

relating to the safety of regulated medical devices and radiation-emitting products. FDA must conduct needed research to ensure that such programs have the highest likelihood of being effective. Improving communications about medical devices and radiation-emitting products will involve many research methods, including individual in-depth interviews, mall-intercept interviews, focus groups, self-administered surveys, gatekeeper reviews, and omnibus telephone surveys.

The information collected will serve three major purposes. First, as formative research it will provide critical knowledge needed about target audiences to develop messages and campaigns about medical device and radiation-emitting product use. Knowledge of consumer and health care professional decisionmaking processes will provide the better understanding of target audiences that FDA needs to design effective communication strategies, messages, and labels. These communications will aim to improve

public understanding of the risks and benefits of using medical devices and radiation-emitting products by providing users with a better context in which to place risk information more completely.

Second, as initial testing, it will allow FDA to assess the potential effectiveness of messages and materials in reaching and successfully communicating with their intended audiences. Testing messages with a sample of the target audience will allow FDA to refine messages while still in the developmental stage. Respondents will be asked to give their reaction to the messages in either individual or group settings.

Third, as evaluative research, it will allow FDA to ascertain the effectiveness of the messages and the distribution method of these messages in achieving the objectives of the message campaign. Evaluation of campaigns is a vital link in continuous improvement of communications at FDA.

Annually, FDA projects about 30 studies using a variety of research

methods and lasting an average of 0.17 hours each (varying from 0.08–1.5 hours). The operating and maintenance costs include contractor expenses for designing and conducting information collection activities, specifically, drawing samples, training interviewers, collecting and analyzing information, and reporting and disseminating findings. FDA estimates the burden of this collection of information based on prior recent experience with the various types of data collection methods described earlier. FDA is requesting this burden so as not to restrict the Agency's ability to gather information on public sentiment for its proposals in its regulatory and communications programs.

In the **Federal Register** of July 13, 2010 (75 FR 39952), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received one comment, however it was not related to the collection of information.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

Anticipated data collection methods	Number of respondents	Annual frequency per response	Total annual responses	Hours per response	Total hours
Individual in-depth interviews .....	360	1	360	.75	270
General public focus group interviews .....	144	1	144	1.5	216
Intercept interviews: Central location .....	600	1	600	.25	150
Intercept interviews: Telephone .....	10,000 <sup>2</sup>	1	10,000	.08	800
Self-administered surveys .....	2,400	1	2,400	.25	600
Gatekeeper reviews .....	400	1	400	.50	200
Omnibus surveys .....	2,400	1	2,400	.17	408
<b>Total (general public) .....</b>	<b>16,304</b>		<b>16,304</b>		<b>2,644</b>
Physician focus group interviews .....	144	1	144	1.5	216
<b>Total (physician) .....</b>	<b>144</b>		<b>144</b>		<b>216</b>
<b>Total (overall) .....</b>	<b>16,448</b>		<b>16,448</b>		<b>2,860</b>

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

<sup>2</sup> Brief interviews with callers to test message concepts and strategies following their call-in request to an FDA Center 1-800 number.

Dated: October 13, 2010.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

#### Disease, Disability, and Injury Prevention and Control Special Emphasis Panel: Notice of Charter Renewal

This gives notice under the Federal Advisory Committee Act (Pub. L. 92-463) of October 6, 1972, that Disease, Disability, and Injury Prevention and Control Special Emphasis Panel, Centers for Disease Control and Prevention, Department of Health and Human

Services, has been renewed for a 2-year period through September 18, 2012.

For information, contact Gladys G. Lewellen, M.B.A., M.P.A., Designated Federal Officer, Disease, Disability, and Injury Prevention and Control Special Emphasis Panel, Centers for Disease Control and Prevention, Department of Health and Human Services, 1600 Clifton Road, NE., Mailstop E11, Atlanta, Georgia 30333, telephone (404) 498-1519 or fax (404) 498-1541.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee

management activities, for both CDC and the Agency for Toxic Substances and Disease Registry.

Dated: October 8, 2010.

**Elaine L. Baker,**

*Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.*

[FR Doc. 2010-26114 Filed 10-15-10; 8:45 am]

**BILLING CODE 4163-18-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.

#### Prevention and Treatment of Herpes Virus Infection by Inhibition of the JMJD2 Family of Histone Demethylases

*Description of Invention:* Investigators at the NIH have discovered a potential means for preventing or treating a herpes virus infection by inhibiting the activity of the host cell's histone demethylases. When herpesviruses enter a cell, they are inactivated by cellular defense mechanisms that wrap the viral genome in repressive chromatin structures. In order for viral replication to progress, the host's own histone demethylases are recruited to the viral genome to reverse this repression. In a preceding invention, the laboratory disclosed that viral replication and reactivation can be significantly reduced through inhibition

of the histone demethylase LSD1 using Mono-Amino Oxidase Inhibitors (MAOIs); drugs that are in clinical use. The current invention further discloses that inhibition of a second set of histone demethylases (JMJD2 family) using a specific JMJD2 inhibitor, dimethylloxaloylglycine (DMOG), also results in significant repression of herpes viral replication.

Either alone or in combination, small molecule inhibition of LSD1 and the JMJD2 family present novel approaches for preventing herpes virus infection and halting viral reactivation that can lead to a disease that ranges from mild core sores to herpesvirus keratitis and life-threatening encephalitis. Additionally, chromatin-mediated repression of viral genomes and the requirement to de-repress these genomes for productive infection appears to be general to herpesviruses. Therefore, this treatment could also be applicable to chicken pox, shingles, CMV disease, mononucleosis, and Kaposi's sarcoma.

*Applications:* Prevention or treatment of infection by herpes simplex virus and other diseases caused by herpesviruses (i.e. Epstein-Barr virus, cytomegalovirus, varicella zoster, and Kaposi's sarcoma-associated herpesvirus).

*Advantage:* Inhibition of histone demethylases provides an alternative pathway for repressing herpes virus infection as compared to purine analog antivirals. While purine analogs are the most widely prescribed treatment for herpes infection, drug resistance is prevalent. Additionally, inhibition of histone demethylases results in no expression of viral gene products; in contrast to DNA replication inhibitors.

#### *Development Status:*

- Early-stage development
- Pre-clinical data available for mice
- Further pre-clinical and clinical development is needed

#### *Market:*

• Genital herpes can result from infection with either HSV type 2 or type 1, mainly by HSV type 2 in the U.S., which typically causes more recurrent and severe manifestations of the disease.

• According to the Centers for Disease Control and Prevention, nationwide, 16.2%, or about one out of six, people 14 to 49 years of age have genital HSV-2 infection.

• HSV keratitis is the most frequent cause of corneal blindness in the United States.

*Inventors:* Thomas Kristie et al. (NIAID)

*Publications:* None related to this invention available at this time.

*Patent Status:* U.S. Provisional Application No. 61/366,563 filed 22 Jul 2010 (HHS Reference No. E-184-2010/0-US-01).

*Related Technologies:* "Use of Mono-Amine Oxidase Inhibitors to Prevent Herpes Virus Infections and Reactivation from Latency"—HHS Reference No. E-275-2008/2-PCT-02.

*Licensing Status:* Available for licensing.

#### *Licensing Contacts:*

- Eric W. Odom, PhD; 301-435-5009; [odome@mail.nih.gov](mailto:odome@mail.nih.gov).
- Susan O. Ano, PhD; 301-435-5515; [anos@mail.nih.gov](mailto:anos@mail.nih.gov).

#### *Collaborative Research Opportunity:*

The NIAID Laboratory of Viral Diseases is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize prevention and treatment of viral diseases. Please contact Thomas Kristie, PhD at 301.496.3854 or [tkristie@niaid.nih.gov](mailto:tkristie@niaid.nih.gov) for more information.

#### Treatment of Inflammatory Bowel Disease (IBD) Using IL-13 Modulators and Inhibitors

*Description of Invention:* Ulcerative colitis (UC), a chronic inflammatory disease of the colorectum, affects approximately 400,000 people in the United States. The cause of UC is not known, although an abnormal immunological response to bacterial antigens in the gut microflora is thought to be involved. Available for licensing are broad claims covering (1) treatments preventing the inflammatory response of colitis by modulating IL-13 and Natural Killer T cell (NKT) activity and (2) methods for screening for therapeutic compounds effective for colitis. NIH scientists and their collaborators have used a mouse model of experimental colitis (oxazolone colitis, OC) to show that IL-13, a Th2 cytokine, is a significant pathologic factor in OC and that neutralizing IL-13 in these animals effectively prevents colitis. Inflammation in this mouse model has also been shown to be effectively blocked by neutralizing IL-13 or by inhibiting the activation of NK-T cells through CD1.

Oxazolone colitis (OC) is a colitis induced by intrarectal administration of a relatively low dose of the haptening agent oxazolone subsequent to skin sensitization with oxazolone. A highly reproducible and chronic colonic inflammation is obtained that is histologically similar to human ulcerative colitis. Studies show that NKT cells, rather than conventional CD4+T cells, mediate oxazolone colitis,