June 15, 2009

Honorable Kathleen Sebelius
Secretary, Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, DC 20201

RE: HRAC Recommendations on CER

Dear Secretary Sebelius:

In 2006, the American Indian and Alaska Native (AI/AN) Health Research Advisory Council (HRAC or Council) was established to provide the Department of Health and Human Services (HHS) a venue for consulting directly with Tribes about health research priorities and needs in the AI/AN communities and to collaborate on approaches to effectively address their health issues and needs. As an advisory body to the Department, HRAC is comprised of elected Tribal officials (one delegate and alternate from each of the 12 Indian Health Service (IHS) areas and Washington-based Tribal organizations) and has federal partners representing HHS Operating and Staff Divisions.

The American Recovery and Reinvestment Act (ARRA)/CER debate has elicited concern by Tribal health leaders and health care professionals who carry out research in AI/AN communities. Tribal leaders will ask, first, "How will the Obama Executive Branch implement the standing Presidential Executive Order for Tribal consultation (Clinton 2000) and supporting implementation memoranda that require that all Executive agencies ensure that there is "meaningful," and "timely," Tribal input when formulating and implementing the ARRA of 2009, and subsequent Sec. 804 to establish the Federal Coordinating Council (FCC) for Comparative Effectiveness Research (CER)?" Secondly, does the FCC for CER fully understand the special circumstances that Tribes face, which include the inability of Tribal people to access primary, specialty, emergency services and long-term care because of geographic constraints and by the historic and continued under funding of the Indian health care system?

The U.S. Federal government recognizes the debt owed to Tribal governments. The provision of health care to AI/ANs is deemed a federal trust responsibility, and is deeply rooted in the U.S. Constitution's Indian Commerce, Treaty, and Supremacy Clauses. In November, of 2000, President William J. Clinton issued Executive Order #13175, "Consultation and Coordination with Indian Tribal Governments," which directs all Executive Branch departments and agencies to consult with Tribes when formulating and implementing polices or taking other actions like CER, which will have a substantial direct impact on Tribes. More recently, the Department of Health and Human Services (HHS) reissued an earlier "Department Tribal Policy," in January 2005 requiring that "each HHS Operating and Staff Division have an accountable process to ensure

meaningful and timely input by Tribal officials in the development of policies that have Tribal implications." Certainly, the ARRA's CER Policy would be under this umbrella. The FCC for CER is charged to develop recommendations to coordinate research and guide the use of resources contained in ARRA to advance improvement in the U.S. health care system. The HRAC recommendations include:

- Additional time should be allowed to consider developing a Tribal consultation process in order for interested Tribes to provide their input into the FCC/CER plan and implementation.
- An AI/AN representative should be assigned to FCC for CER from the Indian Health Service of the HHS.
- Concentration by CER in the areas of health promotion, disease prevention and community–based interventions will benefit Tribal communities.
- Research on cost effectiveness is needed, but should not outweigh the importance of clinical effectiveness and its benefit to Tribal communities.
- CER studies should be broad enough to include an assessment of minority and disability groups and other smaller populations such as AI/AN populations.
- CER should require that AI/AN identity be defined as enrolled, federally-recognized Tribal citizens rather than self-identification, for data quality.
- IHS should be provided stimulus monies to award research grants.
- Any research opportunities that are open to either state or local health departments or to research universities should also be open to Tribal organizations. Tribal organizations are a critical component of the health research and health care delivery system for AI/AN people. In many cases, Tribal organizations - alone or in partnership with other research institutions - will be best suited to conduct CER among AI/AN people. Without their participation, it is likely that the results of CER will not accurately reflect the AI/AN population.
- The ARRA sets aside money for research that compares the clinical outcomes, effectiveness, and appropriateness of items, services, and procedures that are used to prevent, diagnose, and treat diseases, disorders, and other health conditions. It is important for the AI/AN community that the phrase "items, services, and procedures" be broadly interpreted to include:
    - Traditional healing and practices and other culturally appropriate complementary and alternative treatment.
    - Service aimed at primary prevention such as programs to improve access to healthy food or otherwise promote healthy lifestyles.
- CER should consider establishing separate guidelines and measures for Complementary and Alternative Medicine (CAM) and AI/AN traditional healing and practices, but do not exclude them from future CER consideration.
- CER should include analysis of the comparative effectiveness of the various permutations of IHS system integration and levels of Tribal participation in system governance. *(IHS operates a mixed delivery system that reflects Tribal sovereign choices as to the extent of Tribal participation in the management of these resources under the authorities of the Indian Self Determination Act (PL 93-638 seq. et. al.) The IHS delivery system is additionally distinguished by a*

diversity of levels of system vertical integration independent of levels of Tribal participation.)

- The ARRA sets aside money to encourage the development and use of clinical registries, clinical data networks, and other forms of electronic health data that can be used to generate or obtain outcomes. This is one area where the IHS and Tribal health facilities are well suited to participate. There is a wealth of current and historical data available on both treatments and outcomes for IHS beneficiaries. The Tribal Epidemiology Centers, as well as, Tribal researchers are well suited to make use of this data for CER.

Attached, as an addendum, is the Background for HRAC Recommendations. It serves as justification of the Council's recommendations to CER including IHS's involvement in the FCC and need for future grants funding. Please note, HRAC's recommendations can not substitute, but are in addition to, individual Tribal consultation.

On behalf of the Council, we thank you for your time and consideration of these critical recommendations. We hope that future action will be taken to address the needs of AI/AN health research. Should you have any questions, or need further clarification, we would be happy to meet with you and/or your representatives. Please let us know and we will coordinate.

Sincerely,

Cara Cowan Watts
Co-Chair, AI/AN Health Research Advisory Council
Cherokee Nation Tribal Council Representative
PO Box 2922
Claremore, OK 74018
918-752-4342
cara@caracowan.com

Kathy Hughes
Co-Chair, Health Research Advisory Council
Oneida Tribe of Indians of Wisconsin Vice Chairwoman
PO Box 365
Oneida, WI 54155
920-869-4428
khughes@oneidanation.org

Attach: Background for HRAC Recommendations
Cc: Dr. Garth Graham, Dr. Yvette Roubideaux, Jodi Gillette