



September 29, 2023

The Cancer Moonshot: Overview and Issues

Cancer was the second-leading cause of death in the United States in 2021. For decades, Congress has maintained a sustained interest in reducing cancer mortality, particularly by funding cancer research at the National Institutes of Health (NIH). In 2016, the 21st Century Cures Act (Cures Act; P.L. 114-255) authorized appropriations for the Cancer Moonshot initiative at NIH, which expires at the end of FY2023. President Biden previously signaled that reauthorization of the program is a priority. Congress has not considered any bills to reauthorize the Cancer Moonshot program.

The Cancer Moonshot was originally established in 2016 as a biomedical research program with the broad goal of making a decade’s worth of scientific progress in preventing and treating cancer in just five years. In 2022, President Biden announced a “reignited” Cancer Moonshot effort. This new Biden Administration Cancer Moonshot would also incorporate other health policy strategies, such as promoting access to cancer care and screening, in addition to biomedical research. The Biden Administration further announced programs and actions under the Cancer Moonshot in September 2023. If Congress considers reauthorization or other Cancer Moonshot-related legislation, policymakers might consider what priorities, if any, to establish for the Cancer Moonshot initiative, and specifically to what extent the program should support biomedical research compared with other health programs.

Background on Cancer

Cancer refers to a group of diseases characterized by the abnormal growth of cells in the body, which can invade and damage surrounding tissues and organs. There are many different types of cancer, including breast, lung, colon, and prostate cancer, among others. Treatment for cancer may include surgery, radiation therapy, chemotherapy, immunotherapy, or a combination of these approaches, depending on the type and stage of the cancer as well as the overall health of the patient. Cancer can sometimes be detected in early stages through screening, which can, in some cases, improve outcomes from treatment. The exact causes of cancer are not fully understood, but factors that can increase the risk of developing cancer include genetics; lifestyle factors, such as smoking or a poor diet; exposure to certain chemicals or radiation; and infections.

Among adults, the overall death rate from all cancer types decreased from 2015 to 2019 by 2.3% per year (on average) for men and 1.9% per year (average) for women from 2015 to 2019. Death rates vary by cancer type, having decreased significantly for lung cancer and melanoma—some of the most common cancer types. Experts attribute declining cancer mortality to preventive behaviors (e.g., declines in smoking tobacco), new treatments, and enhanced early

detection. Rates of new cancer cases (*incidence*) among adults have decreased overall in the same period, though certain cancer types have seen increases. Some research shows that delayed detection and treatment of cancer during the Coronavirus Disease 2019 (COVID-19) pandemic may affect cancer outcomes.

There are disparities in cancer rates in the United States. For example, black people have overall higher death rates from cancer compared with all other racial/ethnic groups, though rates vary by cancer type. As another example, some research has found that cancer mortality is significantly higher in the lowest-income counties compared with the highest income counties. Cancer disparities may owe to differences in access to care; environmental conditions; health literacy; and other behavioral, life experience, or genetic differences.

21st Century Cures Act Cancer Moonshot Program

Authorization

The Cures Act (P.L. 114-255; §1001), enacted in December 2016, involved a unique funding mechanism for the Cancer Moonshot initiative. The Cures Act transferred funds into an NIH Innovation Account and authorized those funds to be appropriated at various levels in specific fiscal years for four Innovation Projects, including the Cancer Moonshot initiative. Those funds were not available for obligation until appropriated each fiscal year. When appropriations are enacted—up to the authorized amount each fiscal year—those appropriations are subtracted from any cost estimate for the purpose of enforcing the discretionary spending limits. In effect, appropriations to the NIH Innovation Account as authorized by the Cures Act are not subject to discretionary spending limits. The Cures Act authorized a total of \$1.8 billion for the Cancer Moonshot from FY2017 through FY2023. Congress has fully appropriated the authorized funding. Should Congress continue to appropriate funding for the Moonshot after the Cures Act authorization expires, these appropriations would be subject to the discretionary spending limits.

Implementation

In 2016, NIH’s National Cancer Institute (NCI) convened a Blue Ribbon Panel of outside experts to advise on cancer moonshot goals, which made recommendations for the moonshot research to focus broadly on improving cancer data and research platforms, improving treatments and addressing side effects, expanding cancer prevention, and intensifying research on the drivers of pediatric cancer.

With the Cures Act moonshot funding, NCI has invested in research resources and platforms aimed at making it easier

to study cancer in all its types and forms. For example, NCI has invested in platforms for aggregating data across studies. NCI has also funded the Human Tumor Atlas Network, which makes publicly available three-dimensional models of the biological features of human cancer cases. Both these “atlases” and the data resources can be analyzed with computational tools (like artificial intelligence tools) to deepen the scientific understanding of cancer. NCI has also funded research into new treatments and health care delivery practices, among other topics.

Outcomes

In its first four years, Cancer Moonshot funding resulted in thousands of scientific publications, 49 clinical trials, and over 30 patent filings. Still, the full impact of the initiative on cancer health outcomes remains unknown. A time lag often exists between initial investments in research and new medical innovations for patients. As an example, major investments in cancer research followed the National Cancer Act of 1971 (P.L. 92-216). One analysis links the early 1970s funding to new drugs approved by the U.S. Food and Drug Administration (FDA) decades later after the science became established.

Biden Administration “Reignited” Cancer Moonshot

In February 2022, President Biden announced the “reignited” Cancer Moonshot effort, with goals to cut the U.S. death rate from cancer by 50% over the next 25 years and to improve the experience of patients and their families living with cancer. The new effort is focused on increasing cancer screening and early diagnosis; boosting prevention; addressing inequities; ensuring patients get the right treatment; speeding progress against rare and childhood cancers; supporting patients, survivors, and caregivers; and increasing research data sharing. In summary, the “reignited” moonshot has a much broader scope than the original 2016 Cancer Moonshot.

In its FY2024 budget request, the Biden Administration requested reauthorization of the Cures Act Cancer Moonshot program through 2026, and \$2.9 billion in mandatory appropriations in 2025 and 2026. In addition, the FY2024 request included funding for programs tied to the Cancer Moonshot across the Department of Health and Human Services. As mentioned, no bill to reauthorize the Cures Act funding has been introduced or considered this session. It remains to be seen if any of the FY2024 funding will be provided.

In September 2023, the Biden Administration announced programs as a part of the Cancer Moonshot effort. Several of the efforts involve the Advanced Research Projects Agency for Health (ARPA-H), a new agency first funded in 2022 that is focused on taking risks and driving innovation in biomedical and health technology. The Biden Administration has announced that ARPA-H is committing \$240 million to cancer-related research and will invest in new data sharing platforms and a nationwide network for clinical trials. The Administration also announced other programs to reduce smoking and exposures to environmental carcinogens, and to increase screenings. It is

unclear the extent to which some of these programs are “new,” or reflect ongoing agency activities.

Are the Cancer Moonshot Goals Achievable?

Researchers have explored how the Administration’s goal to reduce cancer mortality rates by 50% over the next 25 years could be achieved. The United States would have to sustain reductions in cancer mortality averaging 2.7% per year. Progress in reducing mortality against lung, colorectal, and breast cancers may need to be sustained, and new strategies may be needed for prostate, liver, pancreatic, and other cancers. Some of the reduction could come from prevention and early detection of new cancer cases. Modifiable lifestyle factors, such as reduced smoking and alcohol intake, diet, exercise, and certain vaccinations could play a significant role. In addition, many people do not get recommended cancer screenings (that could help detect and treat cancer cases early) or adhere to recommended treatments. There are significant racial and socioeconomic disparities in cancer screening rates and treatment access. Addressing such disparities could have a measurable impact on overall cancer health outcomes.

Still, researchers note that achieving the Cancer Moonshot goals may require innovation, such as better screening tests, preventive tools (e.g., cancer vaccines), treatments, and care practices. Although many therapies and innovations are in development, new cancer therapies have not always proven “better.” For example, of the 161 FDA approvals for solid cancer therapies since 2017, 35% were graded as delivering substantially meaningful clinical benefit.

Considerations for Congress

As mentioned, no bill to reauthorize the Cures Act Cancer Moonshot program has been introduced or considered. The Administration’s “reignited” Moonshot effort goes beyond the research activities funded under the Cures Act authorization. The Administration has also placed many of the new Moonshot research programs within ARPA-H, a new agency, rather than NCI, the lead for the original Moonshot effort. If Congress were to legislate on the Cancer Moonshot effort, it faces many considerations and questions:

- Should a reauthorized Cancer Moonshot program focus on a broad set of health strategies, as proposed, or continue placing its primary focus on research? For its research efforts, should the program be housed in NCI or ARPA-H? Are there research areas that should be prioritized?
- Some have argued that the “reignited” Cancer Moonshot lacks a cohesive strategy and goals. Should Congress require the Administration to develop a more specific plan for achieving Moonshot goals?
- Some stakeholders have argued that ARPA-H should focus on technologies rather than specific diseases. In addition, ARPA-H was designed to be “bottom-up” and led by its program managers. How does ARPA-H’s involvement in the President’s Cancer Moonshot affect the new agency’s role and purpose?

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