September 12, 2023

NIH Director Likely Confirmed This Fall

Dr. Bertagnolli Agrees to Ethics Contract as REGN Deal Reached

Relevant Companies

REGENERON leaptherapeutics Pfizer BAYER abbvie natera Bristol Myers Squibb

On May 15, 2023, Biden appointed Monica Bertagnolli, the current National Cancer Institute (NCI) head, as NIH director replacement (here). She has faced headwinds in her nomination in the Senate from Sen. Sanders (I-VT) who wants a stronger commitment to drug pricing reform and Sen. Warren (D-MA) who has requested an ethics contract. After a summer of delays, she is expected to be scheduled for Senate confirmation hearings in October.

⋙ Our Take & Next Up

The REGN antibody contract allowed Bernie Sanders (I-VT) to allow NIH leader to be vetted in October; we anticipate full Senate confirmation of Maria Bertagnolli, MD. Bertagnolli has secured Elizabeth Warren's vote by agreeing to an ethics contract (see below), following a recent HHS drug pricing deal with REGN, Sanders has agreed to hold a confirmation hearing in October (but has not given his blessing yet). Notably, Chairman Sanders had demanded the agency take stronger action on pricing and patents, calling for use of march-in rights and is expected to grill Dr. Bertagnolli on her commitments to drug reform. Dr. Bertagnolli is unlikely to allow for march-in rights and will likely maintain status quo. However, she may agree to support agency reforms that address both equity (a Biden admin priority) and pricing as she previously pushed for equity initiatives as NCI director. While the NIH has a limited role in determining drug prices, she could direct the agency to deprioritize clinical trials of patent-protected agents and currently marketed drugs and focus funding on clinical trials that have an economic impact including funding comparative clinical trials that might offer alternatives to expensive treatments.

⋙ Key Points

To secure Sen. Warren's vote, Dr. Bertagnolli has agreed to an ethics contract that prevents work with/for big pharmaceutical companies (or Boards) for 4 years after her NIH tenure. The agreement attempts to address the "revolving

door" between government agencies and the industries that they supervise. This is not a new ethics agreement. FDA Commissioner Dr. Califf agreed to similar commitments in 2022 during his nomination process.

Maria Bertagnolli has pledged to not seek employment or compensation from drug firms with annual revenues of $10 B or more for four years after government. She is also prohibited from joining the boards of directors for those companies. Dr. Bertagnolli has also 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, and Bayer.

Chairman Sanders (HELP Committee) has agreed to schedule a confirmation hearing in October following Regeneron contract announcement. Sanders has not yet agreed to personally support Dr. Bertagnolli's confirmation. He has also pledged to drop his blanket opposition to holding hearings for all administration health nominees, which he planned to continue until the Biden administration released a comprehensive plan to lower drug prices.

On pricing reform, Sanders seems to be satisfied with a recent HHS agreement (here) with Regeneron and a general commitment from the administration to continue working on drug pricing (a given). The $326 M contract with Regeneron was awarded in late August and the pricing clause will go into effect if Regeneron commercializes the funded product in the US. It limits the list price of a next-gen antibody treatment for COVID to equal or less than the price in other countries (i.e., international reference pricing).

The concessions by the administration fall short of Sanders' prior demands. Earlier this summer, Sanders requested agency reforms. These included reinstating the "reasonable" pricing clause, which requires drug companies to sell a medicine at a "reasonable" price when it's developed with help from the federal government; and actual use of "march-in" rights that allows the federal government to seize drug patents to license them out to other manufacturers to lower their prices. March-in has never been used by HHS. Earlier this year, HHS declined to use it on Xtandi, a prostate cancer drug (Astellas, PFE).

We have a new Anthony Fauci @ NIH. Dr. Jeanne Marrazzo, MD does not require Senate approval to assume her role. She is the (former) director of the Division of Infectious Diseases at University of Alabama, Birmingham, was selected (here) on August 2 to be head of the NIAID (part of NIH). NIAID served as a key research institution during the HIV/AIDS epidemic and COVID-19. Marrazzo's past work is centered around female reproductive tract infections and hormonal contraception, prevention of HIV and antibiotic resistance in gonorrhea. She is replacing Dr. Fauci, who retired at the end of 2022 after leading NIAID since 1984.

A myriad of lawmakers (largely GOP) believe that NIH is not producing outcomes at the rate that it should be which will impact the agency's funding for next year. The agency remains in a state of transition since Francis S. Collins stepped down as NIH director in December 2021 after leading NIH for over 12 years. Dr. Collins led the agency in breakthrough biomedical research advancements and the nation's COVID-19 response.

NIH's FY2024 budget is in the works with Senate Appropriations Committee proposing to increase funding by +2% (here), House proposing to cut by -6% (here). 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. This will severely limit HHS funding for the next 2 years, but individual agencies' budgets can still rise and fall under this new cap if the total spending number stays at 2023 level. 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 as the NIH is known to be risk-averse and has seen an aging grantee population.

BACKGROUND

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. This is largely in line with the current goals of the White House and agencies as CMS and HHS have continued to highlight their work on equity in healthcare throughout the administration.

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." Dr. Bertagnolli believes in U.S. citizens, scientists, government, and pharmaceutical companies working together to improve cancer survivorship, as well as overall public health.

Dr. Bertagnolli has connections to the private sector from her board appointments and her previous advisory role. She has served on the board of directors for Natera (NTRA), a diagnostics company, and Leap Therapeutics (LPTX), a biotechnology firm developing targeted and immuno-oncology therapeutics. She also previously served as a consultant to Syntimmune (acquired by Alexion, a subsidiary of AZN). In research, she served as Group Chair and President of the Alliance for Clinical Trials in Oncology Foundation which received research funding from ABBV, AZN, Baxalta, Bayer HealthCare, BMY, Celgene, Eisai, EXEL, Genentech, Gilead Sciences, INCY, PFE, among others.

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