

suggestions from the public on the activities of the Trans-Atlantic Taskforce on Antimicrobial Resistance (TATFAR).

**DATES:** A public meeting will be held in Bethesda, MD, on Friday, October 1, 2010 from 1:30 to approximately 4:30 p.m. Persons wishing to participate, including those who wish to make an oral presentation, must register in advance and provide a copy of their presentation by noon Friday, September 24, 2010.

**Deadline for Registration for all Attendees:** All Other Attendees must register by noon, Friday, September 24, 2010.

**Deadline for Requests for Special Accommodation:** Requests for special accommodation should be submitted by noon, Friday, September 17, 2010.

**ADDRESSES: Meeting Location:** The public meeting will be held on the Campus of the National Institutes of Health, 9000 Rockville Pike, Building 31, Wing C, Room 6, Bethesda, MD 20892.

**Submission of Written Comments:** Written comments can be e-mailed to [OGHA.OS@HHS.gov](mailto:OGHA.OS@HHS.gov) or sent via regular mail to Elana Clarke, Office of Global Health Affairs, Switzer Building Room 2319, 330 C Street, SW., Washington, DC 20201.

**Registration and Special Accommodations:** Individuals wishing to participate or who need special accommodations or both must register by contacting Elana Clarke at [Elana.Clarke@hhs.gov](mailto:Elana.Clarke@hhs.gov). See Registration To Attend and/or Participate in the Public Hearing for instructions on how to submit electronic notices of participation.

**FOR FURTHER INFORMATION CONTACT:** Elana Clarke at [Elana.Clarke@hhs.gov](mailto:Elana.Clarke@hhs.gov) or 202 260-0443.

**Registration To Attend and/or Participate in the Public Meeting:** To ensure there is sufficient room we ask that you pre-register. If you wish to make an oral presentation during the open public comment period of the hearing, state your intention to present on your registration submission. To register, please send an electronic mail message to [Elana.Clarke@hhs.gov](mailto:Elana.Clarke@hhs.gov) by the deadline listed under **DATES**. Your e-mail should include your name and e-mail address.

Please submit a written statement at the time of registration, identifying each focus area you wish to address and the approximate time requested to make your presentation. Organizations should provide this information as well as the names and e-mail addresses of all participants. Registered individuals will

be notified of the approximate time scheduled for their presentation prior to the meeting. Depending on the number of presentations, HHS may need to limit the time allotted for presentations.

#### **SUPPLEMENTARY INFORMATION:**

##### **1. Background**

On November 3, 2009, the United States and the European Union (EU) agreed to establish a task force to focus "on urgent antimicrobial resistance issues focused on appropriate therapeutic use of antimicrobial drugs in the medical and veterinary communities, prevention of both healthcare- and community-associated drug-resistant infections, and strategies for improving the pipeline of new antimicrobial drugs, which could be better addressed by intensified cooperation." (2009 EU-U.S. Summit Declaration).

The TATFAR is made up of government representatives from the U.S. Department of Health and Human Services for the United States and from the European Commission, European Union agencies, and representatives of three EU member states for the EU. Information about the TATFAR is available at: <http://ecdc.europa.eu/en/activities/diseaseprogrammes/TATFAR/Pages/index.aspx>.

##### **2. Public Comment and Meeting**

The public meeting process provides an opportunity for the public to become aware of the activities of the TATFAR to date. In addition, OGHA invites written comments and/or oral presentations of interested persons on the three focus areas of the TATFAR as defined in the 2009 EU/US Summit Declaration:

- Appropriate therapeutic use of antimicrobial drugs in the medical and veterinary communities,
- Prevention of both healthcare- and community-associated drug-resistant infections, and
- Strategies for improving the pipeline of new antimicrobial drugs.

Comments should identify specific antimicrobial resistance-related activities in these three areas where intensified cooperation between the United States and the European Union could have the most impact, keeping in mind that the work of the TATFAR will be carried out using currently available resources. In particular, input is sought on activities that can be undertaken in the near-term, with a reasonable possibility of completion over the next 12–15 months.

Written comments submitted by e-mail should use the following subject line "TATFAR Comments." Comments

and any documentation may be submitted as Adobe PDF, MSWord or Text (.txt) files. Written comments submitted by regular mail should clearly identify "TATFAR Comments" as the subject.

##### **3. Building and Security Guidelines**

The meeting is being held in a Federal government building; therefore, Federal security measures are applicable. In planning your arrival time, please take account of the need to clear security. All visitors must enter through the NIH Gateway Center and must present government-issued photo identification. All persons entering the building must pass through a metal detector. All items brought to HHS are subject to inspection. For more information on NIH security requirements for visitors, please go to: <http://www.nih.gov/about/visitorsecurity.htm>.

Signed: August 23, 2010.

**Nils Daulaire,**

*Director, Office of Global Health Affairs.*

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**BILLING CODE 4150-38-P**

#### **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

##### **Request for Comments on Synthetic Biology**

**AGENCY:** Department of Health and Human Services, Office of Public Health and Science, The Presidential Commission for the Study of Bioethical Issues.

**ACTION:** Notice.

**SUMMARY:** The Presidential Commission for the Study of Bioethical Issues is requesting public comment on the emerging science of synthetic biology, including its potential applications and risks, as well as appropriate ethical boundaries to assure that America reaps the benefits of this new technology.

**DATES:** To assure consideration, comments must be received by October 1, 2010.

**ADDRESSES:** Individuals, groups, and organizations interested in commenting on this topic may submit comments by e-mail to [info@bioethics.gov](mailto:info@bioethics.gov) or by mail to the following address: Public Commentary, The Presidential Commission for the Study of Bioethical Issues, 1425 New York Ave., NW., Suite C-100, Washington, DC 20005.

**FOR FURTHER INFORMATION CONTACT:** Ms. Diane M. Gianelli, Director of Communications, The Presidential Commission for the Study of Bioethical Issues, 1425 New York Avenue, NW.,

Suite C-100, Washington, DC 20005. Telephone: 202/233-3960. E-mail: [info@bioethics.gov](mailto:info@bioethics.gov). Additional information may be obtained by viewing the Web site: <http://www.bioethics.gov>.

**SUPPLEMENTARY INFORMATION:** On November 24, 2009, the President established the Presidential Commission for the Study of Bioethical Issues to advise him on bioethical issues generated by novel and emerging research in biomedicine and related areas of science and technology. The Commission is charged to identify and promote policies and practices that assure ethically responsible conduct of scientific research, healthcare delivery, and technological innovation. In undertaking these duties, the Commission will identify and examine specific bioethical, legal, and social issues related to potential scientific and technological advances; examine diverse perspectives and possibilities for dynamic international collaboration on these issues, and recommend legal, regulatory, or policy actions as appropriate.

As its first order of business, the Commission has begun an inquiry into the emerging science of synthetic biology. The President asked the Commission to address this topic on May 20, 2010, following the announcement that the J. Craig Venter Institute had successfully engineered a synthetic cell—the insertion into a bacterium of a complete, functional genome synthesized entirely from a digitized sequence that replaced the native genome of the host over a series of replications. Daniel G. Gibson *et al.*, *Creation of a Bacterial Cell Controlled by a Chemically Synthesized Genome*, *Science Express* (May 20, 2010). The President charged the Commission to consider any potential medical, environmental, security, and other benefits, as well as any related risks. Additionally, the President asked the Commission to develop “recommendations about any actions the Federal government should take to ensure that America reaps the benefits of this developing field of science while identifying appropriate ethical boundaries and minimizing identified risks.” The Commission will report back its finding and recommendations later this year.

To begin its work, the Commission convened a public meeting in Washington, DC on July 8–9, 2010. At that meeting, representatives with expertise in science, ethics, and public policy, as well as advocates with diverse perspectives on this new field provided information and insight to help guide

the Commission in its thinking. Leading scientists in the field created context for the discussion by explaining the state of the science and discussing possible applications. Among the anticipated benefits discussed were employing bacterial cells as microscopic factories in the production of pharmaceuticals and biofuels.

Additionally, with regard to potential risks, the Commission heard discussion about possible biosafety, biosecurity and environmental concerns, including risks that may arise as synthetic biology relies on organisms that can evolve and self-replicate, and existing practices to protect against these risks. The Commission also heard discussion about ethical boundaries and the views of faith communities.

As the approaches to, and applications of, synthetic biology proliferate, the Commission wishes to develop a multifaceted understanding of its scientific and technological implications, and learn more about the views of the public on the existing or potential ethical and social ramifications. To this end, the Commission is inviting interested parties to provide input and advice through written comments. Among other issues, the Commission is interested in receiving comments on the potential benefits that the emerging field of synthetic biology is likely to yield, now or in the future, the risks that may arise, the ethical boundaries that should be considered, and policies and strategies to assure that the public will benefit from these new tools and products.

Please address comments by e-mail to [info@bioethics.gov](mailto:info@bioethics.gov), or by mail to the following address: Public Commentary, The Presidential Commission for the Study of Bioethical Issues, 1425 New York Ave., NW., Suite C-100, Washington, DC 20005. Comments will be publicly available, including any personally identifiable or confidential business information that they contain. Trade secrets should not be submitted.

Dated: August 17, 2010.

**Valerie H. Bonham,**

*Executive Director, The Presidential Commission for the Study of Bioethical Issues.*  
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**BILLING CODE 4154-06-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Administration for Children and Families

#### Agency Recordkeeping/Reporting Requirements Under Emergency Review by the Office of Management and Budget (OMB)

*Title:* TANF Emergency Fund Subsidized Employment Report, Form OFA-200.

*OMB No.:* New Collection.

*Description:* On February 17, 2009, the President signed the American Recovery and Reinvestment Act of 2009 (Recovery Act) which establishes the Emergency Contingency Fund for State TANF Programs (Emergency Fund) as section 403(c) of the Social Security Act (the Act). This legislation provides up to \$5 billion to help States, territories, and tribes in fiscal year (FY) 2009 and FY 2010 that have an increase in assistance caseloads or in certain types of expenditures. The Recovery Act also made other changes to TANF—extending supplemental grants through FY 2010, expanding flexibility in the use of TANF funds carried over from one fiscal year to the next, and adding a hold-harmless provision to the caseload reduction credit for States and territories serving more TANF families.

The Emergency Fund is intended to build upon and renew the principles of work and responsibility that underlie successful welfare reform initiatives. The Emergency Fund provides resources to States, territories, and tribes (referred to collectively here as “jurisdictions”) to support work and families during this difficult economic period.

Many jurisdictions are implementing subsidized employment programs as a result of the availability of this new funding, and there is substantial interest in understanding how this funding has been used. There is also significant public interest in the number of individuals that are being placed in subsidized employment as a result of the Recovery Act. As a result, we are proposing a voluntary data collection for jurisdictions regarding information on the number of individuals in subsidized employment funded in whole or in part by the TANF Emergency Fund or that were included in the calculation of a TANF Emergency Fund award. We initially requested emergency clearance to collect this data and posted a **Federal Register** notice on June 8 stating our intent to collect this information and invited comments. As a result of our June 8 notice we received