Licensing Contact: Michael Shmilovich, Esq.; 301–435–5019; *shmilovm@mail.nih.gov.*

Collaborative Research Opportunity: The National Institute of Allergy and Infectious Diseases, Research Technologies Branch, Electron Microscopy Unit, is interested in collaborative research to further develop, evaluate, or commercialize potential applications of this invention, including design and development of instrumentation for conducting MWFS. Please contact Barry U. Buchbinder, Ph.D., NIAID/OTD, at 301–594–1696 or *bbuchbinder@niaid.nih.gov*, for more information.

Treatments for Smith-Lemli-Opitz Syndrome and Other Disorders of Cholesterol Biosynthesis

Description of Invention: This technology provides methods for treating Smith-Lemli-Opitz Syndrome and other disorders of cholesterol biosynthesis.

Smith-Lemli-Opitz Syndrome (SLOS) is an autosomal recessive disorder caused by an inborn error of cholesterol biosynthesis. It affects an estimated one in 20,000 to 60,000 newborns, and is most prevalent in Caucasians of Central European ancestry. It is characterized by distinctive facial features, microcephaly, mental retardation or learning disabilities, and behavioral problems, as well as malformations in many parts of the body, such as the heart, lungs, kidneys, gastrointestinal tract, and genitalia. However, the clinical manifestations of this disease can vary widely, ranging from relatively moderate symptoms to profoundly severe and life-threatening symptoms. At least 95% of SLOS patients present with some degree of mental retardation and learning disability.

Biochemically, SLOS is caused by disruption of the DHCR7 gene, which is responsible for the final step in the production of cholesterol; this results in low cholesterol levels and an accumulation of toxic byproducts of cholesterol biosynthesis in the blood, nervous system, and other tissues. Supplementary dietary cholesterol is provided to SLOS patients, but is often of limited clinical benefit; because levels of byproducts remain high, they may interfere with the uptake of free cholesterol.

Although some of the behavioral and learning problems are due to developmental problems, a portion of these symptoms are likely due to a biochemical disturbance. That biochemical disturbance is potentially treatable.

In their recent work, the inventors have discovered that the accumulation in SLOS cells of the cholesterol precursor 7–DHC causes abnormal sphingolipid storage and transport, resulting in a cellular phenotype similar to that observed in the lysosomal storage disease Niemann-Pick type C (NPC). They have also discovered that treatment with inhibitors of sphingolipid biosynthesis corrects these abnormalities, and thus such inhibitors are of potential therapeutic benefit for the treatment of SLOS, as well as for other diseases exhibiting similar defects in sphingolipid trafficking.

This technology claims compounds that inhibit sphingolipid biosynthesis for use in treating diseases which have a secondary Niemann-Pick type C disease-like cellular phenotype, including SLOS, as well as methods of treatment and pharmaceutical compositions.

Applications: Development of therapeutics for Smith-Lemli-Opitz Syndrome and other diseases which have a secondary Niemann-Pick type C disease-like cellular phenotype, which includes inborn errors of cholesterol biosynthesis, Huntington's disease, cystic fibrosis, and autism.

Development Status: In vitro studies have been performed using a sphingolipid biosynthesis inhibitor.

Inventors: Forbes D. Porter *et al.* (NICHD).

Related Publications:

1. FD Porter. Malformation syndromes due to inborn errors of cholesterol synthesis. J Clin Invest. 2002 Sep 15; 110(6):715–724. [PubMed: 12235098]

2. XS Jiang *et al.* Quantitative proteomic analysis of inborn errors of cholesterol synthesis: Identification of altered metabolic pathways in DHCR7 and SC5D deficiency. Mol Cell Proteomics. 2010 Mar 19; Epub ahead of print. [PubMed: 20305089]

3. XS Jiang *et al.* Activation of Rho GTPases in Smith-Lemli-Opitz syndrome: pathophysiological and clinical implications. Hum Mol Genet. 2010 Apr 1;19(7):1347–1357. [PubMed: 20067919]

4. Tierney *et al.* Analysis of short-term behavioral effects of dietary cholesterol supplementation in Smith-Lemli-Opitz syndrome. Am J Med Genet A. 2010 Jan;152A(1):91–95. [PubMed: 20014133]

Patent Status:

- U.S. Patent Application No. 12/666,279 filed 19 Jan 2010 (HHS Reference No. E–206–2007/0–US–06).
- Related International patent applications.

Licensing Status: Available for licensing.

Licensing Contact: Tara Kirby, Ph.D.; 301–435–4426; *tarak@mail.nih.gov.*

Collaborative Research Opportunity: The National Institute of Child Health and Human Development, Section on Molecular Dysmorphology, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize this technology. Please contact Alan Hubbs, Ph.D. at 301–594–4263 or *hubbsa@mail.nih.gov* for more information.

Dated: July 12, 2010.

Richard U. Rodriguez,

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

[FR Doc. 2010–17428 Filed 7–15–10; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–2900–FN2]

Medicare and Medicaid Programs; Approval of the Community Health Accreditation Program for Continued Deeming Authority for Hospices

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final notice of Removal of Conditional Probationary Status.

SUMMARY: Based on our review and observations, we have determined that the standards and processes used by the Community Health Accreditation Program (CHAP) hospice accreditation program meet or exceed our requirements. This final notice announces our decision to approve without condition CHAP's request for continued recognition as a national accreditation program for hospices seeking to participate in the Medicare or Medicaid programs.

DATES: *Effective Date:* This final notice is effective November 20, 2009 through November 20, 2012.

FOR FURTHER INFORMATION CONTACT:

Cindy Melanson, (410) 786–0310.
Patricia Chmielewski (410) 786–6899.

SUPPLEMENTARY INFORMATION:

I. Background

Under the Medicare program, eligible beneficiaries may receive covered services in a hospice, provided certain requirements are met. Section 1861(dd)(1) of the Social Security Act (the Act) establishes distinct criteria for entities seeking designation as a hospice

program. Under this authority, the regulations at 42 CFR part 418 specify the conditions that a hospice must meet in order to participate in the Medicare program, the scope of covered services, and the conditions for Medicare payment for hospice care. Provider agreement regulations are located in 42 CFR part 489 and regulations pertaining to the survey and certification of facilities are located in 42 CFR part 488.

Generally, in order to enter into an agreement, a hospice facility must first be certified by a State survey agency as complying with conditions or requirements set forth in part 418 of our regulations. Then, the hospice is subject to regular surveys by a State survey agency to determine whether it continues to meet these requirements. There is an alternative, however, to surveys by State agencies.

Section 1865(a)(1) of the Act provides that, if a provider entity demonstrates through accreditation by an approved national accreditation organization (AO) that all applicable Medicare conditions or requirements are met or exceeded, we may deem those provider entities as having met the requirements. Accreditation by an AO is voluntary and is not required for Medicare participation.

A national AO applying for approval of deeming authority under part 488, subpart A, must provide us with reasonable assurance that the AO requires the accredited provider entities to meet requirements that are at least as stringent as the Medicare conditions. Our regulations concerning re-approval of AOs are set forth at § 488.4 and § 488.8(d)(3). The regulations at § 488.8(d)(3) require AOs to reapply for continued approval of deeming authority every 6 years, or sooner as determined by CMS. The regulation at § 488.8(f)(3)(i) provides CMS the authority to grant conditional approval of an AO's deeming authority, with a probationary period of up to 180 days, if the AO has not adopted comparable standards during the reapplication process.

We received a complete application from CHAP for continued recognition as a national AO for hospices on March 27, 2009. In accordance with the requirements at § 488.4 and § 488.8(d)(3), we published a proposed notice on May 22, 2009 (74 FR 24015) and a final notice announcing our decision to conditionally approve CHAP's hospice program subject to probationary conditions on October 23, 2009 (74 FR 54832). This final notice provides CMS' final determination in response to the conditional approval with a 180-day probationary period granted to CHAP on October 23, 2009. This notice is required to be published no later than July 18, 2010.

II. Deeming Applications Approval Process

Section 1865(a)(3)(A) of the Act provides a statutory timetable to ensure that our review of deeming applications is conducted in a timely manner. The Act provides us with 210 calendar days after the date of receipt of an application to complete our survey activities and application review process. Within 60 days of receiving a completed application, we must publish a notice in the **Federal Register** that identifies the national accreditation body making the request, describes the request, and provides no less than a 30-day public comment period. At the end of the 210-day period, we must publish a notice in the **Federal Register** of our approval or denial of the application. In accordance with § 488.8(f)(2), if CMS determines following the deeming authority review that the organization has failed to adopt requirements comparable to CMS requirements, the AO may be given a conditional approval of its deeming authority for a probationary period of up to 180 days to adopt comparable requirements. Within 60 days after the end of this period, we must make a final determination as to whether or not the CHAP accreditation program for hospices is comparable to CMS requirements and issue an appropriate notice that includes our reasons for our determination.

III. Provisions of the October 23, 2009 Final Notice

Our review of CHAP's renewal application for hospice deeming authority revealed that CHAP had on-going, serious, widespread areas of non-compliance. Specifically, CHAP's inability to provide us with accurate, timely data on deemed providers; lack of complete and accurate deemed facility survey files; and, failure to ensure that recertification surveys are conducted on an interval not exceeding 36 months. Due to the significant number of areas of noncompliance identified during the review of CHAP's deeming authority, we conditionally approved CHAP's hospice accreditation program with a 180 day probationary period. Under 1865(a)(2) of the Act and our regulations at § 488.4 and § 488.8, we conducted a comparability review of CHAP's hospice accreditation program to determine compliance with Medicare requirements for hospices at 42 CFR part 418.

IV. Provisions of the Final Notice

A. Differences Between CHAP's Standards and Requirements for Accreditation and Medicare's Conditions and Survey Requirements

During the 180 day probationary period, we conducted a comparison of CHAP's accreditation requirements for hospices to our current Medicare conditions of Participation (CoPs) as outlined in the State Operations Manual (SOM). We also conducted a corporate onsite visit to validate proper application of the requirements. Our review and evaluation of CHAP's deeming application yielded the following:

- CHAP's survey files were complete, accurate, and consistent with the requirements at § 488.6(a).
- CHAP's recertification surveys for hospices are conducted no later than 36 months after the date of the previous standard survey in accordance with the requirements at § 488.20(a).
- CHAP's data submission are accurate, complete and timely in accordance with the requirements at § 488.4(b).
- CHAP met the requirements at section 2728 of the SOM by developing an electronic plan of correction that specifically addressed the "who, what, when, and how" the hospice would correct each deficiency cited and ensure ongoing compliance.
- CHAP met requirements at § 488.28(a) and section 2728 of the SOM as evidenced by review of the survey files.
- CHAP policy regarding establishment of an effective date for new providers is consistent with the requirements at § 488.13.

B. Term of Approval

Based on the review and observations, we have determined that CHAP's hospice accreditation program meets or exceeds our requirements. Therefore, we approve CHAP as a national AO for hospices that request participation in the Medicare program, effective November 20, 2009 through November 20, 2012. Under § 488.8(f)(4), notice was given to CHAP on October 23, 2009 (74 FR 54832).

V. Collection of Information Requirements

This document does not impose information collection and recordkeeping requirements. Consequently, it need not be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 35).

(Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program; No. 93.773 Medicare—Hospital Insurance Program; and No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: June 29, 2010.

Marilyn Tavenner,

Acting Administrator and Chief Operating Officer, Centers for Medicare & Medicaid Services.

[FR Doc. 2010–17405 Filed 7–15–10; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Environmental Health Sciences; 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: Environmental Health Sciences Review Committee.

Date: August 10–12, 2010.

Time: 8:30 a.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: Nat. Inst. of Environmental Health Sciences, Building 101, Rodbell Auditorium, 111 T. W. Alexander Drive, Conference Rooms A, B, and C, Research Triangle Park, NC 27709.

Contact Person: Linda K Bass, PhD, Scientific Review Administrator, Scientific Review Branch, Division of Extramural Research and Training, Nat'l Institute of Environmental Health Sciences, P.O. Box 12233, MD EC–30, Research Triangle Park, NC 27709, (919) 541–1307.

(Catalogue of Federal Domestic Assistance Program Nos. 93.115, Biometry and Risk Estimation—Health Risks from Environmental Exposures; 93.142, NIEHS Hazardous Waste Worker Health and Safety Training; 93.143, NIEHS Superfund Hazardous Substances—Basic Research and Education; 93.894, Resources and Manpower Development in the Environmental Health Sciences; 93.113, Biological Response to Environmental Health Hazards; 93.114, Applied Toxicological Research and Testing, National Institutes of Health, HHS)

Dated: July 12, 2010.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2010–17432 Filed 7–15–10; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

National Center for Environmental Health/Agency for Toxic Substances and Disease Registry (NCEH/ATSDR) ATSDR–263; Notice of National Conversation on Public Health and Chemical Exposures Leadership Council Meeting

Time and Date: 1 p.m.–5 p.m. EDT, Tuesday, July 27, 2010.

Location: Teleconference.

Status: The public is invited to listen to the meeting by phone; see "contact for additional information" below.

Purpose: This is the fifth meeting of the National Conversation on Public Health and Chemical Exposures Leadership Council, which is convened by RESOLVE, a non-profit independent consensus-building organization. The National Conversation on Public Health and Chemical Exposures is a collaborative initiative supported by NCEH/ATSDR through which many organizations and individuals are helping develop an action agenda for strengthening the nation's approach to protecting the public's health from harmful chemical exposures. The Leadership Council provides overall guidance to the National Conversation project and is responsible for issuing the final action agenda. For additional information on the National Conversation on Public Health and Chemical Exposures, visit this Web site: *http://www.atsdr.cdc.gov/nationalconversation/*.

Meeting Agenda: The meeting will include discussing (1) options for developing a results-oriented action agenda, (2) progress on work group reports, (3) updates on the community conversation process, and (4) Leadership Council operations.

Contact for Additional Information: If you would like to receive additional information on listening to the meeting by phone, please contact: *nationalconversation@cdc.gov* or Ben Gerhardstein at 770–488–3646.

Dated: July 9, 2010.

Tanja Popovic,

Deputy Associate Director for Science, Centers for Disease Control and Prevention.

[FR Doc. 2010–17357 Filed 7–15–10; 8:45 am]

BILLING CODE 4163–70–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

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 meetings.

The meetings 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: Center for Scientific Review Special Emphasis Panel; Small Business: AIDS/HIV Small Business Innovative Research Applications.

Date: July 29, 2010.

Time: 1 p.m. to 4 p.m.

Agenda: To review and evaluate grant applications.

Place: Bethesda North Marriott Hotel & Conference Center, 5701 Marinelli Road, Bethesda, MD 20852.

Contact Person: Mark P. Rubert, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5218, MSC 7852, Bethesda, MD 20892, 301–435–1775, *rubertm@csr.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.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Nutrition and Diabetes.

Date: August 2–3, 2010.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Reed A. Graves, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6166, MSC 7892, Bethesda, MD 20892, (301) 402–6297, *gravesr@csr.nih.gov*.

This notice is being published less than 15 days prior to the meeting due to the timing