

length of debarment. With respect to the third and fourth factors, he supports the findings that he mitigated the impact of his offenses on the public by fully cooperating with investigators and that he had no convictions involving matters within the jurisdiction of FDA.

Considering all the applicable factors listed in section 306(c)(3) of the FD&C Act, the Chief Scientist finds that Dr. Palaparty's conviction and underlying conduct warrant the 3-year debarment proposed by ORA. It is undisputed that Dr. Palaparty pled guilty to a serious misdemeanor offense by causing the introduction into interstate commerce of drugs that were misbranded by virtue of their unapproved status. It is undisputed that Dr. Palaparty had a managerial role, further cementing the serious nature of Dr. Palaparty's conduct. While Dr. Palaparty ultimately took voluntary steps to mitigate the effect on the public health from the unlawful conduct and does not have any previous criminal convictions related to matters within FDA's jurisdiction, those considerations do not outweigh the nature and seriousness of the conduct to a degree that would warrant a debarment period of less than 3 years. Therefore, a 3-year debarment is appropriate.

Separately, Dr. Palaparty requests that, in lieu of debarment by FDA, he enter into a settlement agreement with FDA whereby he would voluntarily agree to the terms of the proposed debarment for the proposed period of debarment and to not provide services in any capacity to a person that has an approved or pending drug product application. Dr. Palaparty appears to be proposing an informal resolution of this debarment matter. However, his request is now moot, given the foregoing findings, which establish that Dr. Palaparty has failed to justify a hearing with respect to ORA's proposal to debar him for 3 years, and support his debarment for the proposed time.

III. Findings and Order

Therefore, the Chief Scientist, under section 306(b)(2)(B)(i)(I) of the FD&C Act and authority delegated to her by the Commissioner of Food and Drugs, finds that Dr. Palaparty has been convicted of a misdemeanor under Federal law for causing the introduction into interstate commerce of prescription drugs that were misbranded under the FD&C Act and that the conduct underlying the conviction undermines the process for the regulation of drugs. FDA considered the relevant factors listed in section 306(c)(3) of the FD&C Act and determined that a 3-year debarment is appropriate.

As a result of the foregoing findings, Dr. Palaparty is debarred for 3 years from providing services in any capacity to a person with an approved or pending drug product application under sections 505, 512, or 802 of the FD&C Act (21 U.S.C. 355, 360b, or 382), or under section 351 of the Public Health Service Act (42 U.S.C. 262), effective January 25, 2023, (see 21 U.S.C. 335a(c)(1)(B) and (c)(2)(A)(iii) and 21 U.S.C. 321(dd)). Any person with an approved or pending drug application who knowingly uses the services of Dr. Palaparty, in any capacity during his debarment, will be subject to civil money penalties (section 307(a)(6) of the FD&C Act (21 U.S.C. 335b(a)(6))). If Dr. Palaparty, during his period of debarment, provides services in any capacity to a person with an approved or pending drug product application, he will be subject to civil money penalties (section 307(a)(7) of the FD&C Act). In addition, FDA will not accept or review any abbreviated new drug applications submitted by or with the assistance of Dr. Palaparty during his period of debarment (section 306(c)(1)(B) of the FD&C Act).

Dated: January 19, 2023.

Namandje N. Bumpus,
Chief Scientist.

[FR Doc. 2023-01419 Filed 1-24-23; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Meeting Notice Correction

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice; correction.

SUMMARY: HRSA published a document in the **Federal Register** of December 20, 2022, concerning a meeting of the National Advisory Council on the National Health Service Corps (NACNHSC). The document referenced the incorrect year. The meeting date erroneously stated a meeting will occur in November 2022 when it should state November 2023.

FOR FURTHER INFORMATION CONTACT: Diane Fabiyi-King, Designated Federal Official, Division of National Health Service Corps, HRSA, 5600 Fishers Lane, Room 14N23, Rockville, Maryland 20857; phone (301) 443-3609; or NHSCAdvisoryCouncil@hrsa.gov.

SUPPLEMENTARY INFORMATION:

Correction

In the **Federal Register** of December 20, 2022, FR Doc. 2022-27532, page 77850, column 1, section two, bullet three, correct the "November 14, 2022, 9:00 a.m.–5:00 p.m. ET and November 15, 2022, 9 a.m.–2 p.m. ET" caption to read: November 14, 2023, 9 a.m.–5 p.m. ET and November 15, 2023, 9 a.m.–2 p.m. ET.

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2023-01448 Filed 1-24-23; 8:45 am]

BILLING CODE 4165-15-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Biodefense Science Board; Public Meeting

AGENCY: Administration for Strategic Preparedness and Response (ASPR), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The National Biodefense Science Board (NBSB or the Board), authorized under Section 319M of the Public Health Service (PHS) Act, as added by Section 402 of the Pandemic and All-Hazards Preparedness Act of 2006 and amended by Section 404 of the Pandemic and All-Hazards Preparedness Reauthorization Act, will hold a virtual, public meeting on March 9, 2023. The NBSB provides expert advice and guidance to the Department of Health and Human Services (HHS) regarding current and future chemical, biological, radiological, and nuclear threats, as well as other matters related to disaster preparedness and response. The Administration for Strategic Preparedness and Response (ASPR) manages and convenes the NBSB on behalf the Secretary of HHS. The NBSB public meeting will beginning at 11:00 a.m. Eastern time. A detailed agenda and Zoom registration instructions will be available on the ASPR website.

Procedures for Public Participation: The link to pre-register for the public meeting will be posted on the meeting website. The online meeting, which use a webinar format, will include American Sign Language interpretation and live captioning.

Members of the public may provide written comments or submit questions at any time via email to NBSB@hhs.gov. Additionally, the NBSB invites stakeholders to request up to seven minutes to address the Board in-person during the meeting. The Board wishes to hear from experts from relevant

biomedical, biodefense, or health industries; faculty or researchers at academic institutions; health professionals, health system experts, or those who work in health care consumer organizations; or experts in state, Tribal, territorial, or local government agencies. Requests to provide remarks to the NBSB during the public meeting must be sent to NBSB@hhs.gov by March 2, 2023. In that request, please provide the speaker's name, title, position, and organization, with a brief description of the topic that they will address. Requests to speak to the Board will be approved in consultation with the Board Chair and based on time available during the meeting.

FOR FURTHER INFORMATION CONTACT:

CAPT Christopher Perdue, NBSB Designated Federal Official, (202) 480-7226, NBSB@hhs.gov.

Dawn O'Connell,

Assistant Secretary for Preparedness and Response.

[FR Doc. 2023-01460 Filed 1-24-23; 8:45 am]

BILLING CODE 4150-37-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:

Amy F. Petrik, Ph.D., 240-627-3721; amy.petrik@nih.gov. Licensing information and copies of the U.S. patent application listed below may be obtained by communicating with the indicated licensing contact at 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 patent applications.

SUPPLEMENTARY INFORMATION:

Technology description follows:

Antibodies With Potent and Broad Neutralizing Activity Against Antigenically Diverse and Highly Transmissible SARS-CoV-2 Variants

Description of Technology: Emergence of highly transmissible SARS-CoV-2 variants of concern that are resistant to current therapeutic antibodies highlights the need for continuing discovery of broadly reactive antibodies.

Scientists at the Vaccine Research Center of the National Institute of Allergy and Infectious Diseases have identified multiple antibodies that ultra-potently neutralize SARS-CoV-2, including the highly transmissible BA.4, BA.5, BQ.1.1 and XBB subvariants of Omicron, as shown in a pseudovirus neutralization assay. These antibodies target several epitopes in the receptor binding domain of the spike protein that are not impacted by spike mutations that knockout binding to other therapeutic antibodies, including, K417N, N439K, N440K, K444T, V445P, G446S, L452R, Y453F, N460K, S477N, E484A/K, F486S/V and Q498R. Several of the antibodies are able to simultaneously bind to the spike protein and are compatible for use in combination therapies.

This technology is available for licensing for commercial development in accordance with 35 U.S.C. 209 and 37 CFR part 404.

Potential Commercial Applications:

- Treatment of SARS-CoV-2 infection
- Competitive Advantages:*
- Ultra-potent neutralization of currently identified SARS-CoV-2 variants including Omicron subvariants BQ.1.1 and XBB
- Mechanism of Action—Some antibodies directly bind to and block ACE2 receptor binding to the SARS-CoV-2 spike protein

Development Stage: Preclinical Research.

Inventors: John Misasi (VRC, NIAID), Lingshu Wang (VRC, NIAID), John Mascola (VRC, NIAID), Daniel Douek (VRC, NIAID), Nancy Sullivan (VRC, NIAID), Richard Alan Koup (VRC, NIAID), Man Chen, (VRC, NIAID), Wei Shi (VRC, NIAID), Yi Zhang (VRC, NIAID), Eun Sung Yang (VRC, NIAID), Nicole Doria-Rose (VRC, NIAID), Chaim Schramm (VRC, NIAID), Kevina Maria Nabireka Birungi-Huff (VRC, NIAID), Sabrina Bush (VRC, NIAID), Maryam Musayev (VRC, NIAID).

Publications: None.

Intellectual Property: HHS Reference Number E-024-2023 includes U.S. Provisional Patent Application Number 63/433,719 filed December 19, 2022.

Licensing Contact: To license this technology, please contact Amy F.

Petrik, Ph.D., 240-627-3721; amy.petrik@nih.gov.

Dated: January 19, 2023.

Surekha Vathyam,

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

[FR Doc. 2023-01416 Filed 1-24-23; 8:45 am]

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:

Amy F. Petrik, Ph.D., 240-627-3721; amy.petrik@nih.gov. Licensing information and copies of the U.S. patent application listed below may be obtained by communicating with the indicated licensing contact at 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 patent applications.

SUPPLEMENTARY INFORMATION:

Technology description follows: Antibodies with potent and broad neutralizing activity against antigenically diverse and highly transmissible SARS-CoV-2 variants.

Description of Technology:

Emergence of highly transmissible SARS-CoV-2 variants of concern that are resistant to current therapeutic antibodies highlights the need for continuing discovery of broadly reactive antibodies.

Scientists at the Vaccine Research Center of the National Institute of Allergy and Infectious Diseases have engineered a group of human monoclonal antibodies that target epitopes on the receptor binding domain of SARS-CoV-2 spike protein.