

National Center for Advancing Translational Sciences, NIH, 9800 Medical Center Drive, Rockville, MD 20850, Phone: 301-827-7181, or email sury.vepa@nih.gov. A signed Confidential Disclosure Agreement will be required to receive copies of unpublished patent applications.

SUPPLEMENTARY INFORMATION:
Technology description follows.

Thiazole Based Inhibitors of Lactate Dehydrogenase (LDH) for the Treatment of Cancer

Description of Technology: Agents that target enzymes involved in cancer cell metabolism offer an attractive therapeutic route in view of the potential to preferentially target cancer tissue over normal tissue. While normal tissue typically uses glycolysis as a major cellular metabolic path only when the oxygen supply is low, cancer tissue relies heavily on aerobic glycolysis regardless of the oxygen supply level. In addition, metabolic switching to a more glycolytic phenotype is a required step with inflammatory cells and other pathologies which require activated glycolysis in their metabolism. Lactate dehydrogenase (LDH) is involved in the final step of glycolysis, in which pyruvate is converted to lactate and the conversion of NADH to NAD⁺. There are two different genes of LDH, LDHA and LDHB, but both proteins (subunits) have the same active site and catalyze the conversion of pyruvate to lactate or lactate to pyruvate. In cancer patients, serum total lactate dehydrogenase (levels are often increased, and the gene for LDH, is up-regulated. LDH inhibition is expected to reduce the ability of the cell to effectively metabolize glucose and reduce tumor cell proliferation and tumor growth and other pathologies which involve a glycolytic metabolic switch. Thus, compounds that inhibit LDH activity have potential for the development of anti-cancer therapeutics. Previously developed LDH inhibitors have significant drawbacks, including poor potency and/or poor bioavailability, limiting their utility as therapeutics. The present technology provides novel 1 H-PYRAZOL-1 -YL-THIAZOLE based LDH inhibitors with improved potency, selectivity, and/or bioavailability for the treatment of cancer.

This technology is available for licensing for commercial development in accordance with 35 U.S.C. 209 and 37 CFR part 404, as well as for further development and evaluation under a research collaboration.

Potential Commercial Applications:

- Novel therapeutics for cancer AND indications which depend on a

metabolic switch to glycolysis (e.g., inflammation, autoimmune disease, etc.)

Competitive Advantages:

- Novel LDH inhibitors with improved potency, selectivity, and/or bioavailability for the treatment of cancer.

Development Stage:

- Optimized lactate dehydrogenase inhibitors are in pre-clinical development.

Inventors:

- David J. Maloney, Alex Gregory Waterson, Ganesha Rai Bantukallu, Kyle Ryan Brimacombe, Plamen Christov, Chi V. Dang, Victor M. Darley-Usmar, Matthew Hall, Xin Hu, Ajit Jadhav, Somnath Jana, Kwangho Kim, William J. Moore, Brian T. Mott, Leonard M. Neckers, Anton Simeonov, Gary Allen Sulikowski, Daniel Jason URBAN, and Shyh Ming Yang.

Publications: This manuscript reports early compounds in the series: <https://pubs.acs.org/doi/10.1021/acs.jmedchem.7b00941>.

Intellectual Property: 1. SMALL MOLECULE INHIBITORS OF LACTATE DEHYDROGENASE AND METHODS OF USE THERE OF, PCT/US2015/067895 filed on December 29, 2015 and published as WO 2016/109559 on July 7, 2016 (HHS Ref. No. E-244-2014), and 2. 1 H-PYRAZOL-1 -YL-THIAZOLES AS INHIBITORS OF LACTATE DEHYDROGENASE AND METHODS OF USE THERE OF, PCP/US2017/040021 filed on June 29, 2017 and published as WO 2018/005807 on January 8, 2018 9HHS Ref. No. E-190-2016).

Related Intellectual Property: HHS Reference Number E-293-2011.

Licensing Contact: Sury Vepa, Ph.D., J.D., 301-827-7181; sury.vepa@nih.gov.

Dated: July 5, 2018.

Lili Portilla,

*Technology Development Coordinator,
National Center for Advancing Translational Sciences.*

[FR Doc. 2018-15907 Filed 7-24-18; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish a summary of information collection requests under

OMB review, in compliance with the Paperwork Reduction Act (44 U.S.C. chapter 35). To request a copy of these documents, call the SAMHSA Reports Clearance Officer on (240) 276-1243.

Project: Projects for Assistance in Transition From Homelessness (PATH) Program Annual Report (OMB No. 0930-0205)—Revision

The Center for Mental Health Services awards grants each fiscal year to each of the states, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands from allotments authorized under the PATH program established by Public Law 101-645, 42 U.S.C. 290cc-21 *et seq.*, the Stewart B. McKinney Homeless Assistance Amendments Act of 1990 (section 521 *et seq.* of the Public Health Service (PHS) Act) and the 21st Century Cures Act (Pub. L. 114-255). Section 522 of the PHS Act and the 21st Century Cures Act require that the grantee states and territories must expend their payments under the Act solely for making grants to political subdivisions of the state, and to nonprofit private entities (including community-based veterans' organizations and other community organizations) for the purpose of providing services specified in the Act. Available funding is allotted in accordance with the formula provision of section 524 of the PHS Act.

This submission is for a revision of the current approval of the annual grantee reporting requirements. Section 528 of the PHS Act and the 21st Century Cures Act specify that not later than January 31 of each fiscal year, a funded entity will prepare and submit a report in such form and containing such information as is determined necessary for securing a record and description of the purposes for which amounts received under section 521 were expended during the preceding fiscal year and of the recipients of such amounts and determining whether such amounts were expended in accordance with statutory provisions.

The proposed changes to the PATH Annual Report are as follows:

1. Reporting on Contacts

To ensure that all contacts made by PATH providers are reflected in the report, a new question has been added that reports out on all contacts provided during the reporting period. The previous PATH Annual Report only reported on contacts through the date of enrollment.

2. Referrals Provided

To align with the HMIS Data Standards, all PATH Referral response categories are now included in the PATH Annual Report.

3. HMIS Data Standards Updates

When needed, field response options and questions have been updated to align with the most recent version of the HMIS Data Standards.

The estimated annual burden for these reporting requirements is summarized in the table below.

Respondents	Number of respondents	Responses per respondent	Burden per response (hrs.)	Total burden
States	56	1	20	1,120
Local provider agencies	487	1	15	7,305
Total	543	8,425

Written comments and recommendations concerning the proposed information collection should be sent by August 24, 2018 to the SAMHSA Desk Officer at the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB). To ensure timely receipt of comments, and to avoid potential delays in OMB's receipt and processing of mail sent through the U.S. Postal Service, commenters are encouraged to submit their comments to OMB via email to: OIRA_Submission@omb.eop.gov. Although commenters are encouraged to send their comments via email, commenters may also fax their comments to: 202-395-7285. Commenters may also mail them to: Office of Management and Budget, Office of Information and Regulatory Affairs, New Executive Office Building, Room 10102, Washington, DC 20503.

Summer King,
Statistician.

[FR Doc. 2018-15825 Filed 7-24-18; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Center for Substance Abuse Treatment: Notice of Meeting

Pursuant to Public Law 92-463, notice is hereby given that the Substance Abuse and Mental Health Services Administration's (SAMHSA's) Center for Substance Abuse Treatment (CSAT) National Advisory Council will meet on September 11, 2018, 2:00 p.m.–3:00 p.m. (EDT) in a closed teleconference meeting.

The meeting will include discussions and evaluations of grant applications reviewed by SAMHSA's Initial Review Groups, and involve an examination of confidential financial and business

information as well as personal information concerning the applicants. Therefore, the meeting will be closed to the public as determined by the SAMHSA Assistant Secretary for Mental Health and Substance Use in accordance with Title 5 U.S.C 552b(c)(4) and (6) and Title 5 U.S.C. App. 2, 10(d).

Meeting information and a roster of Council members may be obtained by accessing the SAMHSA Committee website at <http://www.samhsa.gov/about-us/advisory-councils/csat-national-advisory-council> or by contacting the CSAT National Advisory Council Designated Federal Officer; Tracy Goss (see contact information below).

Council Name: SAMHSA's Center for Substance Abuse Treatment National Advisory Council.

Date/Time/Type: September 11, 2018, 2:00 p.m.–3:00 p.m. EDT, CLOSED.

Place: SAMHSA, 5600 Fishers Lane, Rockville, Maryland 20857.

Contact: Tracy Goss, Designated Federal Officer, CSAT National Advisory Council, 5600 Fishers Lane, Rockville, Maryland 20857 (mail), Telephone: (240) 276-0759, Fax: (240) 276-2252, Email: tracy.goss@samhsa.hhs.gov.

Carlos Castillo,

Committee Management Officer, SAMHSA.

[FR Doc. 2018-15824 Filed 7-24-18; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA-4368-DR; Docket ID FEMA-2018-0001]

New Jersey; Amendment No. 1 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster declaration for the State of New Jersey (FEMA-4368-DR), dated June 8, 2018, and related determinations.

DATES: This amendment was issued July 13, 2018.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW, Washington, DC 20472, (202) 646-2833.

SUPPLEMENTARY INFORMATION: The notice of a major disaster declaration for the State of New Jersey is hereby amended to include the following area among those areas determined to have been adversely affected by the event declared a major disaster by the President in his declaration of June 8, 2018.

Burlington County for Public Assistance.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidially Declared Disaster Areas; 97.049, Presidially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050 Presidially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidially Declared Disasters); 97.039, Hazard Mitigation Grant.

Brock Long,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2018-15840 Filed 7-24-18; 8:45 am]

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