

autoimmunity. *Annu Rev Immunol.* 2008;26:57–79.

2. WJ Leonard and R Spolski. Interleukin-21: A modulator of lymphoid proliferation, apoptosis and differentiation. *Nat Rev Immunol.* 2005 Sep;5(9):688–698.

3. G Wang et al. In vivo antitumor activity of interleukin 21 mediated by natural killer cells. *Cancer Res.* 2003 Dec15;63(24):9016–9022.

*Patent Status:* U.S. Patent Application No. 10/508,978 filed 19 Nov 2004 (HHS Reference No. E–137–2002/0–US–03).

*Licensing Status:* Available for licensing.

*Licensing Contact:* Jennifer Wong; 301–435–4633; [wongje@mail.nih.gov](mailto:wongje@mail.nih.gov).

Dated: July 1, 2009.

**Richard U. Rodriguez,**

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

[FR Doc. E9–16300 Filed 7–8–09; 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, HHS.

**ACTION:** Notice.

**SUMMARY:** The inventions listed below are owned by an agency 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.

#### qPCR Assay for Detection of JC Virus

*Description of Invention:* JC Virus causes a fatal disease in the brain called progressive multifocal leukoencephalopathy (PML) that occurs

in many patients with immunocompromised conditions. For example, more than five percent (5%) of AIDS patients develop PML.

Additionally, these conditions include, but are not limited to, cancers such as leukemias and lymphomas, organ transplants such as kidney, heart and autoimmune conditions with treatment that modulates the immune system such as Multiple Sclerosis (MS), rheumatoid arthritis, psoriasis, and systemic lupus erythematosus. The finding of JCV DNA in the patients with neurological symptoms of PML is a diagnostic criterion and is needed to confirm the diagnosis of PML to rule out other neurological conditions.

This technology describes a qPCR assay that utilizes viral DNA standards and testing samples to detect the presence of the JC viral genome in patients' cerebrospinal fluid and blood, blood products, and tissue samples from biopsy or autopsy.

*Application:* Development of JC Virus (JCV) diagnostics, calibration of existing JCV assays.

*Advantages:* Assay is sensitive, reproducible and highly specific because the amount of JCV DNA in cerebrospinal fluid or blood or blood product samples may be very small.

*Development Status:* Materials and assay have been developed and tested.

*Inventors:* Eugene O. Major and Caroline Ryschkewitsch (NINDS).

#### Publications

1. ML Landry *et al.* False negative PCR despite high levels of JC virus DNA in spinal fluid: Implications for diagnostic testing. *J Clin Virol.* 2008 Oct;43(2):247–249.

2. C Ryschkewitsch *et al.* Comparison of PCR-southern hybridization and quantitative real-time PCR for the detection of JC and BK viral nucleotide sequences in urine and cerebrospinal fluid. *J Virol Methods.* 2004 Nov;121(2):217–221.

3. T Yousry *et al.* Evaluation of patients treated with natalizumab for progressive multifocal leukoencephalopathy. *N Engl J Med.* 2006 Mar 2;354(9):924–933.

*Patent Status:* HHS Reference No. E–152–2009/0—Research Material. Patent protection is not being pursued for this technology.

*Licensing Status:* Available for licensing.

*Licensing Contact:* Peter A. Soukas, J.D.; 301–435–4646; [soukasp@mail.nih.gov](mailto:soukasp@mail.nih.gov).

#### A Locking Device for Permanently Securing Surgical Suture Loops

*Description of Invention:* This technology relates to a device that can be used to non-invasively secure surgical suture loops when combined with a percutaneous delivery system. It has been shown to be effective in correcting mitral valve regurgitation (MVR) in an animal model. During the procedure, a guidewire is percutaneously conveyed to the atrium of the heart and is used to secure the “cerclage” suture encircling the mitral valve annulus, which is delivered using a delivery catheter. The locking device is advanced over the suture by the delivery catheter and it permanently secures the suture and maintains the tension on the annulus once the delivery system is removed. This locking device, in combination with the percutaneous procedure, allows for more complete coaptation of the valve leaflets and correction of MVR without the need for open heart surgery and its associated risks. The locking device is also adjustable, allowing the user to vary the tension on the suture if further tightening or loosening is required. It is also MRI compatible and all follow-up studies can be performed under MRI.

This invention has demonstrated its ability to correct MVR in animals where the locking device was observed to maintain the correct position and tension after implantation. This device has the potential to replace the traditional loop and knot method used for surgical correction of MVR, and may also be useful for other conditions that require permanently secured suture loops.

*Applications:* Non-invasive and effective correction of MVR and other conditions; Tensioning device for securing suture loops.

*Advantages:* Technology amenable to a non-invasive technique; Control of tension on surgical sutures.

*Development Status:* Early stage.

*Inventor:* Ozgur Kocaturk (NHLBI).

*Patent Status:* U.S. Provisional Application No. 61/157,267 filed 04 Mar 2009 (HHS Reference No. E–048–2009/0–US–01).

*Licensing Status:* Available for licensing.

*Licensing Contact:* Jeffrey A. James, Ph.D.; 301–435–5474; [jeffreyja@mail.nih.gov](mailto:jeffreyja@mail.nih.gov).

*Collaborative Research Opportunity:* The National Heart, Lung and Blood Institute Cardiac Catheterization Lab is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize the

tension fixation device. Please contact Peg Koelble at 301-594-4095 or [koelblep@nhlbi.nih.gov](mailto:koelblep@nhlbi.nih.gov) for more information.

### Modulators of Pregnane X Receptor (PXR) as Therapeutics for Bowel Disorders (BD)

*Description of Invention:* This technology is based on the novel findings that susceptibility to BD is strongly associated with genetic variation in the PXR gene, a member of the nuclear receptor family, and rifaximin is a specific activator of human PXR. PXR is an integral component of the body's defense mechanism involved in endogenous and xenobiotic detoxication. Based on these novel findings, the present technology provides (a) methods of screening for compositions that modulate inflammatory bowel disease (IBD), (b) methods of inhibiting inflammation of the bowel and related tissues and organs, and (c) methods of treatment of inflammatory bowel disease.

*Applications:* Therapeutics for bowel disorders; Screening assays for candidate drugs to treat bowel disorders.

*Development Status:* Early stage.

*Market:* It is estimated that as many as one (1) million Americans have IBD, with that number evenly split between Crohn's disease and Ulcerative Colitis (UC). Further, it is estimated that the IBD therapeutic market will grow to reach four (4) billion U.S. dollars in 2017.

*Inventors:* Frank J. Gonzalez (NCI), Xiaochao Ma (NCI), *et al.*

*Publication:* X Ma, Y Shah, C Cheung, GL Guo, L Feigenbaum, KW Krausz, JR Idle, FJ Gonzalez. The PREGnane X receptor gene-humanized mouse: a model for investigating drug-drug interactions mediated by cytochromes P450 3A. *Drug Metab Dispos.* 2007 Feb;35(2):194-200.

*Patent Status:* U.S. Provisional Application No. 60/999,234 filed 17 Oct 2007 (HHS Reference No. E-002-2008/0-US-01); PCT Patent Application (HHS Reference No. E-002-2008/0-PCT-02).

*Licensing Status:* Available for licensing.

*Licensing Contact:* Suryanarayana (Sury) Vepa, PhD, J.D.; 301-435-5020; [vepas@mail.nih.gov](mailto:vepas@mail.nih.gov).

*Collaborative Research Opportunity:* The Laboratory of Metabolism, Center for Cancer Research, NCI, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize compounds that ameliorate bowel disorders through the

PXR pathway. Please contact Lisa Finkelstein, PhD at 301-451-7458 or [lfinkels@mail.nih.gov](mailto:lfinkels@mail.nih.gov) for more information.

### The Protein Cyanovirin Inactivates HIV and Influenza

*Description of Invention:* Cyanovirin-N (CV-N) potently and irreversibly inactivates diverse primary strains of HIV-1, including M-tropic forms involved in sexual transmission of HIV, as well as T-tropic and dual-tropic forms. CV-N also blocks cell-to-cell transmission of HIV infection. CV-N interacts in an unusual manner with the viral envelope, binding with extremely high affinity to poorly immunogenic epitopes on gp120. Further, CV-N and homologous proteins and peptides potentially inhibit diverse isolates of influenza viruses A and B, the two major types of influenza virus that infect humans.

The described technology includes glycosylation-resistant mutants, which code sequences to enable ultra large-scale recombinant production of functional CV-Ns in non-bacterial (yeast or insect) host cells or in transgenic animals or plants. Therefore, these glycosylation-resistant mutants may allow industry to produce CV-Ns on a large scale and make CV-Ns cheap enough for developing countries to benefit from this invention.

CV-N was benign *in vivo* when tested in the rabbit/monkey vaginal toxicity/irritancy model and was not cytotoxic *in vitro* against human immune cells and lactobacilli. CV-N is readily soluble in aqueous media, is remarkably resistant to physicochemical degradation and is amenable to very large-scale production by a variety of genetic engineering approaches.

#### Applications

- Therapeutics and prevention of HIV and influenza infections.
- Topical microbicide to protect HIV infection.
- *Ex vivo* devices incorporating CV-N to remove or inactivate HIV from fluid samples.

#### Advantages

- Potent anti-HIV and anti-influenza activity.
- Can be applied both systematically or locally.
- Can be applied both *in vivo* and *ex vivo*.
- Inexpensive and large scale manufacturing.

#### Development Status

- Preclinical (rabbit/monkey) data in microbicide field are available at this time.

- Initial animal efficacy studies (both mouse and ferret) against influenza (H1N1) have been completed and published.

*Market:* For HIV therapeutics market, a published report by the financial services firm Griffin Securities suggested that sales of HIV/AIDS drugs reached \$13 billion annually in 2007 (<http://www.hivandhepatitis.com>).

For microbicide market, it has been estimated that the global market size of microbicide will reach to \$900 million by 2011 and will reach the sales of over \$1.8 billion by 2020. "Promising microbicides" *Frontline* (Volume 21—Issue 14, Jul. 03-16, 2004).

For influenza market, based on Report Buyer which is a UK-based independent online store supplying business information on major industry sectors: By 2010, the worldwide influenza market is likely to reach \$7.1 billion, with average annual growth estimated at 19.8%.

*Inventors:* Michael R. Boyd (NCI), Barry R. O'Keefe (NCI), *et al.*

#### Publications

1. B Giomarelli, R Provvedi, F Meacci, T Maggi, D Medaglini, G Pozzi, T Mori, JB McMahon, R Gardella, MR Boyd. The microbicide cyanovirin-N expressed on the surface of commensal bacterium *Streptococcus gordonii* captures HIV-1. *AIDS.* 2002 Jul 5;16(10):1351-1356.

2. CC Tsai, P Emau, Y Jiang, MB Agy, RJ Shattock, A Schmidt, WR Morton, KR Gustafson, MR Boyd. Cyanovirin-N inhibits AIDS virus infections in vaginal transmission models. *AIDS Res Hum Retroviruses.* 2004 Jan; 20(1):11-18.

3. DF Smece, KW Bailey, MH Wong, BR O'Keefe, KR Gustafson, VP Mishin, LV Gubareva. Treatment of influenza A (H1N1) virus infections in mice and ferrets with cyanovirin-N. *Antiviral Res.* 2008 Dec;80(3):266-271.

#### Patent Status

- E-117-1995/0—US Patent Numbers 5,843,882; 6,015,876; 5,962,653; 6,245,737 and 6,586,392.

- E-117-1995/1—US Patent Numbers 5,821,081; 5,998,587; 6,987,096; and 5,962,668.

- E-117-1995/2-PCT-01 (WO 96/34107)—entered in AU with Patent Numbers 707781 and 746809; in CA with Patent application Numbers 2219105; in JP with Patent Numbers 3803115 and 4081484; and in EP with Patent Number 836647 and registration GB, FR, DE, BE and CH.

- E-117-1995/3-PCT-02 (WO 00/11036)—entered in USA with Patent Number 6,193,982; in AU with Patent Number 746313; in CA with Patent Application Number 2340787; in JP

with Patent Application Number 566308/2000; and in EP with Patent Application Number 99943784.1.

- E-074-1999/0—US Patent Numbers 6,420,336 and 6,743,577.

- E-074-1999/1—US Patent Numbers 7,105,169; 7,048,935; and 6,428,790.

- E-074-1999/2-PCT-01 (WO 00/53213)—entered in AU with Patent Numbers 762704 and 2003252207; in CA with Patent Application Numbers 2364500; in JP with Patent Application Number 603702/2000; and in EP with Patent Number 1162992 and registration GB, FR, DE, BE and CH.

- E-074-1999/3-PCT-02 (WO 02/077189)—entered in USA with Patent Numbers 7,339,037 & 6,780,847 and Patent Application Number 10/857,265; in AU with Patent Number 2002254382; in CA with Patent Application Number 2441287; in JP with Patent Application Number 576632/2002; and in EP with Patent Number 1456382 and registration GB, FR, DE, BE and CH.

- E-198-2006/0-PCT-02 (WO 2008/022303)—entered in USA with Patent Application Number 12/377875; and in EP with Patent Application Number 07814209.8.

*Licensing Status:* Available for licensing.

*Licensing Contact:* Sally Hu, PhD, 301-435-5606, [HuS@mail.nih.gov](mailto:HuS@mail.nih.gov).

*Collaborative Research Opportunity:* The National Cancer Institute, Molecular Targets Development Program, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize this technology. Please contact John D. Hewes, PhD at 301-435-3121 or [hewesj@mail.nih.gov](mailto:hewesj@mail.nih.gov) for more information.

### Novel Osteobiologic Proteins for Treatment of Osteoporosis, Rheumatoid and Neurologic Diseases

*Description of Invention:* In an effort to find effective strategies for treatment of body tissue and structural damage as the result of trauma, cancer and other diseases, scientists at the National Institutes of Health (NIH) and the Food and Drug Administration (FDA) have identified proteins and associated pathways instrumental in replacing or regenerating damaged tissue. The identified proteins include Cartilage-Derived Morphogenetic Proteins (CDMP), Bone Morphogenetic Proteins (BMPs) and a tissue fate modifying FRZB Protein. Each has unique activities likely to be useful as stand alone agents or in construction of engineered tissues.

CDMPs appear helpful in the healing of bone and joint surface lesions, and

also for the repair or reconstruction of cartilaginous tissues, tendons and ligaments. BMP antagonists will be useful in the study of stem cell differentiation. FRZB Protein, a tissue fate modifying secreted antagonist of Wnt signaling, is involved in the formation of cartilage, bone, neural and muscle tissue.

### Potential Areas of Application

- Rheumatic diseases of the bone.
- Osteoporosis and osteoarthritis.
- Wound healing.
- Neurodegenerative disorders.
- Growth and repair of musculoskeletal tissues.
- Tissue engineering.

### Cartilage-Derived Morphogenetic Proteins (HHS Reference No. E-138-1994/0)

- Useful in the therapeutic induction, repair, and maintenance of skeletal tissues and cartilage growth.
- Polynucleotides encoding these proteins are effective diagnostic reagents for detecting genetic abnormalities associated with poor skeletal development.

### Tissue Fate Modifying FRZB Protein (HHS Reference Nos. E-127-1995/0/1/2)

- Involved in the formation of cartilage, bone, neural and muscle tissue.
- Regenerative agent to treat degenerative disorders (*i.e.*, Huntington's, Alzheimer's or spinal cord injuries), myodegenerative disorders (*i.e.*, muscular dystrophy, myasthenia gravis or myotonic myopathies) and osteodegenerative disorders (*i.e.*, osteoporosis or osteoarthritis)
- Selectively blocks diseases associated with Wnt family of signaling molecules including neoplasias.

### Bone Morphogenetic Protein Variants (HHS Reference No. E-196-2004/0)

- Promote repair of menisci, cruciate and collateral ligaments of the knee, and rotator cuff or other tendons and/or ligaments.
- Induce the proliferation and differentiation of progenitor cells into functional bone, cartilage, tendon, or ligament tissue.

*Advantages:* Osteobiologics, such as BMPs, have the ability to stimulate musculo-skeletal repair instead of using donated human tissue allografts and synthetic materials.

*Market Size:* Ankylosing spondylitis afflicts least half a million people in the United States. Currently, there remains a need for the development of effective therapeutics for treating

spondyloarthropathies that could overcome the disadvantages of current drugs.

Osteoarthritis overall affects an estimated 30 million US adults. Direct medical expenses for arthritis and other rheumatic conditions are estimated at \$80.8 billion. In the United States, 10 million people have Osteoporosis. Osteoporosis related fractures attributed for \$21 billion with the number expected to rise to \$26 billion in 2025.

*Inventors:* Malcolm C. Moos Jr. (FDA), Frank P. Luyten (NIDCR), *et al.*

### Related Publications

1. K Lin, S Wang, MA Julius, J Kitajewski, M Moos Jr., FP Luyten. The cysteine-rich frizzled domain of Frzb-1 is required and sufficient for the modulation of Wnt signaling. *Proc Natl Acad Sci. USA* 1997 Oct 14;94(21):11196-11200.

2. B Hoang, M Moos Jr, S Vukicevic, FP Luyten. Primary structure and tissue distribution of FRZB, a novel protein related to Drosophila frizzled, suggests a role in skeletal morphogenesis. *J Biol Chem.* 1996 Oct 18;271(42):26131-26137.

### Patent Status

Cartilage-Derived Morphogenetic Proteins (HHS Reference No. E-138-1994/0)

- U.S. Patent 7,148,036 issued 12 Dec 2006.
- U.S. Patent 7,220,558 issued 22 May 2007.
- U.S. Patent Application No. 11/592,811 (allowed).

Tissue Growth-Inducing FRZB Protein (HHS Reference Nos. E-127-1995/0/1/2)

- U.S. Patent 6,884,871 issued 26 Apr 2005.
- U.S. Patent 6,924,367 issued 02 Aug 2005.
- U.S. Patent 7,049,291 issued 23 May 2006.
- U.S. Patent Application No. 11/184,005 (allowed).
- U.S. Patent Application No. 11/369,089 (pending).

Bone Morphogenetic Variants (HHS Reference No. E-196-2004/0)

- U.S. Patent Application No. 11/916,990 (pending).

*Licensing Status:* Available for licensing.

*Licensing Contact:* Surekha Vathyam, PhD; 301-435-4076; [vathyams@mail.nih.gov](mailto:vathyams@mail.nih.gov).

Dated: June 30, 2009.

**Richard U. Rodriguez,**

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

[FR Doc. E9-16299 Filed 7-8-09; 8:45 am]

BILLING CODE 4140-01-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute of Mental Health; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* National Institute of Mental Health Special Emphasis Panel; Time Sensitive Applications.

*Date:* July 16, 2009.

*Time:* 1 p.m. to 2 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852, (Telephone Conference Call).

*Contact Person:* Aileen Schulte, PhD, Scientific Review Officer, Division of Extramural Activities, National Institute of Mental Health, NIH, Neuroscience Center, 6001 Executive Blvd, Room 6140, MSC 9608, Bethesda, MD 20892-9608, 301-443-1225, [aschulte@mail.nih.gov](mailto:aschulte@mail.nih.gov).

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.242, Mental Health Research Grants; 93.281, Scientist Development Award, Scientist Development Award for Clinicians, and Research Scientist Award; 93.282, Mental Health National Research Service Awards for Research Training, National Institutes of Health, HHS)

Dated: July 1, 2009.

**Jennifer Spaeth,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. E9-16214 Filed 7-8-09; 8:45 am]

BILLING CODE 4140-01-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute of Diabetes and Digestive and Kidney Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel, IBD Genetics Ancillary Studies.

*Date:* July 29, 2009.

*Time:* 1:30 p.m. to 2:30 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892 (Telephone Conference Call).

*Contact Person:* Dan E. Matsumoto, Ph.D., Scientific Review Administrator, Review Branch, DEA, NIDDK, National Institutes of Health, Room 749, 6707 Democracy Boulevard, Bethesda, MD 20892-5452, (301) 594-8894, [matsumotod@extra.nidDK.nih.gov](mailto:matsumotod@extra.nidDK.nih.gov).

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: July 1, 2009.

**Jennifer Spaeth,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. E9-16092 Filed 7-8-09; 8:45 am]

BILLING CODE 4140-01-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

#### Subcommittee on Procedures Reviews, Advisory Board on Radiation and Worker Health (ABRWH), National Institute for Occupational Safety and Health (NIOSH)

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), the Centers for Disease Control and Prevention (CDC) announces the following meeting for the aforementioned subcommittee:

*Time and Date:* 10 a.m.–5 p.m., August 13, 2009.

*Place:* Cincinnati Airport Marriott, 2395 Progress Drive, Hebron, Kentucky 41018. Telephone (859) 334-4611, Fax (859) 334-4619.

*Status:* Open to the public, but without a public comment period. To access by teleconference dial the following information 1(866)659-0537, Participant Pass Code 9933701.

*Background:* The Advisory Board was established under the Energy Employees Occupational Illness Compensation Program Act of 2000 to advise the President on a variety of policy and technical functions required to implement and effectively manage the compensation program. Key functions of the Advisory Board include providing advice on the development of probability of causation guidelines that have been promulgated by the Department of Health and Human Services (HHS) as a final rule; advice on methods of dose reconstruction which have also been promulgated by HHS as a final rule; advice on the scientific validity and quality of dose estimation and reconstruction efforts being performed for purposes of the compensation program; and advice on petitions to add classes of workers to the Special Exposure Cohort (SEC).

In December 2000, the President delegated responsibility for funding, staffing, and operating the Advisory Board to HHS, which subsequently delegated this authority to CDC. NIOSH implements this responsibility for CDC. The charter was issued on August 3, 2001, renewed at appropriate intervals, and will expire on August 3, 2009.

*Purpose:* The Advisory Board is charged with (a) Providing advice to the Secretary, HHS, on the development of guidelines under Executive Order 13179; (b) providing advice to the Secretary, HHS, on the scientific validity and quality of dose reconstruction efforts performed for this program; and (c) upon request by the Secretary, HHS, advise the Secretary on whether there is a class of employees at any Department of Energy facility who were exposed to radiation but for whom it is not feasible to estimate their radiation dose, and on whether there is reasonable likelihood that such radiation doses may have endangered the health of members of this class. The Subcommittee on Procedures