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The Honorable Tom Daschle
Special Policy Advisor
Alston & Bird LLP
The Atlantic Building
950 F Street, NW
Washington, DC 20004-1404

Dear Senator Daschle:

The Association of Academic Health Centers (AAHC) congratulates you on your appointment as the U.S. Secretary of Health and Human Services designee for the Obama Administration. We understand the many important issues that you will be addressing in your first days in Washington and offer our strongest support to help accomplish the many tasks before you.

The AAHC is writing to bring to your attention the peril facing the U.S. academic health center research enterprise, which has implications for the U.S. economy for the future. The AAHC wishes to urge the Obama Administration to provide new and visionary leadership for the Medicare program through reform of the policy governing the National Coverage Decision on Clinical Trials (or "Clinical Trial Policy") and the associated Centers for Medicare & Medicaid Services (CMS) administrative structures. The Clinical Trial Policy has not fulfilled its stated purpose and the promise made to the American people in 2000 when President Clinton issued an Executive Memorandum and took action to direct Medicare to pay for the cost of routine patient care for seniors who participated in clinical trials. The dismantling of the clinical trial policy over the years has had a significant impact on the research enterprise, and contributed to the migration of research overseas.

The AAHC, representing more than 100 academic health centers nationwide, is dedicated to advancing health and well-being through the vigorous leadership of academic health centers. As leaders of the biomedical research enterprise, AAHC members have a strong interest in an effective and efficient national clinical trials policy. Towards that end, the AAHC has raised grave concerns about the current Clinical Trial Policy, as well as the associated CMS administrative structures and decision making processes related to that policy, and has actively advocated for remedial change (most recent correspondence attached).

The aging of America's population, and the consequent search for new treatments and cures for cancer and other diseases that disproportionately strike the elderly, highlight the urgent need for an effective and efficient clinical trial policy. The current Clinical Trial Policy established through an executive order in 2000, as interpreted and administered by CMS, threatens access to clinical trials for Medicare beneficiaries and the quality and validity of the trial results. It also endangers the nation's clinical research enterprise that is essential for a strong and growing economy for the United States.

The AAHC urges the Obama Administration to evaluate and reform CMS and the Medicare Clinical Trial Policy in order to remedy major deficiencies in current policy development and CMS operations that have discouraged growth of U.S. clinical research, burdened research with inappropriate rule making, and caused confusion and inconsistent policies within and among government agencies charged with oversight of the nation's research enterprise. Specifically, we believe that the Clinical Trials Policy must be reformed because, in its present state, the policy:

- Compromises the quality and credibility of many research studies by discouraging enrollment of elderly patients in clinical research studies;
- Limits coverage for elderly patients to potentially life-saving therapies and treatments;
- Undermines the financial viability and preeminence of the academic health center research enterprise during a time of economic distress; and
- Increases the likelihood of an adverse impact on the nation's economy and job market.

CMS has not responded to critical operational questions from the academic health centers and has deferred decision-making on key issues to the local contract medical directors, thus perpetuating inconsistent "policy" based on geographic areas as well as pre-denying coverage of routine services that would be paid if the Medicare beneficiary were not in a clinical trial. CMS has failed to construct a viable and credible infrastructure including staff with firsthand knowledge of clinical trials processes and operations. The end result: CMS clinical trial policy does not fit and reflect the real world of science and the conduct of a clinical trial.

The AAHC believes the urgently needed reform of Medicare's Clinical Trial Policy and associated CMS administrative structures and decision making processes should include:

- Immediate change in the current Clinical Trials Policy related to Medicare coverage for Phase I trials and to address all clinical trial policy related guidelines and questions at the national--not local--level;

The Honorable Tom Daschle
December 15, 2008
Page 3

- Assessment of additional changes needed to reflect the advancement of science;
- Establishment of a research coordinator at CMS to oversee clinical research coverage policy; and
- Establishment of an interagency task force within the Department of Health and Human Services to harmonize the conflicting regulations of CMS, the National Institutes of Health, and the Food and Drug Administration regarding clinical trials.
- Establishment of an academic health center advisory forum to exchange information with government officials and to ensure communication on scientific, technical, and operational issues with major institutions conducting clinical trials in the U.S. today.

Thank you for considering these recommendations. While our letter specifically addresses Medicare policy, we also urge that clinical research be considered in any new health reform policy and that all health care plans explicitly cover participation in clinical trials. The AAHC stands ready to assist the new Administration in any way possible to ensure that the intended goal of the clinical research policy—to open essential and necessary realms of treatment to Medicare beneficiaries—can be achieved.

Sincerely,



Steven A. Wartman, MD, PhD
President/CEO

cc: Peter Orszag
Thomas E. Perez