis is a significant social policy issue, the remote connection between the Proposal and legal compliance does not support exclusion.

The Proposal Would Not Micromanage Mallinckrodt

⁶⁰ Pfizer Inc. (Mar. 1, 2016)

⁶¹ Eli Lilly and Company (Feb. 10, 2017)

⁶² AmerisourceBergen Corporation (Jan. 11, 2018)

⁶³ Staff Accounting Bulletin No. 99, "Materiality" (Aug. 12, 1999)

⁶⁴ Staff Legal Bulletin 14I (Nov. 1, 2017)

⁶⁵ Exchange Act Release No. 40018 (May 21, 1998)

The Commission has articulated the two “central considerations” animating the ordinary business exclusion:

1. “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”; and
2. “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.”⁶⁶

Mallinckrodt urges that the Proposal would micromanage it because it seeks to control “decisions regarding the manufacture and sale of particular products, compliance with laws and regulations and its allocation of capital resources.”⁶⁷

Unlike the proposals in many of the determinations cited by Mallinckrodt, the Proposal does not seek to control which products Mallinckrodt distributes, but rather asks for a single report to shareholders. We acknowledge that allowing shareholders to make day-to-day decisions about product selection would be impractical and undesirable. Nor does the Proposal ask for detailed reporting or operational changes related to a technical subject, as the proposals in Ford Motor Co.⁶⁸ and Marriott International⁶⁹ did.

Mallinckrodt also urges that the Proposal would require disclosure of complex information that would be difficult for shareholders to understand. There is no support in the Proposal for Mallinckrodt’s claim that it seeks disclosure about “the decisions necessary to manage its ordinary business of producing and selling opioid-containing products while attempting to minimize harm associated with potential diversion and misuse of such products.”⁷⁰

The kinds of governance measures discussed in the Proposal—board oversight of risk, compensation metrics, stakeholder engagement and political activity policies—are the subject of shareholder proposals on which shareholders frequently cast votes, and companies themselves often make significant amounts of disclosure on these governance arrangements. The Proposal does not even urge the adoption of any particular governance measure, but only asks for reporting on what Mallinckrodt has already done. Accordingly, the Proposal cannot be said to micromanage Mallinckrodt.

Substantial Implementation

Mallinckrodt contends it has substantially implemented the Proposal through its existing disclosures. First, Mallinckrodt points to its website disclosure regarding anti-diversion efforts and disclosure in its annual report regarding compliance and anti-diversion programs. None of those disclosures is responsive to the Proposal, which focuses on governance rather than operational measures.

Mallinckrodt also argues that it has substantially implemented the Proposal’s request for disclosure of board oversight of opioid-related risks. Mallinckrodt asserts that the Company’s 2017 proxy statement “describes the committees of the Board and their and management’s roles in regularly reviewing and monitoring key risks, including financial and reputational risks related to the sale of opioid-containing

⁶⁶ Exchange Act Release No. 40018 (May 21, 1998)

⁶⁷ No-Action Request, at 11

⁶⁸ Ford Motor Company (Mar. 2, 2004)

⁶⁹ Marriott International Inc. (Mar. 17, 2010)

⁷⁰ No-Action Request, at 12

products.”⁷¹ But the terms “opioid” and “controlled substance” do not appear in the Company’s proxy statement. The No-Action Request refers obliquely to Mallinckrodt’s Corporate Governance Guidelines and board committee charters, but the Corporate Governance Guidelines, Compliance Committee Charter and Audit Committee Charter are all silent on both opioids and controlled substances.

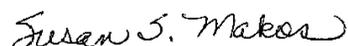
Mallinckrodt would apparently like shareholders to infer that references to risk and compliance in the Company’s governance documents encompass opioid-related matters. There is no reason for shareholders to make those assumptions, though. The purpose of the Proposal is to obtain information about governance measures that Mallinckrodt affirmatively states are intended to help the Company more effectively manage opioid-related risks. Disclosures that refer generically to risk or compliance do not provide the requested information. If indeed opioid-related risks are simply lumped in with other risks, with no special governance mechanisms or considerations, then Mallinckrodt could substantially implement the Proposal by saying so. Its current disclosures, however, fall far short.

* * *

For the reasons set forth above, Mallinckrodt has not met 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). The Proponents thus respectfully request that Mallinckrodt’s request for relief be denied.

The Proponents appreciate the opportunity to be of assistance in this matter. If you have any questions or need additional information, please contact me at (513) 673-9992 or Donna Meyer, Director of Shareholder Advocacy, (713) 299-5018, dmeyer@mercyinvestments.org.

Sincerely,



Susan S. Makos, JD
Vice President of Social Responsibility
Mercy Investment Services, Inc.
smakos@mercyinvestments.org

cc: Victor Goldfeld
VGoldfeld@wlrk.com

⁷¹ No-Action Request, at 14



February 9, 2018

[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 Mallinckrodt plc to omit proposal submitted by Mercy Investment Services, Providence Trust and co-filers

Ladies and Gentlemen,

Pursuant to Rule 14a-8 under the Securities Exchange Act of 1934, Mercy Investment Services Inc., Providence Trust and Catholic Health Initiatives (together, the "Proponents") submitted a shareholder proposal (the "Proposal") to Mallinckrodt plc ("Mallinckrodt" or the "Company"). The Proposal asks Mallinckrodt's board to report to shareholders on governance measures ABC has implemented since 2012 to more effectively monitor and manage financial and reputational risks related to the opioid crisis in the U.S.

In a letter to the Division dated January 12, 2018 (the "No-Action Request"), Mallinckrodt stated that it intends to omit the Proposal from its proxy materials to be distributed to shareholders in connection with the Company's 2018 annual meeting of shareholders. Mallinckrodt argues that it is entitled to exclude the Proposal in reliance on Rule 14a-8(i)(7), as relating to Mallinckrodt's ordinary business operations; and Rule 14a-8(i)(10), on the ground that Mallinckrodt has substantially implemented the Proposal. As discussed more fully below, Mallinckrodt has not met its burden of proving its entitlement to rely on either exclusion; accordingly, the Proponents respectfully ask that the Company's request for relief be denied.

The Proposal

The Proposal states:

"RESOLVED, that shareholders of Mallinckrodt plc ("Mallinckrodt") urge the Board of Directors (the "Board") to report to shareholders by September 30, 2018 on the governance measures Mallinckrodt has implemented since 2012 to more effectively monitor and manage financial and reputational risks related to the opioid crisis in the U.S., given Mallinckrodt's sale of opioid medications and active

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www.mercyinvestmentservices.org

pharmaceutical ingredients in opioid medications, including whether Mallinckrodt has assigned responsibility for such monitoring to the Board or one or more Board committees, revised senior executive compensation metrics or policies, adopted or changed mechanisms for obtaining input from stakeholders, or altered policies or processes regarding company political activities.

The report should be prepared at reasonable cost and should omit confidential and proprietary information.”

Ordinary Business

Mallinckrodt argues that it is entitled to omit the Proposal in reliance on Rule 14a-8(i)(7), which allows exclusion of proposals related to a company’s ordinary business operations. Specifically, Mallinckrodt urges that the Proposal’s subject is the “manufacture and sale of products” or the Company’s compliance program and that the Proposal does not deal with a significant social policy issue with a nexus to Mallinckrodt. Mallinckrodt also claims the Proposal would micromanage the Company.

As discussed below, Mallinckrodt has not met its burden of establishing that the Proposal relates to its ordinary business operations. The Proposal addresses a significant social policy issue with which opioid manufacturers have a strong connection. The Proposal asks for disclosure of governance measures, not a specific policy change or detailed reporting about operations, and thus cannot be said to micromanage Mallinckrodt. Accordingly, the Proponents ask that Mallinckrodt’s request for relief be denied.

The Opioid Crisis Is a Significant Social Policy Issue and a Strong Nexus to Opioid Manufacturers Exists

The opioid epidemic is undoubtedly a “sustained” and “consistent topic of widespread public debate,” the standard the Staff has applied in determining whether a proposal deals with a significant social policy issue.¹

According to the Center for Disease Control and Prevention (“CDC”), the number of opioid painkillers dispensed in the U.S. quadrupled from 1999 to 2010, despite no change in reported pain levels.² In 2015, opioid overdoses killed more than 33,000 Americans, and that number is expected to be up significantly when official data for 2016 are released.³ Opioid addiction alone has lowered U.S. average life expectancy by 2.5 months.⁴

The sheer volume of national media coverage, expressions of public sentiment and legislative and regulatory initiatives spawned by the opioid epidemic precludes an exhaustive list. Some key examples are:

¹ See Exchange Act Release No. 40018 (May 21, 1998); Comcast Corp. (Mar. 4, 2011); Verizon Communications Inc. (Feb. 13, 2012).

² <https://www.cdc.gov/drugoverdose/epidemic/index.html>.

³ Centers for Disease Control and Prevention data on 2015 deaths (<https://www.cdc.gov/drugoverdose/>); Lenny Bernstein, “Deaths from Drug Overdoses Soared in the First Nine Months of 2016,” *The Washington Post*, Aug. 8, 2017 (<https://www.washingtonpost.com/news/to-your-health/wp/2017/08/08/deaths-from-drug-overdoses-soared-in-the-first-nine-months-of-2016/>) (“Given available state data and anecdotal information, many experts are expecting a big increase in deaths in 2016, driven by the worsening crisis in overdoses from opioids, especially fentanyl and heroin”).

⁴ <http://www.chicagotribune.com/news/nationworld/ct-opioids-life-expectancy-20170920-story.html>

- President Trump declared the opioid epidemic a public health emergency in October 2017.⁵ He has empaneled a Presidential Commission on Combating Addiction and the Opioid Crisis to make recommendations on the federal response.⁶
- During the 2016 Presidential election campaign, addressing the opioid crisis ranked as the most important issue for voters in some areas.⁷ Candidates discussed the opioid epidemic on the campaign trail in both the primaries⁸ and general election.⁹
- Continuous coverage of the epidemic over the past several years in national publications, including The New York Times,¹⁰ The Washington Post,¹¹ The Wall Street Journal¹² and USA Today.¹³
- Seventy-three bills dealing with opioids have been introduced in the 115th Congress, including the Effective Opioid Enforcement Act, the DEA Opioid Enforcement Restoration Act, the Opioid Addiction Prevention Act and the Combating the Opioid Epidemic Act.¹⁴
- Concerns over the effect of cuts in Medicaid and resulting loss of access to opioid addiction treatment featured prominently in the debate over repeal of the Affordable Care Act.¹⁵
- Local budgets are being strained by the increase in opioid overdoses and hikes in the price of overdose reversal drug naloxone.¹⁶
- The opioid epidemic is taxing child welfare and foster care systems: Between 2013 and 2016, the number of children removed from their parents' care grew by 40%, driven mainly by opioid

⁵ <http://www.cnn.com/2017/10/26/politics/donald-trump-opioid-epidemic/index.html>

⁶ <https://www.whitehouse.gov/the-press-office/2017/03/30/presidential-executive-order-establishing-presidents-commission>

⁷ <https://www.wsj.com/articles/drug-deaths-becoming-a-2016-presidential-election-issue-1446596075>

⁸ E.g., <https://www.wsj.com/articles/drug-deaths-becoming-a-2016-presidential-election-issue-1446596075>; <http://www.cnn.com/2016/02/06/politics/donald-trump-new-hampshire-drug-epidemic/index.html>

⁹ E.g., <https://web.archive.org/web/20170504001021/https://www.donaldjtrump.com/press-releases/donald-j.-trump-remarks-in-portsmouth-nh>

¹⁰ E.g., <https://www.nytimes.com/2017/01/06/us/opioid-crisis-epidemic.html>;

<https://www.nytimes.com/2017/10/26/us/opioid-crisis-public-health-emergency.html>;

<https://www.nytimes.com/2017/08/21/health/hospitals-opioid-epidemic-patients.html>;

<https://www.nytimes.com/2016/02/22/us/politics/governors-devise-bipartisan-effort-to-reduce-opioid-abuse.html>;

<https://www.nytimes.com/2014/06/18/us/governors-unite-to-fight-heroin-in-new-england.html>;

<https://www.nytimes.com/2015/01/13/us/after-stabilizing-overdose-deaths-rose-in-2013-.html>.

¹¹ E.g., https://www.washingtonpost.com/graphics/2017/investigations/dea-drug-industry-congress/?tid=a_inl&utm_term=.84592cf7ad5d; https://www.washingtonpost.com/national/health-science/no-longer-mayberry-a-small-ohio-city-fights-an-epidemic-of-self-destruction/2016/12/29/a95076f2-9a01-11e6-b3c9-f662adaa0048_story.html?tid=sm_fb&utm_term=.91264e23e0fa; https://www.washingtonpost.com/news/to-your-health/wp/2017/03/?utm_term=.c6d46b0eeefe.

¹² E.g., <http://www.wsj.com/graphics/toll-of-opioids/>; <https://www.wsj.com/articles/opioid-addiction-diagnoses-up-nearly-500-in-past-seven-years-study-shows-1498737603>; <https://www.wsj.com/articles/colleges-take-action-on-opioid-epidemic-1494158403?tesla=y>; <https://www.wsj.com/articles/the-children-of-the-opioid-crisis-1481816178>.

¹³ <https://www.usatoday.com/story/news/politics/2017/10/23/fda-chief-supports-opioid-prescription-limits-regrets-agencys-prior-inaction/774007001/>; <https://www.usatoday.com/story/news/2017/11/08/its-far-more-than-overdoses-iv-opioid-users-diseases-overwhelm-hospitals/821693001/>;

<https://www.usatoday.com/story/news/nation/2016/09/25/drug-addiction-treatment-insurance-heroin/91079496/>;

¹⁴ Data as of November 20, 2017 from Carol Nolan Drake, President and CEO, Carlow Consulting LLC (private correspondence dated November 20, 2017).

¹⁵ E.g., <http://www.latimes.com/politics/la-na-pol-obamacare-repeal-opioids-20170621-story.html>;

<http://www.nejm.org/doi/full/10.1056/NEJMp1700834#t=article>

¹⁶ <https://www.cnn.com/2017/01/04/as-opioid-epidemic-worsens-the-cost-of-waking-up-from-an-overdose-soars.html>; https://www.washingtonpost.com/world/as-opioid-overdoses-exact-a-higher-price-communities-ponder-who-should-be-saved/2017/07/15/1ea91890-67f3-11e7-8eb5-cbcc2e7bfbf_story.html?utm_term=.adb4f9214ba6.

addiction.¹⁷ Several Ohio counties asked voters to approve ballot initiatives providing additional funding for family services in November 2017 due to opioid addiction.¹⁸

- Opioid use has been identified as a possible reason working-age men's participation in the labor force has been low.¹⁹
- The hospital costs associated with treating addicted newborns rose to \$1.5 billion in 2013, from \$732 million in 2009, according to a study in the Journal of Perinatology.²⁰ Stories like the one about James Schenk, born addicted to opioids, illustrate the difficulties of weaning these babies after birth.²¹

Mallinckrodt claims that manufacturers are too remote from physicians and patients to have a sufficiently strong nexus to the opioid crisis. But manufacturers of opioid medication have played an important role in creating and perpetuating the opioid crisis, and they are facing efforts to hold them accountable for their behavior, both legally and otherwise.

Numerous large cities, including Chicago, New York, Philadelphia and Seattle, and countless more small municipalities,²² have sued opioid manufacturers in the past few years.²³ States²⁴ and counties²⁵ have done the same. Suits claim that manufacturers made misleading marketing claims, downplaying the risk of addiction and the efficacy of opioids for chronic pain, leading to opioid abuse and associated costs.²⁶ More than 250 cases have been consolidated in Ohio, where they are being overseen by Judge Dan Polster. Judge Polster has convened not only the parties in these cases, but others such as addiction experts, representatives of insurance companies, and officials of the FDA and DEA, with the goal of producing a settlement.²⁷

¹⁷ <https://www.wsj.com/articles/the-children-of-the-opioid-crisis-1481816178>

¹⁸ <https://www.nytimes.com/aponline/2017/11/06/us/ap-us-opioid-crisis-children.html>

¹⁹ <https://nypost.com/2017/07/23/yellen-links-opioid-crisis-to-low-workforce-participation/>

²⁰ <https://www.nytimes.com/2016/12/12/health/rise-in-infant-drug-dependence-in-us-is-felt-most-in-rural-areas.html>

²¹ http://host.madison.com/wsj/news/local/health-med-fit/babies-dependent-on-opioids-wisconsin-sees-surge-in-infants-born/article_1da6faee-827d-5435-aada-23a1d5fc8024.html

²² <http://hot96.com/news/articles/2018/feb/07/city-of-evansville-suing-opioid-manufacturers/>

²³ <https://www.citylab.com/life/2017/10/the-cities-suing-big-pharma-over-opioids/542484/>; J. David Goodman & William Neuman, "New York City Sues Drug Companies Over Opioid Crisis," The New York Times, Jan. 23, 2018 (<https://www.nytimes.com/2018/01/23/nyregion/nyc-de-blasio-opioid-lawsuit.html>)

²⁴ <https://www.theatlantic.com/business/archive/2017/06/lawsuit-pharmaceutical-companies-opioids/529020/>; <https://www.nbcphiladelphia.com/news/local/New-Jersey-Sues-Evil-Painkiller-Company-449651983.html>; http://www.theadvocate.com/baton_rouge/news/crime_police/article_7c667572-02f8-11e8-ba90-53c92cef1f7c.html; https://www.google.com/search?q=opioid+manufacturers&ei=T_l8WtCKGYOO5wKyi5LgCw&start=30&sa=N&biw=1352&bih=693

²⁵ E.g., <https://www.lohud.com/story/news/health/2018/02/06/westchester-targets-pharma-heroin-opioid-crisis-taxpayers/307951002/>; <http://www.islandpacket.com/news/local/article198598909.html>; <http://www.baltimoresun.com/news/maryland/baltimore-city/bs-md-ci-city-opioid-suit-20180131-story.html>; http://www.syracuse.com/news/index.ssf/2018/01/onondaga_county_sues_drug_companies_over_opioid_crisis.html; <http://www.gainesville.com/news/20180208/alachua-osceola-counties-take-aim-at-opioid-manufacturers>

²⁶ J. David Goodman & William Neuman, "New York City Sues Drug Companies Over Opioid Crisis," The New York Times, Jan. 23, 2018 (<https://www.nytimes.com/2018/01/23/nyregion/nyc-de-blasio-opioid-lawsuit.html>); see also Rebecca L. Haffajee & Michelle M. Mello, "Drug Companies' Liability for the Opioid Epidemic," New England Journal of Medicine, Dec. 14, 2017 (<http://www.nejm.org/doi/full/10.1056/NEJMp1710756>)

²⁷ <https://www.usnews.com/news/news/articles/2018-01-30/federal-judge-wants-opioid-lawsuits-to-end-in-settlement>

Whether opioid manufacturers are ultimately held legally liable for various costs associated with the opioid crisis, they are being held responsible in the broader public debate about appropriate public policy responses and measures to deter opioid abuse. One article on the opioid crisis summed up this view as follows: “Managing pain, specifically chronic pain, is an essential part of any doctor’s practice. It is terrible to see people suffer and whenever possible and prudent, pain should be treated. And some of the players in this story were driven by real concern for patients’ quality of life. But others, specifically the manufacturers, were driven by crasser motives: the realization that they could make a fortune by pushing for wider use of prescription opioids.”²⁸

More specifically, drug manufacturers have been attacked for their promotion of opioid medications, both directly and indirectly. Materials provided to patients claimed that addiction was a “myth” and “rarely” occurred when opioids were prescribed for chronic pain. The PainKnowledge.com website, sponsored by Endo, made similar claims.²⁹ The study often cited in support of these assertions was very small, only 38 patients, and its author no longer stands behind it.³⁰

The American Pain Foundation (“APF”), described in a 2011 ProPublica investigation as an “influential champion” for opioids, came under scrutiny early in the opioid crisis. The ProPublica investigation, published in the Washington Post,³¹ revealed that the APF garnered nearly 90% of its funding in 2010 from the drug and medical device industry.³² It also unearthed financial relationships between opioid manufacturers and APF board members.³³ Critics charged that it was serving as an ostensibly “patient-oriented” mouthpiece for opioid makers. The APF’s publications were charged with being misleading and inappropriately downplaying the risks associated with opioids.³⁴ For example, the APF put out a publication sponsored by OxyContin manufacturer Purdue Pharma, asserting that only 1% of children prescribed opioids become addicted.³⁵

In 2012, the Senate Finance Committee, as part of an investigation into drug manufacturers’ responsibility for the opioid epidemic, wrote to the APF requesting information about funding of the APF by opioid manufacturers, collaborations between the APF and those funders and distribution of any publications written by opioid manufacturers.³⁶ The same day the letter was sent, the APF announced that it was immediately dissolving.³⁷

A 2016 investigation by the Associated Press and Center for Public Integrity described a “pro-painkiller echo chamber” in Washington DC created by the Pain Care Forum (“PCF”), a “loose coalition of

²⁸http://www.slate.com/articles/health_and_science/medical_examiner/2016/06/prince_s_death_reveals_how_wrong_our_over_reliance_on_dangerous_opioids.html

²⁹ <https://www.vox.com/policy-and-politics/2017/6/7/15724054/opioid-companies-epidemic-lawsuits>

³⁰

http://www.slate.com/articles/health_and_science/medical_examiner/2016/06/prince_s_death_reveals_how_wrong_our_over_reliance_on_dangerous_opioids.html

<https://www.wsj.com/articles/SB10001424127887324478304578173342657044604> (interview with study author Dr. Russell Portenoy)

³¹ https://www.washingtonpost.com/national/health-science/patient-advocacy-group-funded-by-success-of-painkiller-drugs-probe-finds/2011/12/20/gIQAgvczDP_story.html?utm_term=.1c1e597c5206

³² <https://www.propublica.org/article/the-champion-of-painkillers>

³³ <https://www.propublica.org/article/two-leaders-in-pain-treatment-have-long-ties-to-drug-industry>

³⁴ <https://www.propublica.org/article/the-champion-of-painkillers>

³⁵ <https://www.vox.com/policy-and-politics/2017/6/7/15724054/opioid-companies-epidemic-lawsuits>

³⁶ <https://www.documentcloud.org/documents/354941-opioid-investigation-letter-to-american-pain.html>

³⁷ <https://www.propublica.org/article/senate-panel-investigates-drug-company-ties-to-pain-groups>

drugmakers, trade groups and dozens of nonprofits supported by industry funding.”³⁸ It was founded by the Washington lobbyists for Purdue Pharma, the OxyContin manufacturer that in 2007 settled claims of deceptive promotion of that drug. The investigation found that PCF participants spent massive amounts on lobbying, including on opioid-related matters, and political contributions.³⁹ The APF was “one of the [PCF’s] principal members.”⁴⁰ The PCF played a role in watering down the FDA’s risk management plan around opioids, generating thousands of public comments.⁴¹ Senator Ron Wyden raised concerns last year about the participation of industry-financed groups in an FDA workshop on opioid prescribing.⁴²

Opioid manufacturers also influenced physicians through medical groups such as the American Pain Society (“APS”) and the American Academy of Pain Medicine. Many fault these groups’ increased emphasis on eliminating pain for contributing to the opioid crisis and trace the origin of that shift to the keynote address of the 1996 annual conference of the APS, which coined the phrase “the fifth vital sign” to encourage physicians to take pain management more seriously.⁴³ Purdue Pharma contributed funding to the APS during this time.⁴⁴

Purdue also funded programs of the Joint Commission (formerly known as the Joint Commission on Accreditation of Healthcare Organizations) for complying with standards regarding pain management; the Joint Commission’s 1999 pain policy stated that “Some clinicians have inaccurate and exaggerated concerns about addiction, tolerance and risk of death . . . despite the fact there is no evidence that addiction is a significant issue when persons are given opioids for pain control.”⁴⁵ A CNN story from 2016 reported that the Joint Commission produced a book for use in continuing medical education, funded by Purdue, calling physician worries about opioid addiction “inaccurate and exaggerated.”⁴⁶

Similarly, a Purdue executive helped draft a 1998 policy from the Federation of State Medical Boards aimed at alleviating physician anxieties that they would be pursued by regulators for prescribing opioids; the Federation published an industry-funded book about the policy, pocketing the proceeds.⁴⁷

Reviewing the history of the opioid abuse crisis, an article in the Cleveland Clinic Journal of Medicine explained the role of manufacturers: “Opportunistically, or perhaps wielding inappropriate and

³⁸ <https://www.apnews.com/3d257452c24a410f98e8e5a4d9d448a7>

³⁹ <https://www.apnews.com/3d257452c24a410f98e8e5a4d9d448a7>

⁴⁰ <https://www.apnews.com/3d257452c24a410f98e8e5a4d9d448a7>

⁴¹ <https://www.apnews.com/3d257452c24a410f98e8e5a4d9d448a7>

⁴²

<https://www.finance.senate.gov/imo/media/doc/050517%20Senator%20Wyden%20to%20Secretary%20Price%20re%20FDA%20Opioid%20Prescriber%20Working%20Group.pdf>

<http://www.modernhealthcare.com/article/20170508/NEWS/170509883>

⁴³ <https://www.vox.com/2017/6/5/15111936/opioid-crisis-pain-west-virginia>;

http://www.slate.com/articles/health_and_science/medical_examiner/2016/06/prince_s_death_reveals_how_wrong_or_over_reliance_on_dangerous_opioids.html

⁴⁴ <https://www.vox.com/2017/6/5/15111936/opioid-crisis-pain-west-virginia>

⁴⁵

http://www.slate.com/articles/health_and_science/medical_examiner/2016/06/prince_s_death_reveals_how_wrong_or_over_reliance_on_dangerous_opioids.html

⁴⁶ <https://www.cnn.com/2016/05/12/health/opioid-addiction-history/>

⁴⁷ <https://www.wsj.com/articles/SB10001424127887324478304578173342657044604>

sketchy influence, some drug manufacturers in the early 2000s funded publications and physician presentations to encourage the expanded use of opioids and other medications for pain control.”⁴⁸

In September 2017, forty-one attorneys general wrote to America’s Health Insurance Plans (“AHIP”), the trade association for health insurers, asking it to “encourage [its] members to review their payment and coverage policies . . . to encourage healthcare providers to prioritize non-opioid pain management options over opioid prescriptions for the treatment of chronic, non-cancer pain.”⁴⁹ AHIP launched the Safe, Transparent Opioid Prescribing (“STOP”) Initiative, which is “designed to support widespread adoption of clinical guidelines for pain care and opioid prescribing,” a month later.⁵⁰ As part of STOP, AHIP released the STOP Measure, which allows plans to compare physician prescribing practices to the Centers for Disease Control (“CDC”) Guideline for Prescribing Opioids for Chronic Pain.⁵¹

The CDC Guideline was released in March 2016, after a notice and comment process, to help physicians decide whether to prescribe opioids and to provide advice on “medication selection, dosage, duration and discontinuation of treatment.”⁵² An article in *JAMA Internal Medicine* reviewed the comments submitted on the Guideline and found that, among the 150 organizations that submitted comments, opposition to the Guideline was associated with having received funding from opioid manufacturers, as was opposition specifically to the recommendations about dosing and duration of treatment.⁵³

The Senate’s Homeland Security and Governmental Affairs Committee opened an investigation in Mar. 2017 into the makers of the five opioid medications with the highest sales.⁵⁴ The investigation sought to determine “whether pharmaceutical manufacturers—at the head of the opioids pipeline—have contributed to opioid over-utilization and over-prescription”⁵⁵ Senator Claire McCaskill, in her letter to the manufacturers, who did not include Mallinckrodt, opined that the opioid epidemic “is the direct result of a calculated sales and marketing strategy major opioid manufacturers have allegedly pursued over the past 20 years to expand their market share and increase dependency on powerful — and often deadly — painkillers.”⁵⁶ Specifically, she wrote, manufacturers “downplay[ed] the risk of addition”

In sum, the opioid abuse crisis is one of the most urgent social problems facing the U.S., with major effects on health, prosperity and well-being. Significant attention and criticism have focused on opioid manufacturers for deceptively promoting opioids, inappropriately intervening the legislative and political process and influencing physician prescribing, both directly and indirectly, through trade associations and other groups. Accordingly, the subject of the Proposal—how Mallinckrodt has changed its corporate

⁴⁸ <https://www.mdedge.com/ccjm/article/109138/drug-therapy/fifth-vital-sign-complex-story-politics-and-patient-care>

⁴⁹ [http://myfloridalegal.com/webfiles.nsf/WF/JMAR-ARCKCD/\\$file/NAAG-Opioid-Letter-to-AHIP.pdf](http://myfloridalegal.com/webfiles.nsf/WF/JMAR-ARCKCD/$file/NAAG-Opioid-Letter-to-AHIP.pdf)

⁵⁰ <https://www.ahip.org/health-plans-launch-new-stop-initiative-to-help-battle-opioid-crisis-in-america/>

⁵¹ <https://www.ahip.org/health-plans-launch-new-stop-initiative-to-help-battle-opioid-crisis-in-america/>

⁵² <https://www.cdc.gov/media/releases/2016/p0315-prescribing-opioids-guidelines.html>

⁵³ <https://jamanetwork.com/journals/jamainternalmedicine/article-abstract/2598092?redirect=true>

⁵⁴ Dan Mangan, “Opioid Epidemic: Senate Committee Opens Probe of Five Big Painkiller Makers,” CNBC, Mar. 28, 2017 (<https://www.cnbc.com/2017/03/28/senate-committee-opens-probe-of-five-big-opioid-makers.html>); <https://www.motherjones.com/politics/2017/03/opioid-investigation-mccaskill-pharmaceutical-companies/>

⁵⁵ Dan Mangan, “Opioid Epidemic: Senate Committee Opens Probe of Five Big Painkiller Makers,” CNBC, Mar. 28, 2017 (<https://www.cnbc.com/2017/03/28/senate-committee-opens-probe-of-five-big-opioid-makers.html>)

⁵⁶ Dan Mangan, “Opioid Epidemic: Senate Committee Opens Probe of Five Big Painkiller Makers,” CNBC, Mar. 28, 2017 (<https://www.cnbc.com/2017/03/28/senate-committee-opens-probe-of-five-big-opioid-makers.html>)

governance to monitor and manage opioid-related risks—is a significant social policy issue with a strong connection to Mallinckrodt.

The “Sale of Products” Determinations Do Not Apply Because the Proposal Deals with a Significant Social Policy Issue

Mallinckrodt rests its argument on previous determinations in which the Staff permitted companies that sold or distributed products to exclude proposals related to those products on ordinary business grounds. The proposals in those determinations, which fall into three categories, differ from the Proposal in important ways. Mallinckrodt also neglected to mention a recent determination declining to allow exclusion on ordinary business grounds of a proposal nearly identical to the Proposal submitted at a pharmaceutical distributor.

First, Mallinckrodt points to proposals submitted last year to AbbVie⁵⁷ and Johnson & Johnson,⁵⁸ which asked those companies to report on their policies for safe disposal of prescription drugs to prevent water pollution and possible options to address that problem, including the endorsement or funding of industry take-back programs. Both AbbVie and Johnson & Johnson argued, among other things, that the proposals dealt with their ordinary business operations, urging that they addressed customer disposal and misuse of their products. The Staff concurred with the companies’ positions, stating simply that the proposals related to the companies’ ordinary business operations.

The Staff thus implicitly rejected the proponents’ claims that the proposals dealt with a significant social policy issue. In opposing the Johnson & Johnson no-action request, the proponent had argued that the proposals addressed “the significant public policy issue of reducing water pollution caused by disposal of used pharmaceuticals.” In responding to both requests, the proponents had attempted to tie the take-back issue to the larger problem of the opioid crisis.

The AbbVie and Johnson & Johnson determinations are not dispositive here, however, because the connection to the opioid crisis was more remote in those proposals. Both proposals’ supporting statements addressed concerns over water pollution in addition to the possibility of poisoning or opioid misuse resulting from the lack of safe disposal options for leftover opioid medications. The public debate described in the Johnson & Johnson no-action response related almost entirely to take-back programs.

The AbbVie and Johnson & Johnson proposals’ supporting statements also discussed the mechanics and funding of take-back programs for prescription drugs and other hazardous products. In that way, the AbbVie and Johnson & Johnson proposals were much more operationally focused than the Proposal, which confines its scope to governance measures aimed at better managing opioid-related risks. Unlike the proposals in AbbVie and Johnson & Johnson, the Proposal does not concern itself with specific product-related practices.

The second group of determinations on which Mallinckrodt relies involve proposals submitted to distributors or retailers, but not manufacturers, addressing risks related to the sale or distribution of controversial products such as tobacco, firearms and products tested on animals, which were deemed excludable on ordinary business grounds.⁵⁹ Although the reasoning for those determinations is not provided, it is possible to infer that the Staff believed that the proposal subjects did not qualify as significant

⁵⁷ AbbVie Inc. (Mar. 16, 2017)

⁵⁸ Johnson & Johnson (Jan. 30, 2017)

⁵⁹ See determinations cited on pages 4-6 of the No-Action Request.

social policy issues or that a sufficient nexus did not exist between the companies, whose involvement with the products was essentially passive, and the policy issues associated with the products themselves.

Mallinckrodt also cites two determinations allowing omission of proposals at drug manufacturers Pfizer⁶⁰ (drugs used in executions) and Eli Lilly⁶¹ (price increases on specific drugs). As with the proposals described above, it appears likely that the Staff did not view the issues raised by the proposals as significant social policy issues, given that the nexus between the companies and issues was strong.

The Staff's recent determination in AmerisourceBergen Corporation,⁶² on a proposal nearly identical to the Proposal, supports our contention that the opioid crisis is a significant social policy issue and was not mentioned by Mallinckrodt. In that determination, the Staff rejected a drug distributor's argument that the required nexus between the opioid crisis and the company's activities as a distributor did not exist. If the nexus is strong enough for a distributor, manufacturers, who are blamed equally, if not more, for opioid misuse, must have a sufficiently strong nexus.

Mallinckrodt's protestation that "[o]pioid products account for only a small portion—less than 10%—of Mallinckrodt's total revenues" does not undermine the strength of the nexus. Companies sometimes use a "rule of thumb" that a misstatement or omission is material if it involves 5% or more of revenues, though the Staff has indicated that solely using a numeric threshold is inappropriate.⁶³ As well, under the recent Staff Legal Bulletin 14I,⁶⁴ an argument like this one about nexus should be part of a submission reflecting the board's consideration of the Proposal's subject in the context of the company's business. The absence of such a submission substantially weakens Mallinckrodt's argument.

The Proposal's Subject is Not Mallinckrodt's Compliance Program

Mallinckrodt also contends that the Proposal's topic is the Company's compliance program, citing determinations that have permitted omission on ordinary business grounds of proposals addressing legal compliance. That claim is inconsistent with the actual language of the Proposal and ignores the fact that the Proposal deals with a significant social policy issue.

Unlike the numerous determinations discussed on page six of the No-Action Request, the Proposal does not ask for reporting on how Mallinckrodt is ensuring compliance with a specific law or adoption of a new policy aimed at improving compliance. Potential liability stemming from culpability in the opioid crisis forms the backdrop for the Proposal, but is not the Proposal's primary thrust. Instead, the Proposal focuses on governance measures to manage risk going forward.

It is worth noting that even a proposal focused more directly on compliance is not excludable if the subject qualifies as a significant social policy issue. For example, the Commission has stated that "significant employment discrimination matters," which by their nature involve legal compliance, are a significant social policy issue.⁶⁵ Here, given that the opioid crisis is a significant social policy issue, the remote connection between the Proposal and legal compliance does not support exclusion.

The Proposal Would Not Micromanage Mallinckrodt

⁶⁰ Pfizer Inc. (Mar. 1, 2016)

⁶¹ Eli Lilly and Company (Feb. 10, 2017)

⁶² AmerisourceBergen Corporation (Jan. 11, 2018)

⁶³ Staff Accounting Bulletin No. 99, "Materiality" (Aug. 12, 1999)

⁶⁴ Staff Legal Bulletin 14I (Nov. 1, 2017)

⁶⁵ Exchange Act Release No. 40018 (May 21, 1998)

The Commission has articulated the two “central considerations” animating the ordinary business exclusion:

1. “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”; and
2. “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.”⁶⁶

Mallinckrodt urges that the Proposal would micromanage it because it seeks to control “decisions regarding the manufacture and sale of particular products, compliance with laws and regulations and its allocation of capital resources.”⁶⁷

Unlike the proposals in many of the determinations cited by Mallinckrodt, the Proposal does not seek to control which products Mallinckrodt distributes, but rather asks for a single report to shareholders. We acknowledge that allowing shareholders to make day-to-day decisions about product selection would be impractical and undesirable. Nor does the Proposal ask for detailed reporting or operational changes related to a technical subject, as the proposals in Ford Motor Co.⁶⁸ and Marriott International⁶⁹ did.

Mallinckrodt also urges that the Proposal would require disclosure of complex information that would be difficult for shareholders to understand. There is no support in the Proposal for Mallinckrodt’s claim that it seeks disclosure about “the decisions necessary to manage its ordinary business of producing and selling opioid-containing products while attempting to minimize harm associated with potential diversion and misuse of such products.”⁷⁰

The kinds of governance measures discussed in the Proposal—board oversight of risk, compensation metrics, stakeholder engagement and political activity policies—are the subject of shareholder proposals on which shareholders frequently cast votes, and companies themselves often make significant amounts of disclosure on these governance arrangements. The Proposal does not even urge the adoption of any particular governance measure, but only asks for reporting on what Mallinckrodt has already done. Accordingly, the Proposal cannot be said to micromanage Mallinckrodt.

Substantial Implementation

Mallinckrodt contends it has substantially implemented the Proposal through its existing disclosures. First, Mallinckrodt points to its website disclosure regarding anti-diversion efforts and disclosure in its annual report regarding compliance and anti-diversion programs. None of those disclosures is responsive to the Proposal, which focuses on governance rather than operational measures.

Mallinckrodt also argues that it has substantially implemented the Proposal’s request for disclosure of board oversight of opioid-related risks. Mallinckrodt asserts that the Company’s 2017 proxy statement “describes the committees of the Board and their and management’s roles in regularly reviewing and monitoring key risks, including financial and reputational risks related to the sale of opioid-containing

⁶⁶ Exchange Act Release No. 40018 (May 21, 1998)

⁶⁷ No-Action Request, at 11

⁶⁸ Ford Motor Company (Mar. 2, 2004)

⁶⁹ Marriott International Inc. (Mar. 17, 2010)

⁷⁰ No-Action Request, at 12

products.”⁷¹ But the terms “opioid” and “controlled substance” do not appear in the Company’s proxy statement. The No-Action Request refers obliquely to Mallinckrodt’s Corporate Governance Guidelines and board committee charters, but the Corporate Governance Guidelines, Compliance Committee Charter and Audit Committee Charter are all silent on both opioids and controlled substances.

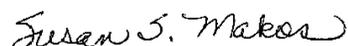
Mallinckrodt would apparently like shareholders to infer that references to risk and compliance in the Company’s governance documents encompass opioid-related matters. There is no reason for shareholders to make those assumptions, though. The purpose of the Proposal is to obtain information about governance measures that Mallinckrodt affirmatively states are intended to help the Company more effectively manage opioid-related risks. Disclosures that refer generically to risk or compliance do not provide the requested information. If indeed opioid-related risks are simply lumped in with other risks, with no special governance mechanisms or considerations, then Mallinckrodt could substantially implement the Proposal by saying so. Its current disclosures, however, fall far short.

* * *

For the reasons set forth above, Mallinckrodt has not met 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). The Proponents thus respectfully request that Mallinckrodt’s request for relief be denied.

The Proponents appreciate the opportunity to be of assistance in this matter. If you have any questions or need additional information, please contact me at (513) 673-9992 or Donna Meyer, Director of Shareholder Advocacy, (713) 299-5018, dmeyer@mercyinvestments.org.

Sincerely,



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⁷¹ No-Action Request, at 14

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January 12, 2018

VIA EMAIL (SHAREHOLDERPROPOSALS@SEC.GOV)

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

Re: *Shareholder Proposal to Mallinckrodt plc by Mercy Investment Services, Inc.,
Providence Trust and Catholic Health Initiatives*

Ladies and Gentlemen:

Pursuant to Rule 14a-8(j) promulgated under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), we are writing on behalf of our client, Mallinckrodt plc, an Irish public limited company ("Mallinckrodt" or the "Company"), to request that the Staff of the Division of Corporation Finance (the "Staff") of the U.S. Securities and Exchange Commission (the "Commission") concur with Mallinckrodt's view that, for the reasons stated below, it may exclude the shareholder proposal (the "Proposal") and the statement in support thereof (the "Supporting Statement") received from Mercy Investment Services, Inc., Providence

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Trust, and Catholic Health Initiatives (collectively, the “Proponents”) from Mallinckrodt’s proxy statement and form of proxy for its 2018 Annual General Meeting of Shareholders (collectively, the “2018 Proxy Materials”).

Pursuant to Rule 14a-8(j) under the Exchange Act, we have:

- transmitted this letter by email to the Staff at shareholderproposals@sec.gov no later than eighty (80) calendar days before the Company intends to file its definitive 2018 Proxy Materials with the Commission, which is currently anticipated to be on or about April 6, 2018; and
- concurrently sent copies of this letter, together with its attachments, to the Proponents at the email addresses they have provided as notice of the Company’s intent to exclude the Proposal and the Supporting Statement from the 2018 Proxy Materials.

Rule 14a-8(k) and Staff Legal Bulletin No. 14D (Nov. 7, 2008) (“SLB 14D”) provide that stockholder proponents are required to send companies a copy of any correspondence that the proponents elect to submit to the Commission or the Staff. Accordingly, we are taking this opportunity to inform the Proponents that if the Proponents elect to submit additional correspondence to the Commission or the Staff with respect to the Proposal, a copy of that correspondence should be furnished concurrently to the undersigned on behalf of the Company pursuant to Rule 14a-8(k) and SLB 14D.

THE PROPOSAL

The Proposal, dated September 15, 2017 (in the case of the letter from Mercy Investment Services, Inc. and Providence Trust) and September 19, 2017 (in the case of the letter from Catholic Health Initiatives), sets forth the following proposed resolution for the vote of the Company’s stockholders at the Annual General Meeting of Shareholders in 2018:

RESOLVED, that shareholders of Mallinckrodt plc (“Mallinckrodt”) urge the Board of Directors (the “Board”) to report to shareholders by September 30, 2018 on the governance measures Mallinckrodt has implemented since 2012 to more effectively monitor and manage financial and reputational risks related to the opioid crisis in the U.S., given Mallinckrodt’s sale of opioid medications and active pharmaceutical ingredients in opioid medications, including whether Mallinckrodt has assigned responsibility for such monitoring to the Board or one or more Board committees, revised senior executive compensation metrics or policies, adopted or changed mechanisms for obtaining input from stakeholders, or altered policies or processes regarding company political activities.

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The report should be prepared at reasonable cost and should omit confidential and proprietary information.

Copies of the Proposal and the Supporting Statement are attached to this letter as Exhibit A.

BASES FOR EXCLUSION

The Company respectfully requests that the Staff concur in its view that the Proposal and the Supporting Statement may be excluded from the 2018 Proxy Materials pursuant to (i) Rule 14a-8(i)(7), because the Proposal involves matters that relate to the ordinary business operations of the Company and/or (ii) Rule 14a-8(i)(10), because the Company has already substantially implemented the Proposal.

ANALYSIS

I. The Company May Exclude the Proposal Pursuant to Rule 14a-8(i)(7) Because the Proposal Involves Matters that Relate to Mallinckrodt's Ordinary Business Operations.

A. Rule 14a-8(i)(7) and the Ordinary Business Exclusion.

Rule 14a-8(i)(7) permits a company to exclude a stockholder proposal from its proxy materials “[i]f the proposal deals with a matter relating to the company’s ordinary business operations.” The “general underlying policy” of the ordinary business exclusion is “to confine the resolution of ordinary business problems to management and the board of directors, since it is impracticable for shareholders to decide how to solve such problems at an annual shareholders meeting.” Exchange Act Release No. 34-418 (May 21, 1998) (the “1998 Release”). The Commission has identified two central considerations that underlie this policy: First, that “[c]ertain 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,” and second, “the degree to which the proposal seeks to ‘micro-manage’ the company by probing too deeply into matters of a complex nature upon which stockholders, as a group, would not be in a position to make an informed judgment.” Id. (citing Exchange Act Release No. 12999 (Nov. 22, 1976)).

B. Whether Proposals Requesting Reports Relate to Ordinary Business Depends on the Underlying Subject Matter of the Proposed Report.

With respect to proposals requesting the preparation and dissemination of a report regarding one or more aspects of a company’s business, the Commission has stated that the Staff “will consider whether the subject matter of the special report . . . involves a matter of ordinary

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business; where it does, the proposal will be excludable” under Rule 14a-8(i)(7). Exchange Act Release No. 34-20091 (Aug. 16, 1983). Similarly, where a proposal relates to an evaluation of risk, “rather than focusing on whether a proposal and supporting statement relate to the company engaging in an evaluation of risk, [the Staff] will instead focus on the subject matter to which the risk pertains or that gives rise to the risk.” Staff Legal Bulletin 14E (Oct. 27, 2009) (“SLB 14E”).

C. The Subject Matter of the Proposal Fundamentally Involves Matters of Ordinary Business.

- i. The core subject matter of the proposal is the manufacture and sale of products, which are at the heart of the Company’s ordinary business.

The Staff has consistently taken the position that shareholder proposals relating to the sale of particular products are excludable because they relate to ordinary business operations. The Proposal requests a report on “measures Mallinckrodt has implemented since 2012 to more effectively monitor and manage financial and reputational risks related to the opioid crisis in the U.S., given Mallinckrodt’s sale of opioid medications and active pharmaceutical ingredients.” The measures that Mallinckrodt has taken, which are summarized in Section C below, are fundamentally ordinary business matters and the Proposal is therefore excludable on this basis.

As set forth in SLB 14E, the Staff will “look to the underlying subject matter of the report . . . to determine whether the proposal relates to ordinary business.” The Staff has routinely found that decisions regarding the selection of products for sale and the manner of manufacturing and selling products are core aspects of companies’ ordinary business activities.

For example, the Staff recently granted no-action relief to Abbvie and Johnson & Johnson when each of them sought to exclude a shareholder proposal requesting that the company’s board of directors prepare and publish a report reviewing the company’s existing policies for safe disposition by users of prescription drugs to prevent misuse (and thereby prevent water pollution), and setting forth policy options for a proactive response, including determining whether the company should endorse partial or full industry responsibility for take-back programs by providing funding or resources for such programs. Abbvie Inc. (Mar. 16, 2017) and Johnson & Johnson (Jan. 30, 2017). See also Cardinal Health, Inc. (Aug. 4, 2017) (concurring in the exclusion of a proposal requesting that the company issue a report describing the controlled distribution systems it implements to prevent the diversion of restricted medicines to prisons for use in executions, and its process for monitoring and auditing these systems, noting that the proposal related “to the sale or distribution of particular products to its customers”); McKesson Corp. (Jun. 1, 2017) (same); Pfizer Inc. (Mar. 1, 2016) (granting relief to exclude a proposal describing the steps the company has taken or will take to identify and remedy the flaws in its current distribution system for medicines listed in the formal execution protocols of certain

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U.S. states in order to prevent their sale to prisons for the purpose of aiding executions); Rite Aid Corporation (Mar. 24, 2015) (granting relief regarding a proposal requesting additional board committee oversight concerning the sale of certain products, in particular, tobacco products, and noting that “[p]roposals concerning the sale of particular products and services are generally excludable under rule 14a-8(i)(7)”; and Wal-Mart Stores, Inc. (Mar. 20, 2014) (granting relief regarding a proposal requesting additional board committee oversight concerning the sale of certain products, in particular, firearms).

Similarly, in Walgreens Boots Alliance, Inc. (Nov. 7, 2016, recon. denied Nov. 22, 2016), the Staff concurred with the exclusion of a proposal requesting that the board issue a report “assessing the financial risk, including long-term legal and reputational risk, of continued sales of tobacco products in the company’s stores” because the proposal related to the company’s ordinary business operations of selling products. Like the proposal in Walgreens, which focused on the financial and reputational risks of tobacco products, the Proposal focuses on “financial and reputational risks related to the opioid crisis,” which are a subset of the risks related to the Company’s sale of products containing opioids. Decisions regarding the management of these risks are not suitable for direct shareholder oversight and are “fundamental to management’s ability to run a company on a day-to-day basis” as described in the 1998 Release. See also Wells Fargo & Co. (Jan. 28, 2013, recon. denied Mar. 4, 2013) (concurring in the exclusion of a proposal requesting that the board prepare a report discussing the adequacy of the company’s policies in addressing the social and financial impacts of direct deposit advance lending because the proposal related to the products and services offered for sale by the company); Amazon.com, Inc. (Mar. 11, 2016) (concurring in the exclusion of a proposal requesting that Amazon issue a report addressing animal cruelty in its supply chain, including assessing “the reputational and financial risks associated with lack of a consistent prohibition on products involving animal cruelty,” because the proposal related “to the products and services offered for sale by the company”); Eli Lilly and Company (Feb. 10, 2017) (concurring in the exclusion of a proposal requesting that the board issue a report including, among other things, an assessment of the legislative, regulatory, reputational and financial risks related to the rates of price increases of the company’s top ten branded prescription drugs by sales); and AT&T Inc. (Feb. 13, 2012) (concurring in the exclusion of a proposal requesting a report on financial and reputational risks posed by continuing to use technology that inefficiently consumed electricity).

The Proposal seeks a vote on whether Mallinckrodt should prepare a report regarding risks associated with its manufacture and sale of particular products—those containing opioids. Decisions regarding the manner in which the Company manufactures and sells its products, and the selection of the products it sells and management of the associated risks, are critical day-to-day activities of the Company’s management and subject to direct oversight by the Board, as reviewed in more detail below. Control over decisions regarding the manufacture and sale of opioids and managing the risks associated therewith are fundamental to

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management's ability to run the Company on a day-to-day basis and are not well-suited to direct shareholder oversight.

- ii. The subject matter of the proposal involves the Company's compliance with laws and regulations and its efforts to prevent misuse of its products by customers, which are also part of its ordinary business operations.

To the extent that the report requested by the Proposal is intended to review the Company's compliance with existing laws and regulations regarding opioids in particular or controlled substances more generally, this too is an ordinary business matter of the Company that is not well-suited to direct oversight by shareholders. In a long line of no-action letters, the Staff has consistently agreed that proposals relating to compliance with laws and regulations, including in particular several proposals requesting the preparation and dissemination of a report regarding such compliance and/or risk management more generally, involve ordinary business matters and are excludable under Rule 14a-8(i)(7). See, e.g., Navient Corp. (Mar. 26, 2015) (concurring in the exclusion of a proposal requesting a report on the company's internal controls over its student loan servicing operations, including a discussion of the actions taken to ensure compliance with applicable federal and state laws, as "concern[ing the] company's legal compliance program"); Raytheon Co. (Mar. 25, 2013) (concurring in the exclusion of a proposal requesting a report on the board's oversight of the company's efforts to implement the provisions of the Americans with Disabilities Act, the Fair Labor Standards Act, and the Age Discrimination in Employment Act because "[p]roposals that concern a company's legal compliance program are generally excludable under rule 14a-8(i)(7)"); FMC Corp. (Feb. 25, 2011, recon. denied Mar. 16, 2011) (concurring in the exclusion of a proposal requesting that the board establish a product stewardship program by, among other things, preparing a "report . . . addressing all documented [pesticide] product misuses worldwide . . . and proposing changes to prevent further misuse"); FedEx Corp. (July 14, 2009) (concurring in the exclusion of a proposal requesting a report discussing the compliance of the company and its contractors with state and federal laws governing proper classification of employees and independent contractors); Verizon Communications Inc. (Jan. 7, 2008) (concurring in the exclusion of a proposal requesting the board adopt policies to ensure the company and its contractors do not engage in illegal trespass actions and prepare a report to shareholders describing the company's policies for preventing and handling illegal trespassing incidents); and Halliburton Co. (Mar. 10, 2006) (concurring in the exclusion of a proposal requesting a report evaluating the potential impact of certain violations and investigations on the company's reputation and stock price, as well as the company's plan to prevent further violations, "as relating to [the company's] ordinary business operations (i.e., general conduct of a legal compliance program)").

As a long-time manufacturer of controlled substances, Mallinckrodt, its management and its Board are intimately involved in legal and regulatory compliance activities generally and seek strict compliance with controlled substance laws and regulations in particular.

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Mallinckrodt has undertaken robust efforts to prevent misuse of its products as a matter of its day-to-day business activities relating to the manufacture and sale of its opioid-containing products, as discussed in more detail below. The manner in which the Company monitors and enforces its compliance with various laws and regulations, and attempts to prevent misuse of its products by end-users, are ordinary business matters handled directly by management and overseen by the Compliance Committee of the Board in particular and the full Board more generally. The manner in which the Company monitors such compliance, and the decisions it makes in managing the risks associated therewith, are “matters of a complex nature upon which shareholders, as a group, would not be in a position to make an informed judgment.” The 1998 Release.

D. Although Opioid Abuse Is a Serious Issue, the Proposal Does Not Raise a Significant Social Policy Issue that Transcends the Company’s Ordinary Business.

The sole exception to the general rule permitting exclusion on ordinary-course grounds of matters that are fundamental to management’s ability to run a company on a day-to-day basis as outlined above is for “proposals relating to such matters but focusing on sufficiently significant social policy issues (e.g., significant discrimination matters)” that “transcend the day-to-day business matters and raise policy issues so significant that it would be appropriate for a shareholder vote.” The 1998 Release. As discussed below, the Board acknowledges that opioid abuse is a tragic national crisis that demands and deserves a comprehensive policy response. But the fact that a shareholder proposal touches on admittedly important policy issue in and of itself does not render the proposal non-excludable on ordinary-course grounds. See, e.g., PetSmart, Inc. (Mar. 24, 2011) (concurring with the exclusion of a proposal requesting that the board require its suppliers to certify that they had not violated “the Animal Welfare Act, the Lacey Act, or any state law equivalents,” even though the Staff acknowledged that “the humane treatment of animals is a significant policy issue,” because the scope of the proposal was overly broad and related to a variety of ordinary business matters); and General Electric Co. (Feb. 3, 2005) (concurring in the exclusion of a proposal relating to, among other things, the elimination of jobs within GE and/or relocation of U.S.-based jobs to foreign countries, which the Staff had indicated was a significant policy issue, because the proposal also touched upon job losses within the entire company, whether or not related to the overseas relocation of jobs, and thus dealt with ordinary business matters, “i.e., management of the workforce”). See also Rite Aid Corporation (Mar. 24, 2015) (excluded proposal involving sales of tobacco products); Wal-Mart Stores, Inc. (Mar. 20, 2014) (excluded proposal involving sales of firearms with high-capacity magazines); Cardinal Health, Inc. (Aug. 4, 2017) (excluded proposal involving report on diversion of medicines to prisons for executions); McKesson Corp. (Jun. 1, 2017) (same); Pfizer Inc. (Mar. 1, 2017) (excluded proposal involving report on sale of medicines to prisons for executions); and The Walt Disney Company and Comcast Corporation, infra (excluded proposals involving reports on political spending and lobbying). After thorough review and consideration, the Board

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does not believe that the Proposal transcends the day-to-day business operations of the Company.¹

- i. The underlying subject matter of the proposal involves ordinary business matters.

The Proposal requests that the Board to report on “measures Mallinckrodt has implemented since 2012 to more effectively monitor and manage financial and reputational risks related to the opioid crisis in the U.S., given Mallinckrodt’s sale of opioid medications and active pharmaceutical ingredients in opioid medications.” The effective monitoring and management of financial and reputational risks (including with respect to compliance with laws and regulations regarding controlled substances and preventing misuse by end-users of the Company’s products) do not “transcend” Mallinckrodt’s ordinary business. Indeed, making and selling pharmaceutical products, such as opioids, and making the complex judgments associated with managing risks associated with operating its businesses, including ensuring compliance with laws and regulations, are the ordinary business of management, overseen by the Board and its committees.

This Proposal is similar to other proposals that sought to avoid exclusion under Rule 14a-8(i)(7) by attempting to connect a shareholder proposal that was fundamentally about ordinary business matters to an obviously significant policy issue. Very recently, for example, the Staff recognized that although a proposal by shareholders of The Walt Disney Company referred to the company’s political spending and lobbying (which spending the Staff has previously viewed as a significant policy issue), the thrust of the proposal was the content and management of the company’s news programming, decisions about which are the company’s ordinary business. The Walt Disney Company (Dec. 12, 2017). Similarly, another recent shareholder proposal sought a board report on Comcast’s assessment of the political activity and lobbying resulting from its media outlet and its exposure to risks resulting therefrom. Comcast Corporation (Mar. 2, 2017). The proposal sought to characterize Comcast’s spending of funds used to operate its media outlet as political spending and lobbying. However, the crux of the proposal was the company’s operation of its media outlet, an ordinary business matter for

¹ On November 1, 2017, the Staff published Staff Legal Bulletin No. 14I, which announced a new Staff policy regarding the application of Rule 14a-8(i)(7). The Staff stated that the applicability of the significant policy exception “depends, in part, on the connection between the significant policy issue and the company’s business operations,” which may involve a “difficult judgment call,” but that the company’s board of directors “is well situated to analyze, determine and explain whether a particular issue is sufficiently significant because the matter transcends ordinary business and would be appropriate for a shareholder vote.” The Nominating and Governance Committee (the “Governance Committee”) of the Board reviewed the Proposal and Supporting Statement in consultation with management, and the discussion herein reflects the review and analyses of the Governance Committee, which was subsequently approved by the full Board, as well as the Company’s management.

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Comcast. See also Rite Aid Corporation; Wal-Mart Stores, Inc.; Cardinal Health, Inc.; McKesson Corp.; and Pfizer Inc., supra.

As such, the fact that the Proposal relates to the opioid crisis, which itself involves a significant policy issue, does not preclude the Proposal from exclusion under Rule 14a-8(i)(7). See, e.g., Apache Corporation, (March 5, 2008) (proposal seeking the implementation of certain equal employment opportunity principles prohibiting discrimination based on sexual orientation and gender identity excludable where “some of the principles relate[d] to Apache’s ordinary business operations”). As detailed above, the underlying thrust of the Proposal is the Company’s manufacture and sale of particular products in the ordinary course of its business and its compliance with laws in connection with such operations, which are squarely ordinary business matters and do not “transcend” Mallinckrodt’s day-to-day operations.

- ii. There is not a sufficient nexus between the nature of the Proposal—which seeks to reduce opioid abuse—and the Company.

The Staff further elaborated on the significant social policy exception in SLB 14E, stating that “[i]n those cases in which a proposal’s underlying subject matter transcends the day-to-day business matters of the company and raises policy issues so significant that it would be appropriate for a shareholder vote, the proposal generally will not be excludable under Rule 14a-8(i)(7) as long as a sufficient nexus exists between the nature of the proposal and the company” (emphasis added). The Staff also stated that “[c]onversely, in those cases in which a proposal’s underlying subject matter involves an ordinary business matter to the company, the proposal generally will be excludable under Rule 14a-8(i)(7)” (emphasis added).

There is not a sufficient nexus between the policy issues implicated by the Proposal—which, as indicated in the Supporting Statement, ultimately aims to reduce opioid abuse and misuse—on the one hand, and Mallinckrodt’s ordinary business of manufacturing and selling opioid-containing products, on the other hand, for two reasons: First, Mallinckrodt is a manufacturer of controlled substances, including opioids, but does not promote or distribute controlled substances directly to physicians, patients, or any other end-user and, second, opioid products constitute only a small portion of Mallinckrodt’s revenues.

- (A) *Mallinckrodt does not market or promote its opioid products directly to physicians or patients.*

Mallinckrodt does not market or promote its opioid products to physicians or patients and does not prescribe its opioid products to patients. The Supporting Statement misleadingly attempts to present Mallinckrodt as having a starring role in the abuse and misuse of opioids by stating, among other things, that “Mallinckrodt accounted for 43.8 million of the 236 million opioid prescriptions filled in 2016, according to IMS Health,” without mentioning

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that Mallinckrodt itself filled zero such prescriptions—all such prescriptions were given by healthcare providers and filled by pharmacists, who in turn were generally supplied by third-party distributors. More than 90% of Mallinckrodt’s solid dose generic and non-promoted branded opioids are sold to distributors and large centralized distribution centers, who then in turn supply individual retail pharmacies to fill patient prescriptions. Mallinckrodt has robust legal and regulatory compliance programs and takes the opioid crisis very seriously. Nevertheless, it has only an attenuated role in the risks of abuse of opioids by end-users because it does not interact with end-users in the course of its ordinary business operations. The underlying policy concerns of the Proponents—reducing and ultimately solving opioid abuse—must be primarily addressed by parties closer to the ultimate end-users than Mallinckrodt, and a report regarding measures taken to mitigate such risks would itself demonstrate a limited nexus between the Company and the real and ongoing dangers of the opioid crisis.

The Supporting Statement draws attention to the dire consequences of the opioid crisis by, for example, citing data from the Centers for Disease Control and Prevention (the “CDC”) on the high number of recent deaths in the United States from opioid abuse. But the Supporting Statement does not mention that research detailed on the CDC’s website has identified the following specific risk factors that make people particularly vulnerable to prescription opioid abuse and overdose: “[o]btaining overlapping prescriptions from multiple providers and pharmacies . . . [t]aking high daily dosages of prescription pain relievers . . . [h]aving mental illness or a history of alcohol or other substance abuse . . . and “[l]iving in rural areas and having low income.”² None of these risk factors relate to the Company’s ordinary business of manufacturing pharmaceutical products and selling them to third-party distributors.

According to the CDC’s assessment, to prevent opioid overdose deaths, primary care clinicians and physicians must follow proper prescription practices: “[t]o reverse this epidemic, we need to improve the way we treat pain. We must prevent abuse, addiction, and overdose before they start.”³ The CDC’s recommendations focus on assisting physicians to determine when to initiate or continue opioids for chronic pain. The guidelines discuss several effective alternatives for treating chronic pain, suggesting that patients have been prescribed opioids despite the availability of other alternatives. None of these matters relate directly to the Company and are not suitable topics for reports by the Company or proper subjects for votes of the Company’s shareholders because they are simply not sufficiently connected to the Company’s ordinary business or governance.

² <https://www.cdc.gov/drugoverdose/opioids/prescribed.html#tabs-2-2>.

³ Id.

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(B) *Opioid-containing products constitute only a small portion of Mallinckrodt's revenues.*

Mallinckrodt is a global specialty pharmaceutical company that offers a wide range of products. Opioid products account for only a small portion—less than 10%—of Mallinckrodt's total revenues. During that period, Mallinckrodt's Specialty Generics business segment accounted for roughly one-third (1/3) of the Company's overall annual revenue and approximately half of the revenue in that business segment comes from sales of active pharmaceutical ingredients to other manufacturers. Revenues derived from production and sales of "solid dose" medicines (*i.e.*, pills) make up the other half of segment revenues.

E. *The Proposal Seeks to Micromanage the Company.*

The Staff has consistently granted relief under Rule 14a-8(i)(7) for proposals that seek to "micromanage 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." See, e.g., The Wendy's Company (Mar. 2, 2017) (granting relief for a proposal urging the board "to take all necessary steps to join the Fair Food Program as promptly as feasible for the purpose of protecting and enhancing consumer and investor confidence in the Wendy's brand as it relates to the purchase of produce, and to prepare a report concerning the implementation of the proposal"). By seeking a report regarding risk management of fundamentally ordinary business matters, the Proposal seeks to micromanage the Company's business, and in particular its decisions regarding the manufacture and sale of particular products, compliance with laws and regulations and its allocation of capital resources. The Staff has consistently concurred with requests to exclude such proposals. See, e.g., Apple Inc. (Dec. 5, 2016) (proposal requesting that the board generate a feasible plan to reach net-zero GHG emission status by 2030 for business aspects directly owned by the company and major suppliers and report the plan to shareholders was excludable for micro-managing despite the company's recognition that climate change is a significant policy issue); Deere & Company (Dec. 5, 2016) (same proposal as Apple, *supra*, and excluded on the same basis); Marriott International Inc. (March 17, 2010) (proposal to limit showerhead flow to no more than 1.6 gallons per minute and requiring the installation of mechanical switches to control the level of water flow was excludable for micromanaging despite the Staff's recognition that global warming, which the proposal sought to address, is a significant policy issue); and Ford Motor Company (March 2, 2004) (proposal requesting the preparation and publication of a scientific report regarding the existence of global warming or cooling was excludable "as relating to ordinary business operations").

Overseeing compliance with laws and regulations related to specific products and managing risks relating thereto are the types of day-to-day business operating decisions and responsibilities that the Commission stated in the 1998 Release are too impractical and complex to be subject to direct shareholder oversight. The opioid crisis presents a host of interlocking and

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extremely complex issues that are not easily solved by any one actor or group of actors in the healthcare system. The Company's various potential and actual responses to the risks of opioid abuse by end-users, and the decisions necessary to manage its ordinary business of producing and selling opioid-containing products while attempting to minimize harm associated with potential diversion and misuse of such products are inherently too complex for shareholder votes at annual meetings. The report sought by the Proposal, even if prepared, would not be sufficient for shareholders to make informed decisions about the Company's ordinary business decisions regarding the production and sale of opioid-containing products. As described in the 1998 Release, it would be "impracticable for shareholders to decide how to solve such problems at an annual shareholders meeting."

II. The Company May Exclude the Proposal Pursuant to Rule 14a-8(i)(10) Because the Company has Already Substantially Implemented the Proposal.

Rule 14a-8(i)(10) provides that a company may exclude a stockholder proposal from its proxy materials "[i]f the company has already substantially implemented the proposal." In its adopting release, the Commission explained that the Rule was "designed to avoid the possibility of shareholders having to consider matters which have already been favorably acted upon by the management . . ." Exchange Act Release No. 12,598, 9 SEC Dock. 1030, 1035 (1976). In determining whether a proposal has been "substantially implemented," the Staff has held that the determination "depends upon whether [the company's] particular policies, practices and procedures compare favorably with the guidelines of the proposal." Texaco, Inc. (Mar. 28, 1991). A proposal requesting a report has been "substantially implemented" where the company has made the subject matter of the requested report available publicly, such as on its website. See, e.g., Mondelez International, Inc. (Mar. 7, 2014) (granting relief for a proposal requesting the board to report on the company's process for identifying and analyzing potential and actual human rights risks of its operations and supply chain, where the company made relevant information available on its website).

Mallinckrodt has been at the forefront in developing a comprehensive, industry-leading opioid anti-diversion program by working with its customer-distributors, the U.S. Drug Enforcement Agency ("DEA") and law enforcement to prevent prescription drug diversion, misuse and abuse. Mallinckrodt has a demonstrated record of meeting and exceeding the requirements of federal and state laws governing the manufacturing, sale and distribution of controlled substances. As disclosed on the Company's website (and periodically updated as applicable),⁴ the Company has implemented a multi-pronged approach to address the abuse of prescription opioids, including:

⁴ Mallinckrodt plc, Responsible Use Programs, available at: <https://www.mallinckrodt.com/corporate-responsibility/safe-use-initiatives>.

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- Purchase and donation of more than 1.5 million drug deactivation pouches to help combat abuse of prescription pain medications. Through this initiative, families can actively address concerns with the responsible use of pain medications, patient safety and responsible drug disposal. The pouch-based systems deactivate prescription drugs and render chemical compounds safe for landfills;
- Supported improvement of integration of federal and state prescription drug monitoring programs and strongly advocated in support of such a program in Missouri;
- Enhanced addiction rehabilitation and drug take-back programs, including provision of drop boxes to local law enforcement in communities where major Company sites reside;
- Collaboration with law enforcement to help prevent misuse and diversion, including by: (i) providing no-cost placebo tablets of Mallinckrodt opioids to officers and prosecutors for use in law enforcement operations, (ii) attacking pharmacy robberies through tracking devices in selected “dummy” bottles that look like the Company’s product and (iii) contributing testimony on behalf of the prosecution in drug diversion cases;
- Improving stakeholder education for patients, providers and the public at large, including education initiatives validated by measurable outcomes;
- Partnering with stakeholders and strategically aligned third-party organizations, in part through founding the Anti-Diversion Industry Working Group, a collective of leading manufacturers and distributors of controlled substances coming together to collaborate and share best practices with the purpose of exceeding DEA obligations for opioid anti-diversion programs; and
- Joining the Massachusetts Health & Hospital Association in June 2017 to announce the release of the Pain Stewardship Program (PSP) for providers and clinical staff. Developed in collaboration with a multidisciplinary team of expert advisors, the mission of the PSP is to educate hospital stakeholders on multimodal analgesia-based acute pain management to support improvements in in-hospital opioid use, length of stay and satisfaction with treatment. Sponsored by Mallinckrodt, the program provides—at no charge—evidence-based, educational

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pain management tools to help assess current hospital protocols and identify areas for improvement.⁵

Additionally, Mallinckrodt has already made a variety of other public disclosures about these matters. Significantly, in September 2017, Mallinckrodt published six (6) integrated policy initiatives to address opioid abuse and misuse.⁶ In its most recent annual report, Mallinckrodt disclosed the various compliance programs it has established, including ongoing compliance training programs for all employees and a twenty four (24) hour ethics and compliance reporting hotline with a strict non-retaliation policy.⁷ With respect to controlled substances in particular, the Company disclosed that “[w]e have also implemented a comprehensive controlled substances compliance program, including anti-diversion efforts and we regularly assist federal, state and local law enforcement and prosecutors in the U.S. by providing information and testimony on our products and placebos for use by the DEA and other law enforcement agencies in investigations and at trial. As part of this program, we also work with some of our customers to help develop and implement what we believe are best practices for SOM and other anti-diversion activities.”

To the extent the Proposal is viewed as a request for the Board to oversee risk management, the Proposal has been substantially implemented and, therefore, may be excluded under Rule 14a-8(i)(10). As disclosed in the Company’s Proxy Statement for its 2017 Annual General Meeting of Shareholders (the “2017 Proxy Statement”), “[a] fundamental part of risk management is not only understanding the risks we face and what steps management is taking to manage those risks, but also understanding what level of risk is appropriate for us. The involvement of the full Board in approving our business strategy is a key part of its assessment of management’s appetite for risk and the determination of what constitutes an appropriate level of risk for us.”⁸ The 2017 Proxy Statement also describes the committees of the Board and their and management’s roles in regularly reviewing and monitoring key risks, including financial and reputational risks related to the sale of opioid-containing products, which is directly responsive for the Proposal’s request for a report on Board oversight of such risks.

The foregoing disclosures from the 2017 Proxy Statement, as well as the Company’s publicly available Corporate Governance Guidelines, and Board committee charters, make clear that the Board and its committees have responsibility for overseeing reputational and

⁵ News Release of Mallinckrodt plc (Jun. 21, 2017), available at: <https://www.mallinckrodt.com/about/news-and-media/2282198>.

⁶ Mallinckrodt plc, A Prescription for America’s Opioid Epidemic: Six Integrated Policy Initiatives to Address Opioid Abuse and Misuse, available at: <http://www.mallinckrodt.com/Content/files/MNK%20Prescription%20Drug%20Abuse%20Policy%20Proposals%209-21-17.pdf>.

⁷ Mallinckrodt plc, Form 10-K for the fiscal year ended September 30, 2016, available at: <https://www.sec.gov/Archives/edgar/data/1567892/000156789216000098/mnk10-k93016.htm>.

⁸ Mallinckrodt plc, Definitive Proxy Statement on Schedule 14A, filed Jan. 18, 2017, page 12.

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financial risks across the spectrum, including its manufacture and sale of opioid products. The Company does not believe that it is necessary or common to specifically reference risks related to particular categories of products in corporate governance documents, especially when a company sells many types of products across a variety of businesses and the opioid related products constitute a notable minority of the Company's business.

CONCLUSION

Based on the foregoing analyses, the Company respectfully requests the Staff's concurrence with the Company's view or, alternatively, that the Staff confirm that it will not recommend any enforcement action if the Company excludes the Proposal and the Supporting Statement from the 2018 Proxy Materials.

If we can be of any further assistance in this matter, please do not hesitate to call the undersigned at (212) 403-1005. If the Staff is unable to concur with the Company's conclusions without additional information or discussions, the Company respectfully requests the opportunity to confer with members of the Staff prior to the issuance of any written response to this letter. In accordance with Staff Legal Bulletin No. 14F, Part F (Oct. 18, 2011), please send your response to this letter by email to VGoldfeld@wlrk.com.

Very truly yours,



Victor Goldfeld

Enclosures

cc: Michael-Bryant Hicks, Mallinckrodt plc
Stephanie D. Miller, Mallinckrodt plc

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Exhibit A



September 15, 2017

Stephanie D. Miller, Vice President and Corporate Secretary
Mallinckrodt plc
3 Lotus Park
The Causeway
Staines-Upon-Thames, Surrey TW18 3AG
United Kingdom

Dear Ms. Miller:

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

Mercy is requesting Mallinckrodt plc to report to shareholders by September 30, 2018, on the governance measures Mallinckrodt has implemented since 2012 to more effectively monitor and manage financial and reputational risks related to the opioid crisis in the U.S.

Mercy Investment Services, Inc., is co-filing the enclosed shareholder proposal with Providence Trust for inclusion in the 2018 proxy statement, in accordance with Rule 14a-8 of the General Rules and Regulations of the Securities Exchange Act of 1934. Mercy Investment Services, Inc. has been a shareholder continuously for more than one year and will continue to invest in at least the requisite number of shares for proxy resolutions through the annual shareholders' meeting. A representative of the filers will attend the Annual Meeting to move the resolution as required by SEC rules. The verification of ownership is being sent to you separately by our custodian, a DTC participant. Providence Trust may withdraw the proposal on our behalf. We respectfully request direct communications from Mallinckrodt plc, and to have our supporting statement and organization name included in the proxy statement.

Although we prefer to resolve our concerns through dialogue rather than the formal resolution process, we are filing today to assure our shareholder rights are preserved. We commend the company for its openness to dialogue with Mercy Investment Services and other investors and look forward to having productive conversations with the company in the future. Please direct your responses to me via my contact information below.

Best regards,

A handwritten signature in cursive script that reads "Donna Meyer".

Donna Meyer
Director, Shareholder Advocacy
713-667-1715
dmeyer@mercyinvestments.org

RESOLVED, that shareholders of Mallinckrodt plc (“Mallinckrodt”) urge the Board of Directors (the “Board”) to report to shareholders by September 30, 2018 on the governance measures Mallinckrodt has implemented since 2012 to more effectively monitor and manage financial and reputational risks related to the opioid crisis in the U.S., given Mallinckrodt’s sale of opioid medications and active pharmaceutical ingredients in opioid medications, including whether Mallinckrodt has assigned responsibility for such monitoring to the Board or one or more Board committees, revised senior executive compensation metrics or policies, adopted or changed mechanisms for obtaining input from stakeholders, or altered policies or processes regarding company political activities.

The report should be prepared at reasonable cost and should omit confidential and proprietary information.

SUPPORTING STATEMENT

Opioid abuse is undeniably a public health crisis: The Centers for Disease Control and Prevention reported that in 2015, opioid abuse caused more than 33,000 deaths in the U.S., or 91 people per day. The economic and social effects of the opioid crisis have been profound. Opioid use and dependency, according to a recent Goldman Sachs study, is a key factor in why many men of prime working age in the U.S. are unable or unwilling to find work. Costs associated with opioid abuse strain patients, health care payers and state and local budgets.

Mallinckrodt accounted for 43.8 million of the 236 million opioid prescriptions filled in 2016, according to IMS Health, and has come under scrutiny for its sales and marketing practices. Mallinckrodt recently settled federal claims involving its sales and distribution of controlled substances, including opioids. On July 27, 2017, Mallinckrodt received a subpoena from the U.S. Department of Justice seeking information on the company’s promotional practices for, and sales of, opioid products.

Attention has focused on Mallinckrodt’s increased political spending and lobbying amidst public outcry over the opioid crisis and demands for more regulation and enforcement. (E.g., <https://www.nytimes.com/2017/07/21/business/a-drug-maker-spends-big-in-washington-to-make-itself-heard.html?mcubz=1>)

Mallinckrodt discloses on its website a number of steps it has taken in the last several years to combat diversion and illegal sale of opioids, including founding the Anti-Diversion Industry Working Group. We believe, however, that Board-level oversight and governance reforms can play an important role in effectively addressing opioid-related risks and that shareholders would benefit from a fuller understanding of governance mechanisms serving that function.

For example, it is not clear from Mallinckrodt’s Board committee charters or proxy statement whether a specific Board committee monitors opioid-related financial and reputational risks, though the Compliance Committee charter mentions potentially opioid-related matters such as DEA and off-label promotion compliance. As well, Mallinckrodt’s most recent proxy statement asserts that “building a patient- and customer centric high-performing organization” is among the “strategic imperatives” used to assess named executive officer individual performance for incentive compensation purposes, but does not indicate whether any opioid-related objectives, such as promoting ethical conduct or working effectively with stakeholders, were considered.

We urge shareholders to vote for this proposal.



BNY MELLON

September 15, 2017

Stephanie D. Miller
Vice President and Corporate Secretary
Mallinckrodt plc
3 Lotus Park
The Causeway
Staines-Upon-Thames, Surry TW18 3AG
United Kingdom
Phone: +44 017 8463 6700

Re: Mercy Investment Services Inc.

Dear Ms. Miller,

This letter will certify that as of September 15, 2017, The Bank of New York Mellon held for the beneficial interest of Mercy Investment Services Inc., 38 shares of Mallinckrodt Plc and that such beneficial ownership has existed continuously for more than one year as of September 15, 2017. Also, please be advised, The Bank of New York Mellon is a DTC Participant, whose DTC number is 0901.

If you have any questions please feel free to give me a call.

Sincerely,

Thomas J. McNally
Vice President, Service Director
BNY Mellon Asset Servicing

Phone: (412) 234-8822
Email: thomas.mcnally@bnymellon.com

PROVIDENCE TRUST

SAN ANTONIO, TEXAS

September 15, 2017

Stephanie D. Miller, Vice President and Corporate Secretary
Mallinckrodt plc
3 Lotus Park
The Causeway
Staines-Upon-Thames, Surry TW18 3AG
United Kingdom

Dear Ms. Miller:

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

Providence Trust is requesting Mallinckrodt plc to report to shareholders by September 30, 2018, on the governance measures Mallinckrodt has implemented since 2012 to more effectively monitor and manage financial and reputational risks related to the opioid crisis in the U.S.

Providence Trust is filing the enclosed shareholder proposal for inclusion in the 2018 proxy statement, in accordance with Rule 14a-8 of the General Rules and Regulations of the Securities Exchange Act of 1934. Providence Trust has been a shareholder continuously for more than one year holding at least \$2,000 in market value, and will continue to invest in at least the requisite number of shares for proxy resolutions through the annual shareholders' meeting. A representative of the filers will attend the Annual Meeting to move the resolution as required by SEC rules. The verification of ownership is enclosed and is also being sent to you separately by our custodian, a DTC participant. We respectfully request direct communications from Mallinckrodt, and to have our supporting statement and organization name included in the proxy statement.

Although we prefer to resolve our concerns through dialogue rather than the formal resolution process, we are filing today to assure our shareholder rights are preserved. We look forward to having productive conversations with the company. Please direct your responses to Donna Meyer, Director, Shareholder Advocacy, Mercy Investment Services, Inc., 713-667-1715, dmeyer@mercyinvestments.org.

Best regards,



Sister Ramona Bezner, CDP
Trustee

The Quantitative Group
755 E Mulberry Ave
Suite 300
San Antonio, TX 78212
tel 210 277 4400
fax 210 735 1150
coll free 800 733 1150

Graystone
ConsultingSM

September 15, 2017

Stephanie D. Miller, Vice President and Corporate Secretary
Mallinckrodt plc
3 Lotus Park
The Causeway
Staines-Upon-Thames
Surry TW18 3AG
United Kingdom

Re: Providence Trust

Dear Ms. Miller,

This letter will certify that as of September 15, 2017, Morgan Stanley held for the beneficial interest of Providence Trust, 898 shares of Mallinckrodt plc.

We confirm that Providence Trust has beneficial ownership of at least \$2,000 in market value of the voting securities of Mallinckrodt plc, and that such beneficial ownership has existed continuously for one or more years in accordance with rule 14a-8(a)(1) of the Securities Exchange Act of 1934.

Further, it is Providence Trust intent to hold at least \$2,000 in market value through the next annual meeting.

Please be advised, Morgan Stanley, Inc. is a DTC Participant, whose DTC number is 0015.

If you have any questions, please feel free to give me a call at (210) 366-6660

Sincerely,



Heidi Siller
Registered Associate
The Quantitative Group at Graystone Consulting
A Business of Morgan Stanley

RESOLVED, that shareholders of Mallinckrodt plc (“Mallinckrodt”) urge the Board of Directors (the “Board”) to report to shareholders by September 30, 2018 on the governance measures Mallinckrodt has implemented since 2012 to more effectively monitor and manage financial and reputational risks related to the opioid crisis in the U.S., given Mallinckrodt’s sale of opioid medications and active pharmaceutical ingredients in opioid medications, including whether Mallinckrodt has assigned responsibility for such monitoring to the Board or one or more Board committees, revised senior executive compensation metrics or policies, adopted or changed mechanisms for obtaining input from stakeholders, or altered policies or processes regarding company political activities.

The report should be prepared at reasonable cost and should omit confidential and proprietary information.

SUPPORTING STATEMENT

Opioid abuse is undeniably a public health crisis: The Centers for Disease Control and Prevention reported that in 2015, opioid abuse caused more than 33,000 deaths in the U.S., or 91 people per day. The economic and social effects of the opioid crisis have been profound. Opioid use and dependency, according to a recent Goldman Sachs study, is a key factor in why many men of prime working age in the U.S. are unable or unwilling to find work. Costs associated with opioid abuse strain patients, health care payers and state and local budgets.

Mallinckrodt accounted for 43.8 million of the 236 million opioid prescriptions filled in 2016, according to IMS Health, and has come under scrutiny for its sales and marketing practices. Mallinckrodt recently settled federal claims involving its sales and distribution of controlled substances, including opioids. On July 27, 2017, Mallinckrodt received a subpoena from the U.S. Department of Justice seeking information on the company’s promotional practices for, and sales of, opioid products.

Attention has focused on Mallinckrodt’s increased political spending and lobbying amidst public outcry over the opioid crisis and demands for more regulation and enforcement. (E.g., <https://www.nytimes.com/2017/07/21/business/a-drug-maker-spends-big-in-washington-to-make-itself-heard.html?mcubz=1>)

Mallinckrodt discloses on its website a number of steps it has taken in the last several years to combat diversion and illegal sale of opioids, including founding the Anti-Diversion Industry Working Group. We believe, however, that Board-level oversight and governance reforms can play an important role in effectively addressing opioid-related risks and that shareholders would benefit from a fuller understanding of governance mechanisms serving that function.

For example, it is not clear from Mallinckrodt’s Board committee charters or proxy statement whether a specific Board committee monitors opioid-related financial and reputational risks, though the Compliance Committee charter mentions potentially opioid-related matters such as DEA and off-label promotion compliance. As well, Mallinckrodt’s most recent proxy statement asserts that “building a patient- and customer centric high-performing organization” is among the “strategic imperatives” used to assess named executive officer individual performance for incentive compensation purposes, but does not indicate whether any opioid-related objectives, such as promoting ethical conduct or working effectively with stakeholders, were considered.

We urge shareholders to vote for this proposal.

September 19, 2017

Stephanie D. Miller, Vice President and Corporate Secretary
Mallinckrodt plc
3 Lotus Park
The Causeway
Staines-Upton-Thames, Surry TW18 3AG
United Kingdom

Dear Ms. Miller:

Catholic Health Initiatives is one of the largest Catholic health care systems in the country, with operations in 17 states comprised of 100 hospitals, including four academic health centers and major teaching hospitals as well as 30 critical-access facilities; community health-services organizations; accredited nursing colleges; home-health agencies; living communities; and other facilities that span the inpatient and outpatient continuum of care.

As a religiously sponsored organization, Catholic Health Initiatives seeks to reflect its mission, vision and values in its investment decisions. Catholic Health Initiatives has significant concerns about the national opioid crisis. We request Mallinckrodt plc, report to shareholders by September 30, 2018, on the governance measures Mallinckrodt has implemented since 2012 to more effectively monitor and manage financial and reputational risks related to the opioid crisis in the U.S.

Catholic Health Initiatives is the beneficial owner of over \$2000 worth of common stock in Mallinckrodt plc. Through this letter we notify the company of our intention to file the enclosed resolution. We present it for inclusion in the proxy statement for action at the next stockholders meeting in accordance with Rule 14(a)(8) of the General Rules and Regulations of the Securities and Exchange Act of 1934.

Verification of our ownership of this stock for at least one year is enclosed. We intend to maintain ownership through the date of the annual meeting. There will be a representative present at the stockholders meeting to present this resolution as required by the SEC Rules.

I will serve as the contact for Catholic Health Initiatives and can be reached at 303-383-2693. We are filing this resolution along with other concerned investors including primary filer, Providence Trust. It is our tradition as a religiously sponsored organization to seek dialogue with companies on the issue in the resolution offered to the shareholders. We hope that a discussion of this sort is of interest to you as well.

Sincerely,



Colleen Scanlon
Senior Vice President & Chief Advocacy Officer
Attachments

CS/dm

cc: Donna Meyer, Mercy Investment Services
Julie Wokaty, Interfaith Center on Corporate Responsibility

Financial & Reputational Risks Related to the Opioid Crisis 2018 – Mallinckrodt Group Inc.

RESOLVED, that shareholders of Mallinckrodt plc (“Mallinckrodt”) urge the Board of Directors (the “Board”) to report to shareholders by September 30, 2018 on the governance measures Mallinckrodt has implemented since 2012 to more effectively monitor and manage financial and reputational risks related to the opioid crisis in the U.S., given Mallinckrodt’s sale of opioid medications and active pharmaceutical ingredients in opioid medications, including whether Mallinckrodt has assigned responsibility for such monitoring to the Board or one or more Board committees, revised senior executive compensation metrics or policies, adopted or changed mechanisms for obtaining input from stakeholders, or altered policies or processes regarding company political activities.

The report should be prepared at reasonable cost and should omit confidential and proprietary information.

Supporting Statement: Opioid abuse is undeniably a public health crisis: The Centers for Disease Control and Prevention reported that in 2015, opioid abuse caused more than 33,000 deaths in the U.S., or 91 people per day. The economic and social effects of the opioid crisis have been profound. Opioid use and dependency, according to a recent Goldman Sachs study, is a key factor in why many men of prime working age in the U.S. are unable or unwilling to find work. Costs associated with opioid abuse strain patients, health care payers and state and local budgets.

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We urge shareholders to vote for this proposal.



BNY MELLON

September 19, 2017

Jennifer Neppel
Director, Cash & Investments
Catholic Health Initiatives
198 Inverness Drive West
Suite 800
Englewood, CO 80112

RE: Shareholder Activism Account Number *** – Mallinckrodt PLC

Dear Jennifer,

This letter is in response to your request for confirmation that Catholic Health Initiatives currently holds 82 shares of Mallinckrodt PLC in the CHI Operating Investment Program Limited Partnership.

Catholic Health Initiatives has continuously held these shares of stock for at least one year prior to and including submission of CHI's letter of proposal and such investment has a market value greater than \$2,000.

This security is currently held by The Bank of New York Mellon for Catholic Health Initiatives in our nominee name at the Depository Trust Company. This letter is a statement of The Bank of New York Mellon Corporation as record holder of the above referenced common stock.

Should you have any questions, please contact me at 412.234.8014.

Best regards,

Nina Caruso
Vice President, Service Director
The Bank of New York Mellon
BNY Mellon Center
Suite 4040
Pittsburgh, PA 15258