

Consumer/Patient Perspective

- How could HRA data be shared with the patients for their feedback and follow up in the primary care practice?
- What role, if any, do incentives play in motivating patients to take the HRA and/or participate in follow-up interventions?

Data

- With respect to Information Technology (IT), how could HRA data entered in any form populate electronic health records, and what special challenges and solutions occur if the data are entered in a non-electronic form?
- Are there standardized and certified tools available to support this data migration from multiple data entry sources?

Certification

- What certification tools and processes should complement the HRA guidance and how should they be made available to support primary care office selection of an HRA instrument?

Evaluation and Quality Assurance

- How should the HRA guidance be evaluated and updated with respect to individual and population-level (practice-based panel management) health outcomes?

Public Forum: CDC plans to convene a public forum in early February 2011 to highlight some of the key challenges, barriers, opportunities and innovations related to HRA standardization. The public forum will consist of panel presentations followed by public comment. CDC will publish a separate notice in the **Federal Register** announcing additional information for the Public Forum.

Dated: November 8, 2010.

Tanja Popovic,

*Deputy Associate Director for Science,
Centers for Disease Control and Prevention.*

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BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES**National Institutes of Health****Government-Owned Inventions; Availability for Licensing**

AGENCY: National Institutes of Health, Public Health Service, 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.

ADDRESSES: 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.

Novel Anti-HIV Acylthiol Drugs and Thioether Prodrugs

Description of Invention: The inventions provide the compositions, pharmaceutical carrier, and usages of the new Acylthiols (E-329-2000 family) and Thioether pro-drug (E-177-2010 family) compounds in treatment of retroviral infections such as HIV. More specifically, these compounds target the highly-conserved nucleocapsid protein of HIV-1. Activity of these compounds against the nucleocapsid protein leads to inactivation of the virus via disruption of the zinc fingers, integral for infectivity, without significantly affecting cellular proteins. Finally, these inventions can be prepared from inexpensive starting materials and two "one-pot" reactions. Thus, they open the possibility for an effective drug treatment for HIV that could reach underdeveloped countries. These new compounds have the potential to be used both as a systemic drug for the treatment of HIV-1 infection and as a topically-applied barrier to prevent viral transmission.

Applications: Treatment and prevention of HIV infections.

Advantages:

- Potent anti-HIV activity.
- Could be used both systemically and locally.
- Unlikely to develop any drug resistance.
- Can be inexpensively manufactured in a large scale.

Development Status: *In vitro* data available.

Market: According to the 2008 UNAIDS report, there were 33 million people living with AIDS in 2007, with 2.7 million new cases occurring in that year. In the US alone, there are 1.2 million AIDS patients.

The anti-HIV drug market is among the fastest-growing pharmaceutical markets in the world. Due to the large target market, duration of therapy (lifetime), and nature of the disease (incurable), manufacturers will continue to benefit from technological advancements. In 2007, the seven Major Markets (7MM; US, Japan, Italy, Germany, UK, Spain and France) generated \$9.3B in sales of antiretroviral drugs. These markets are expected to grow to \$15.1B by 2017.

The current product market segments for anti-retrovirals are: protease inhibitors (PI), nucleoside reverse transcriptase inhibitors (NRTI), non-nucleoside reverse transcriptase inhibitors (NNRTI), entry inhibitors (EI), integrase inhibitors (II), and maturation inhibitors (Other).

Inventors: Daniel Appella (NIDDK), Ettore Appella (NCI), John K. Inman (NIAID), Deyun Wang (NIDDK), Lisa M. Miller Jenkins (NCI), Ryo Hayashi (NCI).

Publications:

1. Miller Jenkins LM, *et al.* Nature Chemical Biology, in press.
2. Miller Jenkins LM, *et al.* Specificity of acyl transfer from 2-mercaptobenzamide thioesters to the HIV-1 nucleocapsid protein. J Am Chem Soc. 2007 Sep12;129(36):11067-11078. [PubMed: 17705474]
3. Schito ML, *et al.* In vivo antiviral activity of novel human immunodeficiency virus type 1 nucleocapsid p7 zinc finger inhibitors in a transgenic murine model. AIDS Res Hum Retroviruses. 2003 Feb;19:91-101. [PubMed: 12639244]

Patent Status:

- U.S. Provisional Application No. 61/353,274 filed 10 Jun 2010 (HHS Reference No. E-177-2010/0-US-01).
- PCT/US02/23924 (HHS Reference No. E-329-2000/0-PCT-02) and entered national stage in the U.S. (Patent No. 7,528,274 and Patent Application No. 12/414,321), Canada (Patent Application No. 2456083), Australia (Patent No. 2002322721), and Europe (Patent Application No. 02756732.0).

Licensing Status: Available for licensing.

Licensing Contact: Sally Hu, Ph.D.; 301-435-5606; HUS@mail.nih.gov.

Collaborative Research Opportunity: The Laboratory of Cell Biology, Center for Cancer Research is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize the above invention for the treatment/prevention of HIV infection. Please contact John Hewes, Ph.D. at 301-435-3121 or hewesj@mail.nih.gov for more information.

Scanningless Multiphoton Microscopy with Diffraction-Limited Axial Resolution

Description of Invention: The technology offered for licensing is a scanningless multiphoton microscope for performing 3-dimensional imaging that achieves diffraction-limited resolution. The microscope combines temporal multiplexing with spatial dispersion to achieve diffraction-limited resolution without having to mechanically scan the sample (a field of view up to 30x30 microns). The wide-field excitation of the sample allows imaging rates in excess to prior art multiphoton microscopes while still achieving diffraction-limited axial resolution. The microscope includes a laser source that generates a femtosecond laser beam that passes through a stair-step optic having a variable thickness piece of glass arranged such that each "strip" of the laser beam is delivered at a different relative delay. Each strip exits the stair-step optic and is imaged onto the surface of a diffraction grating by two imaging lenses and a mirror. The diffraction grating sends the different wavelengths that compose each horizontal strip of the laser beam in different directions. Another pair of lenses, such as the imaging lens and objective lens (e.g., high numerical aperture objective) images and demagnifies the surface of the diffractive grating into a biological sample that causes an excitation to occur in the sample. The ensuing excitation generates fluorescence in the sample confined to the focal plane of the objective lens, where the excitation is maximized. The fluorescence is collected through the objective lens and then by a CCD camera.

Applications:

- The invention provides a high resolution multiphoton microscopy device to the laboratory instrumentation market.
- The uses of such a device would predominantly be for research in biological imaging.
- The device provides the ability to image a large frame rapidly and with relatively low energy and thus without burning the sample or destroying subcellular structures.

Inventors: Hari Shroff and Andrew York (NIBIB).

Patent Status: U.S. Provisional Application No. 61/385,409 filed 22 Sep 2010 (HHS Reference No. E-105-2010/0-US-01).

Licensing Status: Available for licensing.

Licensing Contacts:

• Uri Reichman, Ph.D., MBA; 301-435-4616; UR7a@nih.gov.

• Michael Shmilovich, Esq.; 301-435-5019; ShmilovichM@mail.nih.gov.

Collaborative Research Opportunity: The National Institute of Biomedical Imaging and Bioengineering Section on High Resolution Optical Imaging is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize this invention. Please contact Dr. Henry Eden at edenh@mail.nih.gov for more information.

Myosin-Based Protein-Protein Interaction Assay

Description of Invention: Investigators at the National Institute on Deafness and Other Communication Disorders (NIDCD) have developed an assay for the detection of protein-protein interactions in living cells. This assay uses readily-available reagents and straightforward techniques that avoid the difficulty of purifying proteins or generating antibodies required for other binding studies. Proof-of-concept for this assay has been demonstrated, and a manuscript is in preparation for publication.

This technology utilizes a molecular motor, myosin X, which migrates along actin filaments within cells. A protein fused to a fragment of myosin X will carry its binding partners to the cell periphery. Since the myosin fusion protein and its partner are labeled with different fluorescent tags, an unambiguous fluorescence overlap will be visible as discrete points along the periphery of the cell. The inventors have designed a number of cDNAs for the construction of fusion proteins appropriate for such an assay.

Available for licensing are a variety of cDNAs which may be used for generating fluorescently-tagged myosin X fusion proteins, for use in the assay described above. Also available are a number of constructs incorporating other fluorescently-tagged myosins, kinesins, myosin and kinesin binding partners and a variety of PDZ scaffold proteins. Further details of the available cDNAs are available upon request.

Applications:

- Identification of protein-protein binding interactions in living cells.
- DNA-based tools for study of myosins, trafficking, signaling complexes and other research focusing on molecular motors.

Advantages:

- Assay avoids the need to purify proteins or generate antibodies for binding studies.

• Protein-protein interactions can be unambiguously identified.

Development Status: Proof of concept has been demonstrated.

Inventors: Erich T. Boger, Inna A. Belyantseva, Thomas B. Friedman (NIDCD).

Relevant Publication: Belyantseva IA et al. Myosin-XVa is required for tip localization of whirlin and differential elongation of hair-cell stereocilia. *Nat Cell Biol.* 2005 Feb;7(2):148-156. [PubMed: 15654330]

Patent Status: HHS Reference Nos. E-069-2009/0, E-069-2009/1, E-069-2009/2, E-069-2009/3, E-069-2009/4, E-069-2009/5, E-069-2009/6, and E-069-2009/7—Research Tool. Patent protection is not being sought for this invention.

Licensing Status: Available for licensing under a Biological Materials License Agreement.

Licensing Contact: Tara L. Kirby, Ph.D.; 301-435-4426; tarak@mail.nih.gov.

Dated: November 9, 2010.

Richard U. Rodriguez,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2009-D-0448]

Guidance for Industry, Mammography Quality Standards Act Inspectors, and Food and Drug Administration Staff; The Mammography Quality Standards Act Final Regulations: Modifications and Additions to Policy Guidance Help System #13; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled "The Mammography Quality Standards Act Final Regulations: Modifications and Additions to Policy Guidance Help System #13." This document is intended to assist mammography facilities and their personnel in meeting the requirements of the Mammography Quality Standards Act (MQSA) regulations.

DATES: Submit either electronic or written comments on this guidance at any time. General comments on Agency