

# CAPITOL STREET

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June 21, 2023

## NIH Nominee Maria Bertagnolli (NCI) Faces a Bernie Sanders Grilling

NCI Director Is Well-Regarded, Confirmation Likely

Relevant Industries

### Biopharma, MedTech, and Diagnostics

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On May 15, 2023, Biden appointed Monica Bertagnolli, current National Cancer Institute (NCI) head, as NIH director replacement [here](#). President Biden expressed enthusiasm about Dr. Bertagnolli's scientific research background and experience as an oncologist.

### »» Our Take & Next Up

**We believe Dr. Bertagnolli, MD, will be confirmed by the Senate, despite Sen. Bernie Sanders' demands for additional Biden action on drug pricing.** Dr. Bertagnolli, MD, enjoys widespread approval as NCI Director, is non-controversial, and is a cancer- survivor with a health equity emphasis to oncology therapy access. While Bertagnolli does not boast an extensive political background, her research experience, progress at NCI, and dedication to innovation accessibility has meant that she has garnered support from industry and Congressional leaders.

On June 12, 2023, 115 non-profit organizations and institutions sent in a [letter](#) to Senate leadership asserting that Dr. Bertagnolli's leadership capabilities are crucial to the NIH. One thorn in her side: Bernie Sanders (I-VT), who chairs the HELP Committee, believes that the NIH should be tougher on high drug prices and will likely try to extract something from the Administration before giving her the green light.

### »» Key Points

**Prior to her appointment as NCI director, Dr. Bertagnolli served as an oncology surgeon with experience in treating gastrointestinal cancers and soft tissue sarcomas.** Bertagnolli grew up in rural Wyoming and is a graduate of Princeton University and the University of Utah School of Medicine. She completed surgical residency at Brigham and Women's Hospital and became board certified in 1993. Bertagnolli has served as the Richard E. Wilson Professor of Surgery in the field of surgical oncology at Harvard Medical School, a surgeon at Brigham and

Women's Hospital, and a member of the Gastrointestinal Cancer Treatment and Sarcoma Centers at Dana-Farber Cancer Institute.

**Dr. Bertagnolli's clinical background informed a push for equity initiatives at NCI.** With considerable experience in rural areas, Dr. Bertagnolli believes equity within clinical trials, cancer treatment, and in science and healthcare leadership is a primary concern. If confirmed, one of her goals is likely to be related to diversity engagement in federal research, particularly as the NIH grapples with boosting younger talent in the agency. However, Dr. Bertagnolli may see some progressive opposition to her appointment. Sen. Bernie Sanders (I-VT) stated his concern on Dr. Bertagnolli's commitment to lowering drug prices.

**Sen. Sanders (I-VT), has vowed to block confirmation until Pres. Biden releases a comprehensive plan to lower drug prices.** He noted the same demand for all other health nominations, until the Biden administration releases a comprehensive plan to lower prescription drug prices.

**As NCI director, Dr. Bertagnolli has coordinated diverse government agencies, particularly moving the Biden Cancer Moonshot ball forward.** Dr. Bertagnolli supports the Cancer Moonshot goal at NCI by bringing together "partners and resources from different sectors to launch groundbreaking efforts in cancer prevention and early detection, a national navigation program for childhood cancers, and additional programs that bring more clinical trials to more Americans" ([link](#)). Dr. Bertagnolli believes in U.S. citizens, scientists, government, and pharmaceutical companies working together to improve cancer survivorship, as well as overall public health.

**While Dr. Bertagnolli has yet to announce her stance we believe that she does not want to march-in under her watch.** Dr. Bertagnolli will be questioned about march-in rights during the confirmation process. March-in rights have never been used by the agency and we predict she will likely maintain status quo, particularly as HHS has recently declined to use march-in on Xtandi, a prostate cancer drug (Astellas, PFE). March-in rights allow federal agencies access to use the research that they have sponsored at universities or businesses to meet agency missions. High drug prices raise multiple concerns, but march-in rights remain controversial in pharmaceutical investment and innovation.

**NIH is in a time of transition and many lawmakers believe that it is not producing outcomes at the rate that it should be.** Francis S. Collins stepped down as NIH director in December 2021 after leading NIH for over 12 years. He spearheaded biomedical research advancements and the nation's COVID-19 response. Change has proven to be difficult for the NIH. For FY 2024, NIH received flat funding, with less than a 0.1% increase from the previous year. ASCO has publicly criticized the decline in funding, stating that it will "considerably restrict potential resources for the NIH and NCI at a time when scientists are on the cusp of so many promising cancer discoveries". In recent years, NIH's pace of work and efficiency have raised many concerns across party lines. Some have proposed that NIH even needs a complete revamp on who and what they fund.

**ARPA-H.** ARPA-H is a new research machine that invests in high-risk biomedical health solutions at a faster pace than before. Currently, ARPA-H is progressing, expanding, and has selected project managers. While NIH has flat funding for FY 2024, ARPA-H's funding increased 66% from the current year. This creates concern that NIH and ARPA-H could be rivals, or that the two agencies will work together when ARPA-H is provided funding for unique projects, undermining the independence of ARPA-H.

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