completely rescued by basolateral addition of IFN-gamma. These results suggest that IFN-gamma can be used to reduce adverse events (retinal edema) associated with the therapeutic use of MEKis.

Potential Commercial Applications: Treatment for or prevention of adverse side effects in cancer patients undergoing MEK inhibitor therapy.

Competitive Advantages: A simple and unique mode of reducing or eliminating ocular side effects in cancer patients undergoing treatments with MEK inhibitors.

Development Stage:

- Early-stage.
- In vitro data available.

Inventors: Sheldon S. Miller (NEI), Arvydas Maminishkis (NEI), Charlotte E. Remé (Merck KGaA).

Intellectual Property: HHS Reference No. E–248–2012/0—

- US Provisional Application No. 61/721,810 filed 02 Nov 2012.
- PCT Patent Application No. PCT/US2013/068056 filed 01 Nov 2013.

Related Technologies: HHS Reference No. E–169–2008/0—

- US Patent No. 8,697,046 issued 15 Apr 2014 (Methods of Administering Interferon Gamma to Absorb Fluid From the Subretinal Space; Li R, et al.).
- US Patent Application No. 14/252,489 filed 14 Apr 2014.

Licensing Contact: Suryanarayana Vepa, Ph.D., J.D.; 301–435–5020; *vepas@mail.nih.gov.*

Lubiprostone To Treat Retinal Diseases Associated With Fluid Accumulation in Retina & Subretinal Space

Description of Technology: Use of Lubiprostone for treating age-related macular degeneration, chronic macular edema, diabetic retinopathy, retinal detachment, glaucoma, or uveitis by decreasing excess fluid accumulation in the retina and/or subretinal space (SRS) is described. The retinal pigment epithelium (RPE) is a highly pigmented, terminally differentiated monolayer of cells at the back of the eye. The RPE performs numerous processes that are critical for the maintenance of photoreceptor cell health and function. The pathological accumulation of fluid beneath the RPE is a symptom and a contributing factor in the loss of vision in a variety of ocular conditions. Previously, the inventors have shown that human RPE contains apical and basolateral membrane receptors that can be activated to increase cell cAMP or Ca followed by basolateral membrane activation of CFTR or Ca-activated chloride channels resulting in a clinically significant increase in fluid absorption across the RPE. For the first time, using human RPE *in vitro,* the inventors demonstrated that lubiprostone can increase fluid transport from the retinal to the choroidal side of the RPE by activating CLC–2 at the RPE basolateral membrane. Further, they also showed that this increase can be blocked by addition of methadone, a specific CLC–2 channel blocker. Lubiprostone added from either the apical or basolateral side of the epithelium. Methadone also increased transepithelial potential (TEP) and this increase is consistent with a lubiprostone-induced increase in basolateral membrane CLC–2 conductance and subsequent membrane depolarization. These results suggest lubiprostone can be a therapeutic in retinal disease to increase fluid absorption from retina and subretinal space.

Potential Commercial Applications: Treatment for or prevention of age-related macular degeneration, chronic macular edema, diabetic retinopathy, retinal detachment, glaucoma, or uveitis by decreasing the amount of fluid present in the subretinal space (SRS).

Competitive Advantages: A simple and novel therapeutic for retinal diseases characterized by the abnormal fluid accumulation in subretinal space.

Development Stage:

- Early-stage.
- In vitro data available.

Inventors: Sheldon S. Miller, Arvydas Maminishkis, Jeffrey Adijanto, Tina M. Banzon, and Qin Wan (all of NEI).

Intellectual Property: HHS Reference No. E–283–2012/0—

- U.S. Provisional Application No. 61/777,073 filed 12 Mar 2013.
- PCT Patent Application No. PCT/US2014/024724 filed 12 Mar 2014.

Related Technology: HHS Reference No. E–169–2008/0—

- U.S. Patent No. 8,697,046 issued 15 Apr 2014 (Methods of Administering Interferon Gamma to Absorb Fluid From the Subretinal Space; Li R, et al.).
- U.S. Patent Application No. 14/252,489 filed 14 Apr 2014.

Licensing Contact: Suryanarayana Vepa, Ph.D., J.D.; 301–435–5020; *vepas@mail.nih.gov*.

Dated: March 7, 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: Family Treatment Drug Court Services Evaluation (OMB No. 0930–0330)—REINSTATEMENT

In 2010, the Substance Abuse and Mental Health Services Administration (SAMHSA), Center for Substance Abuse Treatment (CSAT), provided funding to 12 existing Family Treatment Drug Courts (FTDCs) for enhancement and/or expansion of their FTDC's capabilities to provide psycho-social, emotional and mental health services to children (0–17 years) and their families who have methamphetamine use disorders and involvement in child protective services. This program was authorized in House Report 111–220 accompanying HR 3293 in 2010. The Committee language stated that ''these grants will support a collaborative approach, including treatment providers, child welfare specialists, and judges, to provide community-based social services for the children of methamphetamine-addicted parents,'' and were to be awarded to Family Dependency Treatment Drug Courts.

SAMHSA is requesting to reinstate OMB approval of instruments used in the Children Affected by Methamphetamine (CAM) grant program through 2020 for a new cohort of grantees under the new program name of Family Treatment Drug Courts, or FTDCs. The continued use of these instruments will allow SAMHSA to collect data on The FTDC grantees that is not otherwise captured: The national evaluation of the FTDC project will collect data on: (1) Child Outcomes; (2) Parent/Caregiver Outcomes; and (3) Family Functioning. The results from this data collection will serve to inform future decisions regarding funding by SAMHSA as well as establish an evidence base for the practices undertaken for other localities and programs implementing Family Treatment Drug Courts. The overall reporting burden is estimated at 720.5 hours.

Providing children's services in an FTDC was a new activity for FTDCs and the grantees. The purpose of the evaluation was to monitor the grantees progress and to measure their performance on child, family and adult outcomes. These outcomes were compared to referent data available at the local and/or State level, and to pre-post measures for family functioning. Previous data collection efforts have measured occurrence of maltreatment and substance exposed newborns, The child/youth indicators related to permanency assess whether they remain in their home, the length of stay in foster care (if they are out of their home), the proportion who re-enter foster care, the proportion who were reunified, the length of time to reunification and whether the children and youth exit services with adoption or legal guardianship if they are not reunified with their parents. The adult indicators related to recovery include substance use, access to treatment, treatment outcomes, employment and criminal behavior. The results of the evaluations were used by grantees to measure the progress of their programs, and aided their efforts to sustain the activities once the grants ended.

To the greatest extent possible, the data elements are operationally defined using standard definitions in child welfare and substance abuse treatment. *The use of standard data definitions will reduce the data collection burden on grantees as these variables are collected through data collection procedures that currently exist through all publically funded child welfare and substance abuse treatment systems.* The FTDC performance measures are data currently collected by programs as part of their normal operations (*e.g.,* placement status in child welfare services, substance abuse treatment entry dates). Thus, minimal data collection from clients will be required as the grantees will be abstracting existing data. The only new information collected will be from the North Carolina Family Assessment Scale (NCFAS) assessment obtained from participants during the intake and discharge interviews. If needed, the FTDC staff member may supplement this information by obtaining information from other staff that interact with the client (*i.e.,* the social worker familiar with the family) or during a home visit (if this is part of their program activities).

It should be re-emphasized that the FTDC projects are expansions or enhancements of FTDC partnerships that currently have existing relationships (and information sharing/confidentiality agreements) in place. It is through this existing information sharing forum that the FTDC grantees will be able to obtain the requisite child welfare and substance abuse treatment performance measures. The grantees will use electronic abstraction and secondary data collection for elements that are already being collected by counties and States in their reporting requirements of Federally-mandated data.

Table 1 presents the estimated total cost burden associated with the collection of the FTDC data elements. The following estimates represent the number of anticipated participants based on experience with the previous CAM program. There are two sources of data collection burden for the performance system. First, FTDC staff extracts data from secondary sources for the child, parent/caregiver and family functioning data elements for biannual data uploads. The total number of responses is two per year; with each upload taking approximately 16 hours at each site. In addition to the data extraction, FTDC staff will complete 2 administrations (intake and discharge) of the NCFAS for each family (approximately 267 families per year based on estimates extrapolated from the CAM program). The NCFAS takes approximately .75 hours to complete per family per administration. The estimated total cost of the time FTDC staff will spend completing data collection is $15,952 per year (total number of staff hours, 720.5 hours, multiplied by $22.14, the estimated average hourly wages for social work professionals as published by the Bureau of Labor Statistics, 2013). See Table 1.

TABLE 1—ANNUALIZED HOUR BURDEN

Form/instrument	Number of records	Responses per record	Total responses	Hours per response	Total hour burden
FTDC Form—Biannual extraction of extant data x 10 grantees	10	2	20	16	320
NCFAS—Administered twice for each family	267	2	534	.75	400.5
Total	277		554		720.5

Note: The estimated response burden includes the extractions and uploads to the FTDC Form and administration the North Carolina Family Assessment Form.

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 June 9, 2015.

Summer King,

Statistician.

[FR Doc. 2015–08272 Filed 4–9–15; 8:45 am]

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