Global Coalition on Aging

Policy Brief: Innovation in Oncology Supports Healthy Aging

MARCH 2024

Preface

On September 27, 2023, **The Global Coalition on Aging** (GCOA) Alliance for Health Innovation and **The American Federation for Aging Research** (AFAR) contributed to the ongoing dialogue on these critical issues with a Cross-Discipline Roundtable Discussion on Healthy Aging, Innovation, and Oncology.[1] The discussion brought together experts on cancer treatment, healthcare policy development, aging, and patient perspectives to explore the value of biomedical innovation and the importance of both the availability and accessibility of innovative treatments as a prerequisite for healthy aging.

This policy brief highlights the outcomes of the roundtable discussion and provides policy recommendations to ensure equitable access to future biomedical innovations and contribute to healthy aging for all. While the discussion during the roundtable focused on improving innovation in oncology, the recommendations apply to the broader United States innovation climate and healthcare ecosystem.

These recommendations build on the outcomes of a separate roundtable held in June of 2023 on health equity and innovation that identified four policy principles to improve innovation and equity for healthy aging:[2]

1.	**Individuals should be at the center of our thinking when discussing healthcare innovations. We need to engage with individual patients in their communities to ensure they can access the healthcare services and support they need.**
2.	**Medical innovation must be sufficiently valued and incentivized.**
3.	**Medical innovation must be accompanied by process innovation across the healthcare ecosystem.**
4.	**Better awareness is needed on the return on investment of innovation and the benefits of distributing funding for healthcare services to the communities and support programs where it is most beneficial.**

Roundtable participants

Michael Hodin
CEO, Global Coalition on Aging (Moderator)

Kirsten Axelsen
Nonresident Fellow, American Enterprise Institute

John Beard
Director, International Longevity Center USA

Laurie Campbell
Executive Director, Metastatic Breast Cancer Alliance

Beverly Canin
Co-Chair, SCOREboard Patient Advocate Board

MJ DeCoteau
Founder and Executive Director, Rethink Breast Cancer

Ibrahim Elhoussieny
Vice President and Global Head of Medical Affairs, Kite Pharma

Lori Frank
Senior Vice President for Research, New York Academy of Medicine

Paige Green
Chief, Basic Biobehavioral, and Psychological Sciences Branch in the Behavioral Research Program, Division of Cancer Control and Population Sciences, National Cancer Institute

Richard Jackson
President, Global Aging Institute

Rajini Jayasuriya
Associate Principal, Charles River Associates

Joseph Hammang
Partner, Vital Transformation

Amy Kelley
Deputy Director, National Institute on Aging

Jim Kirkland
President, AFAR

Melissa Gong Mitchell
Senior Managing Director, Global Coalition on Aging

Duane Schulthess
CEO, Vital Transformation

Jason Sterne
Director, Policy Advocacy and Alliances, Gilead Sciences Inc

Policy Brief:
Innovation in Oncology Supports Healthy Aging

Table of Contents

Introduction and policy recommendations

Biomedical innovation has played an integral role in our ability to live longer, healthier lives, even as rare and chronic conditions such as cancers have created challenges for our society and health systems. Although innovation has improved patients' lives, we must acknowledge that more innovation is needed to continue to benefit patients who do not currently have options, and that our healthcare system does not always produce equitable outcomes. Therefore, it is important that we continue to develop policies that support a robust and sustainable innovation climate to improve the availability of new drugs and treatments to ensure more equitable health outcomes and healthier aging for all.

To improve healthy aging and reap the potential benefits of current and future biomedical innovations, we must ensure the availability and the accessibility of new and effective treatments for all patients by:

1.	**Advancing policies that enable patients access to utilize the best medicines for them as prescribed by their physician.**
2.	**Removing disincentives for innovation in policies such as the Inflation Reduction Act (IRA) and optimizing the use of accelerated pathways for new drug development.**
3.	**Supporting access to innovative treatments with a focus on improving equity in our healthcare system.**
4.	**Embedding patient and caregiver input in policy decisions that define clinical benefit, their perception of value, and that which will impact access to medicines that they rely on.**

Today, our world faces an urgent challenge in providing quality care to the rapidly growing population of older adults while confronting the intricately linked and growing prevalence of cancer in this age group. Geroscience is a crucial intersection between aging and cancer research, potentially enhancing outcomes and improving the quality of life for individuals at risk of developing cancer, those currently undergoing treatment, and cancer survivors.[3]

The recently released *National Cancer Plan* from the National Cancer Institute (NCI) identifies the development of effective treatments as one of eight goals that must be fulfilled to accomplish the plan.[4] Investments in research and development (R&D) efforts are critical to drive scientific discovery and support the broader policy landscape and vision that President Biden set with the renewed Cancer Moonshot.[5] For the Cancer Moonshot to succeed, policies that impact the regulatory framework, access and reimbursement, and intellectual property must align with the need for continued support and investments that lead to new and effective treatments that help people live longer, healthier lives.

"

Kirsten Axelsen, Nonresident Fellow, American Enterprise Institute (AEI)

The point is to accept that living longer costs money, and we want to live longer, so it's going to cost money."

The value of biomedical innovation for healthy aging

Advancements in science and technology must be widely adopted to ensure everybody has an opportunity to age gracefully. Patients and their caregivers must be involved in policy decisions that define clinical benefit and policies must recognize that each patient and their caregiver's perception of value from a therapy is unique and will change over time.

Biomedical innovation is the cornerstone of healthy aging as it leads to advancements in our healthcare ecosystem and improved outcomes for patients. However, work remains to be done to address the current and growing challenges of an aging population. With our increased lifespan, there is a heightened focus on multifactorial non-communicable conditions such as Type II diabetes, cardiovascular disease, autoimmune disease, and cancer, for which aging itself is one of the most fundamental risk factors.

One example of how aging occurs at the cellular and molecular levels is through the immune system, which becomes less resilient and protective with age, resulting in diminished capacity to detect or fight illness. This creates an urgent need for new and innovative therapies to treat conditions like cancer as it becomes increasingly prevalent in older adults.

"

Timely access to an innovative new therapy can be the difference that keeps the conversation in the "curative setting."

The difference that helps ensure those diagnosed at a young age do have the best opportunity to grow old and to age as successfully as possible."

MJ DeCoteau, Founder and Executive Director, Rethink Breast Cancer

A Case Study in Innovation: Breakthroughs in CAR T-cell Therapy

Innovative therapies like chimeric antigen receptor (CAR) T-cells therapy that can deliver targeted benefits across various disease areas have been revolutionary and show great future promise for several conditions that are notoriously difficult to treat successfully, including blood cancer. CAR T-cell therapy is a custom-made, one-time cancer treatment that engineers a patient's own white blood cells and harnesses their immune system to treat certain kinds of cancers. CAR-T therapies have demonstrated that they are very useful in treating blood-based cancers like lymphoma, myeloma, and leukemia and bring new hope to potential patients and families.

However, like other treatments developed to combat cancer, there remains a very high unmet medical need in terms of cancer types that are not currently receptive to these therapies, which emphasizes the need for continued prioritization of investing in the development of the most effective therapies possible.

"

Despite the fact that some of these therapies have been available now for more than five years, we are seeing only two out of ten eligible patients getting access to this therapy.

I think this is something that we all agree needs to change."

Ibrahim Elhoussieny,
Vice President and Global Head of Medical Affairs, Kite Pharma

While CAR-T therapies have been available for several years, access remains a barrier for most as only fifteen to twenty percent of patients indicated for CAR-T have access.[6] From that perspective, it is critical for different aspects of the care delivery ecosystem – including regulatory agencies and reimbursement systems – to work together with a shared objective to increase uptake of these innovative therapies.

To do so, policymakers must consider the disparities in access to new drugs and treatments. This means addressing systemic barriers that exist in our healthcare system, which includes ensuring that the system is equipped to support cancer survivors – who are now more numerous than ever thanks to advancements in treatment and care. Policies that enable patients to access and utilize the best medicines as prescribed by their physician are critically important in protecting against disparities related to healthy aging and ensuring all patients impacted by cancer have the opportunity to live longer, healthier lives.

Availability and accessibility as a prerequisite for healthy aging

To reap the potential benefits of current and future biomedical innovations and improve healthy aging, we must ensure both the availability and the accessibility of these treatment innovations for all patients. We must advance policies that enable patients to access and utilize the best medicines for them as prescribed by their physician which is critically important in protecting against disparities related to healthy aging.

"

In the US, there is this relatively significant availability of innovation compared to other more cost-sensitive countries in the world. But then when you think about actual uptake and true access, you have countries with much higher access."

Rajini Jayasuriya, Associate Principal, Charles River Associate

The United States is a leader in researching, developing, and bringing new therapies to patients where there is an unmet medical need. A patient's ability to easily seek and receive treatments and services is crucial to ensuring effective healthcare delivery. Moreover, the availability of novel therapies is supported through an environment that promotes and rewards investment, and the accessibility of these therapies by any patient who would benefit is achieved when the healthcare delivery system centers equity in its design.

There has been erosion of the bedrock that our innovation sector was built upon, jeopardizing the discovery of new and novel therapies. For example, due to the small populations impacted by rare diseases and cancers, drug discovery has been slow, and as such, patients with a rare disease often have had limited if any treatment options. To stimulate the development of drugs for rare diseases, Congress passed legislation to incentivize investment for the development of effective treatments and granted them Orphan Drug status, including CAR-T for several indications.[7] However, the IRA has introduced disincentives that will impact investment and innovation in rare diseases, as well as small molecule drug development – the latter of which is particularly detrimental to innovation in diseases still awaiting a breakthrough treatment.[8]

This includes cancers, but also diseases in the neurodegenerative space like Alzheimer's, which will likely require small compounds capable of traversing the blood-brain barrier.

While the IRA exempts single-indication orphan drugs from drug price negotiations, approvals for subsequent indications essentially void this provision and consequentially start the countdown toward price negotiations. This effect is exacerbated because the start time for this countdown to price negotiation is the initial date of approval for the first approved indication. This results in an extreme disincentive for continuing trials for additional indications of potentially life-saving medication and stifles the incentive to develop approved treatments for a wider scope of disease. As a result, fewer new drugs and treatments will potentially never become available to patients suffering from rare diseases. In cancer, much of the progress is conducted after they receive their first approval from the FDA, where more than 60% of oncology medicines approved a decade ago received approvals for additional indications in later years.[9] Similar to rare diseases, the IRA creates disincentives to explore additional indications for cancer treatments, particularly for smaller patient population sizes where there is a high unmet need.

Beyond availability, we must ensure that patients are able to access and benefit from innovative treatments. For example, in the case of CAR-T therapies, only a fraction of eligible patients initiate treatment, despite some modalities having been commercially available for more than five years. For new and novel commercialized drugs, health insurance plans may limit patient access through utilization management tactics such as step therapy or high out-of-pocket costs, community treatment centers might not utilize or be aware of the most up-to-date therapies, and/or there may be inadequate awareness and education of the treatments benefits.[10]

Even when innovations are available, they may not be accessible and utilized by patients who might benefit.

"

I think it's worth reminding that with innovation, a lot of it depends on where you sit and what your job is. If you're the head of Health and Human Services, responsible for all Americans, your perspective and your investment is trying to figure out where to place the next bet to get the best return on investment. We must decide what our objective is as we put together the desire for more innovation but also wish to improve equity. People should get the care they need wherever they are."

Jim Kirkland, President, (American Federation for Aging Research) AFAR

Disparities, many of which are structural, also exist in clinical trial access, particularly affecting racial and ethnic minority groups, which hinders study participation and contributes to lower representation of minorities and individuals who live in rural communities.[11] Clinical trials that are not inclusive can not only threaten the validity of the results, but also deny an important avenue of access to the patients that could benefit most from a new treatment. While medical trust must always be considered in the participation discussion, research shows that willingness to participate in clinical trials is actually comparable across most underrepresented groups, especially once structural barriers to participation are addressed. Structural barriers include robust patient engagement, such as representation of patients or advocates in the research process, convenient research site selection, and consideration of opportunity costs for participants, which can be remedied through appropriate participation incentives or provision of transportation or childcare.[12] Clinical trials that are not inclusive can not only threaten the validity of the results, but also deny an important avenue of access to the patients that could benefit most from a new treatment.

"

Ibrahim Elhoussieny,
Vice President and Global Head of
Medical Affairs, Kite Pharma

No matter how innovative a therapy is, we will not close the disparity gap if the treatments are not structurally enabled to ultimately reach the patients that will benefit."

Ultimately, patients will benefit the most from a holistic approach that considers both the positive impact that innovation will have on the availability of new drugs and treatments as well as the positive impact of improving our healthcare system to increase the accessibility of drugs and treatments for those patients that need them.

Improving availability through the right innovation environment

To create an environment that fosters innovation, we must remove policy disincentives and optimize the use of accelerated pathways for the development of new drugs and treatments.

In the process of developing new drugs and treatments, a company first needs to establish if the innovation in development works and, secondly, if there is an observed clinical or therapeutic benefit among a patient population from the innovation. A functioning innovation ecosystem needs to be supportive of both these elements and ensure that there is a clear reason for companies to develop and iterate on the therapies that can help cure cancers and other diseases for which there is a lack of treatment options. Availability of a therapeutic stems from the clear denotation of medical need.

Case Study: Access and Innovation in the European Union

The consequences of disincentivizing innovation are clearly visible in the European Union. For example, the average time to reimbursement that enables patients access innovative treatments across the European Union and the European Economic Area (EEA) countries has reached 517 days- ranging from 128 days in Germany to 1351 days in Malta, according to EFPIA.[13] Price controls, in the form of upper payment limits (UPLs) or other restrictions that disincentivize market access to new drugs and treatments, can be partially attributed to this delay.

As a result of the focus on containing the cost of healthcare in Europe, the research and development landscape has shifted, and the United States is now the driving force behind global biomedical innovation.

Research has shown that a ten percent drop in the price of medicines in price-controlled European Union markets was associated with a decrease of fourteen percent in total venture capital funding for biomedical innovation, a decrease of seven percent in biotech patents, and a decrease of 9 percent in biotechnology start-up funding relative to the United States. In 2020, the United States' share of total annual biotech startups was roughly three times greater than the European Union's share.[14]

"There are always trade-offs between maximizing innovation, ensuring access, and controlling health-care costs. In recent decades, European health systems have stressed cost control and access, at least to a basic package of health-care services, at the expense of innovation. America excels at innovation, but tolerates unequal access and fails dismally at cost control. If there is a way to achieve all three goals at the same time, no one has figured it out yet."

Richard Jackson,
President, Global Aging Institute

Without the incentive to innovate, the availability of new treatments will dwindle, leaving people with medical needs without options. This is especially true of drugs that treat rare diseases and cancers, where innovation must be supported with incentives to pursue clinical trials and indications beyond that of the first.

"We need to make sure that these very rare, very targeted treatments have the ability to flourish. There are currently proposals to try and fix up the disincentives for the orphan drug parts of the IRA, which would be immediately helpful if implemented."

Duane Schulthess, CEO,
Vital Transformation

Improving accessibility by focusing on equity in our healthcare system

We can increase the accessibility of innovative treatments by focusing on equity in our healthcare system.

The fundamentals of the United States healthcare system were designed in an era when access to biomedical innovation was limited, and life expectancy was significantly lower. In a roundtable report on equity and innovation earlier in 2023, GCOA underscored that even though we are trending towards longer and healthier lives, there remain challenges to ensure that this trend includes everyone and that underserved groups and communities reap the benefits of medical innovations.[15]

"It's important to highlight that the burden of illnesses is not distributed equally. Look at the differential impact on communities of color across a whole range of risk factors, including environmental risk factors, and how that may relate to policy-related inequity."

Amy Kelley, Deputy Director, National Institute on Aging

It is essential to include patients, caregivers, and their families from underrepresented communities as an integral part of policy design. In many instances, the availability of new drugs and treatments is higher in the United States than in other countries. However, the accessibility of these treatments for individual patients is not equitable, and there are large disparities in patient access with and without access to health insurance and patients from underrepresented communities and communities of color.

"When accessing a new, innovative treatment, the patient – who is in a very difficult and devastating health crisis – is most often the one banging down doors, jumping through hoops, and drowning in red tape and paperwork to get timely access to the most innovative and effective treatment."

MJ DeCoteau, Founder and Executive Director, Rethink Breast Cancer

In addition to barriers that prevent equitable access to the healthcare system in the United States, it is often difficult for patients and caregivers to get the treatments they need as the healthcare system is complex and challenging to navigate. GCOA recently convened a roundtable discussion at Georgetown University with academia, healthy equity champions, thought leaders, and patient advocates, and developed a set of policy principles to improve innovation and aging. In this report, it was recommended that individuals should be at the center of our thinking when discussing healthcare innovations, because there are many instances where the design of our healthcare system prevents doctors and other medical professionals from focusing on unique patient needs and preferences.[16]

"

John Beard, Director, International Longevity Center USA

If you want to look at the return on investment, it is much likely to be greater when you look at earlier prevention and early interventions which might actually influence the underlying drivers for cancer and other non-communicable diseases."

A focus on early detection and prevention can result in a longer potential payoff period of return on investment. For example, investing strategically in known risk factors that influence the underlying biological drivers of cancer can help prevent cancers from occurring in the first place. One successful example of this kind of early intervention is through human papillomavirus (HPV) immunization and screening initiatives. HPV is a virus that is responsible for approximately 99.7% of cervical cancer cases globally, and cervical cancer takes many years to develop.[17] This leaves a window of opportunity for preventative actions, which range from early immunization to regular HPV screening programs. Widespread implementation of HPV immunization and early detection screening programs have broadly been found to produce economic surpluses, resulting in cost-savings for health systems, and contribute to gender equality.[18] [19] These results would not have been possible without public investments into preventative measures, and the appropriate levers to incentivize the research and development of the technology.

"We also have to give equal input to research, which is aimed at improving quality of life for those that are aging or with advanced disease. Schools that are teaching researchers and clinicians need to change or add to their curriculum so incoming students understand the value of having interactions with patients and patient advocates in their research. So, that we're responding to patients and what's most important to patients."

Beverly Canin, Co-Chair, SCOREboard Patient Advocate Board

For patients, their caregivers, and their families, the quality of life gains that patients enjoy while undergoing treatment can be as important as the lengthening of their lives. Patients may prefer to choose a therapy that offers a higher quality of life over one with side effects that limits their ability to have a positive outlook on life.[20] In an equitable and patient-centric healthcare system, these views should be considered as part of a broader framework for providing the care that each person needs and deserves. This is especially important as people age and cancer survivors live longer than ever. It is crucial to consider the effects of their treatment options and then ensure that they can continue to age as healthily as possible.

"There are so many different impacts as we start thinking about aging and thriving in one's older age, that may change whether someone might take treatments in their later years, or what treatments. Understanding this is essential to a patient-centered view."

Jason Sterne, Director, Policy Advocacy and Alliances, Gilead Sciences Inc

In addition to clinical outcomes, it is important to acknowledge that changes in health-related policies – like the IRA – can have additional effects on patients, their caregivers, and their families, such as an increased caregiver burden when patients are forced to take different drugs or treatments that may adversely affect their quality of life. As with other policy developments, it is important to ensure that underrepresented or disproportionately burdened communities are heard. Otherwise, this can exacerbate disparities and create additional imbalances in the healthcare system, underscoring the necessity to explore opportunities for reform and policy conversations that are equity-first.

References

1 The Global Coalition on Aging (GCOA) Alliance for Health Innovation aims to establish awareness of the importance of innovation in achieving healthy aging through investments, policy reforms, and strategic partnerships – both for the value to patients and for health system sustainability. GCOA's Alliance for Health Innovation is made possible through support from Gilead Sciences.

2 Global Coalition on Aging. (2023, October). *Policy Principles to Improve Innovation and Equity for Healthy Aging.* Policy-Principles-to-Improve-Innovation-and-Equity-for-Healthy-Aging-October-2023.pdf (globalcoalitiononaging.com)

3 Kennedy, B.K., et al. (2014). *Geroscience: The intersection of basic aging biology, chronic disease, and health.* National Institute on Aging. Geroscience: The intersection of basic aging biology, chronic disease, and health | National Institute on Aging (nih.gov)

4 National Cancer Institute. (n.d.). *National Cancer Plan*. National Cancer Plan - Join Us - NCI

5 The White House. (n.d.). *Cancer Moonshot: Ending Cancer as We Know It.* Cancer Moonshot | The White House

6 Zanfagnin, V. & Mathur, G. (2024). *CAR T-Cells Therapies: Opportunities and Challenges.* College of American Pathologists. https://www.cap.org/member-resources/articles/car-t-cells-therapies-opportunities-and-challenges#:~:text=Despite%20their%20success%2C%20there%20are,cell%20malignancies%2C%20antigen%20escape%2C%20limited

7 Hunter, E. (2023, August). FDA Grants Car-T Cell Therapy NXC-201 Orphan Drug Designation for Fatal Multiple Myeloma. *Pharmacy Times*. https://www.pharmacytimes.com/view/fda-grants-car-t-cell-therapy-nxc-201-orphan-drug-designation-for-fatal-multiple-myeloma

8 Potts, S. (2023, March). *Measuring the damage: IRA's impact on small molecule drug development.* No Patient Left Behind. https://www.nopatientleftbehind.org/publications/ira-impact-on-small-molecule-development#:~:text=The%20IRA%20disincentivizes%20development%20of,the%20same%20protections%20as%20biologics.

9 PhAR. "Implications of the Inflation Reduction Ace on Post-Approval Research & Development of Biopharmaceutical Medicines," November 9, 2022

10 Snow, J., Feldman, M., Kappel, J. (2019). The Impact of Step-Therapy Policies on Patients. Xcenda. https://www.xcenda.com/-/media/assets/xcenda/english/content-assets/white-papers-issue-briefs-studies-pdf/impact-of-step-therapy-on-patients_final_1019.pd

11 Tanne J H. US must urgently correct ethnic and racial disparities in clinical trials, says report BMJ 2022; 377 :o1292 doi:10.1136/bmj.o1292

12 Bibbins-Domingo K, Helman A, editors. (2022). Improving Representation in Clinical Trials and Research: Building Research Equity for Women and Underrepresented Groups: National Academies of Sciences, Engineering, and Medicine; Policy and Global Affairs; Committee on Women in Science, Engineering, and Medicine; Committee on Improving the Representation of Women and Underrepresented Minorities in Clinical Trials and Research. Washington (DC): National Academies Press (US). Barriers to Representation of Underrepresented and Excluded Populations in Clinical Research. https://www.ncbi.nlm.nih.gov/books/NBK584407/

13 European Federations of Pharmaceutical Industries and Associations. (2023, April). *The root cause of unavailability and delay to innovative medicines: Reducing the time before patients have access to innovative medicines.* Microsoft Word - CRA EFPIA Root Causes Unavailability Delay 080423 Final .docx

14 Vital Transformation. (n.d.). *The Historical Impact of Price Controls on the Biopharma Industry.* Microsoft Word - The Historical Impact of Price Controls on the Biopharma Industry.docx (vitaltransformation.com)

15 Global Coalition on Aging. (2023, October). *Policy Principles to Improve Innovation and Equity for Healthy Aging.* Policy-Principles-to-Improve-Innovation-and-Equity-for-Healthy-Aging-October-2023.pdf (globalcoalitiononaging.com)

16 Global Coalition on Aging. (2023, October). *Policy Principles to Improve Innovation and Equity for Healthy Aging.* Policy-Principles-to-Improve-Innovation-and-Equity-for-Healthy-Aging-October-2023.pdf (globalcoalitiononaging.com)

17 Okunade, K.S. (2019). Human papillomavirus and cervical cancer. *J Obstet Gynaecol,* 40(5), 602-608. doi: 10.1080/01443615.2019.1634030

18 Carlson, R. (2020, November 17). Cervical Cancer Prevention Investments Produce Significant ROI. *Precision Vaccinations.* https://www.precisionvaccinations.com/cervical-cancer-prevention-investments-produce-significant-roi

19 Herlihy, N., Hutubessy, R., Jit, M. (2016). Current Global Pricing for Human Papillomavirus Vaccines Brings the Greatest Economic Benefits to Rich Countries. *Health Affairs,* 35(2), 227-234. https://doi.org/10.1377/hlthaff.2015.1411

20 Cancer Support Community. Quality of Life For Cancer Patients. https://www.cancersupportcommunity.org/quality-life-cancer-patients accessed, Jan 2024