

CDC, in collaboration with the FDA, has been charged with the responsibility of evaluating this nationwide notification process. An interim nationwide survey (0920-0462) of blood collection establishments and transfusion services was conducted in December 1999 to determine the progress that had been made to date and summarize the lookback results. The objective of this study is to resurvey the blood collection establishments and transfusion services to obtain final results and assess the overall effectiveness of the targeted lookback for

identifying persons infected with HCV. The evaluation has two specific aims:

1. Determine the effectiveness of targeted lookback for identifying prior transfusion recipients with HCV infection, including the proportion of recipients identified who are still alive, the proportion of those alive who were successfully notified, the proportion of those notified who have already been tested, the proportion of those notified who get tested as a result of the notification, and the proportion of those tested who are HCV positive.

2. Determine the cost-effectiveness of targeted lookback, including resources (person-hours, costs of recipient notification and testing, etc.) utilized by blood collection establishments and transfusion services for implementation of the lookback protocol.

The evaluation will comprise the following components:

1. A nationwide survey of blood collection establishments.
2. A nationwide survey of transfusion services.

The total cost to respondents is their time to complete the survey.

Respondents	No. of respondents	No. of responses per respondent	Average burden per response (in hrs.)	Total burden (in hrs.)
Blood collection establishment	140	1	5	700
Transfusion services	5,000	1	5	25,000
Total				25,700

Dated: July 10, 2003

Thomas A. Bartenfeld,

Acting Associate Director for Policy, Planning and Evaluation, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

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

ACTION: Notice.

SUMMARY: The inventions listed below are owned by agencies 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.

Detection of Mutational Frequency in Human Bone Marrow

Neal S. Young *et al.* (NHLBI)

DHHS Reference No. E-320-2002 filed 06 Nov 2002

Licensing Contact: Fatima Sayyid; 301/435-4521; sayyidf@mail.nih.gov

To date there have been no adequate methods to determine the frequency of mutations in humans. This invention discloses a method of measuring the mutational frequency of a mitochondrial DNA sequence by sequencing mitochondrial DNA from clonally expanded single cells such as CD34+ human stem cells. Sequencing for mitochondrial DNA polymorphisms and mutations may also be useful as a general method to detect minimal residual disease in leukemia. The mitochondrial genome is particularly susceptible to mutations and these may be used to measure genomic mutagenesis by virtue of comparison. The application of this invention includes the determination of mutational frequency after chemotherapy, radiation, environmental toxic exposure and genetic disease. The invention also provides a screening for an agent that has a mutagenic effect on a cell.

Structurally Rigid Dopamine D3 Receptor Selective Ligands as Cocaine and Methamphetamine Abuse Therapeutics

Amy Newman *et al.* (NIDA)

DHHS Reference No. E-251-2002/0-US-01 filed 14 Sep 2002

Licensing Contact: Norbert Pontzer; 301/435-5502; np59n@nih.gov

The dopamine D3 receptor subtype has been implicated in a number of central nervous system (CNS) disorders including but not limited to drug abuse, schizophrenia and Parkinson's disease. Since D3 receptor ligands show efficacy in animal models of cocaine self-administration and Parkinson's disease, there has been a significant effort to design and develop novel dopamine D3 ligands. However most currently known compounds are highly lipophilic, leading to poor bioavailability and toxicity, or are not highly D3 selective.

The present invention provides a family of structurally rigid, potent and selective D3 receptor antagonists and partial agonists with lowered lipophilicity. Bioavailable compounds that bind with high affinity and selectivity to D3 receptors can not only provide important tools with which to study the structure and function of this receptor subtype, but may also have therapeutic uses in psychiatric, behavioral and neurologic disorders. More information on these potential therapeutic agents was recently published in Newman *et al.*, *Bioorganic*

Further Testing, Product Disposition, and Notification of Transfusion Recipients Based on

Donor Test Results Indicating Infection with HCV

Rockville, MD: Center for Biologics Evaluation and Research (CBER), December 2001.

Medicinal Chemistry Letters 13 (2003) 2179–2183.

Oral Treatment of Hemophilia

Oral Alpan *et al.* (NIAID)
DHHS Reference No. E-281-2001/0-
PCT-02 filed 02 Aug 2002 (PCT/
US02/24544)

Licensing Contact: Fatima Sayyid; 301/
435-4521; sayyidf@mail.nih.gov

This invention portrays a simple method for treatment of antigen-deficiency diseases by orally administering to a subject a therapeutically effective amount of the deficient antigen, wherein the antigen is not present in a liposome. This method increases hemostasis in a subject having hemophilia A or B, by orally administering to the hemophiliac a therapeutically effective amount of the appropriate clotting factor, sufficient to induce oral tolerance and supply exogenous clotting factor to the subject.

Long-Acting Insulinotropic Peptides and Uses Thereof

Dr. Josephine Egan *et al.* (NIA)
Serial No. 60/309,076 filed 31 Jul 2001;
PCT/US02/24141 filed 30 Jul 2002
Licensing Contact: Pradeep Ghosh;
301/435-5282; ghoshpr@mail.nih.gov

Type-2 diabetes and neurodegeneration (e.g., Alzheimer's disease, Parkinson's disease, peripheral neuropathy, stroke) are leading causes of death in the United States and worldwide. The present invention pertains to the disclosure of novel peptide analogues of Glucagons-like peptide-1 (GLP-1) and Exendin-4 and their uses in the treatment of (i) diabetes and (ii) neurodegenerative disorders.

(i) Type-2 diabetes is caused by dysfunction of the pancreatic beta cells that may result in concomitant decrease in insulin production. Insulin replacement has been an effective therapy for the treatment of Type-2 diabetes. However, insulin therapy, although life saving, does not restore normal levels of glucose and postprandial levels of glucose continues to be excessively high in individuals on insulin therapy. Further, the therapy may result in adverse effects including hyperglycemia, hypoglycemia, metabolic acidosis and ketosis. Therefore, a better therapeutic formula may be needed that may increase the efficacy of the treatment and minimize the side effects. The present invention discloses a method of treating a subject with diabetes with novel GLP-1/Exendin-4 peptides. These are GLP-1 agonists and elicit insulinotropic actions.

(ii) The GLP-1 receptor is additionally found in the brain as well

as associated to pancreatic islets cells. Its stimulation in brain has been found to be neurotrophic and neuroprotective in both tissue culture and *in vivo* against a variety of toxic insults. Peptides of the said invention possess activity in a variety of predictive models of neurodegeneration, and may have potential in a variety of diseases both associated (peripheral neuropathy) and unassociated (Alzheimer's disease, Parkinson's disease, stroke and peripheral neuropathy) with diabetes (J. Alz. Dis. 4: 487–96, 2002; J. Pharmacol. Exp. Ther. 300:958–66, 2002 & 302:881–888, 2002, TIPS in press).

In conclusion, compounds of the present patent application possess potent insulinotropic, neuroprotective and neurotrophic effects that derive from their GLP-1 agonist action and may have a great market potential as therapeutic agents for the treatment of diabetes and/or neurodegenerative disorders.

Dated: July 10, 2003.

Steven M. Ferguson,

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

[FR Doc. 03-18009 Filed 7-15-03; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), 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 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: National Cancer Institute Special Emphasis Panel, Development of High-Yield Technologies for Isolating Exfoliated Cells in Body Fluids.

Date: July 30, 2003.

Time: 12 p.m. to 4 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6116 Executive Boulevard, Rockville, MD 20852, (Telephone Conference Call).

Contact Person: Sherwood Githens, PhD, Scientific Review Administrator, Special Review and Logistics Branch, National Cancer Institute, National Institutes of Health, 6116 Executive Boulevard, Room 8068, Bethesda, MD 20892, (301) 435-1822.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: July 10, 2003.

Anna P. Snouffer,

Acting Director, Office of Federal Advisory Committee Policy.

[FR Doc. 03-18006 Filed 7-15-03; 8:45 am]

BILLING CODE 4140-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), 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 Cancer Institute Special Emphasis Panel, The Agricultural Health Study—Coordinating Center.

Date: July 18, 2003.

Time: 12 p.m. to 3 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institutes of Health, 6116 Executive Boulevard, Rockville, MD 20851, (Telephone Conference Call).

Contact Person: C. Michael Kerwin, PhD, MPH, Scientific Review Administrator, Special Review and Logistics Branch, Division Of Extramural Activities, National