

October 19, 2023

NIH Director Monica Bertagnolli Likely Confirmed

Flat Funding Challenges Abound; March In Rights Unlikely to be Exercised

Relevant Companies



»» Our Take & Next Up

Dr. Monica Bertagnolli is scheduled to appear before the Senate Health, Education, Labor and Pensions (HELP) committee (Chair Sanders, I-VT) on October 25 for a vote to further her nomination. Link [here](#). Dr. Bertagnolli currently serves as the Director of the National Cancer Institute (NCI), one of the 27 institutes and centers of the National Institutes of Health (NIH). As a reminder, Dr. Bertagnolli agreed to ethics clauses (Sen. Warren) and discussed government pricing contracts (Sen. Sanders) this summer, teeing up the nomination process for likely confirmation, in our view, by year end.

»» Key Points

Bipartisan support was loud & clear at the committee meeting on Oct 18. Dr. Bertagnolli was treated well by Republicans and Democrats yesterday. Dr. Bertagnolli supports research and clinical trials that are equitable and accessible to all Americans. Topics discussed:

- Obesity: Additional research is needed. It's only a small % of the budget, per Sen Cassidy, who is pushing for Treat and Reduce Obesity Act (TROA) passage, where Medicare would cover weight-loss drugs given health benefits.
- Antibiotic resistance: Sen. Baldwin (D-WI) was concerned about potential pandemic pathogens. and Dr. Bertagnolli stated she will fulfill oversight to ensure research is conducted safely. Sen. Casey (D-PA) emphasized the need to continue to invest in pandemic research.
- Reasonable pricing: Sanders (I-VT) sees a role for the NIH to substantially lower the price of prescription drugs. Recall, NIH has no ability to force companies to lower prices. Dr. Bertagnolli made it clear that she wants to make healthcare innovation affordable for all.
- March-in rights: Pressed by Bernie Sanders and Ranking Member Cassidy (R-LA), Dr. Bertagnolli stated she would follow the law, avoiding specifics of what she will do, if confirmed. Cassidy reiterated the three scenarios where march-in could take place, noting the pricing clause has driven the industry away from potential scientific collaborations.
- Clinical trials and AI: When asked if AI will provide efficiency in clinical trials, she noted machine learning approaches are new computational methods that must be used in a careful and responsible manner.

- **Mental health:** The topic came up frequently, with questions brought up concerning the LGBTQ and transgender youth state of emergency. Sen Markey (MA) brought up the Children in Media Research Advancement Act (CAMRA Act), which researches the effects of technology and media on the development of infants, children, and teens. Bertagnolli agreed that big tech's exploitation of children through media has created a mental health epidemic.

Bertagnolli's cancer treatments were NIH funded. Bertagnolli made comments in her opening statement that drug prices should reflect NIH's contributions. Remarking on her recent experience as a breast cancer patient — and reporting that the cancer had been detected early, and she had an excellent prognosis — the NIH nominee said that “every treatment I have received was supported by NIH-funded research.”

We expect Dr. Bertagnolli, cancer survivor and the current NCI Director, to be confirmed by year end, and possibly by Halloween. The committee will vote on her on Oct 25. Full confirmation vote timing remains uncertain, but ahead of the continuing resolution (CR) is ideal given the government funding deadline. The threshold for confirmation is 51 votes. As a reminder, the NIH has not had a director since Dr. Collins' departure in December 2021.

Sen. Sanders agreed to a NIH Director confirmation hearing following an HHS agreement with Regeneron (REGN) on Covid-19 mAB, while Sen. Warren (D-MA) requested an ethics contract.

- The \$326 M contract with REGN contains a pricing clause that will limit the list price of the next-gen antibody treatment to equal to or less than the price in other countries (i.e., international reference pricing). Though Sanders was satisfied with the deal, he stated that the administration should add reasonable pricing provisions to all drugs developed with government funding.
- To secure Elizabeth Warren's support, Dr. Bertagnolli agreed to an ethics contract that prevents work with/for big pharmaceutical companies (or Boards) for 4 years after her NIH tenure. These are drug firms with annual revenues of \$10 B or more. She has agreed to recuse herself for four years (up from the standard two years) from NIH decisions related to companies with which she's had prior relationships. She has previously served on the Board of Directors of Natera (NTRA) and Leap Therapeutics (LPTX) and under her presidency, the Alliance for Clinical Trials in Oncology Foundation received institutional research funding from various manufacturers including ABBV, PFE, BMY, Bayer.

We do not anticipate incremental drug reform passing before the year's end, but PBM reforms are (still) likely. There are multiple anti-PBM bills in both chambers that have passed out of committees for full-consideration with bipartisan support. We expect PBM reforms on (1) transparency (2) Medicaid spread pricing ban (3) DIR and pharmacy reforms (4) delinking (possible) and (5) commercial reforms (possible) to be included in a “4 corners” year-end package.

ABOUT MONICA BERTAGNOLLI: She was appointed by Biden in May 2023 ([here](#)) but faced a summer of delays due to opposition from Sen. Sanders (I-VT) who wants a stronger commitment to drug pricing reform and Sen. Warren (D-MA), who requested an ethics contract. 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.

Copyright 2023 Capitol Street.

This communication, including this broadcast and any attachments hereto, is intended solely for the original recipient(s) and may not be redistributed without the written consent of Capitol Street. This communication is for informational purposes only and is not intended as an offer or solicitation for the purchase or sale of any financial instruments, nor is it intended as advice to purchase or sell such instruments