

## American Society of Clinical Oncology Guidance Statement: The Cost of Cancer Care

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### ABSTRACT

Advances in early detection, prevention, and treatment have resulted in consistently falling cancer death rates in the United States. In parallel with these advances have come significant increases in the cost of cancer care. It is well established that the cost of health care (including cancer care) in the United States is growing more rapidly than the overall economy. In part, this is a result of the prices and rapid uptake of new agents and other technologies, including advances in imaging and therapeutic radiology. Conventional understanding suggests that high prices may reflect the costs and risks associated with the development, production, and marketing of new drugs and technologies, many of which are valued highly by physicians, patients, and payers. The increasing cost of cancer care impacts many stakeholders who play a role in a complex health care system. Our patients are the most vulnerable because they often experience uneven insurance coverage, leading to financial strain or even ruin. Other key groups include pharmaceutical manufacturers that pass along research, development, and marketing costs to the consumer; providers of cancer care who dispense increasingly expensive drugs and technologies; and the insurance industry, which ultimately passes costs to consumers. Increasingly, the economic burden of health care in general, and high-quality cancer care in particular, will be less and less affordable for an increasing number of Americans unless steps are taken to curb current trends. The American Society of Clinical Oncology (ASCO) is committed to improving cancer prevention, diagnosis, and treatment and eliminating disparities in cancer care through support of evidence-based and cost-effective practices. To address this goal, ASCO established a Cost of Care Task Force, which has developed this Guidance Statement on the Cost of Cancer Care. This Guidance Statement provides a concise overview of the economic issues facing stakeholders in the cancer community. It also recommends that the following steps be taken to address immediate needs: recognition that patient-physician discussions regarding the cost of care are an important component of high-quality care; the design of educational and support tools for oncology providers to promote effective communication about costs with patients; and the development of resources to help educate patients about the high cost of cancer care to help guide their decision making regarding treatment options. Looking to the future, this Guidance Statement also recommends that ASCO develop policy positions to address the underlying factors contributing to the increased cost of cancer care. Doing so will require a clear understanding of the factors that drive these costs, as well as potential modifications to the current cancer care system to ensure that all Americans have access to high-quality, cost-effective care.

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### INTRODUCTION

Major advances in the early diagnosis of some cancers and better understanding of the pathogenesis of the disease have led to risk reduction and prevention strategies. These advances, plus improvements in therapy, have all contributed to declines in cancer death rates in the United States and Western Europe.<sup>1</sup> However, with these successes have come substantial increases in cost to a level that is now causing a serious financial burden to patients, families, and society at large.<sup>2</sup> Even patients with health

insurance, those historically viewed as immune to the cost of care, are facing serious financial challenges. A national survey of cancer patients and their family members showed that among those with insurance, 25% of people reported that they used up all or most of their savings dealing with cancer, and 33% of families reported a problem paying their cancer bills. The study also showed that among those individuals who were ever uninsured, 27% reported that they or their family member delayed or decided not to obtain care for cancer because of the cost.<sup>3</sup>

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The American Society of Clinical Oncology (ASCO) is the world's leading professional organization representing physicians who treat people with cancer. ASCO is committed to advancing the education of oncologists and other oncology professionals, to advocating for policies that provide access to high-quality cancer care, and to supporting the clinical trials system to increase clinical and translational research. To address concerns about the cost of cancer care, ASCO established the Cost of Cancer Care Task Force in 2007, which is charged with defining the challenges related to the cost of cancer care and developing strategies to address these challenges in the context of ASCO's mission.

On the basis of the Task Force's deliberations, ASCO presents this Guidance Statement on the Cost of Cancer Care to highlight salient issues relevant to delivery of high-quality cancer care. The purpose of this Guidance Statement is to raise awareness among clinicians in all oncologic specialties about the many factors contributing to the cost of cancer care and how each of the stakeholders involved affects and is impacted by increasing costs; to offer recommendations to assist ASCO and the oncology community as a whole in communicating with patients and their families about the cost of care as it impacts clinical decision making; and to identify relevant policy issues that ASCO will address in the next phase of its cost of care initiative.

#### WHAT IS THE NATURE OF THE PROBLEM?

The United States spends approximately 16% (more than \$2 trillion) of its gross domestic product on health care.<sup>4</sup> Because the growth in health care spending exceeds that of the overall economy (approximately 6% to 8% v 4% to 6%),<sup>5,6</sup> the proportion of our economy devoted to health care continues to increase and is expected to reach nearly 20% by 2017. Cancer care accounts for approximately 5% of health care spending, and this proportion is expected to increase.<sup>7</sup> According to National Institutes of Health estimates, \$89 billion were spent on cancer care in 2007, with the economic burden totaling \$219.2 billion when including indirect costs associated with lost productivity and death.<sup>8</sup> Recent trends suggest that cancer spending growth will accelerate, in part as a result of costly new treatments and the increase in the number of cancer patients as the population ages.<sup>9</sup>

Recently, drug costs in general, and cancer drug costs in particular, have received increased attention. This focus is, in part, a result of the high pricing of new agents with prices that can exceed commonly used thresholds for cost effectiveness.<sup>10,11</sup> These prices may represent the costs and risks of drug development and production for the pharmaceutical industry and the high value attributed to these agents by patients and physicians. It can be argued that cancer prescription drug costs contribute only a small fraction (1%) to overall health care costs and therefore represent misplaced focus. However, it is important to note that prescription drugs account for a high and increasing fraction of spending in oncology. For example, antineoplastics are now the leading class in hospital drug expenditures.<sup>12</sup> In 2007, antineoplastics and hematopoietic growth factors accounted for 11 of the top 15 clinic drug expenditures and seven of the top 15 hospital drug expenditures. In 2005 to 2006, there was a 20.8% increase in clinic drug expenditures, driven largely by the novel targeted therapies such as bevacizumab, cetuximab, and trastuzumab.

Biologics account for 15% of all prescription drug costs, increasing 23% in 2005 to 2006.<sup>9</sup>

Cancer drugs are by no means the only drivers of increasing costs. Technologic advances in imaging, robotics as applied to surgery, and therapeutic radiology significantly contribute to the rapid growth in overall health care spending, with estimates suggesting that approximately half of real health care expenditure growth can be attributed to medical technology.<sup>13,14</sup> Concern has been raised that the early adoption and widespread penetration of some new technologies in the marketplace may be a result, in part, of the level and type of regulation of medical devices, for which licensing approval requires a less stringent level of therapeutic evidence compared with drugs.<sup>15</sup>

The impact of increasing costs on individual patients and the care they receive is profound and can occur in a number of ways. The most direct concern is the impact on patients' economic burden and clinical outcomes. Of particular concern is the impact of increasing costs on the uninsured and underinsured. Approximately 47 million citizens in the United States currently lack health insurance.<sup>17</sup> This number is increasing, in part, as a result of the high cost of health insurance and its impact on employers and the self-insured. There is evidence to suggest a direct relationship between increases in health insurance premiums and the number of uninsured. Various studies indicate that 164,000 to 300,000 people lose employer-paid health insurance if the premium increases by only 1%.<sup>18-21</sup> This problem will be compounded in a time of economic recession and increasing unemployment. Furthermore, adherence to prescribed treatment declines as out-of-pocket costs increase.<sup>22-24</sup> Recent studies have demonstrated that lack of insurance is associated with lower rates of cancer screening, later stage at diagnosis, and increased cancer mortality.<sup>25</sup> Moreover, cancer has been shown to be the highest-cost diagnosis among those declaring bankruptcy for medical reasons.<sup>26</sup>

#### STAKEHOLDER PERSPECTIVES

To effectively address the increasing cost of cancer care, it is important to understand how increasing costs affect each of the stakeholders involved. In addition, understanding the role each stakeholder plays in contributing to increasing costs is crucial to identify potential solutions.

##### Patients

Several studies have illustrated the profound financial impact that comes with the breadth of problems posed by a cancer diagnosis.<sup>25,27,28</sup> Even for insured patients, the cost of cancer diagnosis and treatment can present a barrier to obtaining high-quality care. In the absence of insurance, cancer screening and diagnosis is delayed, and survival is worse.<sup>25</sup> For patients with insurance, out-of-pocket expenses associated with cancer treatment may still be substantial and lead to delay in treatment, noncompliance, exhaustion of savings, and personal bankruptcy. Moreover, these expenses have a disproportionate effect on those with lower incomes. Increased cost sharing for patients is accomplished through various mechanisms, including insurance premiums, copays, coinsurance, deductibles, and tiered formularies. One example is the donut hole in Medicare Part D plans, which creates a novel scenario with a gap in prescription coverage until a defined amount is paid by the beneficiary.

A cancer diagnosis may also have substantial impact on the employment status of patients and their families. For example, in a national survey of cancer patients and their family members, 19% reported that they lost or changed jobs or needed to work fewer hours because of the family illness. More than one third reported they were unable to perform their job as well, and 22% reported lower income.<sup>3</sup>

In addition to its financial impact, increasing cancer care costs can affect the psychosocial well-being of patients, as well as their ability to make optimal treatment decisions and implement them.<sup>29</sup> Patients face uncertainty about what treatment will cost and where to seek information and support services. Patients also can have difficulty determining whether the treatment represents good value. It is well recognized that cancer patients in the face of life-threatening illness perceive high-cost treatments to be more valuable than healthy individuals view them to be.<sup>30,31</sup> These patients may feel pressure to fight the battle against cancer at any cost, and they and their families may subjugate financial concerns to medical ones. Patients also may experience barriers in communicating with their physician or other health care providers about cost. They may feel uncomfortable discussing financial concerns with their health care providers, or they may think that their health care providers do not have time to discuss cost. Patients also may feel concern that raising the issue of cost will bias physician recommendations or that their physicians will not have the capacity to provide strategies for coping with the high cost of treatment.

### Industry

The pharmaceutical and medical device industries develop products designed to improve the health of the population through innovation, a goal that is shared with patients and medical providers. Innovation in these industries is dependent on investment, which is driven by potential returns. Like any product in a market, pricing decisions are multifactorial but ultimately reflect demand. For medical interventions, this demand is not only driven by patients, but also by the prescribers who serve as expert agents for their patients. In the case of cancer, the willingness to pay for new treatments varies among societies, and in the United States, we have been willing to pay high prices for new treatments with some delivering only modest benefit. Marketing efforts by the pharmaceutical and medical device industry also contribute to patient and physician demand, including off-label use, which ultimately impact cost. These factors have led to concern that drugs and medical devices (for diagnosis and treatment) are increasingly expanding into patient populations where the benefits of their use may be less clear or unknown.<sup>32</sup>

Demand by patients and physicians for innovations to help cancer patients drives investment in relevant biotechnology and pharmaceutical development, given the potential profits for these industries. From the industry perspective, pricing of new cancer innovations is influenced by development costs (including risk at each stage of development), production costs, potential market size, pricing of comparables, and ultimately, the novelty and value of the new product in the marketplace. For pharmaceuticals, the cost of development is estimated at approximately \$1 billion, including the opportunity cost of sunken capital.<sup>33</sup> New devices aimed at improving cancer diagnosis and treatment are also costly in their development, have a lower regulatory threshold to overcome before introduction into the clinical marketplace, and are often expensive.

The increasing integration of personalized approaches to cancer therapy, based on prognostic and predictive classifiers, will also have an impact on cost and pricing of new products, although whether such approaches will ultimately reduce or increase drug development and clinical costs is unclear.

Producers have responded to the challenge of making high-cost therapies available to underinsured and uninsured populations by initiating patient assistance programs to provide treatment to those who cannot afford to pay. It is uncertain to what extent these programs have been used and how effective they are in meeting the needs of patients.

### Payers

In the United States, approximately 54% of health care is paid with private funds, predominantly through health insurance and out-of-pocket payments. Federal sources account for the majority of public funding, with Medicare covering 42% of public expenditures.<sup>4</sup> Medicare makes coverage decisions based on a definition of “reasonable and necessary” and does not explicitly integrate cost in these deliberations.<sup>34,35</sup> However, Medicare has recently undertaken efforts to measure quality and outcomes through demonstration projects in which oncologists have been paid to provide additional clinical data in specific settings (eg, symptoms associated with chemotherapy administration, positron emission tomography scans in uncertain indications).<sup>36,37</sup> Private payers have historically taken Medicare’s lead in coverage decisions, although reimbursement rates often differ.

The increasing cost of health care is experienced directly by payers. In an effort to modulate the cost of insurance through decreased utilization of services, insurers are offering health plans with increased patient financial responsibility, including high deductibles, copays, and coinsurance. Requirement for prior authorization is another common method for controlling resource use. Benefit plan managers are dealing with the increased cost of outpatient specialty drugs (eg, cancer) with increased cost sharing through tiered formularies and coinsurance. Although not restricted to cancer care, the increase in health care costs is resulting in a greater out-of-pocket burden for the insured population. Furthermore, individuals who receive insurance through their employer may experience downward pressure on wages as insurance costs increase.

The high cost of new innovations is also leading to greater scrutiny of off-label applications, especially those falling outside of established clinical guidelines and compendia, and this scrutiny is likely to increase as the cost of prescription drugs increases. From the payer perspective, as well as that of patients and providers, the importance of using evidence-based medicine is crucial in addressing the increasing cost of cancer care. All stakeholders, including both public and private payers, have an interest in providing financial and other resources to support well-designed and timely clinical trials that gather evidence on indications that fall outside of the existing clinical literature.

### Providers

The oncology specialist is an expert agent for his/her patient and, as such, has an important role in considerations about the cost of cancer care. The increasing cost of cancer treatment adds complexity to therapeutic recommendations and communication between physicians and their patients. Consistent with the historical focus of medical training on healing, the physician’s wish is to provide treatment of greatest benefit, without regard for cost. However, the reality is that the

patient may be dealing with pressing financial issues related to out-of-pocket expenses. Thus, fulfillment of the primacy of patient welfare must go beyond recommendations of the ideal therapeutic approach because of the need to take into account concerns in addition to physical well-being. At the same time, physicians have a societal responsibility to provide care that minimizes waste and is evidence based. Thus, the oncologist, when faced with an individual patient, finds it necessary to integrate cost implications for patients into treatment considerations.<sup>38-40</sup>

The challenges of doctor-patient communication about cost of care are highlighted by a survey in which oncologists generally agreed that addressing cost is important, but only 37% were always or mostly comfortable discussing costs of cancer treatment with patients.<sup>41</sup> Furthermore, 30% of the oncologist sample reported that they sometimes omit discussion of expensive treatment when they know the cost will “place great strain on my patients’ resources,” and an additional 16% stated that they always or mostly omit such discussion. Other potential challenges to discussion of treatment cost with patients include inadequate time and patient perception that their physician lacks solutions to such concerns.<sup>42</sup> Finally, true cost-effectiveness data on most cancer therapies are scarce. Although oncologists recognize the importance of cost considerations for patients, they often are not adequately equipped with the information necessary to engage in these discussions because it does not exist.

The utilization of effective but expensive drugs in cancer care plans contributes to the increasing costs of cancer care. In contrast to other markets in which the consumer is the sole judge of value, the demand for medical interventions is, in part, driven by the prescribers. It is apparent that improvements in the medical therapy of cancer have brought important benefits to society. In situations when cure is possible, the value of an intervention is often clear. In the palliative situation, there is ambiguity as to what degree of benefit is worth what cost. In these cases, decisions must be individualized for patients; however, it also must be recognized that these decisions have important socioeconomic implications. Similar tensions surround the therapeutic use of costly technologic advances such as robotic surgery or advances in the delivery of high-energy photons and protons in therapeutic radiology. Here, too, the physician, by adopting a novel and possibly (but not necessarily proven) better technology, may increase the costs of care.

#### ASCO INITIAL RECOMMENDATIONS

The increasing cost of medical care is a major societal issue that impacts the health of the population and exacerbates disparities in care and outcomes. The ASCO Cost of Care Task Force has defined the impact of cost of cancer care on a variety of stakeholders, including patients, physicians, payers, and producers. In particular, this Guidance Statement outlines the need for oncologists to recognize the implications of cost for individual patients, understand its practical dimensions, and increasingly integrate this information into treatment discussions, such that medical decisions can be optimized. The oncology community plays an important role in addressing cancer care cost. ASCO recommends the following initial steps be taken to address immediate needs.

#### **Discussion of Cost As an Important Component of High-Quality Care**

*ASCO affirms the critical role of oncologists in addressing cost of care with their patients. Given the potential impact of diagnostic and treatment out-of-pocket expenses on patients and their families, oncologists must assist patients in integrating cost considerations into their treatment decision making. ASCO believes that communication with patients about the cost of care is a key component of high-quality care.*

Oncologists make treatment recommendations based on scientific evidence regarding benefit and toxicity of specific drugs and treatment programs. As noted earlier, an increasingly significant component of the decision-making calculus for patients is their personal treatment cost. To serve the overall goal of preference-sensitive decision making, oncologists must recognize that discussion of cost considerations represents an important component of high-quality care. These discussions should include an acknowledgment that treatment may be costly and should seek to identify any specific cost-related barriers to optimal treatment for individual patients. Furthermore, oncologists should seek to identify areas where costs may be reduced for individual patients, such as selection of treatment schedules that minimize travel time or time away from work, and use lower priced options when they are available. In addition, whenever possible, oncologists are obligated to provide evidence-based care that is cost effective and minimizes waste.

To assist patients with decisions that integrate cost considerations, oncologists should be armed with information that will help them assess and communicate the value of specific cancer treatments. It is no longer sufficient to simply identify that a treatment’s benefits outweigh adverse effects. Rather, oncologists must be able to discuss how much benefit might be expected from a particular therapeutic option. This information is expected to be increasingly relevant to patients as the expense of treatment increases. Discussions of value may be informed by data provided by comparative effectiveness and cost-effectiveness analyses. Comparative effectiveness studies seek to quantify differences in outcomes between two treatments that might be applicable to a particular disease context.<sup>43</sup> Cost-effectiveness studies seek to quantify the incremental costs and benefits associated with the addition of a particular medical intervention. Although often conducted from a societal rather than patient perspective, cost-effectiveness studies may provide relevant context and help frame discussions with patients.<sup>10,44</sup> As a community, we have the following two obligations in this area: to promote the conduct and dissemination of cost-effectiveness research on cancer treatment and to educate physicians on the interpretation and practical application of comparative effectiveness and cost-effectiveness data. Attaining a thorough understanding of the costs of the therapies and procedures they recommend will enable physicians to help patients assess the value they assign to particular treatment options.

#### **Physician Education**

*ASCO recognizes that discussion of treatment value and relevant cost information is complex and requires appropriate communication skills, physician education, and practice infrastructure. ASCO is committed to the development and dissemination of clinical support tools to help prepare oncologists to engage in cost discussions with their patients.*

ASCO has taken the lead in educating practitioners and trainees about integrating other, sometimes difficult discussions, such as end-of-life care, with patients into their daily practice. ASCO

supports development of educational resources to help oncologists address cost of care issues with their patients. To address educational needs, the Cost of Cancer Care Task Force is developing tools and resources, including cost of care education sessions for the ASCO Annual Meeting, that will help to clarify the role of oncologists regarding cost, effectively prepare oncologists for questions that patients may raise about cost, and help oncologists to identify existing resources already available to assist patients with cost. Additionally, the Task Force is exploring methods to help oncologists compare the costs and effectiveness of available treatments in a practical way, such that they may integrate this information into their discussion with patients.

### **Patient Education**

*Oncologists must understand the unique needs of each patient when making treatment decisions, including consideration of out-of-pocket costs. ASCO will work with others in the oncology community to assure availability of resources that integrate cost of treatment and other relevant information to support patient decision making.*

The process of medical decision making is the integration of information about clinically appropriate therapies with patient preferences.<sup>45</sup> The cost of cancer care has become an important component in weighing the benefits and risks of treatment options. For individuals with a diagnosis of cancer, understanding what costs to expect before starting treatment is important to effectively manage the financial impact. It also is important that patients recognize that their personal costs will depend on several factors, including the length and type of the cancer treatment plan and the extent of their health insurance coverage.

Patients must receive assistance to recognize that out-of-pocket expenses associated with treatment may represent a substantial burden for themselves and their families. They must have access to appropriate information about likely treatment costs, which will vary based on insurance status. Furthermore, patients should have tools available to assist them in communicating with their physicians about cost.

Just as ASCO has supported oncologist-developed patient educational tools,<sup>46-48</sup> ASCO supports development of educational resources to help patients address cost of care issues with their physicians and health care team. To this end, the following educational needs for patients have been defined: to communicate effectively with providers about the cost of their care; to identify the direct and indirect costs involved in cancer care; to understand the costs and benefits of their treatment; and to identify financial resources. To meet these needs, the Task Force is developing patient education materials to help patients communicate with their physicians and health care team about cancer care costs.

### **Addressing the Underlying Factors Contributing to the Increasing Cost of Cancer Care**

*ASCO recognizes that the factors underlying increasing costs of cancer care are multifactorial and occur in the context of a health care system that is not integrated, is poorly coordinated, and values clinical interventions, the uses of advanced technology, and cognitive care in markedly different ways.*

The current health care system in the United States does not promote use of the most cost-effective medical care. Nevertheless, it is the responsibility of ASCO and all cancer care stakeholders to work together to identify alternative approaches that focus on the quality of

care and the appropriate recognition of cognitive effort and communication skill as a component of comprehensive cancer care. Moreover, it is crucial that the oncology community identify ways to ensure that clinical decision making is based on evidence-based medicine. The oncology community must define the value of specific cancer interventions, integrate judgments of value in clinical guidelines, and proactively define the appropriate role of cost considerations in establishing standards of care. On behalf of the cancer provider community it represents, ASCO intends to be an active participant in the dialogue about substantive health care reform. The overall goal is to modify our health care system to become one with a consistent focus on high-quality, cost-effective care for all members of society.

### **NEED FOR FUTURE RESEARCH**

There are limited empirical data regarding the influence of cost (societal and/or patient out of pocket) on patient and physician communication and decision making. Furthermore, few studies have addressed the increasing costs of cancer care from a broader societal perspective.<sup>49</sup> ASCO believes that efforts to guide policy regarding the increasing cost of health care in general, and cancer care in particular, must take into account the perspectives of all stakeholders, including patients, industry, payers, and providers. These deliberations must be based on credible information that is not yet at hand. The ASCO Cost of Care Task Force recommends the following areas as targets for future research.

#### **Physician-Patient Communication**

First and foremost, research into patient-physician communication is required to discern how patients and clinicians perceive that this issue ought to be handled and what gaps exist in the information necessary to inform these discussions. Because it is likely that perceptions vary, it will be important to determine what patient, provider, and health system characteristics are associated with such differences. Once these predictors are determined, barriers to effective communication can be addressed, and optimal communication strategies can be identified and evaluated.

#### **Medical Decision Making**

Clinicians often have to weigh competing concerns—for example, the desire to support important research or important public health interventions against the needs of the individual patient. When it comes to economic considerations about the costs of treatment, these conflicts may fall into particularly sharp relief because the stakes are so high. Many advanced cancer patients may feel under pressure and will naturally be hopeful that a particular treatment will produce remarkable results in their unique case, notwithstanding the population statistics that may suggest otherwise.

Research can help oncologists understand their own internal biases in medical decision making. Behavioral economists have long recognized the perfectly rational irrational decisions that humans make. Understanding these biases in the context of decision making about expensive cancer treatments for advanced cancer might help to improve the process of communication.

## Defining Value in Cancer Care

Although it is usual for randomized clinical trials to collect data on efficacy and toxicity, economic data are seldom collected prospectively in clinical trials because of the added cost, because the information is not used by the US Food and Drug Administration in making regulatory decisions about drug approval, and because the relevance of these data to specific payers differs greatly.<sup>43</sup> In addition to the characterization of safety and efficacy in studies with high internal validity, more research on the economic consequences of cancer interventions is needed. For example, appropriately designed clinical trials should be conducted to provide physicians with increased resources to help their patients assess the value they assign to particular treatment options. Moreover, research to identify strategies for determining value is required. This may help physicians balance their desire to deliver optimal health care to each individual with their commitment to use societal resources wisely. Research also can identify ways to help physicians recognize these conflicts and devise strategies to cope with them.

## FUTURE DIRECTIONS AND NEXT STEPS

The issues raised in this article have important policy implications that must be addressed to effectively deal with the increasing cost of cancer care. As the next step in its efforts, the Cost of Care Task Force will consider economic policy issues relevant to cancer care, with a goal of contributing to this complex discussion of critical importance to our patients. These efforts will include an attempt to clarify the drivers of cost in cancer care and suggest ways these drivers can be addressed; define the value of new innovations, with subsequent integration of value into treatment recommendations and guidelines; and develop strategies to mitigate the impact of cost on disparities in access to cancer care.

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## AUTHORS' DISCLOSURES OF POTENTIAL CONFLICTS OF INTEREST

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## Appendix

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