NOTICE OF EXEMPT SOLICITATION

NAME OF REGISTRANT: Merck
NAME OF PERSON RELYING ON EXEMPT SOLICITATION: Oxfam America
ADDRESS OF PERSON RELYING ON EXEMPT SOLICITATION: 77 North Washington Street, Suite 5-1, Boston, MA 02114

Written materials are submitted pursuant to Rule 14a-6(g)(1) promulgated under the Securities Exchange Act of 1934. Submission is not required of this filer under the terms of the Rule, but is made voluntarily in the interest of public disclosure and consideration of these important issues.

Oxfam America urges you to vote FOR Proposal 6 asking Merck for greater transparency on whether and how R&D funding from the US government is accounted for in its access strategy at Merck’s annual meeting of shareholders on May 23, 2023.

I. SUMMARY OF RESOLUTION

RESOLVED: shareholders of Merck & Co, Inc. (“Merck”) ask the Board of Directors to report to shareholders, at reasonable expense and omitting confidential and proprietary information, on whether and how the direct and indirect receipt of public financial support for development and manufacture of a therapeutic for COVID-19 is being, or will be, taken into account when making decisions that affect access to such products, such as sharing intellectual property through voluntary licenses or setting prices.

Merck’s antiviral medicine, molnupiravir (LAGEVRIO), is approved on an emergency basis for use as a treatment against COVID-19. Molnupiravir, which was initially developed in the labs of Emory University, received $35 million in US government funding, before being further developed by Ridgeback and Merck.

With the persistence of both the COVID-19 pandemic and vaccine inequity, treatment for COVID-19 remains a critical element to avert further global morbidity and mortality. According to the US National Institutes of Health, molnupiravir is authorized for people with COVID-19 “who are at high risk of progressing to severe disease, and for whom alternative antiviral therapies are not accessible or clinically appropriate.” Merck brought in more than $5.68 billion from sales of this publicly funded treatment in 2022, making it Merck’s third highest revenue product. However, the company has not been transparent about whether and how public investment in this medicine has factored into the company’s access considerations, such as pricing and licensing decisions.

1 https://www.who.int/publications/i/item/WHO-2019-nCoV-therapeutics-2022.4
4 https://www.covid19treatmentguidelines.nih.gov/therapies/antiviral-therapy/molnupiravir/#-.text=In%20nonhospitalized%20patients%20aged%20%25,E2%89%A5,(Paxlovid)%2C%20sotrovimab%2C%20or
In March 2022, Merck announced its commitment to make the medicine more widely available and stated that “global access has been a priority,” but Merck has not disclosed how the US government’s funding of the product factors into decisions that affect access. Setting inaccessible prices or otherwise failing to deliver equitable access to this publicly funded treatment poses both public health and financial risks. It jeopardizes the company’s reputation and invites risks of increased regulation and oversight, ultimately harming investor returns. This Proposal addresses these risks by asking Merck to explain whether and how public contributions to its products affect how Merck considers access, for example in setting prices or deciding the scope of voluntary licenses.

II. ARGUMENTS IN FAVOR OF A “FOR” VOTE

1. Merck’s access strategy for molnupiravir creates reputational risk for the company and its investors.

Merck’s uneven licensing and pricing strategies of its treatment could cause reputational harm to the company. The company’s “access” strategy for molnupiravir centers on voluntary licenses – through bilateral agreements and with the Medicines Patent Pool (MPP) – that leave approximately half of the world’s population without affordable access to the medicine. Competitor Shionogi has since signed an MPP agreement for their candidate oral COVID-19 treatment that includes more countries than Merck’s license. The countries Merck’s license excludes, including developing middle-income countries, are subject to the company’s opaque and non-transparent tiered pricing strategy. Tiered pricing often results in unaffordable prices for medicines. The fact that tiered pricing can result in unaffordable prices for LMICs is evidenced by the high prices documented across a range of countries for other products from Merck, including its human papillomavirus (HPV) vaccine and its antiretroviral medicines, such as raltegravir.

Merck’s uneven access strategy attracted public criticism. The World Health Organization (WHO) reportedly “acknowledge[d] that cost and availability issues associated with molnupiravir may make access to low- and middle-income countries challenging and exacerbate health inequity.” The report of the WHO’s ACT-Accelerator’s Working Group on COVID-19 Diagnostics and Therapeutics similarly noted that affordability challenges for oral antivirals persist for LMICs “as a result of high prices on originator products and limited opportunities to negotiate prices.”

16 https://www.who.int/publications/m/item/act-accelerator-facilitation-council-working-group-report-on-diagnostics-and-therapeutics
Furthermore, Merck is charging high prices in high-income countries, such as the United States, even though the US government contributed to research and development for the medicine.\textsuperscript{17} In particular, Merck’s price in the United States is at a price per course that is more than 35 times the estimated sustainable generic price.\textsuperscript{18} For the 3.1 million doses the US government purchased,\textsuperscript{19} that represents an estimated markup of over $2.1 billion on a treatment developed with public funding. Merck anticipates generating more than $7.6 billion in cumulative molnupiravir sales globally by the end of 2023.\textsuperscript{20} Previously Merck has attracted negative public attention due to the high prices the company has charged for its HPV\textsuperscript{21} and HIV/AIDS\textsuperscript{22} products (including price hikes for its HPV vaccine). The company could face criticism and reputational damage if high prices for molnupiravir are shifted to US patients via the private market despite prior US government R&D investment.\textsuperscript{23} Merck’s pricing also faces questions in other high-income countries with the UK’s agency responsible for recommendations on drug coverage recommending against the use of molnupiravir due to a lack of cost effectiveness.\textsuperscript{24}

2. **Merck faces increased regulatory risks during and after the COVID-19 pandemic due to its failure to be transparent about the role of public funding in treatment access.**

Merck’s lack of pricing transparency for molnupiravir risks potential increased regulation and oversight from governments. As demonstrated by the Inflation Reduction Act,\textsuperscript{25} the Pandemic Preparedness Treaty negotiations,\textsuperscript{26} and the TRIPS Agreement COVID-19 Decision deliberations,\textsuperscript{27} if corporations do not voluntarily cooperate with governments to make their life-saving products sustainable, equitable, and timely in access, mandatory government regulation may be more likely and potentially more costly to implement. For example, in response to public outcry over the high prices of medicines, Congress passed the Inflation Reduction Act enabling price negotiations for certain medicines under Medicare. Moody’s warns that the $100 billion in savings the US government will generate over 10 years by negotiating prices will be “generally borne by the industry.”\textsuperscript{28}

\begin{itemize}
  \item \textsuperscript{17} https://theintercept.com/2021/10/05/covid-pill-drug-pricing-merck-ridgeback/
  \item \textsuperscript{18} https://scholar.harvard.edu/files/melissabarber/files/estimated_cost-based_generic_prices_for_molnupiravir_for_the_treatment_of_covid-19_infection.pdf
  \item \textsuperscript{21} https://www.fiercepharma.com/pharma/merck-amgen-adopt-double-digit-price-hikes-test-to-pharma-s-drug-cost-limits-analysts
  \item \textsuperscript{23} https://www.washingtonpost.com/health/2022/03/10/congress-covid-funding/
  \item \textsuperscript{24} https://www.nice.org.uk/news/article/nice-recommends-3-treatments-for-covid-19-in-draft-guidance
  \item \textsuperscript{25} https://www.kff.org/medicare/issue-brief/explaining-the-prescription-drug-provisions-in-the-inflation-reduction-act/
  \item \textsuperscript{26} https://www.reuters.com/business/healthcare-pharmaceuticals/big-pharma-may-have-reveal-government-deals-whos-draft-pandemic-rules-2022-11-17/
  \item \textsuperscript{27} https://www.reuters.com/business/healthcare-pharmaceuticals/exclusive-wto-faces-new-battle-over-covid-tests-drugs-2022-07-07/
  \item \textsuperscript{28} https://www.fiercepharma.com/pharma/us-drug-pricing-reform-here-effects-wont-be-felt-some-time-analysts
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The US government has the option to intervene on the pricing of molnupiravir by practicing its march-in rights under the Bayh-Dole Act. Under this provision of the law, the US government has the ability to “march-in” and license patents for products, over a company’s objections. In recent years, policymakers have increased their scrutiny of the role of public funding in medicine pricing throughout the development pipeline domestically. Public funding is already a factor in the government’s price negotiation process under the Inflation Reduction Act.

International stakeholders are also seeking more information on the role of public funding and considering measures to improve access to current and future pandemic tools. The World Trade Organization continues to deliberate on extending a temporary relaxation of intellectual property (IP) rules under the TRIPS Agreement to enable governments to take steps to improve access to COVID-19 treatments with or without cooperation from companies. The US government has launched its own investigation on the value of such an extension. The “zero draft” of the WHO’s “Convention, Agreement or Other International Instrument on Pandemic Prevention, Preparedness and Response” also proposes greater transparency of public funding of pandemic response products, measures to promote access to the results of publicly funded research, and other measures to improve access to pandemic products, including consideration of more flexible IP rules.

By acting proactively, Merck can be a leader in modeling transparency and may help to prevent a situation in which governments regulate and oversee the company in a manner that affords the company less independence and control and threatens shareholder interests.

II. CONCLUSION

Merck’s development of a drug that received $35 million in federal funding should be accompanied by transparency, so that investors can gauge the risks that accompany receiving significant public investment while failing to ensure global access. Instead, Merck has pursued a strategy that leaves this publicly funded product out of reach for many and threatens to drain already stretched public health resources. Investors have voiced these reputational and regulatory concerns to the company for several years, and have yet to receive commitments to increase transparency.

We urge shareholders to vote “For” Proposal 6 to ask Merck for greater transparency on whether and how R&D funding from the US government is accounted for in its access strategy.

29 https://www.keionline.org/36648
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