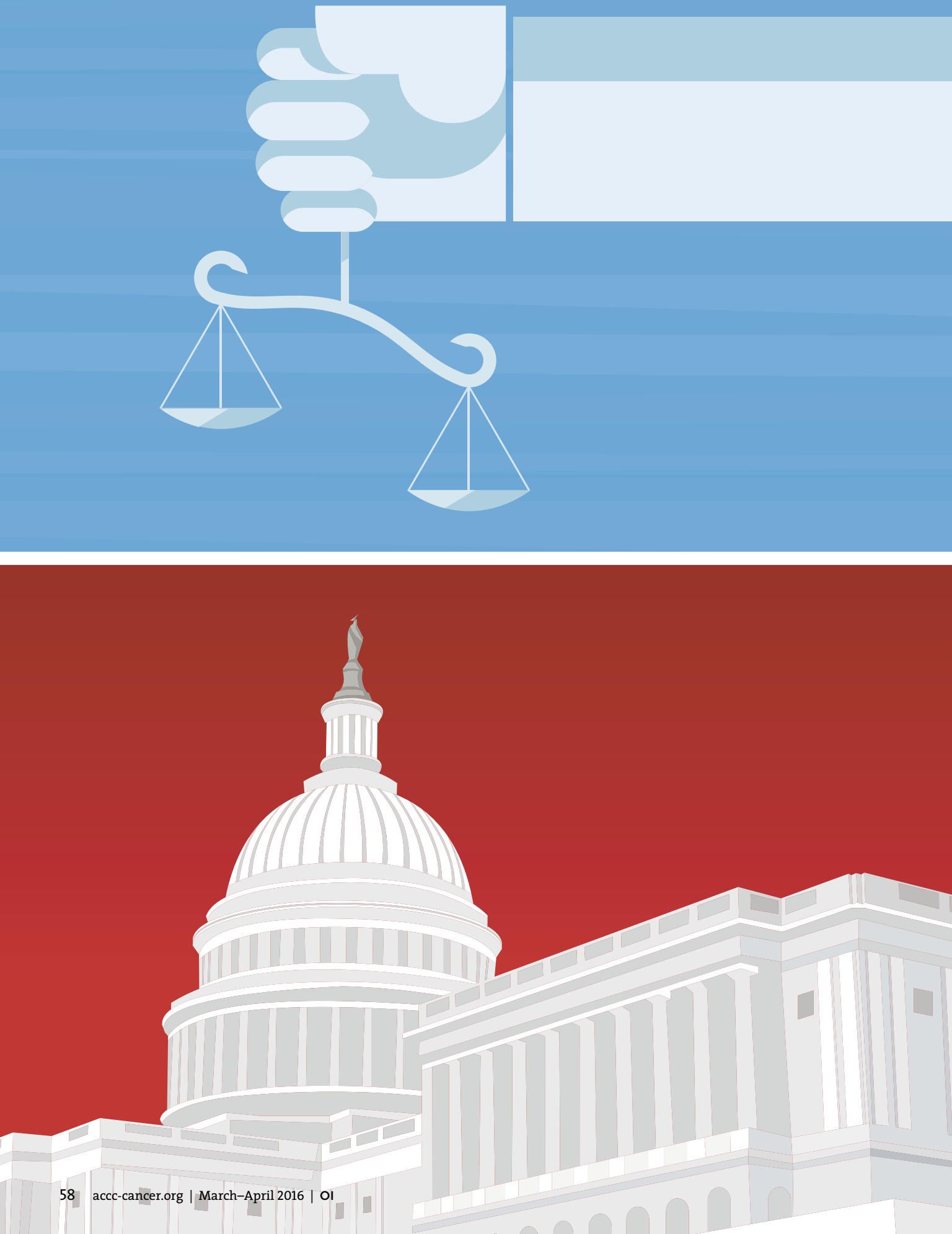

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# Exploring the Issue of Cancer Drug Parity

Understanding the magnitude and underlying considerations surrounding the multidimensional and controversial issue of cancer drug parity is important for evaluating the value of cancer treatments and the impact of related legislative efforts. This article offers a snapshot of where we are today on the issue of cancer drug parity, including implications for patient care.

## Oral Therapies to Treat Cancer

Innovative discoveries in cancer treatment have led to the development and approval of more than 40 orally administered anticancer agents in the U.S. While many cancer therapies continue to be administered by infusion and injection, oral agents have indications to treat more than 50 types of cancer.[1,2] Experts estimate between 25 and 50 percent of oncolytics currently being studied are orally administered "smart" or targeted agents.[2,3-6] While targeted oral therapies are cutting-edge advancements in personalized healthcare, creating more treatment options for refractory and recurrent disease, their use increases the complexity of treatment and is not without controversy.

With the focus on patient-centered care, the decision to treat cancer with oral agents greatly impacts shared decision making due to physical, psychosocial, economic, and organizational factors. The value of treatment across each of these domains is important to consider.[2,7,8] Physically and psychosocially, oral antineoplastics are widely perceived to enhance patient quality of life due to convenience in self-administration, lower work absenteeism, and increased survivorship. However, home administration highlights concerns related to patient self-reporting of side effects, the potential for incorrect self-dosing, and safe handling issues for agents with hazardous characteristics.[2,4,5,6,9] Furthermore, most of these agents are novel targeted biotherapies, costing more to develop. These oral agents are priced higher than those administered by other routes, traditional chemotherapy, and drugs with generic equivalents, and they fall into the highest formulary cost tiers.[2-6, 9-12]

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The economic issue is complicated by the multiple payment, reimbursement, and incentivization channels in the U.S., which vary depending on care setting. Dispensing oral therapies typically occurs in a pharmacy while injected treatments are administered in a clinical care setting. As a result, injected antineoplastics are usually covered through medical health plans, while orally administered cancer therapies are often covered by prescription drug plans. When compared to medical plans, cost-sharing may be substantially higher for agents with no generic equivalent and paid through prescription drug plans. The most expensive oral

cancer treatments carry high compulsory cost-sharing.[2-6,9,10,12] Some plans require up to a 30 percent cost-sharing rate.[2,4,8] The difference in dispensing settings and cost has created disproportionate payment for patients by some insurance plans.

## Cancer Drug Parity Legislation

"Parity" refers to equality in cost-sharing between different routes of medication administration. Many states have addressed this issue by enacting oral parity laws. According to the Patients Equal Access Coalition (PEAC), as of January 2016, 40 states plus the District of Columbia have enacted cancer drug parity legislation, with 5 more states actively working to pass similar legislation. State fact sheets can be viewed and printed to share with community oncologists on the PEAC website: peac.myeloma.org.

Essentially, state-based oral parity laws affect insurance pricing to the consumer; pricing set by drug companies is not restricted.[3,5,6] State rulings affect only plans already offering coverage for antineoplastics, requiring equal cost-sharing for oral cancer therapies as for cancer drugs administered by other routes.[2-6,9,10,12] In a few states parity laws differ, placing out-of-pocket caps on expenditures.[13] Additionally, cancer drug parity laws prevent insurers from adjusting costs of injected cancer drugs to balance increased coverage of oral therapies.[2-6,9,10,12]

It is important to note that state cancer drug oral parity legislation primarily affects private, small group, and state-based insurance policies. These laws do not apply to patients covered by the Employee Retirement Income Security Act of 1974 (ERISA) or by Medicare. (Patients need to opt into Medicare Part D for outpatient prescription drug coverage.) Traditionally, Medicare reimburses for drugs administered in a clinical setting. Reimbursement for self-administration is limited to certain agents, diseases, and situations. Strict criteria determine whether oral anticancer agents are reimbursed, and prior authorization is required.[3,4,6,9,12] Furthermore, the Medicare threshold price for many anticancer drugs is quickly reached in regimens with multiple treatment cycles.

## Federal Initiatives

As stated above, cancer patients insured by federal health plans are not covered by oral parity laws enacted at the state level.[13] Thus, action at the federal level is still needed. The most recent Congressional activity involves the bipartisan Cancer Drug Coverage Parity Act of 2015 introduced by Congressman Leonard Lance (R-NJ), Congressman Brian Higgins (D-NY), Senator Mark Kirk (R-IL), and Senator Al Franken (D-MN). Supporters believe that enacting cancer drug parity at the federal level will equalize coverage to include federal insurance recipients, and will benefit states without parity legislation. The outcomes of this parity bill are aimed at group and individual insurers to require equal or "no less favorable" coverage for all prescribed antineoplastics meeting guidelines for clinical necessity and appropriateness regardless of administration route or setting. Similar to state acts, the bill proposes to ban insurers from creating situations of noncompliance and from imposing increased cost-sharing or limitations on other anticancer medications to counterbalance the oral drug costs. According to Leslie Brady, Health Policy Advisor to Rep. Higgins, the bill is hoped to be a starting point that eventually includes a re-evaluation of federal insurance plans specific to anticancer agents.[14,15]

Some experts question the value and convenience of newer oral cancer therapies due to the higher cost being transferred to consumers upon drug approval, referring to this as "financial toxicity."[7,8,19]

## Collaboration for Change

Policymaker recognition of the rapid rise in patient financial responsibility for cancer treatments is promising, yet more aggressive advocacy and cost management are needed. Patients and providers must be able to measure the value-based benefits of therapeutic agents and understand cost stipulations to facilitate collaborative treatment decision-making. As discussed above, the quality and value of care are impacted by underlying factors that determine the rapid rate of therapy development, importance of treatment compliance, and appropriateness of treatment regimens in vulnerable populations. Delving deeper into these factors may assist in improving collaborative advocacy efforts pushing for drug parity in cancer care.

## Accessibility & Cost Control

The Institute for Healthcare Improvement (IHI) approaches optimizing the health system based on the "Triple Aim." The framework pursues improvement of the patient experience (quality and satisfaction), improvement in population health, and reduction in healthcare costs.[16] The Affordable Care Act (ACA) includes provisions that medical treatments are accessible and affordable with expanded drug coverage, decision-making is shared, and therapies are based on clinical necessity. Access to innovative therapies, such as biologic oncolytics, includes a time-sensitive pathway for development of generic medications. The ACA also expands incentives to enable hospitals

to obtain cancer treatment medications for their formularies at discounted prices.[17]

While both the Triple Aim and ACA set forth general provisions to limit treatment costs, specific metrics for determining accessibility and affordability are lacking. New oncologic agents may not be universally covered. Consumer pricing is addressed with varying details of out-of-pocket cost capping. Determining treatment necessity is unclear with the exception that decisions are not based on life expectancy. Lastly, discount pricing for hospitals does not apply to private oncology practices.[18] These issues generate concern and are partially driving state drug parity initiatives.[2,18]

While some insurers and a few state cancer drug parity laws limit consumer cost-sharing, no capping or benchmark pricing exists for costs set by pharmaceutical companies in the U.S. The price of a drug is dependent on who may use it and the market share based on patient volume. Greater volume initiates lower pricing and lesser cost to the patient. Most innovative cancer therapies are biologic agents, costing more to develop than traditional therapies. Some experts question the value and convenience of newer oral cancer therapies due to the higher cost being transferred to consumers upon drug approval, referring to this as "financial toxicity."[7,8,19] While drug companies offer payment assistance programs aimed to alleviate cost burdens for patients, many of these programs are not comprehensive, are difficult to navigate, and have time-intensive application processes.[20,21] ACCC has developed two key resources to help meet these challenges: the *2016 Patient Assistance and Reimbursement Guide* (accc-cancer.org/PatientAssistanceGuide) and the Financial Advocacy Network (accc-cancer.org/FAN).

Reimbursement is another cost-controlling issue that is increasingly dependent on and incentivized based on prescribing of standard of care treatments. Pharmacies and healthcare organizations are often offered discounted drugs that may have less efficacy but are more affordable.[1,2,5,8,9,22] Recently, two large U.S. managed care pharmacies removed specific drugs from formulary after pharmaceutical companies denied requests for price cuts. Provider complaints then resulted in pharmaceutical companies lowering drug prices to attain formulary status once again.[6] Also, the growing use of specialty pharmacies may impact price negotiations and the work of traditional retail pharmacies.[23]

## Patient Outcomes & Quality of Life

Cancer patients and their families have healthcare expectations, including treatment standards based on efficacy, quality of life, safety, and financial considerations. Patients routinely desire to receive treatment considered to have the best outcomes, sometimes regardless of cost or side effects. Most standard regimens include quality-of-life data in post-marketing studies; however, economic data is rarely collected. Treatment standards do not consider value of options, such as cost of care, influence of disparities and culture, patient preference, or compliance issues. Furthermore, life expectancy is not considered in most treatment standards.[1,2,7,10]

Lastly, many parity advocates believe oral agents offer greater quality of life, including the convenience of at home self-administration, decreased travel expense, fewer work hours lost, and avoidance of infusions with potential risk for infection and extravasation.[4,5,9,12,20] However, in some cases, convenience of oral agents and infusion risks are not true issues, as there may be no other choice for treatment, or no equivalent administration route options.[2,20] Travel and time may be a priority depending on patient performance status, work and home life, and geographic location. Clear communication is critical to addressing quality of life issues when considering appropriate route of administration.[3,20,21]

## Patient Safety, Compliance & Satisfaction

Safety issues in managing oral drug therapy include monitoring treatment adherence and compliance; reporting, assessing, and managing toxicities; assessing for drug interactions; and safe handling of hazardous oral agents.[5,12,24,25] Adherence issues are most problematic because of complex dosing schedules. Survival and well-being may depend on precise administration, and studies indicate up to 80 percent of patients do not take oral oncolytics as prescribed. This overuse, underuse, or misuse may result in greater risk for complications and treatment failure.[2,8]

At home administration requires specific, intense, and ongoing educational efforts to optimize patient self-reporting of complications and other issues that may arise. Community or home-based caregivers may be needed. Staff availability and training to triage incoming calls and monitor electronic communication from patients must be considered as the use of oral agents increases with or without cancer parity legislation.[3,6] Patient involvement in planning care and follow-up is vital to success.[3,20,21]

## Proponents & Opponents of Cancer Drug Parity

Proponents of cancer drug parity legislation primarily focus on easing the cost burden for patients whose best treatment option includes an oral agent. Simply put, without parity laws some patients cannot afford to pay for cancer treatment. As a result, providers may not be able to prescribe optimal therapies based on clinical guidelines and considered standard of care.[1,2]

Opponents believe the issue is important but needs to include stipulations related to the value of treatment and cost of drugs assessed by pharmaceutical companies.[6,8,9,26] Concerns also exist related to the increased use of oral antineoplastics, specifically safety and care related to adherence and proper use.[5,12] With parity legislation, many insurers face a surge in cost for oral cancer drugs; use of treatments with higher costs are usually

**Table 1. Key Stakeholder Position Statements Related to the Cost of Cancer Care**

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| • | **American Society of Clinical Oncology (ASCO).** The healthcare system is "not integrated, is poorly coordinated, and values clinical interventions, the uses of advanced technology, and cognitive care in markedly different ways."[27] |
| • | **Association of Community Cancer Centers (ACCC).** The Association advocates for quality comprehensive cancer care for all, including passing legislation at the state and federal level that would require health insurance plans to cover orally administered chemotherapy at the same rate as IV-infused counterparts.[28] |
| • | **The Institute of Medicine (IOM).** Providers must supply patients with "understandable information at key decision points on such matters as cancer prognosis, treatment benefits and harms, palliative care, psychosocial support, and costs of care."[7] |
| • | **The Oncology Nursing Society (ONS).** Posits that healthcare should be accessible and affordable with coverage that "includes consumer choice and control, including providing the patient with information about the cost of treatment options and allowing for informed treatment decisions."[29] |

dissuaded by most payers.[4] However, without parity legislation, increased care costs may be incurred due to less effective treatment options that lead to recurrence or complications.[20]

Various organizations have tackled the issue of treatment cost as it relates to information-sharing, patient engagement in decision-making, and quality outcomes. Table 1, above, offers excerpts from key position statements that help guide professional standards, including ethical considerations for quality care.

## Advocating for Change

Advocating for cancer drug parity legislation with amendment recommendations from community cancer centers may bolster support for the issue at the federal level. Based on the evidence and literature in support of cancer drug parity, amendments may include:

- Accountability for and measurement of implementation, evaluation, and compliance processes
- Resources for determination of medical necessity and clinical appropriateness for the entire treatment plan
- Incentives for compliance and sanctions for noncompliance
- A timeline with tools and resources to address healthcare literacy with participant notification.

Alternative or additional proposals to consider based on information presented include:

- Measures and stipulations regarding cost-sharing limits
- Inclusion of adequate supplying of supportive care agents
- Immersion of economic disparities in clinical guideline development
- Recommendations for service coding changes
- Negotiations, price caps, and benchmarks for pharmaceuticals
- Timeline development changes for generic equivalents.

Interest in passing oral parity legislation at the federal level remains high and is expected to move forward in 2016. OI

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