

October 16, 2023

## NIH Director Monica Bertagnolli Likely Confirmed

Senate HELP Cmte Chair Bernie Sanders Likely to Hold Pharma CEO Hearing

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 18 for a hearing NOT a vote to further NIH nomination.** A vote is not expected at this hearing. 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). How she will pivot from cancer research (deep experience) to the wider spectrum of biomedical research is likely to be discussed, along with March-In Rights, COVID misinformation and Alzheimer's research. As a reminder, Dr. Bertagnolli agreed to ethics clauses (Sen. Warren) and government pricing contracts (Sen. Sanders) this summer, teeing up the nomination process for likely confirmation, in our view, by year end.

### »» Key Points

**We expect Dr. Bertagnolli, who is a cancer survivor and the current NCI Director, to be confirmed by year end.**

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. Chair Sanders (I-VT) is expected to grill the nominee on whether she will promote fair pricing agreements, agree to routinely licensing technologies developed using government funding, and leveraging march-in and royalty free rights.

**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 Regeneron 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 Sen. Sanders was satisfied with the Regeneron deal, he stated that the administration should add reasonable pricing provisions to all drugs developed with the help of 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 Naterra (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.

**With a perpetual bee in his bonnet over drug pricing reforms not going far enough for Americans, Chair Sanders is also expected to hold a hearing to grill pharmaceutical CEOs this fall.** Medicare & Medicaid does not typically fall under HELP jurisdiction, but this hearing likely serves as a messaging and headline vehicle to keep the administration and the public focused on drug pricing.

**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.

**The hearing will serve as a preliminary opportunity to assess Dr. Bertagnolli's future priorities at NIH and how she will handle current issues at the agency.** Challenges at the agency include clinical trial and researcher diversity and addressing the rising public mistrust of science. Key NIH topics that Senators are expected to ask about and discuss include:

- March-In Rights
- NIH licensing
- Alzheimer's research
- NIH's infectious disease research programs (including research on next gen therapies and vaccines)
- NIH funding for Chinese researchers

**Lawmakers (largely GOP) believe that NIH is not producing outcomes at the rate that it should be and distrust the agency, which will impact NIH funding.** In recent years, NIH's pace of work and efficiency have raised concerns. Some have proposed that NIH even needs a complete revamp on who and what they fund as the NIH is known to be risk-averse with an aging grantee population.

**Misinformation regarding COVID-19 & vaccinations has also eroded public trust in the agency.** Dr. Bertagnolli will likely navigate a more constrained budget in the near term as the government attempts to tighten federal spending. As a part of the debt ceiling deal earlier this year, Congress capped nondefense discretionary spending at FY 2023 levels for 2024 and allows for just a 1% increase in FY2025, but individual agencies' budgets can still rise and fall under this new cap if the total spending number stays at 2023 level. This will severely limit HHS funding for the next 2 years.

**Dr. Bertagnolli 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.

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