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August 21, 2015

Allen S. Lichter, MD
Chief Executive Officer
American Society of Clinical Oncology
2318 Mill Road, Suite 800
Alexandria, VA 22314

Lowell Schnipper, MD
Chair, Value in Cancer Care Task Force
American Society of Clinical Oncology

Re: ASCO Draft Value Framework

Dear Dr. Lichter and Dr. Schnipper:

The Pharmaceutical Research and Manufacturers of America (PhRMA) appreciates the opportunity to provide feedback to the American Society of Clinical Oncology (ASCO) on its draft Value Framework. PhRMA is a voluntary, non-profit organization representing the nation's leading research-based pharmaceutical and biotechnology companies who are devoted to inventing medicines that allow patients to lead longer, healthier, and more productive lives. PhRMA companies are leading the way in the search for cures.

We appreciate the considerable work ASCO and the Value in Cancer Task Force have done on the Value Framework, its consideration of stakeholder input, and ASCO's commitment to advancing tools to support informed decision-making. PhRMA strongly supports enhancing provider and patient engagement to inform treatment decision-making. Tools and policy that support shared decision-making have been shown to improve clinical and economic outcomes. Further, cancer patients want and need to be engaged in decision-making about their health care and treatment options, and the high variability in optimal care for individual patients makes this essential in oncology.

We support ASCO's commitment to "help[ing] oncologists and their patients weigh potential treatment options based both on high-quality scientific evidence and a thoughtful assessment to each patient's needs and goals."[1] ASCO's focus on developing a tool to support physician-patient decision-making, as well as the complexity in assessing value that the Framework itself illustrates, underscore the importance of ensuring that it is not misused at the level of payer or policy decision-making in ways that could discount the patient's perspective or restrict physician flexibility.

Cancer patients are an extremely heterogeneous group with variable circumstances and preferences. Even assuming that patients assess treatment options on the same dimensions of value, individual patients will weight each dimension differently according to their individual circumstances.

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[1] ASCO. ASCO Publishes Conceptual Framework to Assess the Value of New Cancer Treatment Options. June 22, 2015.

Heterogeneity of comorbidities and physical condition may also drive varied patient preferences; these factors will have a direct impact on patient outcomes and should also be recognized in the tool.

As ASCO refines the Framework, it will be important to ensure that value scores generated at the population level can be tailored by patients at the individual level. This will help ensure that the tool is sensitive to differences in perspectives on value among patients and other stakeholders. For example, a study published in *Health Affairs* asked patients to compare two treatment regimens for melanoma that, statistically speaking, yielded equivalent survival gains. However, when one regimen provides assurance of a shorter survival gain, and one offers a 50% chance of twice the survival gain, a large majority of cancer patients chose the latter.[2] Without allowing for patient customization, such choices are not easily captured in a value framework like ASCO's which may present these regimens as equivalent to a patient.

ASCO should continue to move the Framework in a direction that is focused on physician-provider decision-making rather than shifting to focus on payer decision-making and average value. In addition to recommending steps to advance a sound framework for shared decision-making, PhRMA recommends that ASCO include clearer, stronger language on the limitations of using the Framework in population-level decision-making. The importance of such language is illustrated by recent suggestions that the Value Framework could be used to support or validate clinical pathways or similar utilization management tools developed by payers.[3] These suggestions appear to misunderstand the design of the Framework and undermine its intent of supporting shared decision-making. For example, ASCO notes that, because the appraisals in the tool rely on single treatment-specific clinical trials, the value scores are not readily comparable to those of other treatments that may be available for treating a specific cancer. Because clinical pathways are designed to be grounded in evidence on the clinical role and value of all available treatments, the usefulness of the Value Framework in validating the value judgments made in clinical pathways will be limited at best.

PhRMA supports the open process the ASCO Value in Cancer Task Force has used for obtaining input from a range of stakeholders as it develops the Value Framework, and we look forward to continued engagement with ASCO. At the same time, we are concerned that the Value Framework, in its current form, does not support sound physician-patient shared decision-making. We urge ASCO to:

- Ensure that the Value Framework supports physician-patient decision-making by incorporating and conveying information in a way that is relevant to patients;
- Clarify methods and validate use of the Framework;
- Include mechanisms to better account for the value of innovative cancer therapies; and

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[2] Lackdawalla, D., et al. How Cancer Patients Value Hope And The Implications For Cost-Effectiveness Assessments Of High-Cost Cancer Therapies. *Health Affairs*. April 2012.

[3] Cathy Kelly. ASCO Value Framework Could Inform Clinical Pathways, Payers Say. *The Pink Sheet*. July 13, 2015.

- Incorporate all aspects of oncology care into efforts to improve the quality of cancer care and contain costs.

Recognizing the considerable work that ASCO and its Task Force have already performed in developing the framework, we appreciate the opportunity to provide additional input and offer the suggestions below to address some of the concerns we have identified.

1) Ensure that the Value Framework incorporates patient-centric data and information.

PhRMA agrees with ASCO's recognition that the patient perspective needs to be central. We also agree with the Task Force's recognition of the limitations of existing models for value assessment in this regard and support its goal of "contribut[ing] to the effort to ensure value for patients while preserving and enhancing quality and sustaining innovation."

ASCO's objectives are consistent with the work of other leaders in the oncology field who recognize the importance of assessing the comparative clinical benefit of cancer interventions but also call for a "move beyond traditional approaches to comparative effectiveness research and health technology assessments to achieve better alignment with patient needs and values, as well as with the emerging science and changing clinical practice of oncology."[4] Ultimately, the goal is to help patients understand trade-offs presented by the range of health care or treatment options and help them understand how population-level data applies to them as an individual.

PhRMA has significant concerns that the net health benefit (NHB) framework appears designed primarily for use in population-level decision-making. Citations provided by ASCO reference an article from 1998 that relates to use of a NHB score to reduce uncertainty in cost-effectiveness analysis, and a more recent white paper describing the use of the NHB score as a tool in population-level formulary decision-making.

As a result, the NHB framework suffers from some of the same limitations of cost-effectiveness described by ASCO in its manuscript. For example, ASCO notes in the manuscript that QALYs as a measure of disease burden have significant limitations, because individuals with the same illness may have different preferences for a health state. For example, one individual with advanced cancer may prefer length of overall survival above all else, whereas another might view minimization of symptoms as the highest priority. It is unclear how the NHB calculation used in the Value Framework incorporates different individual preferences.

ASCO should aim to fill in a key gap in developing a model that supports high-quality patient-centeredness and innovation in oncology, and effectively connects evaluation of evidence at the

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[4] Abernethy A, Abrahams E, Barker A et al. Turning the Tide Against Cancer Through Sustained Medical Innovation: The Pathway to Progress. *Clinical Cancer Research*. March 2014.

population level with tools for decision-making at the individual level. PhRMA would be pleased to continue working with ASCO to meet this challenge.

2) Build a foundation for high-quality shared decision-making.

To achieve ASCO's goal of developing a "tool to assist the physician and patient in shared decision-making," the Value Framework should be refined so that it better aligns with recognized objectives, standards and best practices for shared-decision-making.

In particular, the Federal Government has established objectives for shared decision-making in the Patient Protection and Affordable Care Act (ACA). The section establishing the Patient-Centered Outcomes Research Institute (PCORI), directs it to "convey the findings of research in a manner that is comprehensible and useful to patient and providers in making health care decisions; fully convey[s] findings and discuss considerations specific to certain subpopulations, risk factors, comorbidities as appropriate; [and] include[s] limitations of the research and what further research may be needed as appropriate."[5]

Similarly, Congress spoke to the importance of shared decision-making in Section 3506 of the ACA. This language aligns with ASCO's emphasis on the importance of patient-driven decision aids, stating "[t]he term 'patient decision aid' means an educational tool that helps patients, caregivers or authorized representatives understand and communicate their beliefs and preferences related to their treatment options, and to decide with their health care provider what treatments are best for them based on their treatment options, scientific evidence, circumstances, beliefs, and preferences."[6]

In addition, organizations like the International Patient Decision Aid Standards (IPDAS) Collaboration have outlined best practices for shared decision-making. For example, in its standard regarding providing information about options in patient decision aids, the IPDAS Collaboration states that patient decision aids should include:

- How the untreated condition is expected to develop;
- The procedures involved in each treatment option;
- The potential benefits – including their likelihoods – of each treatment option; and
- The side effects and potential harms – including their severity and their associated likelihoods – of each treatment option.

The IPDAS Collaboration standard also states that patients' information needs that are outside these content areas also need to be identified and addressed.[7] ASCO should evaluate models like the IPDAS

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[5] Sec. 6301, Patient-Centered Outcomes Research. Patient Protection and Affordable Care Act.
[6] Sec. 3506, Program to Facilitate Shared Decision-making. Patient Protection and Affordable Care Act.
[7] The International Patient Decision Aid Standards (IPDAS) Collaboration's Quality Dimensions: Theoretical Rationales, Current Evidence, and Emerging Issues. November 2013.

Collaboration to ensure that the Value Framework aligns with best practices as it is finalized. To achieve better alignment, the Value Framework will need to address several important related issues.

a) Address limitations associated with net health benefit construct

The use of the term "net health benefit" overstates the degree to which all relevant clinical and economic data have been included and synthesized into this metric. Traditionally, net health benefit includes concepts of quality of life impact, total resource consumption (pharmacy, medical, lab, etc.), and incremental changes in cost-effectiveness to represent a more global measure of value. While clinical efficacy and toxicity are important components of consideration for determining appropriate treatments for cancer, they are certainly not the only factors that should be considered when determining value to the patient and any "net" benefit. PhRMA suggests that ASCO consider an alternative term for the score that results from the clinical and toxicity assessment so as not to overstate its implied inclusion of more global patient and system-related outcomes.

b) Consider including a broader range of evidence and incorporate rigorous data synthesis methods

PhRMA is concerned by ASCO's sole reliance on randomized clinical trials (RCTs) as the basis for the NHB calculation. While such information is foundational to ascertaining efficacy, it likely will be too limited for purposes of informing physician-patient treatment decisions. ASCO should afford inclusion of the range of rigorous and widely available scientific evidence in the Framework to ensure value is measured in the most well-designed, robust, and relevant way possible. While we understand the challenges of incorporating different types of data and evidence, we are concerned that incorporating only a portion of available evidence will ultimately limit the utility of the framework in practice.

The initial indication for a new oncology drug is often for treating patients with late-stage malignancies who have failed prior treatments – a population who is inherently difficult to treat, with large clinical benefits unlikely to occur. However, subsequent approved indications frequently are for earlier stages of disease, which offers a greater likelihood of clinical response. Therefore, defining value based on the initial trial and initial indication may not reflect the true value of the drug over the entire life cycle because the patients treated can vary substantially as new evidence emerges, and as new indications are approved.

Deriving clinical benefit under the current Value Framework requires utilizing results from a single RCT comparing a new drug with a comparator, presumably the standard of care. It is unclear how results from multiple trials may be integrated or assessed as part of the framework. Moreover, cancer care is

complex and the value of innovative drugs often times increases over time[8] – well past the introduction of the drug in the marketplace. Defining value based off initial trial evidence can lead to erroneous conclusions, especially as newer, real-world data emerge. It is important that real-world data is incorporated into any value assessment tool.

As noted above, current standards for shared decision-making are grounded in recognized methods for evidence synthesis. The IPDAS Collaboration concluded that the "synthesis of evidence should be comprehensive and up-to-date, and the evidence itself subject to critical appraisal. Ethical (informed patient choice), quality-of-care (patient-centered care), and scientific (evidence-based medicine) arguments justify this requirement."[9] ASCO should examine and consider adoption of a sound method for evidence synthesis. This will be essential not only for capturing the full body of available scientific evidence, but ensuring the framework remains up-to-date as new research becomes available. Without a method for synthesizing new research, ASCO risks creating a framework that is not flexible enough to keep pace with the quickly evolving evidence base in oncology.

c) *Incorporate consideration of patient and treatment effect heterogeneity*

An unbiased average treatment effect is easily estimated in randomized trials; however, treatment effect heterogeneity – defined as the degree to which different treatments have differential causal effects on subsets of patients – plays an essential role in evaluating efficacy to inform treatment choice/s at the patient-physician encounter. In cancer drugs' randomized trials, the average treatment effect, presumably the estimate input into the framework, may over- or underestimate the treatment effect on various treatment subgroups. Therefore, the Framework should include a mechanism to incorporate valid and reliable trial subgroup data, to more accurately inform and tailor treatments that provide the greatest clinical benefit to specific patients. In addition, as ASCO develops tools that enable individual physicians and patients to customize results, they should do so in ways that account for subgroup differences (including those illuminated through molecular diagnostics and other tests) and help patients understand what average results mean to the individual due to their particular clinical circumstances and preferences.

Additionally, ASCO should develop a mechanism to enable and provide guidance for patients and their providers to vary the clinical benefit weights and toxicity points to better reflect a patient-specific preference of balancing the survival benefits and side effects of the drugs. As ASCO states in the Value

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[8]Paddock, Silvia, Lauren Brum, Kathleen Sorrow, Samuel Thomas, Susan Spence, Catharina Maulbecker-Armstrong, Clifford Goodman et al. "PACE Continuous Innovation Indicators—a novel tool to measure progress in cancer treatments." ecancermedicalscience 9 (2015).

[9] The International Patient Decision Aid Standards (IPDAS) Collaboration's Quality Dimensions: Theoretical Rationales, Current Evidence, and Emerging Issues. November 2013.

Framework manuscript, "the ability to modify the framework at the point of care would facilitate decision making by enabling patients to create a personalized NHB score that takes into account not only the specific clinical problem but also existing comorbidities, personal preferences, and values." PhRMA strongly agrees with this statement, and encourages ASCO to ensure customization is incorporated into its tool.

d) *Clarify and revisit reliance on median overall survival (OS) as a measure of benefit*

While median overall survival is a key metric and often reported in trial results, other endpoints, including mean OS, time to tumor progression and time to treatment failure are not accounted for in the Value Framework. ASCO should integrate other measures of survival into its framework to allow patients and providers to make well-informed decisions regarding treatment.

To help physicians and patients translate average results to the level of individual decision-making, ASCO should also consider providing a broader perspective on clinical outcomes beyond median survival. Median OS does not fully capture value of innovative treatments, nor will it consider potential long-term survival, therefore incorporation of multiple measures is appropriate on a patient-level basis. For example, the percent of patients who achieve long-term survival (measured at a subsequent period(s) post-treatment initiation) is also an outcome that provides important patient-centric information for decision-making that introduces the notion of the distribution of survival across the patient population. Understanding what percent of patients achieve survival at certain time periods post-initiation of treatment and the comparison between the standard of care and the newer agent can provide meaningful information for patients to assess options and determine treatment preference in collaboration with their provider.

Moreover, the Value Framework's clinical outcome weighting method for OS, progression free survival (PFS), and response rate (RR) is based on assumptions, and not derived from structured research. Also, the weighting scheme can introduce problems when studies are powered to detect statistically significant differences in primary outcomes other than OS. If OS is captured as a secondary outcome in such cases, the framework states that OS should be used, and the use of OS in these cases could potentially lead to uninformed clinical decision-making. PhRMA recommends that ASCO clarify the basis for the weights so stakeholders can better understand the research behind ASCO's decisions.

e) *Develop a method for incorporating other patient-relevant endpoints such as quality of life and patient-reported outcomes.*

PhRMA agrees with ASCO's recognition of the importance of quality of life and patient-reported outcomes, and we are concerned that ASCO has not incorporated these outcomes into the Value Framework. In its 2013 report, "Delivering High Quality Cancer Care: Charting a New Course for a System in Crisis", the Institute of Medicine notes that patient-reported outcomes are widely accepted by

authoritative regulatory bodies such as the FDA and the European Medicines Agency. The report also notes that patients often report different outcomes for treatments than providers and researchers. It is important that stakeholders continue to find ways to collect such data, and we strongly encourage ASCO to work to incorporate patient-centric endpoints into the Value Framework.

f) Recognize complexities regarding toxicity comparisons

PhRMA is concerned that the Framework oversimplifies how it classifies and rates toxicities between new medicines and its comparator. This is an important patient-centric consideration and the current approach could obscure important differences in side-effects and lead patients to inaccurate assumptions that treatment options present similar toxicity risks when in fact they do not. The proposed framework for scoring relative toxicity between a new agent and comparator lacks sufficient nuance to adequately demonstrate how one medicine may be safer and more well tolerated than its comparator, or vice versa. Specifically, as each reported toxicity is given equal weighting across Grades 3 through Grade 5, there is no recognition of the degree to which more severe toxicities may be reported or alleviated between the two medicines being compared. As such, clinically meaningful changes will be undervalued. The Value Framework does not incorporate patient preferences regarding tolerance of toxicities either systematically or meaningfully. It should be extended beyond grade 3-5 toxicities and include bothersome side effects which drive treatment decisions. Furthermore, by using a straight tally of total toxicities and comparing the percentage difference, this oversimplifies interpretation. ASCO should reconsider the way it incorporates toxicities into the Value Framework and ensure that it accurately conveys the significant differences in toxicity levels and types among cancer treatments.

g) Include consideration of the relative uncertainty of trade-offs or confidence in evidence underlying net benefit score

As outlined in the framework, there appears to be an over-reliance on point estimates for reporting of key clinical endpoints without consideration for the relative statistical significance between these point estimates. For example, while differences in key endpoints may translate into a moderate or large percentage difference in outcomes, there is no reference to confidence intervals around these point estimates to determine if there is overlap in these intervals which would provide more meaningful interpretation of the significance in reported outcomes. Clinical trials are powered based on the selected design, and in cases where the number of patients in a trial is relatively small, differences that appear large may in fact may not be statistically significant based on the distribution of data around the point estimates. PhRMA recommends that ASCO provide further guidance as to considering the impact of statistically significant results in determining clinically meaningful differences in order to draw appropriate inferences regarding clinical efficacy.

h) Refine and provide additional guidance on interpretation of net health benefit

PhRMA appreciates ASCO's recognition that the NHB calculation is "not readily comparable to the NHB of other regimens determined on the basis of a different comparator regimen used in another trial." However, we are concerned that, particularly with use of the NHB framework, the Value Framework is vulnerable to being misinterpreted as comparing the relative value of different treatments with different NHB scores. If the trial data from two competing drugs' trials are not conducted in similar populations, or are not compared to a similar comparator therapy or therapies, then any comparisons of their NHBs may be biased with respect to relative scores, or at worst misleading if the directionality of the differences in scores would be changed in the presence of comparable trial populations and comparator treatments. ASCO should consider providing clearer, stronger language cautioning against misuse of the framework in this way. In addition, as it validates decision-support tools using the framework, ASCO should ensure that the framework helps physicians and patients appropriately apply scores to their individual decision-making and does not lead to inappropriate cross-trial comparisons.

3) Conduct additional evaluation against clinical scenarios to ensure that the Value Framework functions as intended.

PhRMA strongly believes that the Value Framework should undergo thorough and transparent validation both before and after it is developed into a decision-making support tool. The scenarios presented by ASCO in the Value Framework demonstrate the complexities and limitations of assessing a cancer treatment's value. For example, ASCO based its assessment of pemetrexed's value on an inappropriate indication. Although PhRMA appreciates that ASCO supplemented its Value Framework to correct that mistake, the pemetrexed example reinforces the importance of further testing and evaluation before developing the Framework into a shared decision-making support tool. We also encourage ASCO to correct the pemetrexed example in the final version of the Framework.

There are a range of comparators used for different sub-types of cancer, which influences a cancer treatment's NHB score under the Framework. As illustrated by the clinical scenarios presented by ASCO, trials studying treatments for a specific type of cancer may employ different comparators, making it more difficult for the patient to gain a sense of the relative value or trade-offs represented by the range of treatment options. The way the Value Framework is currently constructed, it would also be prone to misinterpretation as an implicit ranking of relative value of treatments from different trials. This issue could be addressed through the recommendations made above regarding evidence synthesis. At a minimum, as the Framework is developed, it should be validated to ensure it does not lead to spurious conclusions based on implicit cross-trial comparisons.

4) Modify the framework to ensure it does not under-value new medicines.

PhRMA appreciates ASCO's recognition of the value of new tests and treatments in advancing high quality cancer care and meeting unmet medical needs, as well as ASCO's recognition that our

understanding of a medicine's role and full clinical value typically evolves over time. This is due not only to changes to a therapy's place in a line of treatment, but also changes in the evidence base.

A recent report by Boston Healthcare Associates underscores this point, showing how ongoing research revealed greater clinical value than that demonstrated in initial clinical trials of new treatments for lung cancer, renal cell carcinoma, chronic lymphocytic leukemia, and multiple myeloma.[10] However, the current draft of the Value Framework does not explain the difficult process of going from a static article to becoming a dynamic tool that will repopulate data over time.

While we appreciate ASCO's inclusion of surrogate endpoints that frequently serve as the basis for premarket approval of new cancer medicines, we are concerned that they are weighted in a way that fails to reflect the intrinsic benefits of new treatments. As noted by ASCO, "the net health benefit score may be modest when a product is first introduced," and therefore not reflective of greater value that is demonstrated over time. This is because the Framework applies a significantly lower multiplier to response rate information, resulting in a lower maximum NHB score.

The NHB score of breakthrough drugs will nearly always be lower than older drugs that demonstrate an improvement in overall survival or progression free survival, even when it is generally recognized that the new medicine is superior. Thus, the ratings favor older, established regimens rather than new treatments, which could have the effect of discouraging rather than encouraging adoption of valuable new therapies.

We strongly urge ASCO to develop a mechanism for appropriately rewarding novel treatments of high anticipated value in oncology. Newer and targeted therapies that deliver an improved benefit/cost/toxicity profile overall or among sub-populations will continue to be undervalued if there is no mechanism for regular updates to the evidence that is incorporated into the Value Framework. This is concerning given the rapid pace of technology advancement. PhRMA recommends that, at a minimum, ASCO revise the Value Framework to place greater weight on cancer medicines approved by the FDA within the following categories: designated orphan drugs, breakthrough therapies, fast track products, and priority review products. Finally, as the Framework is translated into a decision-support tool, ASCO should consider a mechanism to allow the physician to adjust the NHB score based on his or her own knowledge of the anticipated benefit. This type of mechanism is not only important for the recognition of breakthrough and targeted therapies, but also to recognize how evidence of value of a treatment evolves over time.

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[10] Nicole Sweeney and Thomas F. Goss, PharmD. The Value of Innovation in Oncology: Recognizing Emerging Benefits Over Time. May 2015.

5) Create a process to incorporate new treatment options and research findings, including consideration of research from manufacturers.

As described above, the Value Framework will need to keep pace with and be able to incorporate new research in a rapidly changing landscape. ASCO should provide a regular interval for updating the framework as well as a mechanism to submit new research when it becomes available, including submission of published literature from manufacturers. ASCO should describe for stakeholders a clear process for submission and consideration of new evidence for potential incorporation into the Value Framework. PhRMA recommends that ASCO ensure that the Value Framework is updated at least quarterly.

6) Convey cost information in a manner that is timely, accurate and meaningful to the patient.

PhRMA supports ASCO's recognition of the relevance of patient out-of-pocket costs in a shared decision-making tool. We also recognize the challenges associated with incorporating patient-specific cost sharing information in the Value Framework. Application of real-time benefit checks as part of a decision support tool could help address this challenge, and we encourage ASCO to reach out to organizations developing this capability, such as the National Council for Prescription Drug Programs, to consider how best to apply it in connection with the Value Framework. If cost is incorporated into a decision-support tool, it is important that the cost information is conveyed in a way that is relevant, accurate, and individualized.

Drug acquisition cost (DAC) also is not a proxy for payer costs as that will depend on what the provider charges and the payer contracts. Should ASCO decide to move forward with inclusion of DAC in the Framework, it should ensure that any cost data is updated regularly and appropriately account for discounts and rebates provided by manufacturers, in order to reflect actual drug costs, and that costs that are relevant to patients, such as patient out-of-pocket costs, are included in the Value Framework as well.

Additionally, PhRMA is concerned that a focus on patient costs may reflect only a limited part of patients' potential total expenditures for care and does not reflect the potential cost-savings associated with both short- and long-term benefits of treatment, such as reduced utilization of physician visits or improved work productivity. An incomplete estimate of a patient's total potential costs and savings will likely yield incomplete information on patients' total costs of care, which may complicate rather than clarify such considerations in a patient's decision-making process.

7) Broaden the framework to align with broader opportunities for advancing high-quality, efficient, individualized care in oncology.

Cost and value are system-wide issues. We appreciate ASCO's view that value frameworks can and should also be applied to more broadly, which is consistent with growing recognition that efforts to

improve value in health care must take a holistic view of health care. PhRMA recommends that ASCO revise the Value Framework to reflect the potential cost savings across the continuum of cancer care.

While we recognize that the strong evidence base for cancer medicines makes it easier to apply a tool such as the Value Framework, we agree that the Framework should be broadened to provide a more complete perspective on value and foster alignment with shared decision-making across the cancer care continuum. It is noteworthy, for example that several prominent examples of success in shared decision-making in oncology relate to screening and surgery, suggesting that the Value Framework could be readily extended beyond cancer medicines. Looking more narrowly at only some components of cancer care could give cancer patients and other decision-makers a skewed perspective on the challenges and opportunities related to cost and value in oncology.

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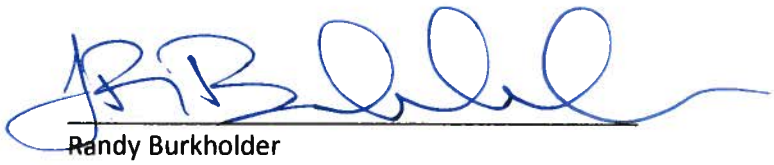
PhRMA and ASCO have a mutual interest in promoting policy that facilitates access to life-changing treatments, sustains innovation in cancer care, and enhances optimal individualized cancer treatment, improve outcomes, and find efficiencies in cancer care. We appreciate ASCO's efforts to engage a broad range of stakeholders in the development of the Value Framework, and we look forward to providing continued input to ASCO as it continues work in this area.

Sincerely,



Randy Burkholder
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