

These amounts include approximately \$16 million by which suppliers in North Carolina and Tennessee will benefit due to implementation of the BIPA ambulance mileage provision for the period of July 1, 2001 through March 31, 2002.

Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects (\$100 million or more in any 1 year). The aggregate amount of program spending to comply with the court's order will be approximately \$81 million. Therefore this notice is not a major notice as defined in Title 5, United States Code, section 804(2) and is not an economically significant notice under Executive Order 12866.

The RFA requires agencies to analyze options for regulatory relief of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and government agencies. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of \$6 million to \$29 million in any 1 year. Individuals and States are not considered to be small entities. We have determined that this notice will not have a significant economic impact on a substantial number of small entities. Therefore, we are not preparing an analysis for the RFA.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 100 beds. We have determined that this notice will not have a significant effect on the operations of a substantial number of small rural hospitals. Therefore, we are not preparing an analysis for section 1102(b) of the Act.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule that may result in expenditures in any 1 year by State, local, or tribal governments, in the aggregate, or by the

private sector, of \$110 million. This notice has no consequential effect on State, local, or tribal governments or on the private sector.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a rule that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. This notice will not have a substantial effect on State or local governments.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

Authority: Sections 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

(Catalog of Federal Domestic Assistance Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: April 1, 2003.

Thomas A. Scully,
Administrator, Centers for Medicare & Medicaid Services.

Dated: April 11, 2003.

Tommy G. Thompson,
Secretary.

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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.

Method and Materials for Promoting Migration of T Cells to the Vasculature of a Tumor

Patrick Hwu and Mary Tschoi (NCI).
Serial No. 60/447,497 filed 14 Feb 2003.
Licensing Contact: Jonathan Dixon;
(301) 435-5559; dixonj@od.nih.gov.

Adoptive immunotherapy with T cells is a promising therapeutic modality for cancer. However, the effectiveness of this method of treatment appears to be limited by the inefficient migration of T cells to the tumor site. The present invention provides materials and methods that promote the migration of T cells to the vasculature of a tumor.

This invention discloses a novel method of administering modified autologous T cells, which bind to cell-surface molecules on endothelial cells of the vasculature of a tumor. Using the disclosed method and modified T cells, investigators were able to promote the migration of T cells to molecules expressed on the vasculature of tumors. It is anticipated that this method and these modified autologous T cells will improve the effectiveness of adoptive immunotherapy for a variety of tumors, including melanoma and many carcinomas and sarcomas.

This research has been described, in part, in Dudley *et al.*, Science 298:850-854 (25 October 2002).

Amplification and Overexpression of Septin9 MLL Septin-Like Fusion (MSF) and Methods Related Thereto

Cristina Montagna *et al.* (NCI).
DHHS Reference No. E-003-2003.
Licensing Contact: Matthew Kiser; (301) 435-5236; kiserm@od.nih.gov.

This invention pertains to methods of detecting cancer, a method of inhibiting a protein, oligonucleotides for use therein, a method of inducing apoptosis, methods of testing a candidate drug for efficacy as an anti-cancer drug and methods for evaluating the progression of cancer.

The inventors have demonstrated that the Septin9 gene in mice (MSF gene in humans) is amplified in cancer models for breast cancer. Furthermore, it has been shown that the product encoded by this gene is overexpressed in cancer. In this regard, the present invention provides methods of detecting cancer in a mammal. One method comprises determining whether or not the mammal has an amplification of the Septin9 (MSF) locus or an ortholog of the gene. In this method, overexpression of the protein or of the nucleic acid molecule is indicative of cancer. Another method