

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 Office of Management and Budget, Office of Regulatory Affairs, New Executive Office Building, Room 10235, Washington, D.C. 20503, Attention: Desk Officer for NIH. To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact: Dr. Robert H. Selwitz, Health Policy Analysis and Development Branch, NIDCR, NIH, Natcher Building, Room 3AN-44J, 9000 Rockville Pike, Bethesda, MD 20892, or call non-toll-free number (301) 594-3977, or e-mail your request, including your address to: Robert.Selwitz@nih.gov.

Comments Due Date

Comments regarding this information collection are best assured of having their full effect if received on or before August 13, 1999.

Dated: July 7, 1999.

Yvonne H. du Buy,
Executive Officer, NIDCR.

[FR Doc. 99-17926 Filed 7-13-99; 8:45 am]

BILLING CODE 4140-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Invention; Availability for Licensing: "Immunotoxin Containing a Disulfide-Stabilized Antibody Fragment Joined to a Pseudomonas Exotoxin that does not Require Proteolytic Activation"

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

ACTION: Notice.

SUMMARY: The invention listed below is owned by an agency of the U.S. Government and is 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.

ADDRESSES: Licensing information and a copy of the U.S. patent application

referenced below may be obtained by contacting J.R. Dixon, Ph.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 206; fax 301/402-0220; E-Mail: jd212g@NIH.GOV). A signed Confidential Disclosure Agreement is required to receive a copy of any patent application.

SUPPLEMENTARY INFORMATION:

Invention Title: "Immunotoxin Containing a Disulfide-Stabilized Antibody Fragment Joined to a Pseudomonas Exotoxin that does not Require Proteolytic Activation"

Inventors: Drs. Ira H. Pastan (NCI), and Chin-Tsun Kuan (NCI)

DHHS Ref. No. E-163-93/1 & 2 & 3—USPA SN: 08/809,668—Filed August 21, 1997, [=60/005,388—Filed: October 13, 1995, & PCT/US96/16327/WO 97/13529—Filed: October 11, 1996]

Licensing Contract: J.R. Dixon, Ph.D., (301)-496-7056 Ext. 206; E-Mail: jd212g@NIH.GOV

Immunotoxins were initially produced by chemically coupling antibodies to toxins to form chimeric molecules. In these molecules, the antibody portion mediates selective binding to target cells, while the toxin portion mediates translocation into the cytosol and subsequent cell killing. Several toxins have been used to make immunotoxins including ricin A chain, blocked ricin, saporin, pokeweed antiviral protein, diphtheria toxin, and Pseudomonas Exotoxin ("PE").

The technology disclosed in the above mentioned patent application relates to the production and use of Pseudomonas-derived immunotoxins modified to increase their toxicity and potency and therapeutic agents. In particular, the immunotoxins of this invention includes a disulfide-stabilized ("ds") target-binding agent, such as the variable region of an antibody molecule, and a Pseudomonas Exotoxin that does not require proteolytic activation for cytotoxic activity. Specifically, the invention provides for immunotoxins comprising a Pseudomonas Exotoxin that does not require proteolytic activation for cytotoxic activity attached to an Fv antibody fragment having a variable heavy chain region bound through at least one disulfide bond to a variable light chain region. The combination of a "disulfide-stabilized" binding agent fused to a PE that does not require proteolytic activation and provides an immunotoxin having surprising cytotoxic activity.

The above mentioned Invention is available, including any available

foreign intellectual property rights, for licensing.

Dated: July 2, 1999.

Jack Spiegel,

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

[FR Doc. 99-17928 Filed 7-13-99; 8:45 am]

BILLING CODE 4140-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Invention; Availability for Licensing: "Methods for Predicting the Efficacy of a Chemotherapeutic Regimen for Gastrointestinal Cancers Using Antibodies Specific for Thymidylate Synthase"

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

ACTION: Notice.

SUMMARY: The invention listed below is owned by an agency of the U.S. Government and is 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.

ADDRESSES: Licensing information and a copy of the U.S. patent application referenced below may be obtained by contacting J. R. Dixon, Ph.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 206; fax 301/402-0220; E-Mail: jd212g@NIH.GOV). A signed Confidential Disclosure Agreement is required to receive a copy of any patent application.

SUPPLEMENTARY INFORMATION:

Invention Title: "Methods for Predicting the Efficacy of a Chemotherapeutic Regimen for Gastrointestinal Cancers using Antibodies specific for Thymidylate Synthase"

Inventors: Drs. Patrick G. Johnson (NCI), Edwin R. Fisher (NCI) and Carmen J. Allegra (NCI)

DHHS Ref. No. E-194-95/1 USPA SN: 08/758,034 [= 60/007,825—Filed: December 1, 1995] Filed: November 27, 1996 [E-194-95/1].

Gastric adenocarcinoma is characterized by an extremely virulent behavior and for which mortality approximates the incidence. The vast majority of patients with gastric cancer are diagnosed with advanced stage disease and even after "curative"

gastrectomy, most will die from recurrent disease. Recently, there has been increasing interest in the use of neoadjuvant or primary chemotherapy, frequently using fluoropyrimidine-based combination chemotherapy, in an attempt to increase respectability and improve survival of patients with locally advanced gastric cancer. Neoadjuvant chemotherapeutic treatment provides an early opportunity to assess individual patient response using the in situ primary tumor. Overall response rates in studies using neoadjuvant 5-fluorouracil ("5-FU") based regimens in locally advanced gastric cancer range from 25–45%. Therefore, at least half of all patients treated in this setting are being subjected to unnecessary toxicity and delay in operation with no therapeutic benefit. Strategies that would accurately predict tumor responsiveness to 5-FU therapy would provide an opportunity to selectively treat patients most likely to benefit from treatment and avoid unnecessary toxicity in those who would not.

The '034 invention is directed to methods for determining whether a chemotherapeutic treatment is appropriate for patients afflicted with gastrointestinal cancers, comprising:

- a. Obtaining a solid tumor tissue sample from the patient;
- b. Measuring a thymidylate synthase expression level in the tissue sample; and
- c. Comparing the thymidylate synthase expression level with a group of standard tumor tissue samples, the standards having known thymidylate synthase expression levels and known responses to the chemotherapeutic treatment, to determine if the chemotherapeutic treatment is appropriate for the patient.

The above mentioned Invention is available, including any available foreign intellectual property rights, for licensing.

Dated: July 2, 1999.

Jack Spiegel,

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

[FR Doc. 99-17929 Filed 7-13-99; 8:45 am]

BILLING CODE 4140-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Program Support Center

Privacy Act of 1974; New System of Records

AGENCY: Program Support Center (PSC), HHS.

ACTION: Notification of a new system of records.

SUMMARY: In accordance with the requirements of the Privacy Act, the PSC is publishing a notice of a new system of records, 09-40-0013, "PSC Parking Program and PSC Transhare Program Records, HHS/PSC/AOS." We are also proposing routine uses for this new system.

DATES: The PSC invites interested parties to submit comments on the proposed internal and routine uses on or before August 18, 1999. The PSC has sent a Report of a New System to the Congress and to the Office of Management and Budget (OMB) on July 2, 1999. The new system of records will be effective 40 days from the date submitted to OMB unless PSC receives comments which would result in a contrary determination.

ADDRESSES: Address comments to the Privacy Act Officer, Program Support Center, 5600 Fishers Lane, Room 17A-08, Rockville, Maryland 20857. We will make comments received available for public inspection at the above address during normal business hours, 8:30 a.m.-5 p.m.

FOR FURTHER INFORMATION CONTACT: Irene West, Room 17A-08, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857, telephone (301) 443-2045. This is not a toll-free number.

SUPPLEMENTARY INFORMATION: The Program Support Center (PSC) proposes to establish a new system of records: 09-40-0013, "PSC Parking Program and PSC Transhare Program Records, HHS/PSC/AOS." This system of records will be used by PSC staff to: (1) Administer the parking program at the Parklawn Building complex; (2) manage the PSC Transhare Program, including receipt and processing of employee applications, and coordination of the fare media distribution to employees; and (3) monitor the use of funds used to support the PSC Transhare Program.

The system will contain records that contain information such as participant's name; pay plan; grade level; employing organization; building and room; duty hours and location; name of supervisor; home address; office telephone number; assigned parking space number; vehicle

information, i.e., tag number and State; make and model of car; physician's statement in support of handicapped parking assignments and query to supervisors in support of handicapped parking assignments, where applicable; Transhare commuter card number; commute mode to work; and type of fare media used.

The amount of information recorded on each individual will be only that which is necessary to accomplish the purpose of the system. Each record is established from an application form that has been submitted to the Parking and Information Office, Building Management Branch, Division of Property Management, Administrative Operations Service, PSC, by the applicant.

Authorities: The Federal Property and Administrative Services Act of 1949, as amended; and, Pub. L. 101-509 section 629, as amended, (5 U.S.C. 7905, "Programs to encourage commuting by means other than single-occupancy motor vehicles").

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

The routine uses proposed for this system are compatible with the stated purposes of the system, i.e., to administer and manage the PSC Parking and Transhare Programs and to monitor the use of funds used to support the PSC Transhare Program.

The PSC will disclose relevant information to third parties outside the Department as follows: Routine use 1: PSC may disclose information from this system of records to city, county, State, and Federal law enforcement agencies should PSC become aware of evidence of a potential violation of civil or criminal law. Routine use 2: Disclosure may be made to a congressional office from the record of an individual upon the written request of the record subject to obtain assistance from his/her congressional representative. Individuals sometimes request the help of a Member of Congress in resolving some issue relating to a matter before HHS. The Member of Congress then writes HHS and HHS must be able to give sufficient information to be responsive to the inquiry. Routine use 3: Disclosure may be made to the Department of Justice, or to a court or other tribunal, in case of litigation where HHS determines that such disclosure is relevant and necessary and would help in the effective representation of the governmental party, provided, however, that in each case HHS determines that such disclosure is compatible with the purpose for which the records were