information and experience on the application of the draft guidance in order to inform the final guidance document.

FDA began accepting nominations for the pilot program on December 12, 2011. In the **Federal Register** notice announcing the pilot program, FDA stated its intention to limit the pilot program to nine candidates. After review of the nominations received in response to the pilot program notice, FDA accepted nine appropriate candidates for the pilot program.

In the pilot program notice, FDA stated its intention to accept nominations to participate in the pilot program until May 8, 2012. Because FDA has already accepted nine sponsors to participate in the program, FDA will no longer accept nominations to participate in the program and will conduct the pilot program for the nine sponsors that have already been accepted.

In the pilot program notice, FDA also stated that the pilot program will terminate on May 8, 2012. Instead, the pilot program will be extended for the nine accepted sponsors until May 8, 2013.

Dated: February 28, 2012.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

[FR Doc. 2012–5311 Filed 3–5–12; 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, Public Health Service, HHS.

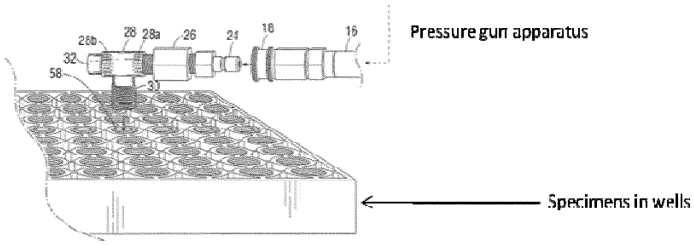
**ACTION:** Notice.

**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.

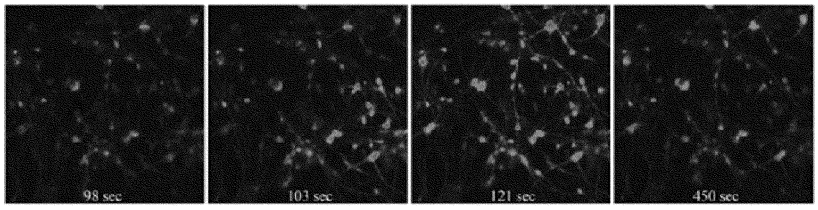
**ADDRESSES:** Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804; telephone: 301–496–7057; fax: 301–402–0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

**Device for Simulating Explosive Blast Trauma**

*Description of Technology:* NIH scientists have developed a novel device to simulate the effects of pressure waves resulting from explosions or blasts on biological tissue. This methodology allows real-time monitoring of tissue damage while it is occurring and can track the secondary effects of pressure damage after tissue insult. This tool is well-adapted for investigating traumatic brain injury and organ damage resulting from explosion pressure waves, such as in military combat.




Images of cells under microscope taken over time during pressure blast
**White label** indicates dying cells




Blast given here

*Potential Commercial Applications:*

- Real-time monitoring of tissue damage from primary blast pressure
- Real-time monitoring of tissue damage from secondary effects of blast pressure, such as tissue shearing against surfaces
- Can monitor tissue through both live imaging and assaying cell viability
- Can measure pressure effects on various tissues

*Competitive Advantages:*

- Allows differentiation of primary and secondary blast pressure effects on tissue damage
- Employs multiple methods to assess cell viability
- Possesses high temporal resolution

*Development Stage:* Prototype.

*Inventors:* Rea Ravin, Paul Blank, Alex Steinkamp, Joshua Zimmerberg, Sergey Bezrukov, and Kim Lee Mcafee (all of NICHD).

*Intellectual Property:* HHS Reference No E–068–2012/0—U.S. Provisional Application No. 61/590,209 filed 24 Jan 2012.

*Licensing Contact:* Michael A. Shmilovich, Esq.; 301–435–5019; *mish@codon.nih.gov.*

**Small-Molecule Inhibitors of Human Galactokinase for the Treatment of Galactosemia and Cancers**

*Description of Technology:* Lactose, found in dairy products and other foods, is comprised of two simple sugars, glucose and galactose. In galactosemia,

where galactose is not properly metabolized, build-up of toxic compounds, such as galactose-1-phosphate, can lead to liver disease, renal failure, cataracts, brain damage, and even death if this disorder is left untreated. Currently, the only treatment for galactosemia is elimination of lactose and galactose from the diet, but in some cases this is not sufficient to avoid long-term complications from the disorder.

This technology describes selective small-molecule inhibitors of human galactokinase, which inhibit the first step in galactose metabolism. These compounds could be used to treat galactosemia by eliminating the build-up of toxic metabolites in brain, liver and other tissues, and could form the basis for the first effective treatment for this disorder.

These inhibitors are also promising candidates for the treatment of certain cancers, such as PTEN/AKT misregulated cancers. The inventors have already shown that the inhibitors are cytotoxic for several cancer cell lines.

*Potential Commercial Applications:*

• Treatment of galactosemia

• Treatment of certain cancers, such as PTEN/AKT misregulated cancers

*Competitive Advantages:*

• There is currently no effective treatment for classic galactosemia, where dietary restriction cannot prevent long-term complications in some cases.

• Cancer therapeutics based on these inhibitors are predicted to have minimal side-effects.

*Development Stage:*

• Early-stage

• In vitro data available

*Inventors:* Matthew Boxer et al. (NCATS).

*Intellectual Property:* HHS Reference No. E–240–2011/0 — PCT Application No. PCT/US2011/053021 filed 23 Sep 2011.

*Licensing Contact:* Tara L. Kirby, Ph.D.; 301–435–4426; *tarak@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 Small-Molecule Inhibitors of Human Galactokinase for the Treatment of Galactosemia and Cancers. For collaboration opportunities, please contact Lili M. Portilla, MPA at *portilll@mail.nih.gov*.

**The Cancer Stem Cell Finder: A Novel Reporter Construct Which Uses Transposition and Green Fluorescent Protein Expression To Identify Cancer Stem Cells**

*Description of Technology:* Scientists at the National Institutes of Health (NIH) have designed a novel reporter construct which can be used to identify, monitor, and allow for the manipulation of cancer stem cells (CSCs). CSCs are a subset of poorly differentiated tumor cells expressed at low frequency within a tumor and are resistant to conventional chemotherapies. CSCs have high metastatic potential and give rise to new tumors that spread cancer throughout the body. These characteristics make CSCs prime targets for developing new therapeutic agents to eradicate cancer.

The reporter construct is a novel expression vector composed of the Sleeping Beauty transposon plasmid and a Nanog promoter linked to green fluorescent protein (GFP). Nanog is a transcription factor that is overexpressed in embryonic stem (ES) cells and tumors that resemble ES cells. When introduced into a population of tumor cells, the Nanog-GFP-Sleeping Beauty transposon construct is able to integrate into tumor cell DNA via transposition. If the transposed cell is a CSC, the Nanog transcription factor overexpressed in that CSC will bind to the Nanog-promoter in the reporter construct to drive GFP expression within the cell. Thus, CSCs can be isolated based on their selective expression of the GFP label. The NIH scientists have utilized their reporter construct to identify small populations of CSCs in mouse and human breast cancer cell models.

*Potential Commercial Applications:*

• Identify CSCs with high metastatic potential in patients to target with therapeutic intervention

• Screen therapeutic drug candidates to identify their effectiveness against CSCs in comparison to more highly differentiated tumor cells

• Investigate genes, surface proteins, and other markers responsible for CSC ''stem-ness'' to develop CSC diagnostics and identify therapeutic candidates to stop or reverse the properties contributing to the high metastatic potential of these cells

•Identify transcription factors/genes activated in the tumor microenvironment that trigger metastasis

*Competitive Advantages:*

• The reporter construct is validated to identify CSCs in both human and mouse tumor cell populations

• Researchers and clinicians can monitor the ''stem-ness'' of a tumor cell population to predict the metastatic potential of a tumor

• CSCs are identified in vivo in somatic cells via GFP labeling without utilizing a virus for transfection

• CSCs can be isolated, monitored, and traced via their GFP label in both in vitro and in vivo experimentation

• Facilitates the generation of a large quantity of CSCs for further study

*Development Stage:*

• Early-stage

• Pre-clinical

• In vitro data available

• In vivo data available (animal)

*Inventors:* Rachel L. de Kluyver (formerly NCI), Jimmy K. Stauffer (NCI), Thomas J. Sayers (SAIC–Frederick).

*Intellectual Property:* HHS Reference No. E–215–2011/0 — Research Tool. Patent protection is not being pursued for this technology.

*Licensing Contact:* Samuel E. Bish, Ph.D.; 301–435–5282; *bishse@mail.nih.gov*

*Collaborative Research Opportunity:* The Cancer and Inflammation Program, NCI, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize Nanog promoter driven GFP constructs for the easy identification and isolation of cancer stem cells. For collaboration opportunities, please contact John Hewes, Ph.D. at *hewesj@mail.nih.gov*.

**Genes and Autoantibodies To Diagnose and Treat Sjögren's Syndrome**

*Description of Technology:* Sjögren's syndrome (SS) is a chronic autoimmune disease of unknown etiology that targets salivary and lacrimal glands and may be accompanied by multi-organ systemic manifestations. To date, no specific diagnostic test has been developed for SS and, as a result, SS is often underdiagnosed and undertreated.

In order to further understand the immunopathology of SS and uncover both therapeutic and diagnostic targets, researchers at NIH compared gene expression profiles of salivary glands with severe inflammation to those with mild or no disease. Results from these studies identified target genes that were further characterized in tissues, serum and in cultured cell populations by real time PCR and protein analyses. Among the most highly expressed SS genes were genes associated with myeloid cells, including members of the mammalian chitinase family. In addition to genes, the researchers have also identified autoantibodies that have increase levels in SS patients. The gene expression levels and autoantibodies

identified in the research represent both promising means for diagnosing SS earlier in disease progression as well as therapeutic targets to treat SS.

*Potential Commercial Applications:*

- Diagnosis of Sjögren's syndrome
- Treatment of Sjögren's syndrome

*Competitive Advantages:* The genes and autoantibodies identified in this technology may lead to one of the first diagnostic tests for Sjögren's syndrome.

*Development Stage:*

- Early-stage
- In vitro data available

*Inventors:* Sharon M. Wahl (NIDCR), et al.

*Publications:*

1. Greenwell-Wild T, et al. Chitinases in the salivary glands and circulation of patients with Sjögren's syndrome: macrophage harbingers of disease severity. Arthritis Rheum. 2011 Oct;63(10):3103–3115, doi: 10.1002/art.30465. [PMID 21618203]

2. Katsifis GE, et al. Systemic and local interleukin-17 and linked cytokines associated with Sjögren's syndrome immunopathogenesis. Am J Pathol. 2009 Sep;175(3):1167–1177. [PMID 19700754]

3. Moutsopoulos NM, et al. Lack of efficacy of etanercept in Sjögren syndrome correlates with failed suppression of tumour necrosis factor alpha and systemic immune activation. Ann Rheum Dis. 2008 Oct;67(10):1437–1443. [PMID 18198195]

4. Mavragani CP, et al. Augmented interferon-alpha pathway activation in patients with Sjögren's syndrome treated with etanercept. Arthritis Rheum. 2007 Dec;56(12):3995–4004. [PMID 18050196]

5. Katsifis GE, et al. T lymphocytes in Sjögren's syndrome: contributors to and regulators of pathophysiology. Clin Rev Allergy Immunol. 2007 Jun;32(3):252–264. [PMID 17992592]

*Intellectual Property:*

- HHS Reference No. E–140–2011/0 — U.S. Provisional Application No. 61/476,192 filed 15 April 2011
- HHS Reference No. E–140–2011/1 — U.S. Provisional Application No. 61/556,729 filed 07 November 2011

*Licensing Contact:* Jaime M. Greene, M.S.; 301–435–5559; *greenejaime@mail.nih.gov*.

**Bacterially Expressed Influenza Virus Recombinant HA Proteins for Vaccine and Diagnostic Applications**

*Description of Technology:* Pandemic H1N1 influenza virus is a recently emergent strain of influenza virus that the World Health Organization (WHO) estimates has killed at least 14,711 people worldwide. Avian influenza viruses are emerging health threats with pandemic potential. Due to their global health implications, there has been a massive international effort to produce protective vaccines against these influenza virus strains. Currently, influenza virus vaccines are produced in chicken eggs, a production method that is disadvantaged by lengthy vaccine production times and by inability to meet large-scale, global demands.

The subject technologies are specific recombinant HA proteins from H1N1, H5N1, and other strains of influenza virus produced in bacteria. The HA proteins properly fold, form oligomers, bind fetuin, agglutinate red blood cells and induce strong neutralizing antibody titers in several in vivo animal models. The key advantages of this technology are that expression of these proteins in bacteria reduces the vaccine production time and offers the ease of scalability for global usage, an issue with current production methods. The recombinant HA proteins can also be used for diagnostic applications.

*Potential Commercial Applications:*

- Vaccines for the prevention of influenza infection
- Diagnostics for influenza virus specific antibodies

*Competitive Advantages:*

- Novel vaccine candidates
- Rapid production time
- Ease of scalability

*Development Stage:*

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

*Inventors:* Hana Golding and Surender Khurana (FDA).

*Publication:* Khurana S, et al. Recombinant HA1 produced in E. coli forms functional oligomers and generates strain-specific SRID potency antibodies for pandemic influenza vaccines. Vaccine. 2011 Aug 5;29(34):5657–5665. [PMID 21704111].

*Intellectual Property:* HHS Reference No. E–032–2010/1—PCT Application No. PCT/US2010/055166 filed 02 Nov 2010.

*Licensing Contact:* Kevin W. Chang, Ph.D.; 301–435–5018; *changke@mail.nih.gov*.

**Potent, Easy To Use Targeted Toxins as Anti-Tumor Agents**

*Description of Technology:* The invention discloses synthesis and use of novel derivatives of 2-[2'-(2-aminoethyl)-2-methyl-ethyl]-l,2-dihydro-6-methoxy-3H-dibenz-[de,h]isoquinoline-l,3-dione as targeted anti-tumor agents. The use of targeted toxin conjugates with anti-cancer antibodies, such as herceptin, is increasing. Based on a comparison with the structurally complex toxins, such as DM1, available in the market, these novel toxins are more stable in circulation, thus making the toxin-conjugates more tumor-selective and less toxic. As such, these compounds are superior alternatives to the existing toxins.

The invention describes a potent and easy to synthesize toxin that can be used for generating a variety of prodrugs. These compounds can be attached to a ligand that recognizes a receptor on cancer cells, or to a peptide that is cleaved by tumor-specific proteases. The compounds are topoisomerase inhibitors and are mechanistically different from DM1 that targets tubulin.

The structure of the toxin allows it to be modified with a peptide linker that is stable, but rapidly cleaved in lysosomes after the compound is specifically taken up by cancer cells.

*Potential Commercial Applications:* The compounds can be used for preparation of a variety of potent anti-cancer agents with low systemic toxicity.

*Competitive Advantages:*

- Easy to prepare
- Structural features make these compounds more stable in circulation
- Toxin conjugates are more tumor-selective and less toxic

*Development Status:*

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

*Inventors:* Nadya Tarasova, et al. (NCI).

*Intellectual Property:* HHS Reference No. E–160–2006/0—U.S. Patent No. 8,008,316 issued 30 Aug 2011.

*Licensing Contact:* Jennifer Wong; 301–465–4633; *wongje@mail.nih.gov*.

Dated: February 29, 2012.

**Richard U. Rodriguez,**

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

[FR Doc. 2012–5356 Filed 3–5–12; 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.