

cancer survivors and 6,000 non-cancer adults. It will enable NCI to collect extensive information on CAM, cancer and other chronic illnesses, and link it with the breadth of basic data already collected from the large, racially and ethnically diverse sample of CHIS respondents.

Comprehensive and detailed collection of information on CAM will enable NCI to increase its understanding of how, why, and to what effect CAM is used. The CHIS-CAM survey data

will allow NCI to compare individuals who report various types of cancer and other chronic conditions and to determine: (1) The major categories of CAM procedures being used, as well as the specific therapies targeted toward cancer prevention and treatment, (2) how various subgroups in the population (defined by race/ethnicity, gender, age, health status, etc.) compare with regards to CAM procedures being used; (3) to what extent persons with cancer used specific types of CAM

before or after diagnoses with cancer, and whether cancer patients used CAM in place of, or in addition to, conventional medical care; (4) whether systematic CAM treatments for cancer might lead to harm or interact with conventional treatments for cancer; and (5) what expenditures people are paying out-of-pocket for CAM procedures. Frequency of Response: One-time. Affected public: Individuals. Types of respondents: U.S. adults. The annual reporting burden is as follows:

TABLE A—ANNUALIZED BURDEN ESTIMATES FOR CHIS-CAM DATA COLLECTION

Type of respondents	Estimated number of respondents	Estimated no. of responses per respondent	Average burden hours per response	Estimated total annual burden hour requested
U.S. Adults .....	8,000	1	.35	2,800

There is no annualized cost to respondents. There are no Capital Costs to report. There are no Operating 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 functions 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.

**FOR FURTHER INFORMATION CONTACT:** To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact Anita Ambs, Project Coordinator, National Cancer Institute, EPN 4106, 6130 Executive Boulevard, Bethesda Maryland 20892-7344, or call non-toll free number (301) 451-8500 or email your request, including your address to [ambsa@mail.nih.gov](mailto:ambsa@mail.nih.gov).

**COMMENTS DUE DATE:** Comments regarding this information collection are best assured of having their full effect if received within 60 days from the date of this publication.

Dated: January 10, 2002.

Reesa L. Nichols,

NCI Project Clearance Liaison.

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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 contacting Marlene Shinn, J.D., at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852-3804; telephone: 301/496-7056 ext. 285; fax: 301/402-0220; e-mail: [shinnm@od.nih.gov](mailto:shinnm@od.nih.gov). A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

#### Thermostable DNA Polymerases that Bypass Lesions in DNA

Dr. Roger Woodgate (NICHD) and Dr. Francois Boudsocq (NICHD)  
DHHS Reference No. E-232-01/0—  
Research tool

Lesions in DNA often block DNA polymerases, especially in those polymerases used in the Polymerase Chain Reaction (PCR). Old DNA, such as that from forensic samples, is often damaged and cannot be used for PCR analysis.

The NIH announces the identification of two novel Y-family DNA polymerases—called Dbh and Dpo4—from the archaea *Sulfolobus solfataricus* P1 and *Sulfolobus solfataricus* P2, respectively. The Y family of polymerases are characterized by their ability to replicate through DNA lesions that may block the activity of other, more conventional, polymerases such as the thermostable enzymes used in PCR. Both Dbh and Dpo4 enzymes have been shown to be as thermostable as the Taq polymerase (Dpo4, in particular) and can copy stretches of DNA up to 1300 bp in length. Because these polymerases are in general more efficient at coping with DNA lesions, they may be useful in the amplification of damaged DNA and could be useful in forensic PCR applications.

#### A Novel Human DNA Polymerase, POL IOTA, Involved in DNA Repair and Mutagenesis

Drs. Roger Woodgate and John McDonald (NICHD)  
DHHS Reference No. E-229-01/0—  
Research tool

The NIH announces the identification of a novel DNA polymerase called POL IOTA, that is highly error prone and

may be responsible for causing mutations that ultimately lead to human cancer formation.

The polymerase could be useful as a target for chemotherapeutic agents that block the polymerase's enzyme activity. This in turn could lead to an increase in the cure rate of cancer patients. In addition, a diagnostic assay could be developed to identify enzyme expression patterns and their mutations, so as to recognize humans with an increased risk of cancers. Therefore, the polymerase could be used as a research tool, or with more development, into a kit that could be used in both research and clinical labs.

### **TMC1 and TMC2 and Applications to Hereditary Deafness**

Dr. Andrew Griffith et al. (NIDCD)  
DHHS Reference No. E-168-01/0 filed  
19 Sep 2001

Hearing loss is a common communication disorder effecting nearly 1 in 1,000 children in the United States alone, and nearly 50% of adults by the age of eighty. Deafness can be caused by both environmental and disease-related factors, however, in at least 50% of the cases, deafness is an inherited trait.

The NIH announces the isolation and purification of two novel genes termed TMC1 and TMC2 that may encode the mammalian hair cell mechanotransduction channel. It is known that the mechanotransduction channel is the critical molecule within the hearing pathway, which detects sound within the inner ear. Our investigators have discovered that dominant and recessive mutations in TMC1 underlie two forms of hereditary deafness known as DFNA36 and DFNB7/11, respectively. This technology would be useful to a company interested in finding new therapies to treat or prevent hearing loss as well as identifying persons at increased risk of developing aminoglycoside-induced hearing loss. This technology is also available for collaboration with a partner under a Cooperative Research and Development Award.

### **Gene Involved in Dietary Sterol Absorption and Excretion and Uses Therefor**

Drs. Michael Dean and Shailendra Patel (NCI)  
DHHS Reference No. E-295-99/1 filed  
25 Sep 2001 (PCT/US01/29859)

The ATP binding cassette proteins are involved in cholesterol regulation. Cholesterol absorption from the diet is an important mechanism for regulating

serum cholesterol levels. It is well known that high serum cholesterol levels are found in several diseases such as diabetes, atherosclerosis, and cardiovascular disease.

The NIH announces the identification and characterization of the ABCG5 gene. The gene maps to human chromosome 2, which has been identified as playing a role in the genetic disorder sitosterolemia. Patients with sitosterolemia display an abnormally high level of blood sterol debris from plants and fish, which can lead to coronary artery disease, atherosclerosis, and arthritis, as well as other diseases. The inventors believe that mutations in the ABCG5 gene interfere with sterol transport thereby causing sitosterolemia. Companies working in this area would find this technology useful in searching for agents that can treat or prevent any disease or condition that has associated with it high cholesterol levels.

Dated: January 11, 2002.

### **Jack Spiegel,**

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

[FR Doc. 02-1439 Filed 1-18-02; 8:45 am]

**BILLING CODE 4140-01-P**

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### **Efficient Inhibition of HIV-1 Viral Entry Through a Novel Fusion Protein Including CD4**

James Arthos, Claudia Cicala, Anthony Fauci (NIAID)  
DHHS Reference No. E-337-01/0 filed  
25 Oct 2001

Licensing Contact: Peter Soukas; 301/496-7056 ext. 268; e-mail:  
[soukasp@od.nih.gov](mailto:soukasp@od.nih.gov)

This invention relates to CD4 fusion proteins for use in the treatment of an immunodeficiency virus infection such as human immunodeficiency virus (HIV). These polypeptides have been shown by the inventors to inhibit the entry of primary isolates of HIV-1 into CD4+ T cells by targeting the gp120 subunit of the HIV-1 envelope. The invention claims recombinant polypeptides comprising a CD4 polypeptide ligated at its C-terminus with a portion of a human immunoglobulin comprising a hinge region and two constant domains of an immunoglobulin heavy chain. The portion of the IgG is fused at its C-terminus with a polypeptide comprising a tailpiece from the C terminus of the heavy chain of an IgA antibody. This protein is very large (greater than 800 kilodaltons), which may contribute to its ability to inhibit entry of primary isolates of HIV-1 into T cells. It presents twelve gp120 binding domains (D1D2) and can bind at least ten gp120s simultaneously. The inventors have shown that the construct efficiently neutralizes primary isolates from different HIV subgroups. Also claimed are use of the construct as a component of a vaccine and as a diagnostic.

### **Methods and Compositions for Production and Purification of Recombinant Staphylococcal Enterotoxin B (rSEB)**

Daniel Coffman, Steven Giardina, Jianwei Zhu (NCI)  
DHHS Reference No. E-075-01/0 filed  
09 Oct 2001

Licensing Contact: Peter Soukas; 301/496-7056 ext. 268; e-mail:  
[soukasp@od.nih.gov](mailto:soukasp@od.nih.gov)

This invention claims processes and compositions for fermentation, recovery, and purification of recombinant bacterial superantigens (rSAGs), exemplified by a recombinant staphylococcal enterotoxin B SEB (rSEB) protein mutated for use in administration to a mammalian recipient. This process generates an economically viable quantity of rSEB vaccine protein meeting FDA parenteral drug specifications. The purification methods generally involve multiple steps including hydrophobic interaction