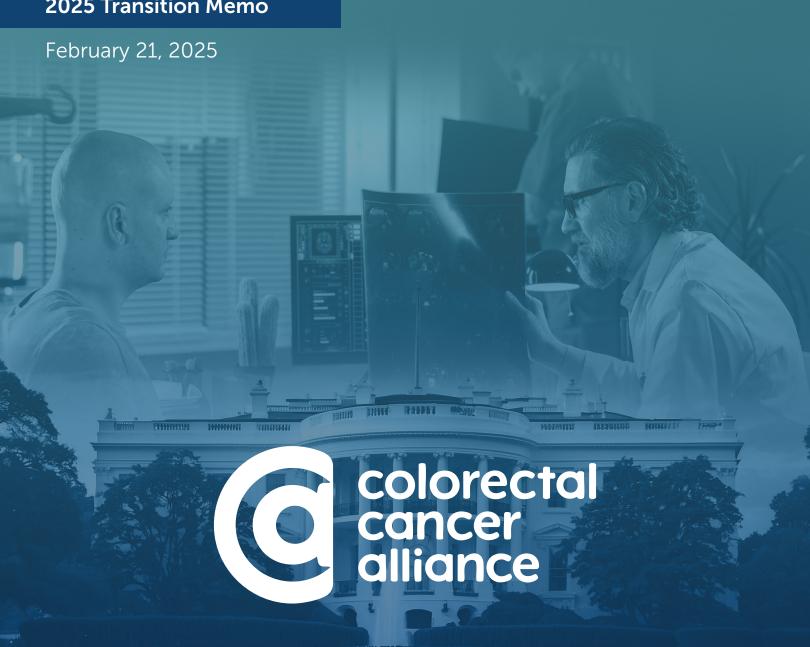
# The Trump Administration's Opportunity to Cure Colorectal Cancer

Colorectal Cancer Alliance 2025 Transition Memo



# **Executive Summary**



Colorectal cancer is currently the leading cancer killer of men under 50 and the second leading cause for women under 50. Colorectal cancer is expected to be the leading cancer killer for both men and women under 50 by 2030. Colorectal cancer is the second leading cause of cancer-related deaths for Americans and its prevalence is on the rise, specifically among Americans aged 20-50. Colorectal cancer impacts countless American families every year and has become one of the deadliest cancers in recent years. The Trump Administration has an opportunity to adequately address Colorectal Cancer, a disease that has not received sufficient federal support despite its widespread impact on American patients and families.

Colorectal cancer has been consistently underfunded and inadequately addressed by the federal government relative to its outsized impact on the American people. With adequate attention and investment, the impact of colorectal cancer can be greatly mitigated and hopefully cured.

We urge the Trump administration to prioritize funding and regulatory reform to address the growing prominence of colorectal cancer and improve care for American patients.



# 1. Urge Congress to address funding disparities for colorectal cancer research

- Dedicate \$1 billion within NCI funding for colorectal cancer research with the goal of increasing the survival rate to 35% (prioritize \$100 million of NCI funds to young-onset colorectal cancer research)
- Create a dedicated \$20 million fund within the Congressionally Directed Medical Research Program (CDMRP) for colorectal cancer research



# 2. Address regulatory barriers that inhibit all Americans from receiving quality care for colorectal cancer, including expanding access to biomarker testing

- Create a federally funded grant program dedicated to covering the cost of biomarker testing for patients
- Increase Medicaid and Medicare reimbursements for biomarker testing
- Create biomarker testing training programs for health care professionals in rural communities



# 3. Improve screening technologies and recommendations for colorectal cancer

- Fully fund and support the CDC's Colorectal Cancer Control program and support nationwide screening efforts
- Support federal regulation that mandates no cost screening for patients ages 45-75.

While truly mitigating the impacts of and eventually curing colorectal cancer will take a large-scale investment from the federal government, there is a significant long-term return on the investment from lowering health care costs. Annually, colorectal cancer treatment costs \$23 billion, accounting for 11.6% of all cancer treatment costs.

### Colorectal Cancer



Colorectal Cancer (CRC) is the number one cancer killer of men under 50 and second leading cancer killer for women under 50. CRC is expected to be the leading cancer killer of both men and women under 50 by 2030. With its prevalence on the rise, especially in young Americans, the federal government must prioritize immediate action to implement a focused, national strategy to uncover the root causes of colorectal cancer, raise awareness, enable early detection, improve care outcomes, and drive innovation in research for better treatments and a cure.

- 154,270 Americans will be diagnosed with colorectal cancer in 2025.
- 53,000 Americans are expected to die from colorectal cancer in 2025.
- Previous gains are being lost: 60% of all new colorectal cancer cases were diagnosed at advanced stages in 2019 versus 52% in the mid-2000s.
- The 5-year survival for Stage IV colorectal cancer patients is only 13%.
- Colorectal cancer treatment costs accounted for 11.6% of all cancer treatment costs in 2020.
- Immunotherapy and combination immunotherapy have only been successful in 3-5% of colorectal cancer cases. Leading treatments for metastatic colorectal cancer have not changed in nearly 20 years due to underinvestment in the disease.

## **Young-onset Colorectal Cancer**

In recent years, cases of young-onset colorectal cancer have increased at an alarming rate. Today, about 13% of colorectal cancer cases are diagnosed in people under 50. The rate of these cases is increasing at about 1-2% each year, and researchers are still attempting to determine the cause. Colorectal cancer incidence rates are increasing the fastest among the youngest adults (ages 20-39). This trend presents a new threat to the nation's military readiness as this population is a key recruiting age for military service. As young Americans are affected by colorectal cancer at an increasing rate, the United States faces a new national security threat if not addressed.

- Young adults are the only population group experiencing an increase in colorectal cancer.
- Colorectal cancer is the number one deadliest cancer for men under 50 and the second deadliest for women under 50.
- Since 1994, cases of young-onsetcolorectal cancer have increased by 51%.
- Early onset Colorectal cancer patients are more often diagnosed with advanced disease, including 27% with distant metastases.

According to the American Cancer Society, "Cancer trends in young adults are the best indicator of progress against disease because they reflect the influence of contemporary exposures as opposed to the cumulative long-term exposures manifest in older adults." The rise of young-onset colorectal cancer cases should not only bring attention to this younger demographic, but also to the widespread impact of colorectal cancer on all Americans.

Colorectal cancer also has a disproportionate impact on the following communities:

- Rural communities throughout the country are experiencing higher rates of colorectal cancer and related deaths. The lack of preventive care and advanced health centers are some of the driving factors for this disparity.
- American veterans are also experiencing higher rates of colorectal cancer due to exposure to toxic metals and substances during service.
- Rates of colorectal cancer are higher in all age groups for American Indian/Alaska Natives (AI/AN). The AI/AN population is notably the only racial or ethnic group for which mortality rates of colorectal cancer are not declining.
- Black Americans have a 15% greater incidence rate and are 35% more likely to die from colorectal cancer.



# **Current Funding Shortfalls**



Colorectal cancer research has been consistently underfunded by the federal government despite the cancer's increasing prevalence. Colorectal cancer has a 5-year metastatic survival rate of 13%. However, the disease has not received commensurate federal resources relative to other leading diseases with higher survival rates, such as breast cancer (35% 5-year metastatic survival rate). The inadequate federal funding for colorectal cancer is highlighted below.

Funding per Cancer Death	
Cancer Type	Research Dollars Per Death
Melanoma	\$16,517
Breast	\$16,189
Brain	\$13,451
Prostate	\$12,084
Thyroid	\$11,343
Leukemia	\$10,224
Ovarian	\$9,240
Non-Hodgkin Lymphoma	\$5,933
Multiple Myeloma	\$4,821
Colorectal	\$4,310
Pancreatic	\$4,231
Kidney	\$4,007
Liver	\$2,706
Bladder	\$2,279
Lung	\$2,134

Funding per Cancer Diagnosis	
Cancer Type	Research Dollars Per Incidence
Brain	\$9,438
Ovarian	\$5,808
Leukemia	\$4,032
Pancreatic	\$3,397
Breast	\$2,605
Multiple Myeloma	\$2,005
Prostate	\$2,002
Liver	\$1,922
Esophageal	\$1,877
Melanoma	\$1,845
Non-Hodgkin Lymphoma	\$1,654
Colorectal	\$1,599
Lung	\$1,495

Funding for colorectal cancer within the Congressionally Directed Medical Research Program (CDMRP) illustrates this underinvestment dramatically. **Colorectal cancer is the only top five cancer killer without a dedicated fund within the CDMRP.** CDMRP is a program within the Department of Defense that funds and conducts medical research on topics identified by Congress. The CDMRP includes dedicated funds for specific research projects on leading cancers and health concerns impacting active duty military personnel, veterans and all Americans. The program has delivered \$4.4 billion in dedicated breast cancer research funding since its inception in 1992. This investment has made a significant impact on improving survival rates for breast cancer, while funding for colorectal cancer remains stagnant, along with the disease's survival rate.

# **Cost of Colorectal Cancer to America**



Beyond the tragic human toll, colorectal cancer has a massive financial cost to America.

- Colorectal cancer has the second highest treatment cost of any cancer and is estimated to cost a total of \$24.3 billion annually for treatment.
- The lost economic contributions from these ill or deceased Americans are also staggering. As youngonset colorectal cancer rates increase, many more Americans are being economically sidelined during the prime earning years. In 2020, the annual productivity cost from all cancer mortality was projected to be \$147.6 billion.

#### I. Research

We urge the Trump Administration to consider robust solutions to provide substantial federal resources to address these funding discrepancies for colorectal cancer. Colorectal cancer research and treatment require dedicated research and technical advancements due to unique challenges of this disease. Colorectal cancer tumor cells, even within a given tumor, are heterogenous making them very difficult to target. The immunosuppressive nature of the colorectal cancer tumor microenvironment has also rendered most immunotherapy ineffective to date. Without dedicated funds, public and private researchers tend to gravitate towards easier to solve cancers, leaving colorectal cancer without critical resources and attention.

We urge the Trump Administration to prioritize the following in the President's Budget Request for FY 2025:

- Dedicate \$1 billion within NCI funding for colorectal cancer research with the goal of increasing the survival rate to 35%
  - Prioritize \$100 million of funds to young-onset colorectal cancer research
- Create a dedicated fund within the Congressionally Directed Medical Research Program (CDMRP) for colorectal cancer research at or above funding levels for similar deadly cancers (\$20-\$40 million).

We also urge the Trump Administration to prioritize research for young-onset colorectal cancer and the development of treatments to increase the 5-year survival rate for young-onset cases. Although young-onset colorectal cancer diagnoses have been increasing at an alarming rate for the past thirty years, new treatments have not been developed. It is critical for federal resources to be strategically utilized to address this growing prevalence amongst young Americans.

#### **Regulatory Reforms**

#### **Approval of Combination Therapies**

One of the greatest challenges in advancing research for colorectal cancer is the reliance on combination therapies for treatment. Unlike other leading cancer killers that benefit from single immunotherapy options, colorectal cancer treatment is most effective when it includes a combination of chemotherapy, immunotherapy and targeted therapies. Immunotherapy alone has not been a successful treatment for 95% of colorectal cancer patients. The FDA's slow approval process of combination therapies significantly hinders research advancements for colorectal cancer. The expense, complexity and time required to receive approval on a combination therapy also disincentivizes researchers from devoting resources to the efforts. We urge the Trump Administration to direct the FDA to incentivize research on combination therapies and minimize barriers that have slowed the approval process in recent years.

#### Clinical Trial Information Sharing & Access

Clinical trials are an essential piece of the research process to develop new treatments for colorectal cancer. Participation in clinical trials have not only advanced treatment for patients nationwide but also saved countless lives of those who were able to participate. We urge the Trump Administration to critically examine and improve the clinical trial process and barriers to entry for patients.

The Food and Drug Administration Amendments Act of 2007 (the "FDAAA") required that the results of all clinical trials after September 2007 be reported to the NIH Director regardless of the results. Unfortunately, the FDAAA falls short of its intended goal because it exempts phase I clinical trials from the reporting requirement. This exemption slows research across the country because different trials are then forced to duplicate previous efforts. The disclosure obligations for other clinical trials were also rarely enforced. Access to trial results is critical for researchers to determine where to direct future efforts and resources. We urge the Trump Administration to amend the exemption on phase I trials and enforce all covered trials.

Additionally, we urge the Trump Administration to eliminate overly restrictive trial exclusion criteria. Today, clinical trials design their own inclusion and exclusion criteria. However, these criteria are often very exclusionary as researchers are motivated to recruit the healthiest patients. This practice often results in new drugs and treatments being tested on populations that do not reflect the general population. The Trump Administration should direct the FDA to ensure real world inclusion and exclusion criteria when approving clinical trials for colorectal cancer.

We commend the Trump Administration for its leadership on the Right to Try Act, which first passed in 2018. The law allows patients with life-threatening conditions, including colorectal cancer, to access certain exploratory treatments without FDA approval. We urge the administration to further strengthen the program by allocating additional funds to this critical program and expanding access to more patients. Patients are often still required to pay for the cost of these potentially lifesaving drugs because insurance companies will not cover them. Additional funds for the program can be used to cover the cost of drugs, therefore increasing participation in the program.

We also urge the FDA to explore regulatory changes that would protect clinical trial drugs from the negative impact of experience data from compassionate use access programs. The data from compassionate use access patients is not comparable to clinical trial patients due to other co-morbidities and health complications.

#### II. Care

Americans diagnosed with colorectal cancer also face significant challenges in receiving quality care. Significant barriers persist in treatment of colorectal cancer for certain communities, including rural Americans and veterans.

#### **Biomarker Testing**

Doctors treating colorectal cancer patients utilize biomarker testing of a patient's blood or tumor sample to better understand mutations of their specific cancer and help determine the most effective treatment. While biomarker testing technology has seen significant advancements in recent years and is widely utilized by leading colorectal cancer oncologists, recent research has demonstrated that biomarker testing is underutilized in many communities. Approximately 85% of Americans receive their cancer care in their own communities and not at large academic centers, this is particularly true for people in rural areas. Use of biomarker testing is significantly lower for patients in these rural areas, contributing to the significant disparity in outcomes for rural colorectal cancer patients. Biomarker testing can prevent costly and ineffective treatments, reducing the financial burden on patients and the healthcare system. Without expanding coverage of and access to biomarker testing, future advancements in precision cancer treatment will increase existing disparities for colorectal cancer patients. By avoiding the "trial-and-error" approach to cancer treatment, we can optimize resources, improve patient outcomes and lower total cost of care.

The Trump Administration has an opportunity to significantly improve the outcomes of rural colorectal cancer patients through a comprehensive effort to expand access to biomarker testing.

- We urge the administration to explore potential strategies to increase usage and coverage of biomarker testing for cancer patients, including grant programs to cover remaining out-of-pocket costs and training programs for health care professionals. In the short-term, the administration should consider a pilot project targeting certain rural communities to increase access and awareness of comprehensive biomarker testing.
- As the administration looks to reform the Affordable Care Act before many subsidies expire next year, we urge officials to expand coverage of comprehensive biomarker testing for Medicare and Medicaid patients. This reform will ultimately lead to significant cost savings due to the enhanced effective care

#### Telehealth Benefits

One of the leading determinants for a colorectal cancer patient's outcome is whether the patient resides in a rural or urban community. While a variety of disparities within rural communities contribute to these poor health outcomes, the Trump Administration has a critical opportunity to improve outcomes for these communities by extending and expanding access to telehealth benefits, connecting leading doctors with rural patients.

Current regulations require a telehealth doctor be licensed in the state where a patient resides. This regulatory structure for telehealth care diminishes access to expert second opinions for many stage IV colorectal cancer patients who may be too sick or lack the resources to travel across state lines. We urge the Trump administration to extend existing telehealth benefits created during the pandemic and declare stage IV colorectal cancer a public health emergency, as you could for all cancers. This declaration could give patients access to telehealth experts and second opinions regardless of their location. Red tape and bureaucracy shouldn't prevent patients living in rural communities from accessing the best care.

#### Women's Health

As rates of young-onset colorectal cancer continue to rise, we urge the Trump Administration to devote research and resources to better understanding the impact of the disease on women's health. For decades, the impact of many treatments on women have not been adequately researched, leading to unforeseen health outcomes, including fertility challenges. The Trump Administration has an opportunity to direct federal researchers and funds to better understand how current cancer treatments impact women's health

#### III. Prevention

Advanced colorectal cancer is largely preventable with accurate and early screening. When colorectal cancer is found at an early stage, treatment is significantly more effective. The Colorectal Cancer Alliance is dedicated to getting as many Americans screened as possible. The Trump Administration has an opportunity to improve screening for American patients and save billions of dollars of colorectal cancer treatment costs and countless American lives.

#### **Colorectal Cancer Control Program**

The CDC's Colorectal Cancer Control Program is dedicated to increasing colorectal cancer screening rates for people between 45 and 75 years of age. The program provides critical funding to clinics and hospitals across the country to support colorectal cancer screening, particularly in underserved communities with limited access to health care.

We urge the administration to fully fund and support the CDC's Colorectal Cancer Control program and support nationwide screening efforts to mitigate the growing prominence of the disease. Additionally, we urge the Trump Administration to revise CMS guidance to ensure that all FDA-approved bowel preparations meeting established medical efficacy standards are covered without cost-sharing.

#### **Understanding Colorectal Cancer & the Nation's Food Supply**

This NCI funding and resulting research should also focus on discovering the root causes of Colorectal Cancer. Only 5-10% of colorectal cancer cases are hereditary, while the remainder are caused by some unknown exposure. Some initial research has been done in areas such as environmental toxins, diet and processed food intake, changes in the gut microbiome, and other potential environmental causes. Better understanding the underlying causes of the disease and potential environmental triggers within the nation's food supply should enable us to avoid the human and financial toll of the rising cases and deaths.

#### **Preventive Services Task Force**

The Preventive Services Task Force aims to improve nationwide health outcomes by making evidence-based recommendations on clinical preventive services. The task force is made up of a volunteer panel of national experts in disease prevention and medicine. The task force reviews and updates guidance on each topic every five years. In recent years, funding for the task force has remained stagnant at \$12 million despite advocacy to increase the budget. Today, innovative privately funded research is leading to new early detecting blood tests and other historic advancements. Meanwhile, the Preventive Services Task Force continues to work with an antiquated model.

Regardless of the future for the Preventive Services Task Force, the Colorectal Cancer Alliance strongly urges the Trump Administration to find a regulatory pathway so that zero cost of preventive services is passed to American patients.

We firmly believe no cost screening for people ages 45-75 should remain intact.

If the Preventive Services Task Force continues to be the organization making these critical recommendations, we urge the Trump Administration to fully fund and modernize the task force to help speed private sector innovations to market like the historic innovation under Operation Warp Speed. The Trump Administration has an opportunity to incentivize greater innovation speed, while not sacrificing the scientific review process.

We encourage CMS and NCQA to create a HEDIS measure that requires the following: A completed colorectal cancer screening only counts towards a healthcare provider or payors HEDIS score if and when any positive stool tests are followed up by a completed colonoscopy.

#### IV. Additional Legislation from the 118th Congress

In addition to this comprehensive approach described above, there are numerous bills in the 118th Congress that can have an immediate and positive impact on colorectal cancer. We urge the Trump Administration to support the passage of these important bills in the 119th Congress

#### **Credit for Caring Act (H.R. 7165 / S. 3702)**

The legislation would provide a federal tax credit of up to \$5,000 for family caregivers, who are facing economic hardship while devoting time and resources to caring for a loved one.

#### Comprehensive Cancer Survivorship Act (H.R. 4363 / S. 2213)

The legislation aims to address the entire continuum of cancer care to improve survivorship, treatment, and transition for all cancer survivors. The legislation would provide coverage for care planning services to address transition to primary care; develop navigation services for survivorship; establish employment assistance grants for survivors, caregivers, and their families; provide education and awareness through resources for survivors and health care providers; ensure coverage for fertility preservation services; and require study of the existing reimbursement landscape and development of an alternative payment model.

#### Medicare Multi-Cancer Early Detection Screening Coverage Act (H.R. 2407 / S. 2085)

The legislation would modernize the Medicare program and create a benefit category for MCED tests, which would allow the Centers for Medicare and Medicaid Services (CMS) to initiate an evidenced-based coverage process for multi-cancer tests upon approval of the tests by the Food and Drug Administration (FDA).

#### V. Partnership Opportunities with the New Administration

The Colorectal Cancer Alliance is prepared to support and partner with the Trump Administration in the years ahead to bring critical awareness and resources to colorectal cancer. Colorectal cancer is at a crisis point. The rising incidence in young adults and high mortality rates demand a coordinated, nationwide response that will expand screening, fund critical research, and break down barriers to quality care. We urge this administration to champion colorectal cancer as a public health priority and drive the change needed to save lives. Together, we can shift the trajectory of this disease. Our network of patients and experts alongside our team are prepared to share the necessary resources to better understand the problem facing Americans with Colorectal Cancer. In the past, the Colorectal Cancer Alliance has successfully organized and utilized celebrities within our network to draw attention key issues related colorectal cancer. This is a cancer that can be much better controlled, and hopefully cured, with the right level of investment.

#### Colorectal Cancer Alliance

The Colorectal Cancer Alliance is the nation's leading nonprofit organization dedicated to colorectal cancer. The alliance was first founded in 1999 by a group of survivors and is now managed by an executive team, board of directors and numerous advisory boards. Together, these groups collaborate to advocate for prevention, magnify support, and accelerate research to end the disease.

The Colorectal Cancer Alliance has galvanized private investment for a cure, with our groundbreaking Project Cure CRC, a \$100 million, multi- year private investment in research for better treatments and a cure. But we cannot do it alone, and we need support and leadership only the federal government can provide. We look forward to working alongside the Trump Administration to bring national attention to this disease.





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