

and gender influences on mechanisms and outcomes of chronic diseases are incomplete, reducing the specificity, sensitivity, and efficacy of diagnostic tests and treatments for women. Research on rare diseases that are more prevalent in women or only occur in women faces similar challenges.

### 3. Stagnant Cervical Cancer Survival Rates

In the United States it is estimated approximately 12,000 new cases of cervical cancer occur each year. Human papillomavirus (HPV) is the cause of cervical cancer as well as a large percentage of cancers of the vulva, vagina, penis, anus, rectum, and oropharynx.<sup>13</sup> Despite cancer prevention efforts through HPV vaccination and cervical cancer screening, incidence and mortality from this malignancy have been stable for the last two decades. Communities historically under-represented in medicine are disproportionately burdened by this disease. The incidence rate of cervical cancer is 30 percent higher in Black women<sup>14</sup> and Black women persistently present at later stages at diagnosis.<sup>15</sup> The overall 5-year relative survival rate for cervical cancer among Black women is 56 percent, compared with 68 percent among White women.<sup>14</sup>

### Information Requested

This Request for Information (RFI) invites the scientific community, health professionals, professional societies, and the general public to provide comments and testimonies on research gaps, pitfalls in clinical practices, and obtaining real-life testimonial experiences (direct or indirect) related to any or all of the listed public health issues. Responses are welcome from associations and professional organizations as well as individuals.

This RFI is for planning purposes only and should not be construed as a solicitation or an obligation on the federal government, the National Institutes of Health, or individual NIH Institutes or Centers. Responses to this RFI Notice are voluntary. The NIH will use the information submitted in response to this RFI at its discretion. NIH will analyze the information submitted and may share it internally or in reports. The information may or may not be reflected in future solicitations, as appropriate and at the government's discretion. NIH advises respondents the government is under no obligation to acknowledge receipt of the information provided and will not provide feedback to respondents. The federal government will not pay for the preparation of any

information submitted or for the government's use. NIH will not consider submitted information confidential. Additionally, the government cannot guarantee the confidentiality of the information provided.

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Dated: June 25, 2021.

**Lawrence A. Tabak,**

*Principal Deputy Director, National Institutes of Health.*

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**BILLING CODE 4140-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### Government-Owned Inventions; Availability for Licensing

**AGENCY:** National Institutes of Health, HHS.

**ACTION:** Notice.

**SUMMARY:** The invention listed below is owned by an agency of the U.S. Government and is available for licensing to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

**FOR FURTHER INFORMATION CONTACT:** David Yang at 240-695-6406 or [yangp3@mail.nih.gov](mailto:yangp3@mail.nih.gov). Licensing information may be obtained by communicating with the Technology Transfer and Intellectual Property Office, National Institute of Allergy and Infectious Diseases, 5601 Fishers Lane, Rockville, MD 20852; tel. 301-496-2644. A signed Confidential Disclosure Agreement will be required to receive copies of unpublished information related to the invention.

**SUPPLEMENTARY INFORMATION:** Technology description follows:

### Pre-Biotic Formulation of Topical Chemicals for Use on Human Skin

*Description of Technology:* Atopic dermatitis (AD) is a common, recurrent, chronic inflammatory skin disease that is a cause of considerable economic and social burden. It is one of the most prevalent skin disorders, affecting ~25% of children in developed and developing countries and is expected to continue to escalate. This increased rate of incidence has changed the focus of research on AD toward epidemiology, prevention, and treatment.

Scientists at NIAID have developed novel topical formulations that promote the growth of health-associated strains of commensal bacteria and inhibit disease-associated bacteria, thereby enhancing skin health.

This technology is available for licensing for commercial development in accordance with 35 U.S.C. 209 and 37 CFR part 404, as well as for further development and evaluation under a research collaboration.

*Potential Commercial Applications:*

- Over-the-counter formulations—this invention could be readily incorporated into popular body lotions or other skincare products to make “enhanced”/“microbiome-friendly” versions that promote the growth of health associated bacterial

*Competitive Advantages:*

- Benign safety profile with multiple mechanisms of action
- Proven enhancement of beneficial microbiota
- Can be readily incorporated into existing products

*Development Stage:*

- Pre-clinical

*Inventors:* Carlos Castillo and Ian Myles, MD, MPH, both of NIAID.

*Publications:* Castillo, Carlos, et al. “Assessing the effects of common topical exposures on skin bacteria associated with atopic dermatitis”, *Skin Health and Disease*, 2021.05.07.

*Intellectual Property:* HHS Reference No. E-100-2021-0; US provisional application No. 63/175,368 filed on April 15, 2021.

*Licensing Contact:* To license this technology, please contact David Yang at 240-695-6406 or [yangp3@mail.nih.gov](mailto:yangp3@mail.nih.gov) and reference E-100-2021-0.

*Collaborative Research Opportunity:* The National Institute of Allergy and Infectious Diseases is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize this technology. For collaboration opportunities, please contact David Yang at 240-695-6406 or [yangp3@mail.nih.gov](mailto:yangp3@mail.nih.gov).

Dated: June 24, 2021.

**Surekha Vathyam,**

*Deputy Director, Technology Transfer and Intellectual Property Office, National Institute of Allergy and Infectious Diseases.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**Prospective Grant of Exclusive License, Inter-Institutional Agreement-Institution Lead: Biomarkers and Immunogenic Compositions for Filarial Parasites**

**AGENCY:** National Institutes of Health, National Institute of Allergy and Infectious Diseases, HHS.

**ACTION:** Notice.

**SUMMARY:** The National Institute of Allergy and Infectious Diseases, an institute of the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an exclusive, sublicensable patent license to New York Blood Center, Inc. (“NYBC”), located in New York, New York, in its rights to the technologies and patent applications listed in the **SUPPLEMENTARY INFORMATION** section of this notice.

**DATES:** Only written comments and/or applications for a license which are received by the Technology Transfer and Intellectual Property Office, National Institute of Allergy and Infectious Diseases, on or before July 16, 2021 will be considered.

**ADDRESSES:** Requests for copies of the patent applications, inquiries, and comments relating to the contemplated Exclusive License should be directed to: Theodoric Mattes, Ph.D., Technology Transfer and Patent Specialist, Technology Transfer and Intellectual Property Office, National Institute of Allergy and Infectious Diseases, 5601 Fishers Lane, Suite 6D, MSC9804, Rockville, MD 20852-9804, phone number 240-627-3827, or [theodoric.mattes@nih.gov](mailto:theodoric.mattes@nih.gov).

**SUPPLEMENTARY INFORMATION:** The following and all continuing U.S. patents/patent applications thereof are the intellectual properties to be licensed under the prospective agreement to NYBC: United States Provisional Patent Application Number 62/317,342, filed May 1, 2016, the title of which is “Biomarkers and Immunogenic Compositions for Filarial Parasites” (HHS Reference No. E-288-2016-0-US-01); PCT Patent Application Number PCT/US2017/025554, filed March 31, 2017, the title of which is “Biomarkers and Immunogenic Compositions for Filarial Parasites” (HHS Reference No. E-288-2016-00-PCT-02); United States Patent Application Number 16/090,013, filed September 28, 2018, the title of which is “Biomarkers and Immunogenic Compositions for Filarial Parasites”

(HHS Reference No. E-288-2016-0-US-03); and United States Patent Application Number 17/076,616, filed October 21, 2020, the title of which is “Biomarkers and Immunogenic Compositions for Filarial Parasites” (HHS Reference No. E-288-2016-0-US-04).

The patent rights to this technology have been assigned to New York Blood Center, Inc. and the Government of the United States of America as represented by the Secretary, Department of Health & Human Services, by each institution’s respective inventors.

The prospective patent license will be for the purpose of consolidating the patent rights to New York Blood Center, Inc., for the development and commercialization of the technology.

Consolidation of these co-owned rights is intended to expedite development of the technology, consistent with the goals of the Bayh-Dole Act codified as 35 U.S.C. 200-212.

The prospective interinstitutional agreement may include an exclusive license for NIAID’s rights in these jointly owned patents. It will be sublicensable, and any sublicenses granted by NYBC will be subject to the provisions of 37 CFR part 404. NIAID will retain its rights to non-exclusively license its rights to the patent applications to third parties for internal research use.

In the subject technology, researchers at NIAID and NYBC isolated and analyzed the transcriptome and proteome of the parasite at various life stages as well as its *Wolbachia sp.* endosymbiont to identify potential biomarkers for diagnostic assays and vaccine candidates. In all, they identified forty-seven (47) biomarkers. The associated patents claim the use of two or more of these biomarkers in conjunction with an adjuvant as an immunological composition, or the detection of any of these biomarkers in a serological-type assay.

This notice is made in accordance with 35 U.S.C. 209 and 37 CFR part 404. The prospective exclusive license will be royalty bearing, and may be granted unless within fifteen (15) days from the date of this published notice the National Institute of Allergy and Infectious Diseases receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR part 404.

In response to this Notice, the public may file comments or objections. Comments and objections, other than those in the form of a license application, will not be treated