register all participants, but to view using one connection per location. Webcast participants will be sent technical system requirements after registration and connection access information after June 4, 2013. If you have never attended a Connect Pro event before, test your connection at *https://collaboration.fda.gov/common/help/en/support/meeting_test.htm*. To get a quick overview of the Connect Pro program, visit *http://www.adobe.com/go/connectpro_overview*. (FDA has verified the Web site addresses in this document, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.)

Comments: FDA is holding this public workshop to obtain information on the topics identified in Section II of this document. In order to permit the widest possible opportunity to obtain public comment, FDA is soliciting either electronic or written comments on all aspects of the public workshop topics. The deadline for submitting comments related to this public workshop is July 10, 2013.

Regardless of attendance at the public workshop, interested persons may submit either electronic comments to *http://www.regulations.gov* or written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. It is only necessary to send one set of comments. Please identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

The Center for Devices and Radiological Health (CDRH) believes that computer modeling and simulation (M&S) has the potential to substantially augment traditional models used to evaluate medical devices; i.e., animal, bench, and human models, and to accelerate and streamline the total product life cycle of a medical device. The use of computer models to simulate multiple use conditions and to visualize and display complex processes and data can revolutionize the way medical outcomes and medical devices are understood. Nonproprietary computer models could benchmark device performance, yet lack of access to biomedical data to construct the models and rigorous methods to validate the models limit their credibility and use. Before substantial advances in the use of M&S for regulatory decision making can be attained, a strategy and consistent framework to assess the credibility of M&S is needed. Moreover, to foster good science for M&S in the medical device community, CDRH needs to leverage the expertise in industry and academia to develop a strategy to scientifically assess the credibility of M&S and to develop a resource to publicize biomedical data, models and their validation for regulatory use.

II. Topics

Historically, M&S have been used as development and design optimization tools, rather than methods by which performance of final devices can be demonstrated. Further, modeling studies that are submitted to the Agency are supplemental and complement animal, bench and human testing provided in:

- Investigational Device Exemptions (investigational devices),
- 510(k) notifications (class II devices), and
- Pre-Market Approval applications (class III devices).

Some of the challenges with the current uses of M&S are:

- Reports typically lack sufficient details for adequate assessment because there are no reporting standards for computational modeling,
- Lack of sensitivity and uncertainty analyses for crucial input parameters, such as geometry, physical properties, boundary conditions,
- Lack of adequate validation to support the use of the computational model, and
- Lack of complete understanding of physiological loads and variations in patient populations.

Adequate verification and validation (V&V) are necessary in order to foster confidence and wider acceptance of M&S for use in medical device evaluation. Therefore, CDRH, in collaboration with the American Society of Mechanical Engineers, has been drafting a guide on the ''Verification and Validation of Computational Modeling for Medical Devices.'' The strategy is meant to create a framework for determining the risk associated with using a computational model in a specific context of use (COU) to inform decision making and for determining ''how much'' V&V is necessary to support the model for its COU. The two main components of this strategy are the Risk Assessment Matrix and the Credibility Assessment Matrix. Both of these tools will be presented and discussed at the workshop. Note that these tools are still in DRAFT format.

The workshop will also describe and discuss FDA's efforts to create a resource or Library of biomedical data and models that can be used in regulatory applications. Key features and questions related to development of the Library and curation of data and models for the Library will be discussed. The goal of the FDA/NIH/NSF Workshop on Computer Modeling and Validation for Medical Devices is to discuss and receive input on these tools to enhance their utility in the community.

Dated: April 1, 2013.

Peter Lurie,

Acting Associate Commissioner for Policy and Planning.

[FR Doc. 2013–07923 Filed 4–4–13; 8:45 am]

BILLING CODE 4160–01–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 inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 207 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: Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804; telephone: 301–496–7057; fax: 301–402–0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

Highly Potent and Selective Deubiquitinating Enzyme Inhibitor

Description of Technology: Available for licensing are inhibitors that target the USP1/UAF1 deubiquitnating enzyme (DUB) complex. The FDA approval and commercial success of

Velcade®, a small molecule proteasome inhibitor, has established the ubiquitin-proteasome system (UPS) as a valid target for anticancer treatment. However, proteasome inhibitors in general suffer from a narrow therapeutic index and acquired resistance. A promising alternative to proteasome inhibition has been to target the enzymes upstream of proteasome-mediated protein degradation, i.e. the ubiquitin conjugation and deconjugation, to generate more specific, less toxic therapeutic agents. The investigators have developed small molecules that target the USP1/UAF1 DUB complex that acts upstream of UPS and has been implicated in the DNA damage response. These compounds are the most potent and selective DUB inhibitors reported to date. Moreover, the inhibitors act synergistically with cisplatin, a DNA damaging anti-cancer drug, to overcome chemoresistance and enhance cytotoxicity. These results suggest the inhibitors may also improve the efficacy and potency of other commonly prescribed chemotherapeutic agents that are known to induce DNA damage.

Potential Commercial Applications:

- Method to treat cancer
- Method to overcome chemoresistance to cisplatin
- Pharmaceutical compositions

Competitive Advantages:

- Represents the most potent and selective DUB inhibitor reported to date.
- Promising alternative to proteasome inhibition offering the potential of more selective and less toxic therapeutic agents.
- Acts synergistically with DNA damaging agents to overcome chemoresistance.

Development Stage:

- Early-stage
- In vitro data available

Inventors: David Maloney (NCATS), Andrew Rosenthal (NCATS), Ajit Jadhav (NCATS), Thomas Dexheimer (NCATS), Anton Simeonov (NCATS), Zhihao Zhuang (University of Delaware), Qin Liang (University of Delaware), Diane Luci (NCATS)

Intellectual Property: HHS Reference No. E–043–2013/0—US Provisional Application No. 61/747,052 filed 28 December 2012

Related Technologies:

- HHS Reference No. E–208–2007/0—US Patent Application No. 12/669,361 filed 15 January 2010
- HHS Reference No. E–156–2012/0—US Provisional Application No. 61/692,560 filed 23 August 2012
- HHS Reference No. E–231–2002/0—US Patent No. 7,498,336 issued 3 March 2009
- HHS Reference No. E–070–2005/0—US Patent No. 8,242,160 issued 14 June 2012 and US Patent Application No. 13/547,417 filed 12 July 2012

Licensing Contact: Jennifer Wong, M.S.; 301–435–4633; *wongje@mail.nih.gov.*

Collaborative Research Opportunity: The National Center for Advancing Translational Sciences is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize this invention. For collaboration opportunities, please contact Lili Portilla at *lili.portilla@nih.gov.*

Therapeutic Applications of a Carboxy-Terminal RTDL Motif

Description of Technology: Mesencephalic Astrocyte-derived Neurotrophic Factor (MANF) is a secreted neurotrophic factor with known anti-neurodegenerative properties. The inventors discovered that the C-terminal RTDL motif of MANF is involved in the anti-degenerative properties of MANF and association of extracellular MANF with the cell surface. Isolated peptides, including the C-terminal RTDL motif of MANF, potentially can be used as a treatment for neurodegenerative disorders and ischemia.

Potential Commercial Applications: Treating neurodegenerative diseases, such as Alzheimer's disease, Parkinson's disease, Huntington disease, etc.

Competitive Advantages: Secreted novel peptides.

Development Stage:

- Early-stage
- Pre-clinical
- In vitro data available

Inventors: Brandon K Harvey, et al. (NIDA)

Intellectual Property: HHS Reference No. E–249–2012/0—US Provisional Application 61/732, 241 filed 30 Nov 2012

Licensing Contact: Betty B. Tong, Ph.D.; 301–594–6565; *tongb@mail.nih.gov*

HIV-Neutralizing Polypeptides: A Novel Use for Platelet Factor 4 or Its Derivatives

Description of Technology: The subject invention describes the method for using Platelet Factor 4 (PF4), also called CXCL4, to inhibit HIV viral entry by blocking GP120 independent of HIV receptor. It also demonstrates that the active polypeptide fragment(s) of PF–4 could be used to identify potential peptide mimics or small molecules that could be used to inhibit HIV infection. PF4 and/or its derivatives may be developed as a systemic therapy or preventive measure using topical applications, such as microbicides. In addition, CXCL4 serum/plasma testing could be used as a clinical marker of HIV disease status to predict/monitor the efficacy of treatment and determine the prognosis of a subject with HIV infection.

Potential Commercial Applications:

- Treatment and prevention of HIV–1 infection.
- Topical application as microbicides.
- A vaccine adjuvant to boost the vaccine efficacy.
- A clinical marker of HIV disease status or to predict/monitor the efficacy of treatment or vaccines.

Competitive Advantages:

- A new HIV–1 inhibitory molecule that acts through a new inhibitory mechanism.
- Any potential derivative or mimicking compound would be unique and have the advantage of hitting a previously unrecognized molecular target in the HIV life cycle.

Development Stage:

- Early-stage
- In vitro data available

Inventors: Paolo Lusso and David J. Auerbach (NIAID)

Publication: Auerbach DJ, et al. Identification of the platelet-derived chemokine CXCL4/PF–4 as a broad-spectrum HIV–1 inhibitor. Proc Natl Acad Sci USA 2012 Jun 12;109(24):9569–74. [PMID 22645343]

Intellectual Property: HHS Reference No. E–140–2012/0—US Application No. 61/649,150 filed 19 Jun 2012

Related Technology: The CXCL4 sequence is in the public domain.

Licensing Contact: Sally Hu, Ph.D., MBA; 301–435–5606; *hus@mail.nih.gov.*

Polarimetric Accessory for Colposcope

Description of Technology: Available for licensing and commercial development is a colposcope accessory device that compensates and resolves tissue borne specular reflections. In medical diagnostic procedures for examining the cervix and the tissues of the vagina and vulva, long working-distance (−30 cm) lighted binocular microscope (colposcope) that provide up to 25x optical magnification are used to create an illuminated magnified view. Speculum dilations can give rise to specular reflections from the tissue surface. The present polarimetric accessory overcomes this limitation and enhances the visibility of subsurface structures of the scattering object. Linearly polarized light is used for cervical illumination and imaging is

performed through an additional polarizer that separates the specularly reflected light from the diffusely backscattered light, which originates in deeper tissue layers, allowing enhanced imaging of the hidden subsurface tissue structure (texture). The region of interest is illuminated by linearly polarized light, and backscattered light passes through the polarization filter to be detected by a digital camera. A custom optical design preserves the polarization state of the backscattered light in the microscope, without interfering with the standard optical path and operation of the microscope, including its binocular system. Special algorithms to visualize regions of statistical similarity in the image have been developed. Though the diffusely backscattered light presents only a small fraction of the detected light, its analysis, using the customized design and image processing procedures, provides useful information about internal structures of biological tissues. The polarimetric accessory includes a linear polarizer for the illuminating beam, two beam splitters for preserving polarization state, lens system for imaging, polarization analyzer, band-pass optical filter, digital camera, and electronic triggering system.

Potential Commercial Applications: Gynecological examinations

Competitive Advantages:

- Image quality
- Resolution of tissue structures at close microscopic distances

Development Stage: Prototype

Inventors: Amir Gandjbakhche (NICHD), Victor Chernomordik (NICHD), Moinuddin Hassan (NICHD), Alexander Sviridov (NICHD), Zachary Alissi (NICHD), Paul Smith (NIBIB), Albert Boccara (NICHD)

Publications:

1. Jacques SL, et al. Imaging superficial tissues with polarized light. Lasers Surg Med. 2000;26(2):119–29. [PMID 10685085]

2. Jacques SL, et al. Imaging skin pathology with polarized light. J Biomed Opt. 2002 Jul;7(3):329–40. [PMID 12175282]

3. Ramella-Roman JC, et al. Design, testing, and clinical studies of a handheld polarized light camera. J Biomed Opt. 2004 Nov–Dec;9(6):1305–10. [PMID 15568952]

4. Sviridov AP, et al. ''Analysis of Biological Tissue Textures Using Measurements of Backscattered Polarized Light'' (presented at the Optical Society of America—Biomedical Optics Topical Meeting, Fort Lauderdale, Florida, March 2006).

5. Sviridov AP, et al. Visualization of biological texture using correlation coefficient images. J Biomed Opt. 2006 Nov–Dec;11(6):060504. [PMID 17212522]

Intellectual Property: HHS Reference No. E–084–2012—US Provisional Patent Application No. 61/620,295 filed 04 Apr 2012

Licensing Contact: Michael A. Shmilovich, Esq., CLP; 301–435–5019; *shmilovm@mail.nih.gov*

CpG Oligonucleotides Treatment To Prevent Chemotherapy-Induced Pulmonary Toxicity

Description of Technology: Bleomycin (BLM) is a chemotherapy agent used to treat multiple types of cancer, but its side effects are life threatening for some patients. About 20% of patients undergoing BLM chemotherapy develop interstitial pneumonitis which may develop to life threatening fibrosis. In such cases, BLM chemotherapy cannot be continued.

This invention identifies a method of pre-treatment using immunostimulatory CpG Oligonucleotide (ODN) molecules to prevent chemotherapy-induced pulmonary toxicity. Administration of certain ODN molecules induces inflammation via stimulation of inflammatory genes (Toll-like receptor 9/TLR9). This stimulation is subsequently down-regulated. This technology makes use of this counter regulatory mechanism to reduce the side effects of chemotherapy agents, such as BML. A properly timed pre-administration of ODN molecules, prior to BML therapy, prevents the lethal side effect of BLM-induced pulmonary inflammation and down-regulates promoters of BLM toxicity (IL–17A and TGF-beta1). Because toxicity from pulmonary inflammation is a side effect limiting use of many chemotherapeutic agents and ODN molecules are relatively inexpensive and have a favorable safety profile, this technology may be useful to improve treatment protocols for many chemotherapy agents.

Potential Commercial Applications: Therapeutic to reduce harmful side effects of pulmonary inflammation caused by chemotherapy.

Competitive Advantages:

- Pulmonary toxicity during chemotherapy is dangerous side effect, this technology uses ODN molecules that are relatively inexpensive and have a favorable safety profile to reduce this side effect.
- This technology may increase the safety and availability of many chemotherapy treatments.

Development Stage:

- Early-stage
- In vivo data available (animal)

Inventors: Dennis Klinman and Takeshi Kinjo (NCI)

Publication: Kinjo T, et al. The counter regulatory response induced by CpG oligonucleotides prevents bleomycin induced pneumopathy. Respir Res. 2012 Jun 18;13:47. [PMID 22708497]

Intellectual Property: HHS Reference No. E–077–2012/0—U.S. Provisional Patent Application No. 61/643,088 filed 04 May 2012

Licensing Contact: Edward (Tedd) Fenn; 301–435–5031; *fenned@mail.nih.gov*

Collaborative Research Opportunity: The National Cancer Institute is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize CpG oligonucleotides for use to down-modulate inflammatory reactions. For collaboration opportunities, please contact John D. Hewes, Ph.D. at *hewesj@mail.nih.gov*.

Dated: April 1, 2013.

Richard U. Rodriguez,

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

[FR Doc. 2013–07917 Filed 4–4–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; 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 contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Aging Special Emphasis Panel; Management of the Primate Aging Database

Date: April 23, 2013.

Time: 1:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue, Suite 2C212, Bethesda, MD 20892, (Telephone Conference Call).