• Terumo BCT Inc. and Marker Therapeutics AG's, Spectra Optia Apheresis System with the Depuro D2000 Adsorption Cartridge (an Extracorporeal Blood Purification (EBP) Device), issued on April 9, 2020;[9] and,

• CytoSorbents, Inc.'s, CytoSorb EBP Device, issued on April 10, 2020.[10]

Dated: May 29, 2020.

**Lowell J. Schiller,**

*Principal Associate Commissioner for Policy.*

[FR Doc. 2020–12117 Filed 6–4–20; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Committee on Vital and Health Statistics

### Pursuant to the Federal Advisory Committee Act, the Department of Health and Human Services (HHS) announces the following advisory committee meeting.

*Name:* National Committee on Vital and Health Statistics (NCVHS), Full Committee Meeting.

*Dates and Times:*

Wednesday, June 17, 2020: 10:00 a.m.–5:00 p.m. EDT

Thursday, June 18, 2020 10:00 a.m.–4:00 p.m. EDT

*Place:* Virtual.

*Status:* Open.

*Purpose:* At the June 17–18, 2020 meeting, the Committee will receive briefings from HHS officials, hold discussions on several health data policy topics and refine its workplan for the upcoming 12-month period.

The Subcommittee on Privacy, Confidentiality and Security will lead a discussion with the full Committee to reach consensus on plans for a project focused on data privacy and security protections related to current public health surveillance activities.

The Subcommittee on Standards will provide updates on plans for the upcoming August hearing intended to solicit information about the costs and benefits of a new operating rule for connectivity and operating rules for the prior authorization transaction proposed by the Council for Affordable Quality Healthcare (CAQH), Committee on Operating Rules for Information Exchange (CORE) Board. The Subcommittee also will provide an update on progress of the Office of the National Coordinator (ONC) Health Information Technology Advisory Committee (HITAC) Task Force on Intersection of Clinical and Administrative Data (ICAD), on which four NCVHS members participate. The Committee will initiate a discussion of the NCVHS 14th Report to Congress, including a proposed approach, major themes, and timeline including reflection on previous reports to Congress for context.

The Committee has invited presentations from the HHS Office of the Assistant Secretary for Planning and Evaluation, Science and Data Policy Division, the National Center for Health Statistics (NCHS), and CDC's Deputy Director for Public Health Science and Surveillance (DDPHSS), to inform Committee discussion of the data landscape transformed by the COVID–19 epidemic. The Committee also has invited CMS's Division of National Standards to provide an update on its activities and plans. On the afternoon of the second day, members will consider and discuss priorities for Committee focus and revise the Committee workplan based on information presented during the meeting.

A public comment period will be offered on the second day. Meeting times and topics are subject to change. Please refer to the posted agenda for any updates.

*For Further Information Contact:* Substantive program information may be obtained from Rebecca Hines, MHS, Executive Secretary, NCVHS, National Center for Health Statistics, Centers for Disease Control and Prevention, 3311 Toledo Road, Hyattsville, Maryland 20782, telephone (301) 458–4715. Summaries of meetings and a roster of Committee members are available on the home page of the NCVHS website: *ncvhs.hhs.gov,* where further information including an agenda and instructions to access the broadcast of the meeting will also be posted.

Should you require reasonable accommodation, please contact the CDC Office of Equal Employment Opportunity on (770) 488–3210 as soon as possible.

**Sharon Arnold,**

*Associate Deputy Assistant Secretary for Planning and Evaluation, Science and Data Policy, Office of the Assistant Secretary for Planning and Evaluation.*

[FR Doc. 2020–12236 Filed 6–4–20; 8:45 am]

**BILLING CODE 4150–05–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* National Institute of Allergy and Infectious Diseases Special Emphasis Panel Vaccine and Treatment Evaluation Units (VTEUs): Enhancing Capability and Capacity (UM1 Clinical Trial Required).

*Date:* July 7, 2020.

*Time:* 10:00 a.m. to 3:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3F21B, Rockville, MD 20892 (Telephone Conference Call).

*Contact Person:* Maryam Feili-Hariri, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3F21B,

[9] As set forth in the EUA, FDA has concluded that: (1) SARS–CoV–2, the virus that causes COVID–19, can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus; (2) based on the totality of scientific evidence available to FDA, it is reasonable to believe that the Spectra Optia Apheresis System with the Depuro D2000 Adsorption Cartridge may be effective in treating patients 18 years of age or older with confirmed COVID–19 admitted to the intensive care unit (ICU) with confirmed or imminent respiratory failure, and that the known and potential benefits of the Spectra Optia Apheresis System with the Depuro D2000 Adsorption Cartridge, when used to treat COVID–19 patients 18 years of age or older, outweigh the known and potential risks of the Spectra Optia Apheresis System with the Depuro D2000 Adsorption Cartridge; and (3) there is no adequate, approved, and available alternative to the emergency use of the Spectra Optia Apheresis System with the Depuro D2000 Adsorption Cartridge for the treatment of these COVID–19 patients.

[10] As set forth in the EUA, FDA has concluded that: (1) SARS–CoV–2, the virus that causes COVID–19, can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus; (2) based on the totality of scientific evidence available to FDA, it is reasonable to believe that the CytoSorb device may be effective in treating patients 18 years of age or older with confirmed COVID–19 admitted to the ICU with confirmed or imminent respiratory failure, and that the known and potential benefits of the CytoSorb device, when used to treat such patients, outweigh the known and potential risks of the CytoSorb device; and (3) there is no adequate, approved, and available alternative to the emergency use of the CytoSorb device for the treatment of these COVID–19 patients.