BIO
BIOTECHNOLOGY
INDUSTRY ORGANIZATION

April 2, 2008

***BY ELECTRONIC SUBMISSION***

Maria Ellis
Executive Secretary for MedCAC
Centers for Medicare & Medicaid Services
OCSQ-Coverage and Analysis Group
C1-09-06
7500 Security Blvd.
Baltimore, MD 21244

**Re: Medicare Program; Town Hall Meeting of the Medicare Evidence Development and Coverage Advisory Committee (MedCAC)—April 30, 2008**

Dear Ms. Ellis:

The Biotechnology Industry Organization (BIO) appreciates this opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS) April 30th public meeting of the Medicare Evidence Development & Coverage Committee (MedCAC). CMS' meeting notice states that the purpose of this MedCAC is to "discuss the priorities for clinical research topics that are important for the Medicare program and the Medicare population, and to make recommendations to CMS." CMS states that this meeting is a follow up to the CMS Evidentiary Priorities MedCAC meeting held on October 22, 2007. [1] During the October meeting, panelists developed and rated a list of evidentiary priorities for research to improve the health of Medicare beneficiaries.

BIO is the largest trade organization to serve and represent the biotechnology industry in the United States and around the world. BIO represents more than 1,200 biotechnology companies, academic institutions, state biotechnology centers, and related organizations in the United States. BIO member companies are strongly committed to increasing the body of

[1] 73 Fed. Reg. 11120, 11121 (Feb. 29, 2008).

evidence available regarding diseases and their treatments. Our members invest millions of dollars each year on clinical studies, both before and after Food and Drug Administration (FDA) approval of their products, to produce high-quality clinical evidence to support medical decision-making. We support a rigorous evidence development process that encompasses all aspects of a disease from examining how it affects the body to studying the overall risks and benefits of various approaches to care.

BIO submitted written comments to CMS in response to the announcement of the October 22, 2007 MedCAC meeting expressing our concerns regarding the transparency and clarity of the process, duplication of the existing roles and responsibilities of other agencies, and the inappropriate introduction of cost into the Medicare coverage process.[2] Our comments to the April 30th MedCAC Town Hall Meeting echo a number of these concerns. Though we appreciate CMS' attempts to seek public input on these highly complex questions, BIO remains concerned that the agency is setting a research agenda without clearly outlining the process it intends to follow, or informing of how it plans to apply the results to the Medicare coverage process. Furthermore, we continue to believe that the MedCAC is not an appropriate forum for CMS to receive meaningful advice from expert stakeholders and the public on the far-reaching clinical topics under consideration.

BIO strongly believes that identifying gaps in the medical evidence and encouraging research into unmet clinical needs are worthy and important policy goals. However, undertaking such a monumental task requires a participatory and transparent process that involves all relevant stakeholders. Over the past year, various lawmakers, government bodies, and stakeholder groups have devoted considerable time and resources to identifying ways to develop better evidence to improve health care decision-making. These efforts have been approached in the broader context of improving the overall health care system, and produced constructive dialogue among stakeholders about the best way to accomplish these goals. While BIO acknowledges CMS' important role, improving the medical research framework extends far beyond the agency's needs under the Medicare coverage process. Thus, rather than envisioning the product of the

[2] BIO Letter to Michelle Atkinson, CMS, "Medicare Program; Meeting of the Medicare Evidence Development and Coverage Advisory Committee (MedCAC)—October 22, 2007," September 17, 2007, available at: http://bio.org/healthcare/medicare/20070917.pdf.

April 30th MedCAC as a "final prioritized list," BIO urges CMS to view this as the next iteration in a more expansive process and to seek ways to work with other government entities and the broader stakeholder community to foster greater participation and continued dialogue.

## I. Efforts to Establish a Research Agenda Must Be Conducted Through Open and Transparent Processes

BIO remains concerned with the transparency of CMS' current MedCAC evidentiary priority-setting process. Transparency and predictability are critical to ensuring the credibility and ultimate success of any evidence development activities, and in particular, those related to identifying and establishing research priorities. CMS' Web site for the April 30th MedCAC states the agency held a Federal Evidentiary Priorities Workshop on February 13, 2008 that included representatives from the Centers for Disease Control and Prevention, the Agency for Healthcare Research and Quality (AHRQ), FDA, and the National Institutes of Health. BIO is concerned that this closed Federal Workshop did not benefit from input from outside stakeholders, and that CMS has not released the details of its proceedings, such as a transcript or meeting minutes. This is of particular concern because it appears that the scored list of evidentiary priorities developed at the February 13th Federal Workshop, rather than the list developed at the October 2007 MedCAC, will serve as the basis for the April 30th MedCAC public meeting. BIO encourages CMS to provide additional information regarding the February 13th Federal Workshop, and to ensure that any future priority setting meetings remain open and transparent to all stakeholders.

With regard to the October 22nd meeting, we note the confusion that persisted among the panelists and expert presenters regarding the type of research questions the MedCAC had been tasked to develop—those that reflected CMS' needs as a payer to inform coverage decision-making or those that reflected the greatest evidence gaps facing doctors and patients in clinical practice. CMS notes that it decided to engage in a Medicare evidentiary priority setting process, in part, because the priority conditions developed by AHRQ under Section 1013 of the Medicare Modernization Act "did not include questions about specific items or services," nor did they address "study designs, important health outcomes, and policy issues that may limit the development of medical evidence." The agency also indicates

that the final product of the MedCAC will be a final list of "significant research needs to fulfill CMS' need to make evidence-based coverage decisions."

CMS stated rationale and objectives of the MedCAC, however, are inconsistent with the types of research questions presented for discussion. For example, many of the research questions listed on the MedCAC Evidentiary Priorities List relate to cost and cost-effectiveness of various therapies and health care services. As BIO noted in previous comments, the consideration of cost would be contrary to CMS' own statements about the factors considered in making Medicare coverage determinations.[3] Thus, the extent to which the list of priorities will fulfill CMS' need to make evidence-based coverage decisions remains unclear. BIO again urges CMS to provide stakeholders with a clearer vision and process of how it intends to finalize and list of priorities, and utilize them to inform the agency's Medicare coverage decision-making.

## II. MedCAC Is Not an Appropriate Venue to Receive Meaningful Stakeholder and Public Input on Such Broad Research Topics

BIO remains concerned that the MedCAC is not an appropriate forum through which to engage in a meaningful and robust public dialogue on the relative importance of the diverse clinical research topics up for consideration by the panel. The deficiencies of the MedCAC used for this purpose were shown at the October 22nd meeting, during which several panelists expressed their inability to offer meaningful advice to CMS on such broad research topics that cut across multiple therapeutic areas in which they had little or no expertise. Indeed, the MedCAC's charter says that the Committee's purpose is to provide "guidance and advice to CMS on specific clinical topics under review for Medicare coverage."[4] Here, instead of reviewing data for a specific item, service, or condition, the panelists and public stakeholders are being asked to comment on a wide range of therapies, services, and health care policy issues that cannot be reasonably addressed in the limited time allotted.

[3] BIO Letter to CMS, September 17, 2007
[4] Charter, Medicare Evidence Development & Coverage Advisory Committee, Oct. 17, 2006 (emphasis added).

If CMS wishes to use the MedCAC to identify gaps in knowledge, it should do so by presenting specific conditions or treatments to the panel through the National Coverage Determination (NCD) process. CMS should not use the MedCAC to provide guidance on broad topics, such as the subject of this meeting, because doing so is contrary to the Committee's charter. Asking the MedCAC to comment on this kind of topic also is an ineffective use of the panel's expertise and time. CMS would be better served by convening a panel with expertise on a particular disease or treatment to discuss that specific topic than by asking panelists to address the full range of Medicare services. Rather, the MedCAC process may better service clinical decision-making when focused on a particular disease or treatment.

## III. Discussions of Research Priorities Should Continue to Encompass All Aspects of the Health Care Delivery System

While our concerns with the current process remain, BIO recognizes that CMS has elected to broaden the discussion of Medicare evidentiary priorities to include benefit design, formulary policies, disease management, care coordination, and other aspects of the overall health care delivery system. These important research areas were excluded from consideration at the October 22nd MedCAC meeting, and ultimately left off the list of evidence priorities developed during that session. Numerous studies have shown that these features of the health care system have a profound impact on the ability of patients to access the care they need, and thus, on their health care outcomes. BIO also acknowledges that CMS for including health IT issues, including the use of electronic medical records. We strongly support efforts to promote the adoption of health IT, and believe that it holds great promise to improve the overall efficiency and effectiveness of the health care system through the improvement in care coordination, prevention of medical errors, and reduction in administrative burden. BIO looks forward to working with CMS and other agencies to explore improvements in the way in way care is managed and delivered to Medicare beneficiaries, and to continue to include such topics in future discussions regarding the knowledge gaps in the Medicare program.

## IV. Conclusion

BIO is firmly committed to increasingly the availability of accurate, scientific evidence about diseases and their treatments to inform clinical decision-making, while at the same time, allowing Medicare beneficiaries to have timely access to new innovative therapies. We remain concerned that CMS' MedCAC agenda-setting process lacks the necessary transparency and clarity to ensure that it meets its worthy objectives of identifying evidence gaps to improve health outcomes for Medicare beneficiaries. BIO encourages CMS to view this MedCAC meeting as part of a much larger effort to identify research gaps in the U.S. health care system that will require the continued input of all stakeholders. We thank CMS for the opportunity to raise our issues and concerns. If you have any questions regarding our comments, or would like to further discuss the issues raised, please contact me at 202-312-9281. Thank you for your attention to this important matter.

Respectfully submitted,

/s/

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