September 12, 2016

Steven D. Pearson, M.D., M.Sc., FRCP
President
Institute for Clinical and Economic Review
Two Liberty Square, Ninth Floor
Boston, MA 02109

Dear Dr. Pearson:

Thank you for the opportunity to comment on the Institute for Clinical and Economic Review's (ICER's) Value Assessment Framework. The Association of Community Cancer Centers (ACCC) is a membership organization whose members include hospitals, physicians, nurses, social workers, and oncology team members who care for millions of patients and families fighting cancer. ACCC represents more than 23,000 cancer care professionals from approximately 2,000 hospitals and private practices nationwide, and it is estimated that 65 percent of cancer patients are treated by a member of ACCC. We are committed to preserving and protecting quality cancer care for our patients and our communities, including access to the most appropriate cancer therapies, and we support efforts to better understand, and define, the value of that care.

High and rising health care costs certainly drive – and perhaps demand – meaningful conversation about the value drug therapies and other health care interventions bring to our patients. As cancer care specifically becomes increasingly cost-prohibitive for cancer patients and their families, we appreciate the work of organizations to facilitate this important and often difficult conversation when it is done in an evidence-based and patient-centered manner. Yet while the value discussion remains fairly conceptual to most on-the-ground clinicians caring for cancer patients every day, ACCC has significant concerns about the growing attention ICER's value assessments have received by payers and policymakers. Particularly as certain methodologies for assessing value emerge at the forefront for payers, ICER must recognize the enormity of their decisions and the significance of developing precise, accurate assessments of treatments that could make the difference between life and death for a cancer patient.

In response to ICER's national call for proposed improvements to its Value Assessment Framework, ACCC asks ICER to consider the following changes:

Better stakeholder engagement: While we appreciate this opportunity to comment, and recent efforts by ICER to educate the public on their process, we remain concerned that ICER has yet to meaningfully engage and incorporate stakeholder perspectives in their methodology and process. Given the growing attention payers and policymakers are giving ICER recommendations, it is critical that your organization broadly incorporate feedback from patient groups, clinical experts, and life science companies to make appropriate value assessments about cancer treatments.

Limit voting members in drug and health intervention reviews and on panels such as the Comparative Effectiveness Public Advisory Council (CEPAC) to subject matter experts: To ensure the clinical accuracy of their assessments, we urge ICER to limit voting members of panels to subject matter experts in the health interventions and disease areas being reviewed, including requirements that a supermajority of voting panel members be board certified in the area of concern and actively remain involved with treating patients and/or conducting research in that specific disease area. Particularly for complex conditions such as cancer, only clinical experts can be expected to keep pace with the continual evolution of the standard of care and the nuance of individual clinical decision making.

Better account for patient preferences and individualization: We share the concerns of several stakeholders that the development of a universal, one-size-fits-all model to quantify the value of one health care intervention or drug therapy over another is in direct contrast with an increasingly individualized approach to cancer care. Scientists have made great strides in recent years in understanding the genetic and molecular make-up of various cancers, giving clinicians a new set of tools to diagnose and treat patients through personalized medicine. Value, therefore, is a nuanced, multi-dimensional concept, and the tradeoff between the efficacy of a drug and subsequent quality of life is highly individualized for each patient, which raises questions about whether the quality-adjusted life year (QALY) used by ICER accurately captures the full value a therapy offers an individual patient, particularly as studies including the 2013 ECHOUTCOME project have indicated that "the underlying assumptions of the QALY calculation model are not in line with behavior from a real-life population." Therefore, we support incorporating more patient-centric measures in ICER's methodological approach and also ask ICER for more clarity around how clinicians can interact with this framework. While various approaches to assessing the value of one therapy over another can help guide a patient's decision-making process, ultimately, the final decision about treatment should remain between the patient and their provider. Our members are looking for sound, easy-to-understand tools to help facilitate meaningful conversations with their patients about various treatment options given their individual treatment goals.

Provide more information about how value assessments will evolve and not stifle innovation: It remains unclear how ICER chooses specific therapies to evaluate and how value determinations will be updated as new evidence and data emerges and the standard of care evolves. As of now, ICER reviews are static, putting newer, innovative therapies with less published data at a disadvantage, including cutting edge immunotherapies that have proven to have great promise for cancer patients. ICER has not been transparent about how therapies in rapidly evolving areas such as ImmunoOncology will be continuously reviewed as new data emerges, or how ICER will manage updates of its recommendations in these contexts. ICER's reports have not been consistent in how abstracts and other emerging data are incorporated into

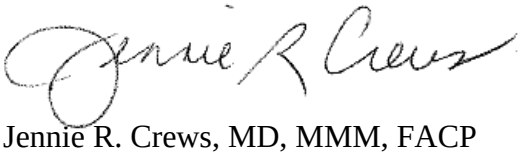
recommendations, which is of particular importance for new therapeutic areas. We are also very concerned that ICER's approach favors therapies that have been on the market for some time and have more data, which could have the unintended consequence of stifling innovation. The short-term budget impact window also puts innovative therapies, with higher upfront costs but long-term benefits, at a disadvantage.

Ensure that ICER's methodologies and evaluations adhere to the scientific standards of transparency and peer review: ICER has not made its methodologies for clinical evaluation or economic evaluation completely transparent in a way that outside researchers could test and validate its approaches. Furthermore, these methodologies have not been subject to peer-review or published in a scientific journal. Given the rapid evolution of some of the therapy areas ICER evaluates, as well as ongoing debates in the health policy and economics communities regarding issues including appropriate use of the QALY and best practices for the development of budget impact models, ICER should ensure that its approaches are transparent and peer-reviewed.

As ICER continues to have a voice in conversations about value and cost in our health care system in a manner that could significantly impact public health and access to innovative therapies, ICER has a major responsibility to account for the nuances of value to the patient, health care system and to society, the complexities of different diseases, and the rapidly changing cancer landscape and continual evolution of evidence for different health care interventions. ACCC and ICER share a common goal to ensure therapies are used appropriately, efficiently and effectively, and we look forward to working with the broader health care community to achieve this goal. We urge ICER to continue to work with stakeholders to refine their methodology, and we look forward to continuing the dialogue.

Thank you for the opportunity to comment. If you have any questions, or need additional information, please feel free to contact Leah Ralph, Director of Health Policy, at lralph@accc-cancer.org or (301) 984-5071.

Respectfully submitted,



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