

information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

Proposed Collection: Title: The Agricultural Health Study: A Prospective Cohort Study of Cancer and Other Disease Among Men and Women in Agriculture (NCI) (OMB#: 0925-0406). **Type of Information Collection Request:** Renewal. **Need and Use of Information Collection:** The purpose of this information collection is to continue and complete updating the occupational and environmental exposure information as well as medical history information for respondents

enrolled in the Agriculture Health Study. This represents a request to continue and complete phase III (2005-2008) of the study. Due to reduced annual budgets for research, a delay in data collection has resulted and there has not been enough time to complete the data collection on the number of respondents that had been originally requested in the 2005 OMB submission. The primary objectives of the study are to determine the health effects resulting from occupational and environmental exposures in the agricultural environment. The data will be collected by using a computer assisted telephone interview (CATI) system. A small

percentage of the respondents will also be asked to participate in a buccal cell collection which is a sample of loose cells from the respondent's mouth. The findings will provide valuable information concerning the potential link between agricultural exposures and cancer and other chronic diseases among agricultural Health Study cohort members, and this information may be generalized to the entire agricultural community. **Frequency of Response:** Once. **Affected Public:** Private sector, farms. **Type of Respondents:** Licensed pesticide applicators and their spouses. The annual reporting burden is as follows:

ESTIMATES OF ANNUAL BURDEN HOURS

Type of respondent	Instrument	Estimated number of respondents	Frequency of response	Average time per response (Minutes/hour)	Annual burden hours
Private Applicators	Interview Only	2,920	1.00	35/60	1,703.33
	Interview & buccal cells	83	1.00	60/60	83.00
Spouses	Interview Only	2,680	1.00	35/60	1,563.33
	Interview & buccal cells	165	1.00	60/60	165.00
Commercial Applicators	Interview Only	930	1.00	35/60	542.50
	Interview & buccal cells	83	1.00	60/60	83.00
Totals	6,861	4,140.17

The annualized cost to respondents is estimated at \$109,652, which amount to a total cost of \$1,348,000 over three years. There are no capital costs, operating costs, and/or maintenance costs to report.

Request for Comments: Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Direct Comments to OMB: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the Attention: NIH Desk Officer, Office of

Management and Budget, at *OIRA_submission@omb.eop.gov* or by fax to 202-395-6974. To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact Michael Alavanja, Dr.P.H, Occupational and Environmental Epidemiology Branch, Division of Cancer Epidemiology and Genetics, National Cancer Institute, NIH, Executive Plaza South, Room 8000, 6120 Executive Blvd., Rockville, MD 20892 or call 301-496-9093 or e-mail your request, including your address to: *alavanjm@mail.nih.gov*.

Comments Due Date: Comments regarding this information collection are best assured of having their full effect if received within 30 days of the date of this publication.

Dated: June 25, 2008.

Vivian Horovitch-Kelley,
NCI Project Clearance Liaison Office,
National Institutes of Health.
 [FR Doc. E8-15072 Filed 7-2-08; 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, 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.

Tendon Stem Cells

Description of Technology: Tendon injuries due to trauma and overuse are common clinical problems that result in significant pain and loss of mobility. Tendon injuries are slow to heal and the healed tendon rarely matches the original in mechanical strength and structural integrity. Due to a limited understanding of basic tendon biology, development of new treatment options for injured tendons has posed significant challenges.

This invention relates to a cell based therapy. Specifically, it relates to the isolation and enrichment of stem cells from adult tendons, known as tendon stem progenitor cells, that can form tendon structures and are capable of integrating into bones to form enthesis-like structures. Two extra-cellular matrix proteoglycans, biglycan and fibromodulin, further assist in the maintenance and multiplication of these tendon stem cells.

Applications:

Treatment of damaged tendons that are slow to repair after injury.

May remedy other pathological conditions that are caused by ectopic calcification such as ectopic calcification that occurs around artificial heart valves or that develops in the rare inherited disease, Fibrodysplasia Ossificans Progressiva (FOP).

Development Status: Early stage.

Inventors: Marian Young *et al.* (NIDCR).

Patent Status: U.S. Provisional Application No. 60/934,606 filed 14 Jun 2007 (HHS Reference No: E-233-2007/0-US-01).

Licensing Status: Available for licensing.

Licensing Contact: Fatima Sayyid, M.H.P.M.; 301-435-4521; Fatima.Sayyid@nih.hhs.gov.

Collaborative Research Opportunity: The NIDCR, Molecular Biology of Bones and Teeth Section is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize the use of tendon stem cells. Please contact Marian Young at 301-496-8860 or myoung@dir.nidcr.nih.gov.

A2 Adenosine Receptor Agonists

Description of Technology: Four adenosine receptor subtypes exist, namely A₁, A_{2A}, A_{2B} and A₃, each with different functions, tissue distributions and ligand coupling abilities. While activation of A_{2B} AR can induce angiogenesis, reduce vascular permeabilization, increase production of

the anti-inflammatory cytokine IL-10, increase chloride secretion in epithelial cells or increase release of inflammatory mediators from human and canine mast cells, there still remains a need for A_{2B} receptor agonists for clinical use.

Recognizing that an unmet medical need exists, the inventors synthesized an assortment of adenosine derivatives with the goal of preparing highly potent and selective A_{2B} receptor agonists. They identified a compound as a full agonist at the A_{2A} and A_{2B} adenosine receptors, capable of reducing infarct size in rabbit hearts induced by 30 minutes of ischemia. As activation of A_{2A} and A_{2B} receptors induces a cardioprotective effect and this compound activates both A_{2A} and A_{2B} receptors, this compound may be beneficial for protecting against myocardial ischemia/reperfusion injury.

Available for licensing and commercial development are compositions and methods of use of A₂ adenosine receptor (AR) agonists for treating conditions modulated by A_{2A} and A_{2B} ARs including myocardial ischemia, reperfusion injury, cystic fibrosis, erectile dysfunction, inflammation, restenosis and septic shock.

Applications:

Potential treatment for heart attacks. Potential treatment of septic shock, cystic fibrosis and erectile dysfunction.

Potential treatment for medical conditions that would benefit from changes in vascular tone.

Market: Heart disease is the number one cause of death in the United States, and the most frequent cause of hospital admission for patients over 65 years of age.

Development Status: Early-stage of development.

Inventors: Kenneth A. Jacobson *et al.* (NIDDK).

Patent Status:

U.S. Provisional Application No. 60/947,066 filed 29 Jun 2007 (HHS Reference No. E-218-2007/0-US-01).

U.S. Provisional Application No. 60/950,250 filed 17 Jul 2007 (HHS Reference No. E-218-2007/1-US-01).

Licensing Status: Available for licensing.

Licensing Contact: Charlene A. Sydnor, PhD.; 301-435-4689; sydnorc@mail.nih.gov.

Collaborative Research Opportunity: The NIDDK Laboratory of Bioorganic Chemistry is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize A_{2A} and A_{2B} adenosine receptor agonists. Please contact Rochelle S. Blaustein at 301-451-3636

or Rochelle.Blaustein@nih.gov for more information.

Therapeutic Application of Fatty Acid Amide Hydrolase Inhibitors

Description of Technology: The enzyme fatty acid amide hydrolase (FAAH) is responsible for the degradation of the lipid anandamide. This is a cannabinoid naturally secreted from both the brain and body. Cannabinoid receptors mediate blood pressure, pain sensation, hunger and anxiety among other actions. Drugs inhibiting FAAH increase cannabinoid receptor activity in a manner distinct from cannabinoid agonists to treat hypertension, relieve pain or have other therapeutic effect with lessened side effects.

Applications:

Treat hypertension and accompanying cardiac hypertrophy.

Treatment of anxiety.

Treatment of glaucoma.

As a pain reliever or sleep aid.

Market:

It is estimated that nearly a third of U.S. adults have high blood pressure. Despite the lack of symptoms, treatment is imperative. People with untreated high blood pressure have an increased chance of developing stroke, heart attack, heart failure or kidney failure.

The forecast of the world hypertension market is that it will grow to nearly \$30 billion per year by 2010.

Development Status: Pre-clinical data available.

Inventors: George Kunos (NIAAA) *et al.*

Publication: Bátkai S, Pacher P, Osei-Hyiaman D, Radaeva S, Liu J, Harvey-White J, Offertáler L, Mackie K, Rudd MA, Bukoski RD, Kunos G. Endocannabinoids acting at cannabinoid-1 receptors regulate cardiovascular function in hypertension. *Circulation*. 2004 Oct 5;110(14):1996-2002.

Patent Status: U.S. Provisional Application No. 60/998,661 filed 12 Dec 2007 (HHS Reference No. E-211-2006/0-US-01).

Licensing Status: Available for exclusive or non-exclusive licensing.

Licensing Contact: Norbert Pontzer, J.D., PhD.; 301-435-5502; pontzern@mail.nih.gov.

Collaborative Research Opportunity: The NIAAA Laboratory of Physiologic Studies is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize fatty acid amide hydrolase inhibitors. Please contact Peter B. Silverman (psilverm@mail.nih.gov) for more information.

Dated: June 27, 2008.

Richard U. Rodriguez,

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

[FR Doc. E8-15178 Filed 7-2-08; 8:45 am]

BILLING CODE 4140-01-P

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A Prophylactic and Therapeutic for Preventing and Treating Tularemia by Rapid Activation of Host Cells and Antigen Recognition

Description of Technology: The invention is a composition and method for prophylactic and therapeutic treatment of tularemia caused by *Francisella tularensis* comprised of Cationic Liposome DNA Complexes (CLDC) complexed with noncoding DNA and membrane antigens isolated from *F. tularensis* strain LVS (MPF). *F. tularensis* is category A pathogen (as designated by the NIH) that was previously weaponized by both the former Soviet Union and the United States of America and is currently a potential bioweapon and bioterrorism threat. Furthermore, tularemia is endemic to the U.S. (majority of the cases occurring in the Midwest) and Europe. The prophylactic and therapeutic activities of this invention

rely in part on rapid activation of host cells and recognition of bacterial antigens. *In vivo* studies in mice show that CLDC + MPF elicit protective immunity against pneumonic tularemia when administered shortly (days) prior to exposure to aerosols of virulent *F. tularensis*. The method can be applicable for eliciting immune response in other infectious diseases.

Applications:

Prophylactic and therapeutic for Tularemia.

Biodefense agent.

Method is applicable to other infectious diseases, particularly for pathogens that are enveloped or encapsulated (i.e. *Pseudomonas aeruginosa*, *Neisseria meningitidis*, *Yersinia pestis* and Influenza).

Advantages:

Rapid induction of protective immunity against *F. tularensis*.

Avoids antibiotic resistance associated with current therapies.

Development Status: *In vitro* and *in vivo* data are available.

Market:

Prophylactic and treatment for tularemia and other infectious diseases.

Biodefense.

Inventors: Catherine M. Bosio (NIAID).

Publication: PowerPoint slide presentation of invention can be provided upon request.

Patent Status: U.S. Provisional Application No. 61/030,984 filed 24 Feb 2008 (HHS Reference No. E-095-2008/0-US-01).

Licensing Status: This invention is available for exclusive or non-exclusive licensing.

Licensing Contact: Sally Hu, PhD.; 301-435-5606, HuS@mail.nih.gov.

A New Method for Screening of Anti-tumor Agents

Description of Technology:

Astrocytomas and glioblastoma multiforme are the most common forms of malignant brain cancer, and are often unresponsive to surgical removal and pharmacological therapy. The 5 year survival rate of glioblastoma is 5%, thus, making it necessary for the identification of more effective anti-tumor agents. Individuals with the familial cancer syndrome neurofibromatosis type 1 are predisposed to developing multiple tumors including astrocytoma and glioblastoma.

Scientists at NCI have discovered a new technology that will help screen multiple anti-tumor and anti-neurofibromatosis agents in a high throughput assay by using an astrocytoma cell line (KR158) that

expresses the luciferase gene under the influence of dual promoters, E2F and CMV.

This new technology distinguishes between cytostatic and cytotoxic compounds, thereby significantly reducing the time and cost required to screen anti-tumor agents.

Advantages:

Quantifiable.

Can be used in high throughput assays.

Distinguishes between cytostatic and cytotoxic activity of compounds.

Applications:

Cancer therapeutics.

Gene therapy.

Screening of anti-tumor agents.

Screening of anti-neurofibromatosis agents.

Pharmacology of drugs.

Market: Neurofibromatosis is inherited by many affected individuals and occurs in 1 in 3500 individuals. In addition, between 30 and 50 percent of new cases arise spontaneously through mutation in an individual's genes which can then be passed on to succeeding generations, leading to increased tumor risk. Astrocytomas and glioblastoma multiforme are the most common malignant brain tumor in adults with very poor prognosis.

Development Status: Late-stage.

Inventors: Jessica J. Hawes and Karlyne M. Reilly (NCI).

Patent Status: HHS Reference No. E-038-2008/0—Research Tool. Patent protection is not being sought for this technology.

Licensing Status: Available for non-exclusive licensing.

Licensing Contact: John Stansberry, Ph.D.; 301-435-5236; stansbej@mail.nih.gov.

Collaborative Research Opportunity: The National Cancer Institute Mouse Cancer Genetics Program is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize anti-astrocytoma or anti-neurofibromatosis therapy. Please contact John D. Hewes, PhD., at 301-435-3121 or hewesj@mail.nih.gov for more information.

A Novel Therapeutic Strategy for the Treatment of Hyperpigmentation and Melanoma

Description of Technology: The present invention describes that the transcription factor SOX9 is expressed by normal human melanocytes *in vitro* and in the skin *in vivo*, and that over-expression of SOX9 decreases the proliferation of mouse and human melanoma cell lines via several pathways. Furthermore, SOX9 (or its