Community Oncology Alliance
Dedicated to high quality, affordable, and accessible cancer care

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August 24, 2015

Lowell Schnipper, MD
American Society of Clinical Oncology
Value in Cancer Task Force
2318 Mill Road
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Dear Dr. Schnipper and Task Force Members:

The purpose of this letter is to provide additional comments to the ASCO *Value in Cancer Task Force* (the "Task Force") regarding ASCO's *Conceptual Framework to Assess the Value of Cancer Treatment Options* (the "*Value Framework*"). The Community Oncology Alliance, which is a member of the Cancer Innovation Coalition (CIC), has joined in sending a letter from CIC members to the Task Force that focuses on several important comments on the *Value Framework*; namely:

- Ensuring Patient Needs Define Value;
- Addressing the Total Costs of Cancer Care; and
- Concerns About the Limitations of the Scoring System.

We will not elaborate on those comments but attach the letter for reference and underscore the comments provided in the letter. We are using this letter to make a few additional points regarding the *Value Framework*.

Practical Considerations

We realize that the *Value Framework* is very much a work in process and the first iteration is just that and provides a vehicle to comment on the *Value Framework*. However, we want to underscore that the *Value Framework* at this initial stage is not a practical "tool" for oncologists to use in practice with their patients. Independent of concerns regarding the clinical validity of the *Value Framework*, in order to practically apply the *Value Framework* in clinical practice would require it to be integrated into the software systems oncologists are increasingly relying on in clinical practice. We understand the Task Force is looking for initial comments at this time; however, the *Value Framework* is not ready for practical use, yet has garnered significant media attention. We ask ASCO and the Task Force to carefully consider releasing subsequent "versions" of the Value Framework not only until the clinical validity of the tool is established and verified, but also until the tool is practically useful. Release of the *Value Framework*, and the media attention that ASCO generates, has the potential to increase anxiety among patients concerned about their cancer treatment.

Drug Price Basis of Value

We understand the difficulty in utilizing some practical, consistent measure of drug price to patients for inclusion in the calculation of value. Admittedly, using a standardized measure of price, such as average sales price (ASP), which is utilized in the *Value Framework*, on the

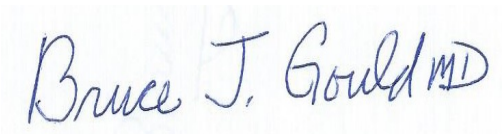
surface provides advantages in order to make global calculations and relative comparisons of value based on price. However, the problem is that the underlying true cost of the drug to the patient can vary substantially according to the type of location where the cancer treatment is administered. For example, a recent analysis and report by the Government Accountability Office (GAO) on Medicare costs in the 11 cancer centers with special Medicare exemptions documents the higher charges to Medicare – and, therefore, patients – of cancer care compared with teaching hospitals. Additionally, another GAO study documents the significant discounts obtainable by disproportionate share hospitals (DSH) participating in the 340B program, yet these discounts are not provided to patients. Instead, as documented in studies by Avalere, Milliman, and Moran, the cost of cancer treatment, specifically with chemotherapy, is more expensive to patients, and payers, when administered in outpatient hospital cancer centers versus independent community cancer clinics. So, the value equation changes based on the location of where the cancer treatment is administered. This makes comparisons of value across treatment settings difficult at best and perhaps meaningless.

Complete Picture of the Cost Drivers of Cancer Care

Our fundamental concern with the *Value Framework* is the singular focus on drugs, for several reasons. Cancer drugs represent only an estimated range of 15-25% of the cost of treating cancer and are interwoven with the other costs associated with cancer care including radiation, advanced imaging, hospitalization, physician services, etc. Furthermore, the mix and interrelationship of these cost components vary depending on the site of treatment delivery, as previously referenced. Because of this, the measurement of real value in cancer care is complex and driven by several overall factors including mix of drugs and services and the site of care delivery. Certainly, the escalating cost of cancer drugs is a real problem that must be addressed by pharmaceutical and biotechnology companies. We have discussed this with many of these companies on several occasions, and are even advancing ideas on conceptual pricing models. However, we question the isolation and practical relevance of a "value" tool based solely on drug price, which is dependent on the site of care. COA has initiated a comprehensive study of the cost drivers of cancer care, which should be completed by the end of this year. Our intent is to shed more light on the comprehensive picture of what is driving the cost of cancer care.

We welcome the opportunity to elaborate on any of these comments on the *Value Framework*.

Sincerely,



Bruce J. Gould, MD
President

CANCER INNOVATION COALITION

August 21, 2015

Lowell Schnipper, MD
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Dear Dr. Schnipper and Task Force Members,

The undersigned organizations are members of the Cancer Innovation Coalition (CIC), a group of cancer stakeholders advocating for policies that support precision medicine and customized cancer treatment based on the best evidence and the individual needs of each patient. With these goals in mind, we appreciate the opportunity to offer a collective perspective on ASCO's *Conceptual Framework to Assess the Value of Cancer Treatment Options*.

Ensuring Patient Needs Define Value

If there is one thing that we all agree upon, it is that every cancer patient is unique. Not only are there more than 200 different types of cancer, but no two individuals diagnosed with cancer will experience their disease in the same way and patients with the same type of cancer may respond very differently to the exact same cancer treatment therapy.

This reality is of central importance in defining "value" when it comes to assessing the benefits and cost of cancer therapies. If value is defined as the standardization of care based on averages, then treatment options will be limited and average. However, if value is defined at the individual patient level, oncologists and their patients will have a greater opportunity to match treatment options with the unique characteristics of each patient and avoid one size fits all approaches to cancer care.

Because our organizations support the personalized approach, we agree with ASCO that oncologists and patients will be better served by models that encourage shared decision-making and individual patient choice. Based on this shared vision, we encourage ASCO to add to the Value Framework's core criteria the provision of patient-centered care, defined as "providing care that is respectful of and responsive to individual patient preferences, needs, and values and ensuring that patient values guide all clinical decisions." (Institute of Medicine 2001). While a medicine's clinical benefits (efficacy), toxicity (safety) and cost can be easily measured, the framework will not achieve the shared purpose of improving treatment decisions for cancer care in a personalized way until there exists a tool that is capable of

incorporating a broader set of data that more comprehensively reflects how patients experience issues like benefits and costs.

Consistent with ASCO's stated premise that "the perspective of the patient is of central importance in defining value," the framework should incorporate data on patient needs, values and preferences in order to create a more robust shared decision-making tool that is going to be clinically relevant to patients. Several CIC organizations have done survey work in this area and can confirm what ASCO acknowledged: "that the patient perception of value is highly individualized, can be subjective, and may change over time." Recent examples include the Cancer Support Community's value survey recently presented at the 2015 conference of the Association of Value-Based Cancer Care[1] and the National Patient Advocate Foundation's Consumer-based Cancer Care Value Index Building on the findings from these and other sources, our organizations encourage ASCO to invest in qualitative and quantitative opinion research that will inform the evolution of a patient-centered value framework.

Addressing the Total Costs of Cancer Care

Because cancer can represent a large financial burden for patients and their families, the Institute of Medicine's report, *Cancer Care for the Whole Patient,*[2] recognizes that cancer therapies are by no means the only drivers of increasing costs to patients and encourages members of the care team to discuss the total and out-of-pocket costs of cancer care with patients. According to estimates from the Agency for Healthcare research and Quality (AHRQ), of the $88.7 billion in direct costs for cancer treatment in 2011, 50% was for hospital outpatient or doctor office visits, 35% involved inpatient hospital stays, and 11% covered the cost of prescription drugs[3]. Based on this evidence, patients will be better served if the ASCO framework incorporates the range of costs a patient is likely to experience as part of a personalized decision support framework intended to help patients make more fully informed decisions. As is the case with the data regarding value, several patient advocacy organizations in the CIC have extensive experience with providing direct support to patients for their financial and medical debt issues that could help inform the cost elements of the framework.

Concerns About the Limitations of the Scoring System

As currently designed, the ASCO Value Framework relies on data from randomized clinical trials to assess the relative benefits, side effects and costs of a new treatment regimen compared with standard of care. The result is a combined "Net Health Benefit" score or NHB that is calculated on the basis of improvements in clinical benefit and on the number and severity of toxicities.

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[1] Cancer Support Community. Study Finds Discrepancy in "Value" Definition in Cancer Care. May 4, 2015. Accessible at www.cancersupportcommunity.org/gm-node/7648.aspx

[2] National Academies Press 2008. Cancer Care for the Whole Patient: Meeting Psychosocial Health Needs. ISBN-13: 978-0-309-11107-2

[3] American Cancer Society. Economic Impact of Cancer. Accessible at http://www.cancer.org/cancer/cancerbasics/economic-impact-of-cancer

Designed to be used in a physician-guided tool that will assist patients in weighing different drug treatment options, the NHB is intended to represent the added benefit patients should expect the receive from the new therapy. We concur with the many limitations ASCO notes in their statement regarding this methodology and believe that these and others need to be addressed in order to arrive at a tool that is ready for clinical application. These limitations are as follows:

- The NHB does not take into account any measure of the value of individual responses to treatments. Rather, the framework uses the average response obtained in clinical trials to measure value, which runs counter to the principles of precision medicine and does not reflect the development of new therapies targeted to specific genetic mutations.
- The scoring system is not designed to measure the relative value of all treatment options for a specific cancer or to evaluate cancer treatment combinations. We understand the difficulties inherent in such an approach, but these must be overcome to a reasonable degree in order to avoid a system that standardizes care based on the "average patient" when every cancer patient is unique.
- Relying on data available from clinical trials means that the framework as outlined is going to lack relevance to the many patient populations that are underrepresented in these studies and especially, adolescents, older adults, women and ethnic minorities. Without adequate representation of these populations in the clinical trial, the NHB cannot reflect potential differences among different patient groups and cannot ensure the generalization of results. This is of special concern when counseling African Americans, who have the highest death rates and shortest survival of any racial and ethnic group in the U.S. for most cancers.
- The ASCO framework does not calculate increases in survival benefit of less than 20%, which is widely considered a treatment advance for many hard-to-treat and rare cancers.
- An exclusive focus on head to head clinical trial may create an unlevel playing field for innovative therapies, which, as ASCO notes, are often used at first in advanced stage patients where the early benefits are typically going to be measured in months. In these cases, the ASCO value framework will likely assign a modest benefit to a novel regimen when it is first introduced. This same agent may prove to have an even greater benefit when it is used in different treatment settings or when appropriate subpopulations are identified based on a biomarker. However, the low NHB score may make it difficult for a novel therapy to have a chance at being applied in broader treatment applications that might yield more significant benefits.

We agree with ASCO that it "should be possible to assess the absolute benefit of different therapies based on the clinical experiences of real-world patients" in the near future. The focus should be on creating the data sets necessary to allow for such comparisons in the decision support tool before it is adopted into clinical practice.

Clearly, extensive time and rigor has gone into developing ASCO's conceptual framework and we commend the ASCO Value in Cancer Care Task Force for publishing this initial version to drive the

discussion about ways doctors and patients can objectively assess the value and costs of new treatments. We agree with ASCO that this effort has a strong likelihood of influencing "policymakers and payers as they consider preferred management options and evaluate the relative value of new treatments introduced into the cancer marketplace." Because of that likelihood, we strongly encourage ASCO to err on the side of caution and not push for clinical release of this framework until many of the limitations and opportunities for expansion are addressed. As ASCO works to evolve this framework, our organizations urge the organization to develop a system that is patient-centered, supports personalized care, is inclusive of all patient populations, and recognizes the small but significant improvements in outcomes for people facing advanced, hard-to-treat and rare cancers.

Thank you in advance for the consideration of these views.

Sincerely,

Association of Community Cancer Centers
Bladder Cancer Advocacy Network
Cancer*Care*
Cancer Support Community
Community Oncology Alliance
Cutaneous Lymphoma Foundation
FORCE: Facing Our Risk of Cancer Empowered
National Patient Advocate Foundation
Sisters Network Inc.
Us TOO International Prostate Cancer Education and Support Network