expressing a 1999 HA neutralized seasonal H1N1 viruses from 1934 to 2007 and protected ferrets from an unmatched 2007 H1N1 virus challenge. This extended neutralization coverage is partially explained by the presence of both type of antibodies, antibodies directed to the conserved HA stem and against the RBS region. Finally, this ferritin nanoparticle vaccine platform has significant advantages in the ability to utilize specific multimerized spikes and it may be applicable to other viral proteins.

Potential Commercial Applications: The ferritin nanoparticles as a vaccine platform can be used to deliver vaccines, such as influenza vaccines, with enhanced magnitude and breadth of the neutralizing antibody responses. This vaccine platform may be applicable to other viral proteins.

Competitive Advantages:

- Forms an octahedron consisting of 24 subunits, allowing for greatly increased presentation of heterologous protein on the ferritin nanoparticles surface, compared to other vaccine platforms.
- *In vivo* data in multiple animal models demonstrated induction of broader and more potent antibody responses.
- Vaccine stimulated broadly neutralizing antibodies against the highly conserved epitope on the HA stem region and against the RBS, thus targeting two independent sites of vulnerability on HA.
- Multivalent influenza HA ferritin vaccines have been tested in animal models.
- Ferritin is extremely stable to temperature ranges, pH, detergent and other factors.
- Easily manufactured, will facilitate influenza preparedness in the face of emerging epidemics.

Development Status:

- Preclinical.
- *In vitro* data available.
- *In vivo* data available (animal).

Inventors: Gary Nabel, Masaru Kanekiyo, Jeffrey C. Boyington, Patrick McTamney (all of NIAID).

Publication: Kanekiyo M, et al. A Self-Assembling Influenza Nanoparticle Vaccine Elicits Two Types of Broadly Neutralizing and Cross-protective Antibodies. Manuscript submitted.

Intellectual Property:

- HHS Reference No. E–293–2011/0 — U.S. Provisional Application No. 61/538,663 filed 23 Sep 2011.
- HHS Reference No. E–293–2011/1 — U.S. Provisional Application No. 61/661,209 filed 18 Jun 2012.

Licensing Contact: Cristina Thalhammer-Reyero, Ph.D., M.B.A.; 301–435–4507; *ThalhamC@mail.nih.gov.*

Salen-Manganese Compounds for Therapy of Viral Infections

Description of Technology: Salen-manganese compounds are synthetic, stable, low toxicity, low cost agents that may provide protection from immune reaction-related oxidative cell damage associated with many illnesses. In particular, oxidative cell damage has been associated with many viral infections including influenza. This invention demonstrates that treating mice with salen-manganese compounds, after lethal pandemic influenza virus infection, significantly enhances survival. Salen-manganese treatment also reduces lung pathology and also improved cellular recovery and repair. Because oxidative damage is observed in many viral infections, administration of salen-manganese compounds may have therapeutic relevance to a wide range of viral infections, in addition influenza. Existing viral therapeutics merely target the infectious viral agent and not the damage caused by the immune system reaction related to infection. Because, salen-manganese treatments target the untapped therapeutic space of infection-induced, immune system-related pathology and have favorable safety and cost profiles, such therapies are ideal candidates for development.

Potential Commercial Applications: Viral therapeutics.

Competitive Advantages: Synthetic, stable, low toxicity, low cost, untapped therapeutic target space.

Development Stage:

- Early-stage.
- Pre-clinical.
- *In vivo* data available (animal).

Inventors: John Kash (NIAID), Jeffrey Taubenberger (NIAID), Rodney Levine (NHLBI), Susan Doctrow (Boston University).

Publications:

1. Doctrow SR, et al. Salen Manganese Complexes: Multifunctional Catalytic Antioxidants Protective in Models for Neurodegenerative Diseases of Aging. In: Medicinal Inorganic Chemistry, ACS Symposium Series, Vol. 903, Chapter 18, pp 319–347; August 25, 2005. [DOI: 10.1021/bk–2005–0903.ch018.]

2. Schwarz KB. Oxidative stress during viral infection: a review. Free Radic Biol Med. 1996; 21(5):641–9. [PMID 8891667]

Intellectual Property: HHS Reference No. E–281–2011/0—U.S. Provisional Application No. 61/558,137 filed 10 Nov 2011.

Licensing Contact: Tedd Fenn, J.D.; 301–435–5031; *Tedd.Fenn@nih.gov.*

Collaborative Research Opportunity: The NIAID Laboratory of Infectious Diseases, Viral Pathogenesis and Evolution Section, 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 Maryann Puglielli at 301–594–6656.

Dated: July 18, 2012.

Richard U. Rodriguez,

Director, Division of Technology Development and Transfer, Office of Technology Transfer, National Institutes of Health.

[FR Doc. 2012–18054 Filed 7–24–12; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Alcohol Abuse and Alcoholism; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), 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 on Alcohol Abuse and Alcoholism Special Emphasis Panel.

Date: September 25, 2012.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 5635 Fishers Lane, Rockville, MD 20852, (Telephone Conference Call).

Contact Person: Beata Buzas, Ph.D., Scientific Review Officer, National Institute on Alcohol Abuse and Alcoholism, National Institutes of Health, 5635 Fishers Lane, Room 2081, Rockville, MD 20852, 301–443–0800, *bbuzas@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.271, Alcohol Research Career Development Awards for Scientists and Clinicians; 93.272, Alcohol National Research Service Awards for Research Training; 93.273, Alcohol Research Programs; 93.891, Alcohol Research Center Grants; 93.701, ARRA Related Biomedical Research

and Research Support Awards, National Institutes of Health, HHS)

Dated: July 18, 2012.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2012–18172 Filed 7–24–12; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Alcohol Abuse and Alcoholism; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the National Advisory Council on Alcohol Abuse and Alcoholism.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The meeting will be closed to the public in accordance with the provisions set forth in section 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 Advisory Council on Alcohol Abuse and Alcoholism.

Date: September 19–20, 2012.

Closed: September 19, 2012, 5:00 p.m. to 7:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 5635 Fishers Lane, T–508, Rockville, MD 20852.

Open: September 20, 2012, 8:30 a.m. to 2:00 p.m.

Agenda: Presentations and other business of the council.

Place: National Institutes of Health, 5635 Fishers Lane, T–508, Rockville, MD 20852.

Contact Person: Abraham P. Bautista, Ph.D., Executive Secretary, National Institute on Alcohol Abuse & Alcoholism National Institutes of Health, 5635 Fishers Lane, Room 2085, Rockville, MD 20852, 301–443–9737, *bautista@mail.nih.gov.*

Information is also available on the Institute's/Center's home page: *http://www.niaaa.nih.gov/Pages/default.aspx,* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.273, Alcohol Research Programs; 93.701, ARRA Related Biomedical Research and Research Support Awards, National Institutes of Health, HHS)

Dated: July 18, 2012.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2012–18171 Filed 7–24–12; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases (NIAID); Notice of Workshop

SUMMARY: The National Institute of Allergy and Infectious Diseases (NIAID), a component of the National Institutes of Health; the Food and Drug Administration (FDA); the Transformational Medical Technologies (TMT); and Biomedical Advanced Research and Development Authority (BARDA) are holding an Animal Model Development Workshop to explore the scientific and regulatory challenges of developing medical countermeasures (MCM) under the ''Animal Rule'' (21 CFR 314.600 for drugs; 21 CFR 601.90 for biological products). The goals of this workshop are to highlight the significant progress made in animal model development for MCMs, review recent case studies of products under development using animal models, and capture lessons learned to inform future animal model development efforts. In addition, the workshop will provide a forum to discuss current challenges and identify potential solutions or mitigation strategies.

DATES: The workshop will be held on September 17–18, 2012, at 8 a.m. EST. Participants must register by September 10, 2012.

ADDRESSES: The workshop will be held at the NIH Natcher Conference Center, Building 45, 45 Center Drive, Bethesda, Maryland 20892.

SUPPLEMENTARY INFORMATION: During the past decade, much progress has been made in the development of candidate medical products to prevent, treat, or diagnose the health effects of exposure to chemical, biological, radiological, and nuclear (CBRN) agents. With the convergence of scientific progress in medical countermeasures (MCMs) development, improvements in containment laboratory infrastructure, technological advances, and additional regulatory guidance, the stage is set for tangible progress in our ability to advance MCMs for CBRN agents. The effects of these efforts were evident in several recent FDA Advisory Committee meetings: *anthrax vaccines (2010), smallpox therapeutics (2011),* and *plague antimicrobials (2012).* Especially promising is the recent emphasis on cooperation among government agencies to leverage resources (scientific, human, and fiscal) in an effort to advance the development of animal models.

A solid regulatory and policy framework for fostering development of well-characterized animal models now exists. The Animal Rule laid the foundation for current efforts. FDA's draft guidance on *Animal Models—Essential Elements to Address Efficacy Under the Animal Rule* (January 2009) built upon that foundation and is currently undergoing substantial revision. More recently, the draft guidance on *Qualification Process for Drug Development Tools* (October 2010) outlined a concrete process for qualifying animal models. However, multiple scientific and regulatory challenges remain in animal model development.

This workshop is designed to explore the unique challenges being faced with the development of animal models for the evaluation of medical countermeasures for CBRN agents, including, but not limited to, the following crosscutting issues:

- Missing or limited data on the pathophysiological mechanisms of disease development in humans, especially with:
  - No recent outbreaks in humans, or outbreaks occur only in remote locations with limited infrastructure and capabilities
  - Altered virulence or other properties of the natural agent
  - A difference between the normal route of exposure and the route likely to be used in a bioterrorism event
- Use of mortality as an endpoint, particularly when case fatality of naturally occurring disease in humans is less than 100 percent
- Incorporation and importance of biomarkers
- Correlates of disease progression
- Definition of supportive care and implementation given:
  - Adequate veterinary care
  - Intervention necessary for model development
  - Intervention to mimic human clinical care
- Acceptability of euthanasia criteria and early study endpoints
- Reproducibility of models