Dated: September 16, 2015.

Walter J. Koroshetz,

Director, National Institute of Neurological Disorders and Stroke, National Institutes of Health.

[FR Doc. 2015–24117 Filed 9–22–15; 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 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. 209 and 37 CFR part 404 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.

SUPPLEMENTARY INFORMATION: Technology descriptions follow.

A Novel Rapid Point-of-Care Diagnostic Method for Infectious and Autoimmune Diseases

Description of Technology: Rapid point-of-care, antibody-based testing is not available for the diagnosis of autoimmune and most infectious diseases. For detecting autoantibodies associated with most autoimmune conditions, fluid-phase immunoprecipitation assays are required. However, these assays usually involve radioactivity and are not feasible for point-of-care applications. The subject invention describes methods of using neodymium magnet for diagnosis of infectious and autoimmune diseases including lupus, Sjögren's syndrome, type I diabetes, HIV and Lyme disease. The assay takes 3.5 minutes, is highly efficient, and has low background.

Potential Commercial Applications

- A rapid assay for point-of-care diagnosis of infectious and autoimmune diseases.
- Applications to different assay platforms, such as a portable, commercially available hand-held luminometer or an automated, high-throughput device.

Competitive Advantages

- Highly efficient, rapid, and easy to perform.
- Low background signals.

Development Stage

- Early-stage
- *In vitro* data available
- Prototype.

Inventor: Peter D. Burbelo (NIDCR)

Publications

1. Burbelo PD, *et al.* Luciferase immunoprecipitation systems for measuring antibodies in autoimmune and infectious diseases. Transl Res. 2015 Feb; 165(2):325–335. [PMID 25241936]

2. Burbelo PD, *et al.* New autoantibody detection technologies yield novel insights into autoimmune disease. Curr Opin Rheumatol. 2014 Nov; 26(6):717–723. [PMID 25203116]

3. Burbelo PD, *et al.* Searching for biomarkers: humoral response profiling with luciferase immunoprecipitation systems. Expert Rev Proteomics. 2011 Jun; 8(3):309–316. [PMID 21679112]

4. Burbelo PD, *et al.* Antibody profiling by luciferase immunoprecipitation systems (LIPS). J Vis Exp. 2009 Oct 7; (32). [PMID 19812534]

Intellectual Property: HHS Reference No. E–190–2015/0—US Provisional Application No. 62/212,973 filed 01 Oct 2015.

Related Technologies

- E–036–2010 family: PCT/US2011/027888, US 8,926,989, issued. US 14/562,068 and EP 11730770.1, pending.
- E–281–2010: US 13/882,850, allowed.
- E–063–2009: US 8,951,723, issued.

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

Collaborative Research Opportunity: The National Institute of Dental and Craniofacial Research is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize using neodymium magnet for rapid diagnosis. For collaboration opportunities, please contact David Bradley, Ph.D. at *bradleyda@nidcr.nih.gov.*

A Mobile Health Platform

Description of Technology: The NIH inventors have developed a mobile health technology to monitor and predict a user's psychological status and to deliver an automated intervention when needed. The technology uses smartphones to monitor the user's location and ask questions about psychological status throughout the day. Continuously collected ambulatory psychological data are fused with data on location and responses to questions. The mobile data are combined with geospatial risk maps to quantify exposure to risk and predict a future psychological state. The future predictions are used to warn the user when he or she is at especially high risk of experiencing a negative event that might lead to an unwanted outcome (*e.g.,* lapse to drug use in a recovering addict).

An internally developed mobile app is now being deployed to deliver an intervention in the context of drug addiction. The inventors are also seeking to test the technology for other health applications.

Potential Commercial Applications

- Real time behavior monitoring
- Therapeutic delivery of an intervention via a mobile device

Competitive Advantages

- Mobile device
- Real time
- Exposure to risk

Development Stage: Prototype

Inventors: Kenzie L. Preston, David H. Epstein, Matthew Tyburski, Massoud Vahabzadeh (all of NIDA)

Publications

1. Epstein DH, *et al.* Real-time tracking of neighborhood surroundings and mood in urban drug misusers: Application of a new method to study behavior in its geographical context. Drug Alcohol Depend. 2014 Jan 1;134:22–9. [PMID 24332365]

2. Kennedy AP, *et al.* Continuous in-the-field measurement of heart rate: Correlates of drug use, craving, stress and mood in polydrug users. Drug Alcohol Depend. 2015 June 1;151:159–66. [PMID 25920802]

Intellectual Property: HHS Reference No. E–049–2015/0—US Provisional Application No. 62/186, 983 filed 30 June 2015

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

Collaborative Research Opportunity: The National Institute on Drug Abuse is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize

mhealth system to analyze and intervene. For collaboration opportunities, please contact Vio Conley at *conleyv@mail.nih.gov.*

Detection and Discrimination of Classical and Atypical L-Type BSE Strains by RT-QuIC

Description of Technology: Statutory surveillance of bovine spongiform encephalopathy (BSE) indicates that cattle are susceptible to both classical (C–BSE) and atypical forms of BSE. Atypical forms of BSE appear to be sporadic and thus may never be eradicated. A major challenge is the lack of sufficiently practical and sensitive tests for routine BSE detection and strain discrimination. The RT-QuIC test, which is based on prion-seeded fibrillization of recombinant prion protein ($rPrP_{Sen}$), is known to be highly specific and sensitive for detection of multiple human and animal prion diseases, but not BSE. This application claims methods for distinguishing whether a sheep, cow or goat has atypical L-bovine spongiform encephalopathy prion or classical bovine spongiform encephalopathy.

Potential Commercial Applications

- Detection and distinguishing of both BSE forms
- Rapid detection and discrimination of BSE forms

Competitive Advantages

- Orders of magnitude more sensitive than ELISA tests
- Eliminates need for multi-phase analyses of samples
- Can be applied to large scale testing of multiple samples

Development Stage

- *In vitro* data available
- *In vivo* data available (animal)
- Prototype

Inventors: Byron W. Caughey (NIAID), Christina D. Orrú (NIAID), Alessandra Favolez (EM), Cristina Casalone (EM), Maria Mazza (EM), Cristiano Corona (EM)

Publications

1. Orrú CD, *et al.* Detection and discrimination of classical and atypical L-type bovine spongiform encephalopathy by real-time quaking-induced conversion. J Clin Microbiol. 2015 Apr;53(4):1115–20. [PMID 25609728]

2. Orrú CD, *et al.* Correction: Bank Vole Prion Protein As an Apparently Universal Substrate for RT-QuIC-Based Detection and Discrimination of Prion Strains. PLoS Pathog. 2015 Aug 18;11(8):e1005117. [PMID 26284358]

3. Orrú CD, *et al.* Bank Vole Prion Protein As an Apparently Universal Substrate for RT-QuIC-Based Detection and Discrimination of Prion Strains. PLoS Pathog. 2015 Jun 18;11(6):e1004983. [PMID 26086786]

Intellectual Property: HHS Reference E–048–2015/0—US Provisional Application No. 62/092,645 filed 16 Dec 2014

Licensing Contact: Peter A. Soukas; 301–435–4646; *ps193c@nih.gov*

Lenalidomide Analogs for the Treatment of Neurodegenerative Disorders and Cancer

Description of Technology: Inflammatory processes associated with the over-production of tumor necrosis-alpha (TNF-alpha), a potent activator of the immune system accompany numerous neurodegenerative diseases. TNF-alpha has been validated as a drug target with the development of the inhibitors Enbrel and Remicade (fusion antibodies) as prescription medications. Both, however, are large macromolecules that require direct injection and have limited brain access. The classical drug, thalidomide is being increasingly used in the clinical management of a wide spectrum of immunologically-mediated and infectious diseases, and cancers. The NIA inventors developed and assessed novel thio analogs of lenalidomide (Celegene's Revlimid and an analog of thalidomide) as immunomodulatory agents, with the potential to reduce chronic systemic and central nervous system inflammation. These compounds were synthesized and evaluated for their TNF-alpha inhibitory activity. This invention was extended from the inventors' prior work to develop potent compounds to reduce neuroinflammation as a treatment strategy for neurodegenerative disorders. The current studies focus the compounds activity in classical models of neurodegeneration as well as cancer.

Potential Commercial Applications

- Treatment for blood disorders (myelodysplastic syndrome), cancer (multiple myeloma), inflammatory processes and erythema
- Immunomodulatory agents
- Reduce chronic systemic and central nervous system inflammation

Competitive Advantages

- Effective smaller molecular weight compound that can enter brain among current agents
- Experimental therapeutic to reduce inflammation systematically and within the brain
- Effective in reducing proinflammatory cytokines than existing agents

Development Stage

- *In vitro* data available
- *In vivo* data available (animal)
- Prototype

Inventors: Nigel H. Greig, Weiming Luo, David Tweedie, Harold W. Holloway, Qian-sheng Yu (all of NIA)

Publication: Luo W, *et al.* Design, synthesis and biological assessment of novel N-substituted 3-(phthalimidin-2-yl)-2,6-dioxopiperidines and 3-substituted 2,6-dioxopiperidines for TNF-alpha inhibitory activity. Bioorg Med Chem. 2011 Jul 1;19(13):3965–3972. [PMID 21658960]

Intellectual Property: HHS Reference No. E–045–2012/0—

- US Patent No. 8,927,725 issued 06 Jan 2015
- US Patent No. 9,084,783 issued 21 Jul 2015
- US Patent Application No. 14/746,512 filed 22 Jun 2015

Related Technologies: HHS Reference No. E–189–2003/0—

- US Patent No. 7,973,057 issued 05 Jul 2011
- US Patent No. 8,546,430 issued 01 Oct 2013
- US Patent Application No. 13/648,625 filed 10 Oct 2012
- US Patent Application No. 14/314,124 filed 25 Jun 2014
- and related international patents/patent applications

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

Novel Regulatory B Cells for Treatment of Cancer and Autoimmune Disease

Description of Technology: The manner by which cancers evade the immune response is not well-understood. What is known is that the manner is an active process that regulates immune responses employing at least two types of suppressive cells, myeloid-derived suppressive cells and regulatory T cells (Tregs), a key subset of $CD4^+$ T cells that controls peripheral tolerance to self- and allo-antigens. Tregs are considered to play a key role in the escape of cancer cells from anti-tumor effector T cells.

Cancer cells have been found to directly activate resting B cells to form suppressive regulatory B cells (tBregs) and utilize them to evade immune surveillance and mediate metastasis. tBregs directly inhibit $CD4^+$ and $CD8^+$ T cell activity in a cell contact-dependent manner, induce $FoxP3^+$ T cell activity, and promote Treg-dependent metastasis.

Researchers from the National Institute on Aging (NIA), NIH, have developed methods for the generation of tBregs, and for using tBregs to produce

Tregs, and methods that inactivate or deplete tBregs. These methods have significant therapeutic value in the combat with cancer immune escape and metastasis, and in the control of harmful autoimmune diseases.

Potential Commercial Applications:

- Production of cellular cancer vaccines
- Treatments for immune-mediated disorders
- Treatments for cancer
- Treatments for chronic viral infections

Development Stage:

- Early-stage
- *In vitro* data available
- *In vivo* data available (animal)
- *In situ* data available
- *Ex vivo* data available

Inventors: Bira Arya and Purevdorj Olkhanud (NIA)

Intellectual Property: HHS Reference No. E–101–2010/0—US Patent Application No. 13/577,226 filed 03 Aug 2012

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

Collaborative Research Opportunity: The National Institute on Aging, Laboratory of Molecular Biology and Immunology, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize the utilization of regulatory B cells to control autoimmune diseases and strategies that inactivate tBregs to control cancer immune escape. Please contact Nicole Darack, Ph.D. at 240–276–5493 or *darackn@mail.nih.gov* for more information.

Immunogenic Tumor-associated Antigen SPANX–B for Selective Cancer Immunotherapy

Description of Technology: Researchers at the National Institute on Aging (NIA) have characterized a novel tumor-associated antigen, SPANX–B, which is naturally immunogenic and is expressed in a variety of human malignancies, including melanoma and lung, colon, renal, ovarian and breast carcinomas. In melanoma specifically, SPANX–B expression is associated with advanced and metastatic disease. Moreover, the researchers have found several agonist epitope peptides from SPANX–B which can be used to activate the immune system to eradicate tumors utilizing T cells. SPANX–B peptides have significant clinical and immunotherapeutic potential for the development of cancer diagnostic assays and potent protective and/or therapeutic vaccines to combat a wide-range of cancers.

Potential Commercial Applications:

- *In vitro* diagnostic assays for highly-metastatic melanomas or other cancers
- Therapeutic monoclonal antibodies
- Cancer vaccine development

Competitive Advantages:

- Immunogenic: SPANX–B peptides are naturally able to elicit immune response.
- Expressed in a wide-range of cancers.
- Use of epitope peptides facilitates the activation of cells of the more therapeutically effective branch of the immune system.
- Small epitope peptides: Can be more easily manufactured in contrast to recombinant proteins.

Development Stage:

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

Publication: Almanzar G, *et al.* Sperm-derived SPANX–B is a clinically relevant tumor antigen that is expressed in human tumors and readily recognized by human CD4+ and CD8+ T cells. Clin Cancer Res. 2009 Mar 15;15(6):1954–63. [PMID 19276289]

Inventors: Bira Arya (NIA) and Vladimir Larionov (NCI)

Intellectual Property: HHS Reference No. E–089–2009/0—

- US Patent No. 8,664,183 issued 04 Mar 2014
- US Patent Application No. 14/155,230 filed 14 Jan 2014

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

Collaborative Research Opportunity: The National Institute on Aging, Laboratory of Molecular Biology and Immunology, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize the use of SPANX–B-based therapeutic approaches to combat cancers. Please contact Nicole Darack, Ph.D. at 240–276–5493 or *darackn@mail.nih.gov* for more information.

Method for the Diagnosis and Prognosis of Age-Related Cardiovascular Disorders

Description of Technology: NIH investigators have discovered a method for the diagnosis and prognosis of cardiovascular aging. Current methodologies include the measurement of patient lipid profiles or expression of up to two proteins. In contrast, this technology utilizes the expression levels of a panel of proteins not previously known to be related to cardiovascular aging and may prove to be a more accurate diagnostic or prognostic of cardiovascular aging than currently available tests or it may improve the accuracy of currently available tests when used in concert.

The technology relates to methods for determining susceptibility to having an extremely common age-associated vascular disorder. It also describes the subsequent use of these proteins as markers for disease. While the underlying cellular and molecular mechanisms of age-related vascular disease remain largely undefined, the expression levels of the genes described in this technology have been empirically determined to differ between healthy and age-inflamed arterial tissue. Further, this technology includes a companion mass spectroscopic-based methodology for reproducible quantification of specific expression levels of interest.

Potential Commercial Applications: Diagnosis of age-related vascular disorder.

Inventors: Mingyi Wang *et al.* (NIA)

Intellectual Property: HHS Reference No. E–219–2008/0—US Patent Application No. 13/202,319 filed 18 Aug 2011

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

Collaborative Research Opportunity: The National Institute on Aging, Laboratory of Cardiovascular Science, Cardiac Biology Section—Vascular Group, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize idea of how to assess and retard accelerated arterial aging and its attendant risks for atherosclerosis and hypertension. Please contact Vio Conley at 240–276–5531 or *conleyv@mail.nih.gov* for more information.

A Novel and Efficient Technology for Targeted Delivery of siRNA

Description of Technology: The biological phenomenon of RNA interference (RNAi) has much promise for developing therapeutics to a variety of diseases. However, development of RNAi therapies remains mainly in preclinical stages largely because of difficulties in delivering small inhibitory RNAs (siRNA) and short hairpin RNAs (shRNA) into target cells. Although viral vector-based siRNA delivery systems have been widely used, their specificity and safety remains significant issue. Without a

solution to this delivery problem, RNAi cannot fulfill its therapeutic promise.

Investigators at the National Institutes of Health have developed novel compositions and methods for delivering inhibitory oligonucleotides to cells in a targeted and efficient manner. The compositions and methods are based on utilizing a cell surface receptor targeting ligand, such as cytokine or chemokine, and a domain that binds an inhibitory oligonucleotide, to efficiently deliver the inhibitory oligonucleotide to the cell that expresses the cell surface receptor targeting ligand. Chemokine receptors are differentially expressed on various cells, including tumors; hence this technology allows targeting siRNA to aberrant cells. Gene silencing can also be achieved in variety of immune cells by targeting cytokine receptors. This technology has great potential for developing into a safe and effective means of delivering therapeutic siRNAs.

Potential Commercial Applications

- Treatment of cancers and autoimmune diseases by delivery of siRNA to tumor cells or various aberrantly functioning immune cells.
- This technology can be used to boost vaccine responses against cancers and chronic infectious diseases.
- Targeted delivery of fluorochrome-labeled RNA both *in vitro* and *in vivo* for diagnostic purposes, for example, to trace or localize various cells and to determine tumor metastasis and aberrant proliferation or homing of immune cells.

Competitive Advantages

- Simple method for linking siRNA to polypeptides to create non-covalent or covalent complexes
- *In vivo* targeted delivery of inhibitory RNAs into cells rather than systemically
- Delivery of multiple inhibitory RNAs to target multiple genes
- Long-term repression of target gene expression through RNAi phenomenon

Development Stage

- *In vitro* data available
- *In vivo* data available (animal)
- *In situ* data available

Inventors: Bira Arya, Purevdorj Olkhanud, Juan Espinoza (all of NIA)

Intellectual Property: HHS Reference No. E–051–2008/0—

- US Patent No. 8,703,921 issued 22 Apr 2014
- US Patent Application No. 14/220,726 filed 20 Mar 2014
- Various international patents/patent applications

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

Collaborative Research Opportunity: The National Institute on Aging, Laboratory of Molecular Biology and Immunology, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize chemokine-based siRNA/shRNA technology for treatment of cancers and autoimmune diseases, *i.e.* to control expression of immunomodulatory cytokines and other factors that facilitate tumor escape, activity of regulatory T cells or Th2 type of cells. This technology can be also utilized to boost vaccine responses against cancers and chronic infectious diseases. Please contact John D. Hewes, Ph.D. at 240–276–5515 or *john.hewes@nih.gov* for more information.

Dated: September 17, 2015.

Richard U. Rodriguez,

Acting Director, Office of Technology Transfer, National Institutes of Health.

[FR Doc. 2015–24137 Filed 9–22–15; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

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 meetings.

The meetings 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: Center for Scientific Review Special Emphasis Panel; Member Conflict: Bioengineering Sciences Biocomputational and Modeling.

Date: October 28, 2015.

Time: 2:00 p.m. to 4:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Joseph Thomas Peterson, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4118, MSC 7814, Bethesda, MD 20892, 301–408–9694, *petersonjt@csr.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Fellowships: Cell Biology, Developmental Biology, and Bioengineering.

Date: October 29–30, 2015.

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

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Raj K. Krishnaraju, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6190, Bethesda, MD 20892, 301–435–1047, *kkrishna@csr.nih.gov*.

Name of Committee: Molecular, Cellular and Developmental Neuroscience Integrated Review Group; Cellular and Molecular Biology of Glia Study Section.

Date: October 29–30, 2015.

Time: 8:00 a.m. to 2:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Hilton McLean Tysons Corner, 7920 Jones Branch Drive, McLean, VA 22102.

Contact Person: Linda MacArthur, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4187, Bethesda, MD 20892, 301–537–9986, *macarthurlh@csr.nih.gov*.

Name of Committee: Oncology 1-Basic Translational Integrated Review Group; Tumor Progression and Metastasis Study Section.

Date: October 29–30, 2015.

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

Agenda: To review and evaluate grant applications.

Place: Embassy Suites, DC Convention Center, 900 10 Street, Washington, DC 20001.

Contact Person: Rolf Jakobi, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6187, MSC 7806, Bethesda, MD 20892, 301–495–1718, *jakobir@mail.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Topics in Bacterial Pathogenesis.

Date: October 29–30, 2015.

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

Agenda: To review and evaluate grant applications.

Place: The Warwick Allerton Hotel, 701 North Michigan Avenue, Chicago, IL 60611.

Contact Person: Richard G. Kostriken, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3192, MSC 7808, Bethesda, MD 20892, 240–519–7808, *kostrikr@csr.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Fellowships: Biophysical, Physiological, Pharmacological and Bioengineering Neuroscience.

Date: October 29–30, 2015.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: The Westin Georgetown, 2350 M St. NW., Washington, DC 20037.