The draft guidance, when finalized, will represent the agency's current thinking on evaluating the effects of orally inhaled and intranasal corticosteroids on growth in children. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Dockets Management Branch (address above) written or electronic comments on the draft guidance. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet can obtain the document at http://www.fda.gov/cder/guidance/index.htm or http://www.fda.gov/ohrms/dockets/default.htm.

Dated: October 26, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01–27756 Filed 11–5–01; 8:45 am]

BILLING CODE 4160–01–S

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 Dale D. Berkley, Ph.D., J.D., at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804; telephone: 301/496–7735 ext. 223; fax: 301/402–0220; e-mail: *berkleyd@od.nih.gov.* A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

Side Exit Guiding Catheter for Percutaneous Endomyocardial Injection

Robert Lederman (NHLBI)
DHHS Reference No. E–108–01/0 filed 10 Aug 2001

The invention is a device for delivering a therapeutic or diagnostic agent to the heart using a flexible catheter having a non-concentric guide wire to facilitate percutaneous delivery of the catheter across the aortic valve into the left ventricular cavity. The catheter has a side port through which the therapeutic or diagnostic can be delivered and, in particular, by which septal ablation for the treatment of conditions such as hypertrophic cardiomyopathy can be accomplished. This catheter is able to ''turn around'' on itself to treat areas of the myocardium immediately underneath the aortic valve through which the catheter enters. The side port can be used to introduce a needle, laser or radiofrequency probe to perform an endomyocardial ablation procedure.

Methods and Devices for Isolation and Analysis of Cellular Protein Content

Lance A. Liotta, Emmanuel P. Petricoin, Nicole Simone, Michael Emmert-Buck (NCI)
U.S. Patent Application No. 60/120,288 filed February 16, 1999; PCT Application No. PCT/US00/04023 filed February 16, 2000; U.S. Patent Application No. 09/913,667 filed August 16, 2001

The invention is a comprehensive Laser Capture Microdissection (LCM) method for determining protein characteristics of a sample tissue cell to quantitatively discern and compare the protein content of healthy cells versus diseased cells. The tissue source of a tumor metastasis is available from the acquisition of this information. The focus in molecular biology is moving from genomics to proteomics, the study of variations in the protein levels of cells, caused by the state of the cell itself, whether healthy or unhealthy. The invention provides a method for using new and innovative methods for cell analysis. Previous methods, such as UV-laser ablation of unwanted tissue regions and oil well isolation of tissue cells, were complex, labor intensive, and did not utilize protein stabilizers. Direct comparisons between healthy cells and tumor cells were not made due to limitations of the methods. The new method consists of first using the new LCM method to obtain pure cell populations. Next, the sample is placed in a device so that the proteins are solubilized. Then the immunological and biochemical methods and subsequent analyses are performed. These techniques include (but are not limited to) immunoassays, 1D and 2D gel electrophoresis characterization, Western blotting, Matrix Assisted Laser Desorption Ionization/Time of Flight (MALDI/TOF) and Surface Enhanced Laser Desorption Ionization Spectroscopy (SELDI), Protein Arrays and Phosphoprotein Fingerprinting. The methods listed above allow for the direct comparison of both qualitative and quantitative tissue content of healthy and diseased cells, from the same sample. The sequential method of using LCM, protein isolation, analysis and comparison is superior to existing methods because the location of the tumor can be found simply using immunohistochemistry, and protein characteristics, such as amino acid sequence and binding ability can also be discerned. In addition, by using protein fingerprinting, the source of the tumor metastasis is found effectively. The invention has been tested extensively with the different methods listed above. This technology can be used in hospitals and research pathology labs for quantitative measure of protein characteristics of cells.

Isolation of Cellular Material Under Microscopic Visualization

Liotta et al. (NCI)
U.S. Patent 5,843,644 issued December 1, 1998; U.S. Patent 5,843,657 issued December 1, 1998; U.S. Patent 6,010,888 issued January 4, 2000; U.S. Patent 6,204,030 issued March 20, 2001; Serial No. 09/765,937 filed January 18, 2001

This Laser Capture Microdissection (LCM) invention is a method for directly extracting cellular material from a tissue sample using a laser beam to focally activate a special transfer film that bonds specifically to cells identified and targeted by microscopy within the tissue section. The transfer film with the bonded cells is then lifted off the thin tissue section, leaving all unwanted cells (which would contaminate the molecular purity of subsequent analysis) behind. The transparent transfer film is applied to the surface of the tissue section. Under the microscope, the

diagnostic pathologist or researcher views the thin tissue section through the glass slide on which it is mounted and chooses microscopic clusters of cells to study. When the cells of choice are in the center of the field of view, the operator pushes a button, which activates a near IR laser diode integral with the microscope optics. The pulsed laser beam activates a precise spot on the transfer film immediately above the cells of interest. At this precise location the film melts and fuses with the underlying cells of choice. When the film is removed, the chosen cell(s) are tightly held within the focally expanded polymer, while the rest of the tissue is left behind. This allows multiple homogeneous samples within the tissue section or cytological preparation to be targeted and pooled for extraction of molecules and analysis. This technology is available for licensing on a non-exclusive basis.

Dated: October 29, 2001.

Jack Spiegel,

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

[FR Doc. 01–27750 Filed 11–5–01; 8:45 am]

BILLING CODE 4140–01–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 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.

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Recombinant Proteins of the Swine Hepatitis E Virus and Their Uses as a Vaccine and Diagnostic Reagents for Medical and Veterinary Applications

Xiang-Jin Meng, Robert H. Purcell, Suzanne U. Emerson (NIAID)

DHHS Reference No. E–304–98/0 filed May 7, 2001

Licensing Contact: Carol Salata; 301/496–7735 ext. 232; e-mail: *salatac@od.nih.gov*

This invention is based on the discovery of the swine hepatitis E virus (swine HEV), the first animal strain of HEV identified and characterized, and its ability to infect across species. The inventors have found that the swine HEV is widespread in the general pig population in the United States and other countries and that swine HEV can infect non-human primates. The inventors have amplified and sequenced the complete genome of swine HEV. The capsid gene (ORF2) of swine HEV has been cloned and expressed in a baculovirus expression system.

The possibility that swine HEV may infect humans raises a potential public health concern for zoonosis or xenozoonosis in the United States and perhaps other countries. Therefore, it is likely that a vaccine based on the recombinant capsid protein of swine HEV will protect humans against zoonotic, as well as other, HEV infections and pigs against infection with the swine HEV. Also, diagnostic reagents based on these recombinant proteins of swine HEV will be very useful in screening donor pigs used in xenotransplantation and in detecting swine HEV or similar virus infection in humans. The diagnostic reagents may also be useful for veterinary studies and monitoring pig herds in general.

Polymorphic Human $GABA_A$ Receptorα-6 Subunit

David Goldman, Nakao Iwata, Mark Shuckit (NIAAA)

DHHS Reference No. E–061–98/0 filed February 19, 1999 and DHHS Reference No. E–061–98/1 filed February 18, 2000

Licensing Contact: Pradeep Ghosh; 301/496–7736 ext. 211; e-mail: *ghoshp@od.nih.gov*

Gamma-aminobutyric acid (GABA) is a key inhibitory neurotransmitter in the mammalian central nervous system. Evidence indicates that GABA receptors are associated with various neuropsychiatric disorders. Currently, there are no reliable and sensitive markers on the market for the molecular diagnosis of alcoholism or anxiety disorders, although both groups of disorders are thought to involve GABA function. Alcohol modulates GABA function and shows cross-tolerance with benzodiazepines. Anxiety disorders are treated with benzodiazepines. Also, there are no molecular predictors of interindividual variation in response to the commonly used benzodiazepine drugs [such as valium) which act through $GABA_A$ receptors. The α-6 subunit of $GABA_A$ receptors is sensitive to alcohol and in a rat genetic model a genetic variant of the α-6 subunit had been directly related to sensitivity to alcohol and benzodiazepine drugs. This invention pertains to a particular polymorphism in the human α-6 subunit gene. This relatively common human sequence variant predicts sensitivity to both benzodiazepine drugs and ethanol. In children of alcoholics this substitution also correlates with susceptibility to alcoholism. Thus, this invention presents commercial opportunities both as a diagnostic screening tool in alcoholism, anxiety disorders and other neuropsychiatric diseases, and as a predictive tool for therapeutic and pathological responses to commonly administered benzodiazepine drugs.

Dated: October 29, 2001.

Jack Spiegel,

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

[FR Doc. 01–27751 Filed 11–5–01; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Interagency Autism Coordinating Committee; Notice of Meeting

The Children's Health Act of 2000 (Pub. L. 106–310), Title I, section 104, mandated the establishment of an Interagency Autism Coordinating Committee (IACC) to coordinate autism research and other efforts within the Department of Health and Human Services (DHHS). In April 2001, Secretary Tommy Thompson delegated the authority to establish the IACC to the National Institutes of Health (NIH). The National Institute of Mental Health (NIMH) at the NIH has been designated the lead for this activity.

The meeting will be open to the public, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other