

designation of regional or national intermediaries for classes of providers.

We make individual contract action decisions after considering these factors in terms of their relative significance and impact on the effective and efficient administration of the Medicare program.

In addition, if the cost incurred by the intermediary or carrier to meet its contractual requirements exceeds the amount that we find to be reasonable and adequate to meet the cost that must be incurred by an efficiently and economically operated intermediary or carrier, these high costs may also be grounds for adverse action.

### VIII. Response to Public Comments

Because of the large number of items of correspondence we normally receive on **Federal Register** documents published for comment, we are unable to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the Dates section of this preamble, and, if we proceed with a subsequent document, we will respond to the comments in the preamble of that document.

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

### IX. Federalism

We have reviewed this notice under the threshold criteria of Executive Order 13132, Federalism. We have determined that the notice does not significantly affect the rights, roles, and responsibilities of States.

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance, and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: September 8, 2000.

**Nancy-Ann Min DeParle,**

*Administrator, Health Care, Financing Administration.*

[FR Doc. 00-27955 Filed 10-30-00; 8:45 am]

BILLING CODE 4120-01-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, 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.

Entitled: "USE OF 14-3-3σ AS A DIAGNOSTIC MARKER AND THERAPEUTIC TARGET"—A Method to Diagnose and Determine the Prognosis of Breast and/or Ovarian Cancers.

*Inventors:* Drs. Olga Aprelikova (NCI) and Edison T. Liu (NCI) DHHS Ref. No. E-307-00/0, Filed with the USPTO on September 7, 2000.

Breast cancer is one of the most significant cancerous diseases that affects women. At the current rate, American women have a 1 in 8 risk of developing breast cancer by age 95 (American Cancer Society, 1992). Treatment of breast cancer at later stages is often futile and disfiguring, making early detection a high priority in medical management of the disease. Ovarian cancer, although less frequent than breast cancer is often rapidly fatal and is the fourth most common cause of cancer mortality in American women. Genetic factors contribute to an ill-defined proportion of breast cancer incidence, estimated to be about 5% of all cases but approximately 25% of cases diagnosed before age 40. Breast cancer has been subdivided into two types, early-age onset and late-age onset, based on an inflection in the age-specific incidence curve around age 50. Mutation of one gene, BRCA1, is thought to account for approximately 45% of familial breast cancer, but at least 80% of families with both breast and ovarian cancer.

The 14-3-3σ checkpoint control gene is significantly downregulated in BRCA1 -/-cells. The cell cycle profile of these cells treated with ionizing radiation showed an inability to sustain G2/M growth arrest typical for 14-3-3σ deprived cells. In addition, 14-3-3σ has been identified as a p53 inducible gene after DNA damage. Thus, BRCA1 synergistically activates p53 dependent transcription of 14-3-3σ gene. These observations demonstrate the role of 14-3-3σ, and the interaction of BRCA1,

p53, and 14-3-3σ in neoplastic conditions, such as breast cancer or ovarian cancer.

The technology disclosed in the E-307-00/0 patent application is directed to a method to identify an agent that modulates 14-3-3σ. The 14-3-3σ checkpoint control gene is significantly downregulated in BRCA1 -/-cells. The method includes incubating the agent and a sample of interest, wherein the sample is capable of expressing 14-3-3σ, under conditions sufficient to allow the compound of interest to interact with the sample, and determining the effect of the compound on the expression or activity of 14-3-3σ. The effect of an agent on the interaction of 14-3-3σ with p53 and/or BRCA1 can also be assessed. A method is also provided for determining the prognosis of a subject diagnosed with a 14-3-3σ-associated disorder. The method includes contacting a sample from the subject with a reagent that binds to 14-3-3σ, detecting binding of the reagent to 14-3-3σ; and correlating the binding of the reagent to the sample with the prognosis of the disorder. The method can also include detecting p53 and/or BRCA1 mutations.

The above mentioned invention is available for licensing on an exclusive or non-exclusive basis.

Dated: October 23, 2000.

**Jack Spiegel,**

*Director, Division of Technology Development & Transfer, Office of Technology Transfer.*

[FR Doc. 00-27890 Filed 10-30-00; 8:45 am]

BILLING CODE 4140-01-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Office of the Director, National Institutes of Health; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Director's Council of Public Representatives, October 31–November 1, 2000, National Institutes of Health, 9000 Rockville Pike, Building 31, Conference Room 6, Bethesda, MD 20982 which was published in the **Federal Register** on October 10, 2000, 65 FR 60200–60201.

The dates, times, and location of the meeting are the same but the agenda has changed to discuss human research protections and medical applications research. The meeting is open to the public.