Submission Rights

Upon submission, each participant warrants that he or she is the sole author and owner of the work, and that the work is wholly original and does not infringe on any copyright or any other rights of any third party of which the participant is aware. Participants retain title and full ownership in and to their application. Participants expressly reserve all intellectual property rights (e.g., copyright). However, each participant may be asked to grant to NIDA and others acting on behalf of NIDA, a royalty-free non-exclusive worldwide license to use, copy for use, and display publicly all parts of the application for the purposes of the Challenge. This license includes posting or linking to the application on the official NIDA Web site and making it available for use by the public.

Liability

By participating in this Challenge, participants agree to assume any and all risks and waive claims against the Federal Government and its related entities, except in the case of willful misconduct, for any injury, death, damage, or loss of property, revenue, or profits, whether direct, indirect, or consequential, arising from their participation in the Challenge, whether the injury, death, damage, or loss arises through negligence or otherwise.

Indemnification

By participating in this Challenge, participants agree to indemnify the Federal Government against third party claims for damages arising from or related to Challenge activities.

Insurance

Based on the subject matter of the contest, the type of work that it will possibly require, as well as an analysis of the likelihood of any claims for death, bodily injury, or property damage, or loss potentially resulting from Challenge participation, participants are not required to obtain liability insurance or demonstrate financial responsibility in order to participate in this Challenge.

Privacy, Data Security, Ethics, and Compliance

Participants are required to identify and address privacy and security issues in their proposed projects, and describe specific solutions for meeting them. In addition to complying with appropriate policies, procedures, and protections for data that ensures all privacy requirements and institutional policies are met, use of data should not allow the identification of the individual from whom the data was collected.

Participants are responsible for compliance with all applicable federal, state, local, and institutional laws, regulations, and policy. These may include, but are not limited to, Health Insurance Portability and Accountability Act (HIPAA), HHS Protection of Human Subjects regulations, and FDA regulations. The following links are intended as a starting point for addressing regulatory requirements, but should not be interpreted as a complete list of resources on these issues:

HIPAA

Main link: *http://www.hhs.gov/ocr/privacy/index.html*.

Summary of the HIPAA Privacy Rule: *http://www.hhs.gov/ocr/privacy/hipaa/understanding/summary/index.html*.

Summary of the HIPAA Privacy Rule: *http://www.hhs.gov/ocr/privacy/hipaa/understanding/summary/index.html*.

Summary of the HIPAA Security Rule: *http://www.hhs.gov/ocr/privacy/hipaa/understanding/srsummary.html*.

Human Subjects—HHS

Office for Human Research Protections: *http://www.hhs.gov/ohrp/index.html*.

Protection of Human Subjects Regulations: *http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html*.

Policy & Guidance: *http://www.hhs.gov/ohrp/policy/index.html*.

Institutional Review Boards & Assurances: *http://www.hhs.gov/ohrp/assurances/index.html*.

Human Subjects—U.S. Food and Drug Administration (FDA)

Clinical Trials: *http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/default.htm*.

Office of Good Clinical Practice: *http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/OfficeofScienceandHealthCoordination/ucm2018191*.

Consumer Protection—Federal Trade Commission (FTC)

Bureau of Consumer Protection: *http://business.ftc.gov/privacy-and-security*.

Dated: May 6, 2013.

Nora Volkow,

Director, National Institute on Drug Abuse, National Institutes of Health.

[FR Doc. 2013–11688 Filed 5–15–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Announcement of Requirements and Registration for ''Propose New Ideas For Prescription Drugs Oral Overdose Protection''

Authority: 15 U.S.C. 3719.

SUMMARY: Prescription drug abuse is a growing drug problem for America. The ''*Propose New Ideas For Prescription Drugs Oral Overdose Protection''* is a Challenge to find new and creative ways that diminish or eliminate overconsumption of intact opioid pills. This notice provides information about the requirements and registration for the Challenge.

DATES: (1) Submission Period begins May 13, 2013, 12:01 a.m., EDT.

(2) Submission Period ends June 14, 2013, 11:59 p.m., EDT.

(3) Judging will take place between June 17–June 30, 2013.

(4) Winners will be notified and prizes awarded July 8, 2013.

FOR FURTHER INFORMATION CONTACT: Dr. Elena Koustova, Director, Office of Translational Initiatives and Program Innovations, Office of Director, National Institute on Drug Abuse; NIDA Challenge Manager; NIDA SBIR/STTR Coordinator; Phone: 301–496–8768; email: *koustovae@nida.nih.gov*; *elena.koustova@nih.gov* .

SUPPLEMENTARY INFORMATION:

Subject of Challenge Competition

Prescription drugs are the second-most abused category of drugs in the United States, following marijuana. The most commonly misused prescription drugs fall into three classes:

- Opioids (pain relievers, analgesics) which include oxycodone (OxyContin, Roxicodone), hydrocodone (Vicodin, Lortab), and methadone (Dolophine);
- Central nervous system (CNS) depressants which include butalbital (Fiorinal, Fioricet, Axocet), diazepam (Valium), and alprazolam (Xanax);
- Stimulants which include methylphenidate (Ritalin) and amphetamine/dextroamphetamine (Adderall)

Because prescription drugs are legal, they are easily accessible, often from a home medicine cabinet. The latest report from the National Survey on Drug Use and Health indicates that 70% of people who abuse prescription pain relievers got them from friends or relatives. Surprisingly, the individuals who abuse prescription drugs, particularly teenagers, believe that these

substances are safer than illicit drugs because they are prescribed by a healthcare professional. However, they are just as dangerous and deadly as illegal drugs when used improperly and for non-medical reasons.

The possibility that patients will abuse, become addicted to, or unlawfully channel their prescribed pharmaceuticals to the illicit marketplace is one of the greatest risks associated with prescribing opioid medications in pain management practice. Meanwhile, overdoses from opiate drugs which were once almost always directly linked to illegal heroin use, are now increasingly due to abuse of prescription painkillers.

Prescription pain medication containing opioids can be abused in several ways, crushing the pills to facilitate nasal entry into the body, dissolving the powder in water to create an injectable substance, or taking the pills orally intact (the focus of this Challenge), just to name a few. Pharmaceutical industry and academic researchers are focusing on drug formulations that limit the availability of drugs that can be abused by pill ''crushing,'' injecting and snorting. Abuse of prescription drugs by the means of injection and inhalation can be limited or prevented when those abuse-deterrent formulation technologies are successfully deployed. Unfortunately, the oral (as intended) administration, when the drug delivery system is not altered by the user, can still lead to addiction and accidental overdose. The misuse of prescription drugs by persons who over-consume prescribed medications remains less of a research focus.

NIDA is seeking ideas on how to reduce or eliminate the risk of harm from accidentally or intentionally swallowing too many pills at the same time. NIDA is particularly interested in approaches that deter overdosing on an intact product. This Challenge is a broad question formulated to obtain access to new ideas, similar to a global brainstorm for producing a breakthrough. This Challenge is not looking for ideas to reformulate medication so that an individual would not be able (abuse resistance) or would not want (abuse deterrence) to manipulate the prescription drug.

Submitted ideas should take into consideration that the proposed approach should also maintain the original drug efficacy, be devoid of new safety issues for the intended population, avoid harming a potential abuser, and be economically viable.

This Challenge is in accordance with NIDA's statutory authority, described in 42 U.S.C. 285o. The general purpose of the National Institute on Drug Abuse is the conduct and support of biomedical and behavioral research, health services research, research training and health information dissemination with respect to the prevention of drug abuse and the treatment of drug abusers. This Challenge is also in accordance with NIDA's strategic goals to prevent the initiation of prescription drug abuse and the escalation to addiction in those who have already initiated use. Furthermore, this Challenge will serve as a vehicle to promote cross-cutting priorities identified in a NIDA's current strategic plan to attract new and diverse expertise and experiences in various non-traditional areas to drug abuse research area, including chemistry, physics, bioengineering, and mathematics. Through this Challenge, NIDA hopes that global brainstorming about the stoppage of inappropriate use of prescription medications, which is a major public health challenge for our nation, will produce breakthrough ideas and reinvigorate the addiction research.

Entry Materials

All Entry Materials, including items a. through d., must be submitted to *Challenge.gov* which is an online challenge platform administered by the U.S. General Services Administration (GSA) that empowers the U.S. Government and the public to bring the best ideas and top talent to bear on our nation's most pressing challenges. Access the *www.challenge.gov* Web site and search for ''Propose New Ideas For Prescription Drugs Oral Overdose Protection.''

Other than providing your contact information as described below, please do not submit any other confidential information. Entry Materials should include a technological summary as follows of not more than 5 pages:

a. TITLE PAGE (1 page). Include a title and abstract (<350 words) for the idea. Each person submitting Entry Materials (each referred to herein as a Solver) should include on the title page his or her name, phone and fax numbers, email and mailing address.

b. DESCRIPTION OF THE IDEA (3 pages). Provide a background and outline how your idea would function to limit/eliminate overconsumption of intact opioid tablets. Use detailed descriptions, specifications, supporting precedents, analysis of existing data, drawings, figures, movies, and/or other media to define your proposal clearly. Up to 5 images (.jpg figures), one 3-min video file, or other media files of comparable length can be included.

c. REFERENCES (no page limit). References should be included in your submission, but this section will not count toward the overall page total.

d. WRITTEN CONSENT to the eligibility rules upon or before submitting an entry.

Solver is eligible to submit as many distinct entries as she/he would like; however, each submission must include a complete package, items a through d, as outlined above. All Entry Materials must be in English.

Rules for Participating in the Challenge Competition

To be eligible to win a prize under this Challenge, an individual or entity:

(1) Shall have registered to participate in the Challenge under the rules promulgated by the National Institute on Drug Abuse (NIDA);

(2) Shall have complied with all the requirements under this section;

(3) In the case of a private entity, shall be incorporated in and maintain a primary place of business in the United States;

(4) In the case of an individual, must be at least 18 years old at the time of entry;

(5) Whether participating singly or in a group, individual(s) shall be a citizen(s) or permanent resident(s) of the United States;

(6) May not be a Federal entity or Federal employee acting within the scope of their employment;

(7) Shall not be an HHS employee working on their submission(s) during assigned duty hours;

(8) Shall not be an employee of the National Institutes of Health (NIH); however, employees of other Operating Divisions within HHS (e.g., Centers for Disease Control and Prevention (CDC), Substance Abuse and Mental Services Administration (SAMHSA)) are eligible to participate;

(9) In the case of Federal grantees may not use Federal funds to develop a Challenge submission unless it is consistent with the purpose of their grant award;

(10) In the case of Federal contractors may not use Federal funds from a contract to develop a Challenge submission or to fund efforts in support of a Challenge submission.

An individual or entity shall not be deemed ineligible because the individual or entity used Federal facilities or consulted with Federal employees during the Challenge if the facilities and employees are made available to all individuals and entities participating in the Challenge on an equitable basis.

Process for Registration and Submitting an Entry

To register for this Challenge, Solvers must access the *www.challenge.gov* Web site and search for ''*Propose New Ideas For Prescription Drugs Oral Overdose Protection*.'' A registration link for the Challenge can be found on the landing page under this Challenge description.

Amount of the Prize

Up to three prizes worth a total of $15,000 ($5,000 each) will be awarded to submission(s) that satisfy all the Challenge criteria (below) and receive the highest cumulative scores.

Payment of the Prize

Prizes awarded under this Challenge will be paid by electronic funds transfer and may be subject to Federal income taxes. HHS will comply with the Internal Revenue Service withholding and reporting requirements, where applicable.

Basis Upon Which the Winner Will Be Selected

This Challenge is formulated to elicit new ideas, similar to a global brainstorm for producing a breakthrough. Submissions will be received and reviewed by the judging panel comprised of the experts in the area of prescription drug abuse research and pain management. The judging panel will evaluate each submission based on the following equally-weighted criteria:

1. Scientific foundation for the proposed idea, e.g. well-founded line of thought that is supported by the scientific literature or otherwise found to be accurate;
2. Idea novelty and originality;
3. Potential for development, including whether the submission will or is likely to:

(1) Preserve the original drug efficacy;

(2) Avoid new safety issues for the intended population of pain patients;

(3) Avoid harming a potential abuser;

(4) Be suitable for further research development and be commercially viable.

Scores from each criterion will be weighted equally for a maximum score of 120 (40 points each). Entry Materials from all submissions will be held until after the deadline is reached for a simultaneous review process. The evaluation process will begin by de-identifying the submissions and removing those that are not responsive to this Challenge or not in compliance with all rules of eligibility. NIDA reserves the right to disqualify and remove any submission which is deemed, in the judging panel's discretion, inappropriate, offensive, defamatory, or demeaning. Judges will examine all submissions in accordance with the criteria outlined above and meet to discuss all responsive submissions. Final ranking and recommendations will be determined by a vote.

Additional Information

Submission Rights

Solvers must agree that their submission is their original work, and that all proposed ideas must be the Solver's original effort. The Entry Materials must not violate or infringe the rights of other parties, including, but not limited to privacy, publicity, or intellectual property rights, or material that constitutes copyright or license infringement.

Intellectual Property (IP)

NIDA does not wish to receive or hold any IP related to submitted ideas. Solvers will retain all IP rights; however, each Solver may be asked to grant to NIDA a royalty-free non-exclusive worldwide license to use, copy for use, perform publicly, and display publicly all parts of the submission for the purposes of the Challenge. This statement serves as a notice to Solvers that granting this license to NIDA, if asked, is a condition of participation.

Liability

By participating in this Challenge, Solvers agree to assume any and all risks and waive claims against the Federal Government and its related entities, except in the case of willful misconduct, for any injury, death, damage, or loss of property, revenue, or profits, whether direct, indirect, or consequential, arising from their participation in the Challenge, whether the injury, death, damage, or loss arises through negligence or otherwise.

Indemnification

By participating in this Challenge, Solvers agree to indemnify the Federal Government against third party claims for damages arising from or related to Challenge activities. This statement serves as a notice to Solvers that they are obligated to indemnify the government as a condition of participation.

Insurance

Based on the subject matter of the Challenge, the type of work that it will possibly require, as well as an analysis of the likelihood of any claims for death, bodily injury, or property damage, or loss potentially resulting from Challenge participation, solvers are not required to obtain liability insurance or demonstrate financial responsibility in order to participate in this Challenge.

Dated: May 10, 2013.

Nora Volkow,

Director, National Institute on Drug Abuse, National Institutes of Health.

[FR Doc. 2013–11689 Filed 5–15–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Start-Up Exclusive Evaluation Option License Agreement: In Vitro Diagnostics for Prediction of Therapeutic Efficacy in Cancer and Other Angiogenesis-Mediated Diseases

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: This is notice, in accordance with 35 U.S.C. 209(c)(1) and 37 CFR Part 404.7(a)(1)(i), that the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of a Start-Up Exclusive Evaluation Option License Agreement to Advanced Personalized Diagnostics, LLC, a company having a place of business in Alexandria, Virginia, to practice the inventions embodied in U.S. Provisional Patent Application No. 60/976,732, entitled ''Stably Transfected Multicolored Fluorescent Cells'', filed October 1, 2007 (HHS Ref. No. E–281–2007/0–US–01); U.S. Patent Application No. 12/060,752, entitled ''Multiplex Assay Method for Mixed Cell Populations'', filed April 1, 2008, (HHS Ref. No. E–281–2007/0–US–02); and U.S. Patent Application No. 12/802,666, entitled ''Methods of Monitoring Angiogenesis and Metastasis in Three Dimensional Co-Cultures'', filed June 10, 2010 (HHS Ref. No. E–281–2007/1–US–01). The patent rights in these inventions have been assigned to the Government of the United States of America. The territory of the prospective Start-Up Exclusive Evaluation Option License Agreement may be worldwide, and the field of use may be limited to ''The use of the Licensed Patent Rights limited to an FDA-approved Class III *in vitro* diagnostic device for prediction of therapeutic efficacy in cancer and other angiogenesis-mediated diseases.''

Upon the expiration or termination of the Start-up Exclusive Evaluation Option License Agreement, Advanced Personalized Diagnostics, LLC will have