Merck & Co., Inc.
Form PX14A6G
April 17, 2017

Open Letter Regarding Trillium Asset Management's Shareholder Proposal at
Merck & Co. Regarding Opportunities to Strengthen Board Oversight of Product Manufacturing Quality and Safety

April 17, 2017

Dear Merck & Co. shareholders and proxy advisory services,

Trillium Asset Management, has filed a shareholder proposal (Proposal 8 on the company proxy materials) at Merck & Co. asking the Board to:

issue a report (at reasonable cost, in a reasonable time and excluding confidential information) evaluating the merits and feasibility of Merck (1) strengthening Board expertise in pharmaceutical manufacturing and product quality and safety, (2) adopting an independent board chair leadership structure, and (3) any other related governance improvements the Board wishes to consider.[1]

Stated briefly, given the extraordinarily high risks for Merck with respect to manufacturing product quality and safety, it is common sense for the Board to take a reasonable amount of time to evaluate and report out on whether they have the right governance in place to oversee these significant and material risks. Specifically, whether the board is developing and selecting the skills, expertise, and experience it needs to correctly evaluate and oversee manufacturing product safety and quality. Unfortunately, experience in product quality, safety or pharmaceutical manufacturing is not identified for any of the company's board members.

Product manufacturing safety and quality is a high risk issue area for Merck & Co.

- Merck develops and globally sells biopharmaceuticals manufactured in high production volumes at numerous facilities in the United States, Puerto Rico, Japan, Singapore, South Africa, Western Europe, Central and South America, and Asia overseen from its manufacturing headquarters in New Jersey. Therefore, the company is exposed to many product safety and quality related risks, including operating, regulatory adherence, financial, reputational, and litigation.
- MSCI's ESG Manager concludes that Merck has a high risk exposure on product safety and quality, but lacks the strong product safety and quality management policies and practices necessary for its level of risk – making it a laggard compared to peers.

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[1] http://www.trilliuminvest.com/shareholder-proposal/merck-product-safety-quality-2017/

- The United States Food and Drug Administration (FDA) and increasingly its international counterparts are prioritizing that biopharma manufacturers produce more consistent and higher quality outcomes in their manufacturing production lots. To provide better regulatory oversight in this area, the FDA formed an Office of Pharmaceutical Quality (OPQ) in 2014 and developed a Pharma Quality System (PQS) with detailed guidelines in the areas of Quality, Production, Laboratory, Facilities Management, Materials, and Packaging/Labeling. Furthermore, the FDA's PQS notes that biopharma company management is responsible for a company's 1) leadership and commitment to quality, 2) quality planning, including addressing complaints, 3) resource management, 4) internal communication, 5) management review of manufacturing and quality, and 6) oversight of outsourced activities.[2] Regulators also consider biopharma companies manufacturing site inspections with new drug approvals, which are key to helping the company achieve sustainable revenue and cash flow growth. As a result, it is important for biopharma companies' Boards to include 1) specific committee oversight for manufacturing product quality and safety and 2) multiple members with biopharma manufacturing skills and experience to ensure the company is a leader in this key operating area and minimize the risks noted earlier.
- Merck received a warning letter in 2016, a Form 483 in 2015, and six Form 483s in 2014, indicating potential manufacturing site and emerging quality issues in the company's operations.
- An October 2016 PWC survey reported that 85% of board members in the pharma/life sciences industry feel that regulatory compliance risks pose the greatest oversight challenges to their boards.[3]
- As Merck's reputation with institutional investors and sell side Pharma Industry Research Analysts improves, particularly with the future commercial potential of Keytruda, pressure may build over time for Merck's management to meet operating margin, cash flow, and earnings metrics that support short-term shareholder return generation. We fear this pressure may potentially incentivize Merck's management to misspend on necessary operating expenses and capital expenditures to support leading manufacturing product quality assurance and controls. Moreover, we know that the company's CEO and Named Executive Officers total compensation is significantly tied to cumulative, three-year Operating Cash Flow and relative total shareholder return performance vs. its peer group, as well as revenues and EPS.

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[2] The Pharmaceutical Quality System (PQS) presentation slides by Robert Iser, Scientific Advisor, Office of Process and Facilities, Office of Pharmaceutical Quality, FDA's "Regulatory Education for Industry: Focus on CGMPs & FDA Inspections" Conference, July 15-16, 2015.

[3] http://www.pwc.com/us/en/corporate-governance/annual-corporate-directors-survey/board-composition-and-diversity.html

The Board's primary assertion in its statement of opposition to this shareholder proposal is that the independence of the members of the board and their commitment to product quality and safety provides effective oversight of the business. However, in Merck's 2017 proxy describing the "Experience and Qualifications of Particular Relevance to Merck" of its director nominees – experience in quality, safety or pharmaceutical manufacturing is not identified for any nominees. In contrast Eli Lilly, Bristol Myers Squib, and Johnson and Johnson proxies each have one director with expressly identified experience in manufacturing.

Merck's 2017 proxy highlights a number of areas of expertise and qualification for being nominated to the board including finance, management, investment banking, operational, technology, marketing, communications, science, medical, and international business. We do not doubt that these are important and necessary areas of expertise. However, we are concerned that in the midst of all of these qualifications, that product safety, quality, and manufacturing are not identified.

As such, the disagreement really comes down to whether the board should re-examine if it has the right expertise on the board to oversee product quality and safety. There is no debate over whether manufacturing product quality and safety is a particularly high-risk issue for Merck. There is no debate over whether product quality and safety is of the utmost importance to the Board and is part of its responsibilities to oversee. The question that is raised is whether the Board should take a reasonable amount of time to evaluate the merits of strengthening Board expertise in manufacturing product quality and safety.

Can the Board effectively oversee operational and executive personnel if they do not themselves have individuals on the board with expertise in biopharmaceutical product manufacturing, quality, and safety? Would the board ask better questions of management and/or external experts/consultants with board members with expertise? Will they be better able to discern the wheat from the chaff in the answers and reports they get from operational, manufacturing, and executive personnel with expertise? Will they be better able to guide and advise the company on product quality and safety with expertise on the board? Would the board's Compensation and Benefits Committee members be better prepared to ensure better alignment of CEO and NEO incentive compensation with the company's important and relevant manufacturing product quality and safety metrics?

We respectfully believe the answer is, yes of course. How could that not be the case? In today's high risk environment this is an area where we believe the Board should make sure it is going above and beyond to demonstrate its command of manufacturing product quality and safety oversight.

We believe the requirement for deep expertise in this key business area is similar to Merck existing priority to seek Board members with skills and experience in 1) medicine, science, research, and development, 2) regulatory affairs, 3) finance and accounting, and 4) talent management. This is of course, good governance and as volumes of research have shown, improving governance is linked to reduced business risk and lower valuation discount rates (increased forward valuation multiples).[4]

For these reasons, we respectfully urge you to support Proposal 8 on the company proxy ballot.

Sincerely,

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IMPORTANT NOTICE: The cost of this communication is being borne entirely by Trillium Asset Management, LLC. Trillium is NOT asking for your proxy card and is not providing investment advice. We will not accept proxy cards, and any proxy cards received will be returned.

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[4] E.g. El Ghoul, Sadok; Guedhami, Omrane; Kwok, Chuck C. Y.; Mishra, Dev R.; Journal of Banking and Finance, 9/2011. Bebchuk, Lucian; Cohen, Alma; Ferrell, Allen; The Review of Financial Studies, 9/2004. Regalli, Massimo; Soana, Maria-Gaia; Working Paper, 12/26/2010. "Learning and the disappearing association between governance and returns", Bebchuk, Lucian; Shoen, Alma; Wang, Charles C.Y.; Journal of Financial Economics, 12/2011. "The AGR Anomaly: Corporate Governance and the Systematic Mispricing of US Stocks", Torous, Walter and Allred, Micah; Working Paper, UCLA Anderson School of Management, 5/19/2010. "Corporate governance and valuation: an integrated approach", QSG Equity Research, 6/2010. "Corporate governance and firm value: International evidence", Ammann, Manuel; Oesch, David; Schmid, Markus; Journal of Empirical Finance, 10/20/2010.