

for treatment of neuropsychiatric indications.

DATES: Only written comments and/or applications for a license that are received by the NIH Office of Technology Transfer on or before February 5, 2015 will be considered.

ADDRESSES: Requests for a copy of the patent application, inquiries, comments and other materials relating to the contemplated Start-Up Exclusive license should be directed to: Susan Ano, Ph.D., Branch Chief, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852-3804; Telephone: (301) 435-5515; Facsimile: (301) 402-0220; Email: anos@mail.nih.gov.

SUPPLEMENTARY INFORMATION:

The subject invention describes the use of scopolamine for the treatment of depression, including major depressive disorder. Scopolamine is a known compound that has been employed in the treatment of nausea and motion sickness, as well as in conjunction with analgesics but the suitability of scopolamine for treating depression was unrecognized prior to this invention.

An important feature of scopolamine, as a treatment for depression, is its fast-acting nature. Currently available treatments can be ineffective in certain depression patients and typically do not show an effect in any patient until four weeks after first administration. However, preclinical data suggests that scopolamine has a rapid, wide-ranging and long lasting effect. This feature makes scopolamine highly desirable as a new treatment for depression.

The prospective Start-Up Exclusive License Agreement is being considered under the small business initiative launched on October 1, 2011 and complies with the terms and conditions of 35 U.S.C. 209 and 37 CFR 404. The prospective exclusive license may be granted unless within fifteen (15) days from the date of this published notice, the NIH receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR 404. Complete applications for a license in the prospective field of use that are filed in response to this notice will be treated as objections to the grant of the contemplated Start-Up Exclusive Patent License. Comments

and objections submitted in response to this notice will not be made available for public inspection, and, to the extent permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C. 552.

Dated: January 13, 2015.

Richard U. Rodriguez,

Acting Director, Office of Technology Transfer, National Institutes of Health.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 concerning opportunity for public comment on proposed collections of information, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the information collection plans, call the SAMHSA Reports Clearance Officer on (240) 276-1243.

Comments are invited on: (a) Whether the proposed collections of information are necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: Substance Abuse and Mental Health Data Archive (SAMHDA) Data Portal Applications—In Use Without Approval

The Substance Abuse and Mental Health Administration (SAMHSA),

Center for Behavioral Health Statistics and Quality (CBHSQ) funded the SAMHDA contract to promote the access and use of the nation's substance abuse and mental health data on December 3rd, 1997. This includes public-use data files, file documentation, and access to restricted-use data files to support a better understanding of this critical area of public health. As a part of the SAMHDA initiative, the Data Portal was created and launched in January of 2013. The Data Portal provides researchers that need access to restricted-use data remote access to confidential data via a virtual desktop from a secure, approved location. Completions of an application process and project approval are required for Data Portal access. The information being collected in this needs assessment will provide CBHSQ the information required to determine whether a researcher is qualified to obtain access to the Data Portal, and restricted-use data collected under the Confidential Information Protection and Statistical Efficiency Act (CIPSEA).

Description of Forms: Applications will include 18 questions and require the submission of CV's. The application asks for information including the name of the organization that the researcher belongs to, name, title and contact information of the researcher and all subsequent researchers on the team, summaries of each applicants experience with restricted data and their CV's, descriptions of the proposed research projects and methodology, what data is being requested and why, and any potential restricted variables that may be requested.

Description of Respondents: The respondent universe for this data collection effort is researchers with a need for access to CBHSQ restricted-use data. These data include the National Survey on Drug Use and Health (NSDUH), the Drug Abuse Warning Network (DAWN), and NSDUH/DAWN supplement data. Respondents are researchers that have a need and want to provide this information. There are open calls for applications that occur 2 times a year, and applications are accepted during a month long period. Anyone may apply.

TABLE 1—ANNUAL BURDEN ESTIMATE

| Form name | Number of respondents | Annual responses per respondent | Total annual responses | Hours per response | Total annual hour burden |
|------------------------------------------------|-----------------------|---------------------------------|------------------------|--------------------|--------------------------|
| Data Portal Application Needs Assessment | 100 | 1 | 100 | 5 | 500 |

Send comments to Summer King, SAMHSA Reports Clearance Officer, Room 2–1057, One Choke Cherry Road, Rockville, MD 20857 or email her a copy at summer.king@samhsa.hhs.gov. Written comments should be received by March 23, 2015.

Summer King,
Statistician.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Proposed Collection; Comment Request

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Proposed Project: National Evaluation of the Comprehensive Community Mental Health Services for Children and Their Families Program: Phase VI (OMB No. 0930–0307)—Revision

The Substance Abuse and Mental Health Services Administration (SAMHSA), Center of Mental Health Services is responsible for the national evaluation of the Comprehensive Community Mental Health Services for Children and Their Families Program (Children's Mental Health Initiative—CMHI) that will collect data on child mental health outcomes, family life, and service system development. Data will be collected on nine (9) service systems, and approximately 2,106 children and families and providers/administrators, using 26 instruments. Data collection will be decreased by 26,960 hours due to program changes resulting from the closing of 19 communities funded in FY 2009 that no longer require data collection and data collection for the Sector and Comparison Study.

Data collection for this evaluation will be conducted over the next 3-year period. Child and family outcomes of interest will be collected at intake and at 6-month follow-up. The individual families will participate in the study for the remaining 12 months. The outcome measures include the following: Child symptomatology and functioning, family functioning, satisfaction, and caregiver strain. The service system data will be collected every 6 months during the remaining 3 years of the evaluation. Service utilization and cost data will be tracked and submitted to the national evaluation every 6 months using two tools—the Flex Fund Tool and the Services and Costs Data Tool—to estimate average cost of treatment per child, distribution of costs, and allocation of costs across service categories. Service delivery and system variables of interest include the following: Maturity of system of care development in funded system of care communities, adherence to the system of care program model, and client service experience. Internet-based technology such as data entry and management tools will be used in this evaluation. The measures of the national evaluation address annual

Congressional reporting requirements of the program's authorizing legislation, and the national outcome measures for mental health programs as currently established by SAMHSA.

Changes:

The previously approved Phase VI evaluation is composed of six core study components: (1) The System of Care Assessment that documents the development of systems of care through site visits conducted every 12–18 months; (2) the Cross-Sectional Descriptive Study that collects descriptive data on all children and families who enter the CMHS-funded systems of care throughout the funding period; (3) the Child and Family Outcome Study that collects data longitudinally on child clinical and functional status, and family outcomes; (4) the Service Experience Study that collects data on family experience and satisfaction with services from a sample of children and families; (5) the Services and Costs Study that assesses the costs and cost-effectiveness of system of care services; and (6) the Sustainability Study, as well as and three special studies: the Alumni Networking Study, the Continuous Quality Improvement (CQI) Initiative Evaluation, and the Sector and Comparison Study. Earlier revisions eliminated one of the core studies, the Sustainability Study, and two of the special studies: the Alumni Networking Study and the Continuous Quality Improvement (CQI) Initiative Evaluation.

This revision requests the elimination of the Sector and Comparison Study. The eliminated studies have provided data to the program and are no longer needed. The Sector and Comparison Study was conducted with a subsample of the FY 2008-funded CA awardees, which are not included in this revision.

The average annual respondent burden is estimated below. The estimate reflects the average number of respondents in each respondent category, the average number of responses per respondent per year, the average length of time it will take to complete each response, and the total average annual burden for each category of respondent, and for all categories of respondents combined.