MOU 225-17-019

MEMORANDUM OF UNDERSTANDING BETWEEN THE FOOD AND DRUG ADMINISTRATION AND THE BILL & MELINDA GATES FOUNDATION

I. PURPOSE

The Food and Drug Administration (FDA) and the Bill & Melinda Gates Foundation (BMGF) (each a "Party" and collectively the "Parties") share interests in scientific progress related to regulatory science and regulatory capacity building in support of advancing global public health. This memorandum of understanding (MOU) establishes a framework for collaboration between FDA and the BMGF to facilitate existing and new mutually agreed upon programs and activities and to carry out their common goal to improve public health by stimulating and fostering medical product innovation and enabling medical product development.

II. AUTHORITY

FDA has authority to enter into this MOU pursuant to section 1003(b)(4) of the Food, Drug and Cosmetic Act ("the Act") (21 USC 393(b)(4)).

III. BACKGROUND

FDA is authorized to implement and enforce the Federal Food, Drug, and Cosmetic Act as amended (21 U.S.C. 301, et seq.) and certain provisions of the Public Health Service Act, including section 351 and 361 (e.g., 42 USC 262, 42 USC

264). In fulfilling these responsibilities, FDA, among other things, is responsible for protecting public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices, and the safety and security of the nation's food supply, cosmetics, and products that emit radiation. FDA also has responsibility for regulating the manufacturing, marketing, and distribution of tobacco products to protect the public health and to reduce tobacco use by minors. FDA also advances the public health by supporting the development of innovative technologies which help to make medical products safer and more effective and available to more patients. As a part of the goal of speeding innovation, FDA seeks to identify and address scientific and technical challenges to the optimum development of safe and effective medical products and technologies. BMGF's mission is to help all people lead healthy, productive lives. In pursuit of the mission, BMGF works with partner organizations worldwide to, among other things, deliver generic and innovative tools—including effective, affordable vaccines, drugs, and diagnostics—as part of innovative approaches to deliver effective health services to those who need them most in low-income countries. As part of this overall mission, BMGF invests heavily in developing new, affordable vaccines to prevent infectious diseases that impose the greatest global health burden and to support the development of integrated health solutions that address major challenges in nutrition and maternal and child health.

IV. SUBSTANCE OF AGREEMENT

Under this MOU, the Parties may seek opportunities to participate together in collaborative efforts, in furtherance of their respective objectives and permitted under appropriate statutory authority and applicable law, to work towards advancing global public health by stimulating and fostering

medical product innovation and enabling medical product development by engaging in activities and programs to facilitate:

Regulatory Science. FDA and BMGF may collaborate and share information, as appropriate, on research concerning enabling technologies—including advancing the availability of tools of regulatory science—that will facilitate the development of innovative medical products, including medical countermeasures. For the purposes of this MOU, regulatory science includes the development and qualification/validation of new test methods, reference materials, or reagents for preclinical and clinical safety/toxicology assessments and for the assessments of product efficacy, safety, or quality, post-market safety, and effectiveness methods development.

Expansion of regulatory capacity building. FDA and BMGF may collaborate in regulatory systems capacity building activities, such as FDA provision of technical input to BMGF funded efforts to address regulatory systems challenges associated with advancing global public health. For the purposes of this MOU, regulatory systems capacity building includes providing support to country-led initiatives to optimize the technical, scientific, and regulatory capacity of foreign government national and regional regulatory agencies and their respective relevant industries.

Global public health. FDA and BMGF may collaborate on the identification of global public health challenges and the development of solutions that have the greatest potential value to global public health.

Before any specific collaboration is initiated or implemented, the Parties shall identify priorities, topics of mutual interest, and develop separate, written agreements for collaboration

and sharing of resources. Where applicable, these agreements may incorporate by reference this MOU. Where appropriate, the Parties may enter into written agreements duly approved in accordance with the internal policies of each Party and in accordance with applicable laws and regulations, and available appropriations. Any such written agreement shall be negotiated and executed by appropriate representatives of the BMGF and of institutions within FDA. In addition, FDA may accept gifts to the extent authorized by Section 231 of the Public Health Service Act (42 U.S.C. § 238).

V. GENERAL PROVISIONS

1. This is an MOU between the FDA and BMGF wherein the Parties agree and understand that this MOU is non-binding and shall not create or give rise to any legally binding obligations upon the Parties to perform any activities or provide any funding. This MOU does not affect or supersede any existing or future agreements or arrangements between the Parties. This MOU and all associated agreements will be subject to the applicable policies, rules, regulations, and statutes under which the Parties operate.

2. FDA and BMGF anticipate the activities covered by this MOU will involve workshops, meetings, scientific collaborations, and other communications between officials of FDA and BMGF. FDA and BMGF participation is predicated on a mutual understanding that activities under this MOU provide a forum for a mutual exchange of opinions and ideas, and that activities must avoid any appearance that investment considerations may influence FDA regulatory decision-making concerning product approval or authorization. In any activities under this MOU, FDA will not disclose to the BMGF non-public information, including "confidential commercial or financial information" (21 CFR

20.61) or trade secret information (21 U.S.C 360j(c)) obtained by or provided directly to FDA from a third party (such as an applicant for product approval) unless there is in place specific written authorization from the owner of such information that permits FDA to reveal such information.

3. Rights to any intellectual property (e.g., patents, copyrights, trademarks, trade secrets, and inventions (as defined under Title 35 of the United States Code) resulting from collaborative efforts under this MOU will be defined and determined by separate written agreements based on current U.S. Government patent regulations and any other applicable statutes and regulations. All such agreements may incorporate by reference this MOU.

4. The Parties may decide to enter into Cooperative Research and Development Agreements (CRADAs), grants, or contracts specific to particular collaborative projects. The terms of such CRADAs, grants, or contracts should address Intellectual Property rights and BMGF's principles regarding Global Access, namely that (a) knowledge and information gained from projects funded pursuant to this MOU will be promptly and broadly disseminated; and (b) the products, services, processes, technologies, materials, software, data, and other innovations, and intellectual property resulting from such projects will be made available and accessible at an affordable price to people most in need within developing countries.

5. Use of FDA's logo, such as on training materials, must be approved in advance by FDA. Likewise, use of BMGF's logo must be approved in advance by BMGF.

VI. RESOURCES

This MOU represents the broad outline of the Parties' present intent to enter specific agreements for collaborative efforts in areas of mutual interest, subject to available personnel, resources, and funds.

VII. POINTS OF CONTACT

The names of FDA and BMGF staff listed below represent the current persons in these assigned roles at the date of signing of this MOU. Each Party may change its point of contact upon reasonable written notice to the other Party.

For FDA:

RADM Carmen Maher
Assistant Surgeon General
Acting Assistant Commissioner for Counterterrorism and Emerging Threats
Acting Director
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Food and Drug Administration (FDA)
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For BMGF:

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(mailto:Murray.lumpkin@gatesfoundation.org)

VIII. EFFECTIVE DATE, DURATION, TERMINATION

This MOU becomes effective upon the signature of authorized representatives of both Parties and remains in effect, unless otherwise terminated. This MOU may be

modified by mutual consent or terminated by either Party upon 60 calendar days written notice.

IX. APPROVAL

APPROVED AND ACCEPTED FOR THE FOOD AND DRUG ADMINISTRATION
Luciana Borio, M.D.
Acting Chief Scientist
Office of the Chief Scientist
June 26, 2017

APPROVED AND ACCEPTED FOR THE BILL & MELINDA GATES FOUNDATION
Trevor Mundel, M.D. Ph.D.
President, Global Health
June 27, 2017