NATIONAL COALITION FOR CANCER SURVIVORSHIP

The power of survivorship. The promise of quality care.

August 21, 2105

Allen S. Lichter, MD, Chief Executive Officer
Richard Schilsky, MD, Chief Medical Officer
Lowell Schnipper, MD, Chair, Value in Cancer Care Task Force
American Society of Clinical Oncology
2318 Mill Road, Suite 800
Alexandria, VA 22314

Re: Draft ASCO Conceptual Framework to Assess the Value of Cancer Treatment Options

Dear Dr. Lichter, Dr. Schilsky, and Dr. Schnipper:

The National Coalition for Cancer Survivorship (NCCS) appreciates the opportunity to comment on the "Conceptual Framework to Assess the Value of Cancer Treatment Options."

We were invited by the American Society of Clinical Oncology (ASCO) to a meeting in August 2014 at which ASCO volunteers and staff presented a version of the value framework. We also listened to a conference call at the time of publication of the value framework on June 22, 2015, and we participated in a post-publication discussion with ASCO staff members regarding the value framework at a Cancer Leadership Council meeting on July 14, 2015. We are pleased to have the opportunity to comment on a written work-in-progress, and we hope we will have additional discussions about ASCO's work on value and other elements of the cancer care system in the future.

We commend ASCO for focusing on the value of cancer care options as well as the cost of cancer care, difficult topics for analysis and broad-based discussion. In reading the ASCO explanation of the value framework and its development over many months, it seems to us that the work of ASCO might be better defined and approached as two separate projects and initiatives. One might be focused on the cost of cancer therapies, the impact of cancer care costs on the cancer care system and the overall health care system, and potential policy solutions to rising cancer drug costs. The second might focus on the communication of value of cancer care to individual patients.

The effort to address cancer care costs and the separate initiative to improve shared decision-making with an emphasis on cancer care quality – which we see as distinct efforts within the ASCO value initiative -- are both valuable efforts. We stand ready to engage with ASCO regarding a public policy effort related to overall cancer care costs. We think that this effort should include an emphasis on the analysis of the value of cancer care, comprehensive payment reform, and patient-focused delivery reforms. Only a comprehensive approach to cancer care delivery, payment, and value can serve the needs of patients, oncologists, and the overall cancer care system.

In the remainder of these comments, we will concentrate on the communication of cancer care value to individual patients, as described in the value framework.

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Net Health Benefit

In its article defining the value framework, ASCO describes a consensus process that considered "the results of prospective, randomized trials comparing a new treatment with a prevailing standard of care." The process also considered toxicity by calculating "the relative toxicity of the new agent against the comparator regimen." Finally, bonus points were awarded in the net health benefit calculation if "a statistically significant improvement in any cancer-related symptom is reported in a randomized trial of the new treatment."

According to ASCO, the "net health benefit" score will be defined on a 130-point basis for advanced disease and a 100-point basis for the "curative framework." Although we commend the effort of ASCO to define net health benefit, we have a fundamental question about the advantages of presenting a patient with a numerical score to assist in the assessment of treatment options and to inform treatment decision-making. In our discussions related to this topic at the Cancer Leadership Council meeting of July 14, patient advocates were encouraged to consider this numerical score as part of the analysis of "clinically meaningful" treatment options by the patient and oncologist. However, we question whether the numerical score facilitates that process.

We are concerned that the ASCO scoring process encourages a false "binary" process for evaluating treatment options, when in fact patients and their care teams will often be considering more than two treatment options and attempting to assess risks and benefits of all of them. In this context, it is unclear if a net health benefit score, as defined by the ASCO process, is useful. If an oncologist presents a patient a treatment option with a score of 16, for example, or a score of 48, what is the patient to take away from those scores? Although ASCO presents a methodology for arriving at these product scores, does it achieve transparency by doing so? Will the patient who is presented a product score during shared decision-making be aided in that process because a score is communicated? And will the oncologist have a deeper understanding of possible treatment options because those options are given a value score? We are concerned that the communication of a net health benefit score will not improve the strength of the shared decision-making process.

It is our concern that the communication by the oncologist to the patient of a net health benefit number may have the impact of harming, instead of strengthening, the overall doctor-patient communication and the treatment planning process. Instead of presentation of a value score, we believe that a consideration of all clinically meaningful treatment options and their risks, benefits, and financial costs should frame the patient decision-making process. In addition, we believe that the comprehensive treatment planning process that has been defined by the Institute of Medicine – a definition arrived at with substantial input from oncologists and patients -- be the standard for doctor-patient communication about cancer care. That process identifies patient preferences and assumes a discussion about the aims of treatment, elements of communication that are critical to planning and delivery of quality care.

The *Journal of Clinical Oncology* article that describes the value framework states, "Because patient perception of value is so individualized, it is crucial that discussions with patients include an assessment of which treatments are most likely to support their needs, goals, and preferences, and that information that could affect their treatment decision making be provided as transparently as possible." However, it is not clear that the

communication of a net health benefit score, calculated according to the ASCO methodology, will enhance the patient decision-making process.

Cost of Care

In the description of the value framework, ASCO indicates:

> Two types of cost estimates are to be presented when the value of an intervention is being considered. One is the drug acquisition cost (DAC), and the other is the patient cost, which directly affects the patient but is highly variable depending on the patient's insurance benefits.

The determination of patient cost-sharing, which of course depends on the individual patient's insurance plan, is not easily determined. We are aware of the challenges of ascertaining individual patient cost-sharing responsibilities, but of course that is the information that may be most important in guiding patient decision-making. The ASCO manuscript on the value framework does not provide details about how patient cost-sharing will be determined or advice to practices about how to undertake that determination. We know that some practices dedicate considerable resources to financial counselors to assist patients in understanding their costs of care, but not all are able to do so. We believe it is critical that all patients be given access to information about their cost-sharing responsibilities, and we encourage ASCO to consider resources and assistance to oncologists to ensure that they are prepared to provide this information to patients.

Although we agree with ASCO that the cost of a drug – the drug acquisition cost – is important information for practices, patient advocates, and policymakers, we are not persuaded that this is information that must be shared with the individual patient to inform treatment decision-making, especially if it is not accompanied by data about the overall cost of a patient's care. Instead, we think that drug acquisition cost is a critical subject for consideration and possible action by the patient advocacy community and the professional community. For the patient, his or her cost-sharing is the critical matter, and overall cost of care should be communicated, not limited to drug cost.

If ASCO takes the position that drug acquisition cost must be communicated in pursuit of transparency in the relationship between oncologist and patient, we would recommend that other financial elements of cancer care should also be disclosed to achieve more complete transparency. For example, the so-called margin on physician-administered drugs might be included in this disclosure, along with deep 340B discounts on drugs that some institutions receive and the payments for pathway adherence that are paid by some third-party payers. Some parties believe that all of these incentives or payments should be disclosed because they may affect treatment choices, site of care, or means of administration of therapy. In other words, all of these elements of the cancer care payment system may affect treatment choices and delivery. We are not yet persuaded that all of these issues should be disclosed to the patient in treatment decision-making, but neither do we believe that transparency as to only some of the challenges in cancer care reimbursement is wise. If there is to be transparency about the money in the cancer care system and how it affects patients, we advocate disclosure and transparency regarding all elements of care and their financing.

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Toxicities of Treatment

In its analysis of toxicities, ASCO indicated that:

> Thus, we relied on a comparison of high-grade, acute toxicity, including rates of treatment-related death, to assess the negative physical effects of treatment that detract from overall health benefit. We acknowledge that certain chronic, low-grade toxicities can be troubling to patients as well and should be incorporated into future versions of the framework if relevant data are available.

We urge ASCO to dedicate resources to ensuring that low-grade toxicities are reflected in future version of the framework. If ASCO hopes to see the value framework evolve into a truly patient-centered tool, it is critically important that so-called low-grade toxicities be reflected in the value framework. Patients also wish to understand the risk of late and long-term effects from their cancer treatment; this information may be crucial to understanding what their quality of life after active treatment will be. We urge that these side effects of treatment – in addition to high-grade, acute toxicity – be incorporated in the assessment of the toxicities of treatment.

We understood on the patient advocates' call of June 22, 2015, that ASCO hopes in future versions of the value framework to incorporate patients' acceptance or tolerance related to various toxicities. We think this revision is critical for the next version of the framework.

Treatment Decision-Making in an Age of Personalized Medicine

We strongly support a cancer care planning process that will produce a patient-specific care plan that will guide treatment decisions and also facilitate care coordination. This plan should include information related to diagnosis, prognosis, treatment goals, expected response to treatment, treatment benefits and harms, total and patient cost of care, and a plan for meeting psychosocial needs. The care planning process should also include consideration of advance care planning and advance directives and lead to the development of a survivorship plan following treatment.

Patient-physician communication that results in such a comprehensive treatment plan is not a simple matter. The cancer care team must be appropriately reimbursed for the time required for such communication, physicians must be trained to undertake treatment planning in a comprehensive way, and patients must be encouraged to participate and even to request treatment planning.

We also believe that, as a matter of cancer care delivery, the treatment planning process must remain a dynamic one. For example, the treatment planning process must be adapted to ensure that those patients who might benefit from targeted therapies receive appropriate molecular diagnosis and a discussion of the risks and benefits of targeted treatments. Those who might benefit from immunotherapies should also engage in a treatment decision process that weighs the risks and benefits of those treatments, the financial burden on patients that may be posed by immunotherapies, and the

site for delivery of care of certain immunotherapies. Treatment with immunotherapies may raise a number of issues related to the cancer care process, and the planning process may help patients prepare for them.

As we consider the need for the treatment planning process to be undertaken for each patient, we are also evaluating how the net health benefit number and the overall cost and patient cost of care, as envisioned by the ASCO value framework, would be incorporated into the treatment planning discussion. In addition to the reservations about the net health benefit number and the cost of care communication that we have identified above, we add our concerns about how the value framework would be implemented. How would the value framework be communicated to practicing oncologists, and what might its impact be on their delivery of cancer care? How would the value framework be communicated to patients by their physicians? ASCO has suggested that technology may be the key to dissemination of the value framework, but we believe that more discussion of that development is necessary.

We agree with ASCO regarding the need to address the cost of cancer care and the need to improve cancer care delivery and financing, including through treatment planning that assesses the goals of a patient's treatment. We are not persuaded that the value framework is the best means of addressing these issues, but we look forward to working with ASCO in the future to address all of these issues that relate to patient access to quality care.

We commend ASCO for initiating the discussion about value of cancer care, and we look forward to future discussions about the points we have raised about the Value Framework and its relationship to comprehensive and rigorous communication between oncologists and patients that results in a treatment plan and coordination of cancer care.

Sincerely,

Shelley Fuld Nasso
Chief Executive Officer

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