July 31, 2020

Gary L. Disbrow, Ph.D. Acting Director Biomedical Advanced Research and Development Authority U.S. Department of Health and Human Services Via Email: Gary.Disbrow@hhs.gov

Dear Dr. Disbrow:

The Biomedical Advanced Research and Development Authority (BARDA) has a provision in its contract with Moderna to develop a COVID-19 vaccine that requires Moderna to publicly disclose information about how the development of the vaccine was funded. In particular, Moderna is required to report the total cost of the project or program and the amount and percentage share of the costs provided by the federal government.

Moderna is ignoring this provision, and BARDA is not enforcing the obligation. We request that BARDA immediately enforce the provision in this contract and all other applicable contracts.

We are referring to the BARDA contract with Moderna to fund preclinical and clinical research on mRNA-1273, the investigational COVID-19 vaccine candidate jointly invented by the National Institutes of Health and Moderna.

Page 43, section H.7 of the contract includes this language:

H.7 Acknowledgement of Federal Funding - Publication and Publicity

... The Contractor shall clearly state, when issuing statements, press releases, re quests for proposals, bid solicitations and other documents describing projects or programs funded in whole or in part with Federal money: (1) the percentage of the total costs of the program or project which will be financed with Federal money; (2) the dollar amount of Federal funds for the project or program; and (3) the percentage and dollar amount of the total costs of the project or program that will be financed by nongovernmental sources.

This obligation mirrors language in the Further Consolidated Appropriations Act, 2020, Public Law No. 116-94 (and other Health and Human Services appropriations acts), which states, at Section 505:

Sec. 505. When issuing statements, press releases, requests for proposals, bid solicitations and other documents describing projects or programs funded in whole or in part with Federal money, all grantees receiving Federal funds included in this Act, including but not limited to State and local governments and recipients of Federal research grants, shall clearly state--

(1) the percentage of the total costs of the program or project which will be financed with Federal money;

(2) the dollar amount of Federal funds for the project or program; and(3) percentage and dollar amount of the total costs of the project or program that will be financed by non-governmental sources.

The disclosure requirements in the Moderna contract have a public-facing component because they extend to press releases about Moderna's vaccine, and the heading uses the terms "Publication and Publicity."

Transparency is critical. It is in the public interest for U.S. taxpayers to have an understanding of what portion of the cost of developing the vaccine was shouldered by the public. This information could enable consumers to better assess the reasonableness of whatever price Moderna sets for the vaccine, the performance of government officials in negotiating the prices for the federally-subsidized vaccine, and more generally the role of federal funding in driving medical innovation.

Our review of Moderna press releases revealed that Moderna is not complying with this contractual obligation. A July 28, 2020 press release announcing results from a preclinical study contains no statement disclosing the breakdown of costs to develop the vaccine that will be financed by the government versus nongovernmental sources. The press release states only the following regarding the vaccine's funding:

The Biomedical Advanced Research and Development Authority (BARDA), part of the Office of the Assistant Secretary for Preparedness and Response (ASPR) within the U.S. Department of Health and Human Services (HHS), partially supported the research and development of mRNA-1273 with federal funding under Contract no. 75A50120C00034. A summary of the company's work to date on COVID-19 can be found here.

We could locate no Moderna press release that makes the disclosures, though Moderna has been prolific in announcing developments in its vaccine program.

Recent reports of encouraging data from clinical trials of Moderna's investigational vaccine candidate have raised hopes for a safe and effective vaccine by the end of the year. The promise of a potential vaccine, the public's billion dollar investment in Moderna, and news of Moderna's pricing strategy have generated considerable interest in how the vaccine's development was funded. As a servant of the public, BARDA should use its existing authority to compel Moderna to disclose the required information. BARDA possesses both the legal authority and responsibility to the public to do so.

We also would like to schedule a call with BARDA to discuss the ramifications of Section 505 in PL 115-94, as it relates to other BARDA contracts and grants, including but not limited to those relevant to COVID-19.

Sincerely,

Kathryn Ardizzone Counsel Knowledge Ecology International kathryn.ardizzone@keionline.org

Zain Rizvi Law and Policy Researcher Public Citizen zrizvi@citizen.org