

Cancer Moonshot Refresh

Biden Appoints Ginkgo VP to Direct ARPA-H, Liquid Biopsy A Focus

Today, Biden traveled to Boston to provide remarks on the progress for Cancer Moonshot, a major White House initiative to halve cancer deaths in the next 25 years. Moonshot has a lofty goal of “ending cancer as we know it”. The investments in next gen technology and biomanufacturing capabilities shows that the administration is looking for ways to improve the progress made by the biotech private sector.

- **Blood-based cancer detection technology & new 4 year pilot is a top priority for the Cancer Moonshot.** The National Cancer Institute is launching a vanguard study on multi-cancer detection. This is a national trial that, if successful, will identify effective blood tests for the detection of one or more cancers. A new four-year pilot study will enroll 24,000 people ages 45 to 70 years to lay the groundwork for a large randomized controlled trial. This is helpful for the liquid biopsy market, the study provides an opportunity for molecular testing to be widely accepting, opening the door to coverage and greater adoption. We noted previously that the *Multi-Cancer Screening Act* (GH, EXAS, Grsil + others) could pass by year end, another plus for cancer diagnostics.
- **New Executive Order (EO) & National Biotechnology and Biomanufacturing CEO Meeting Sept 14 aims to increase biomanufacturing in US.** On Wednesday, the White House will host a Summit on the National Biotechnology and Biomanufacturing Initiative with private stakeholders in attendance. There the administration is expected to announce a wide range of new investments and resources and solicit feedback from companies on funding priorities.
- **Dr. Renee Wegrzyn (DNA) was announced as the inaugural Director of ARPA-H.** Dr. Wegrzyn is currently the VP for Business Development at Ginkgo Bioworks, which specializes in using cell programming to produce bacteria with industrial and pharmaceutical applications. This is helpful for companies in the SynBio space as her experience in genetic engineering will inform ARPA-H priorities. New government funding may stimulate research and public-private partnerships in this area. The administration has highlighted Dr. Wegrzyn’s prior work at the Defense Advanced Research Projects Agency (DARPA) and Intelligence Advanced Research Projects Activity (IARPA) to demonstrate experience in federal research. Those two institutions inspired the creation of ARPA-H.
- **The Cancer Cabinet priority actions to reach Moonshot goals.** The Cancer Cabinet, formed in February, brings together federal departments, agencies, and physicians to advance progress on Cancer Moonshot goals.
 - **Diversity is still an administration priority.** The National Cancer Institute (NCI) has opened a brand-new early-career grant opportunity, Cancer Moonshot Scholars Program, to invest in the next gen of cancer researchers with a focus on developing a cancer research workforce that is more representative of the U.S. population.
 - **Increasing access to federal research.** This past month, the Office of Science and Technology Policy (OSTP) issued guidance to make the results of Federally-Funded research available to the public.
 - **DOD’s Murtha Cancer Center Research Program launches a new program on toxic exposure.** PROMETHEUS, or the PROject for Military Exposures and Toxin History

Evaluation, will aim to understand the impact of service-related toxic exposure on the development of cancer in members of the military.

- **Telehealth expansion.** Last month, NCI announced \$23M to support the creation of a Telehealth Research Centers of Excellence (TRACE), which will study the role of telehealth in cancer prevention, screening, diagnosis, treatment, survivorship, and equity of access and outcomes. Four funded research centers will conduct large trials in real-world clinical settings, including hospitals, and primary care offices, to determine whether the use of telehealth can effectively deliver quality cancer care.
- **Centralizing Cancer Care Data.** As part of the new Biotechnology and Biomanufacturing Initiative, NIH is expanding the Cancer Research Data Ecosystem, a national data infrastructure that encourages data sharing to support cancer care for individual patients and enables discovery of new treatments. USDA is working with NIH to ensure that data on persistent poverty can be integrated with cancer surveillance.
- **OUR TAKE/NEXT STEPS:** Agencies (HHS, NIH, FDA, CMS.) working on Moonshot are looking for big ideas and public-private partnerships to define the future of the Moonshot 2.0. This speech is the first announcement, in our opinion, of many. We wait to see how partnerships will play out in improving oncology policy and increasing access. Policy riders (clinical trial diversity, Accelerated Approval reform) seen in the FDA user fee package could also improve FDA oncology approvals and aid patients. We anticipate UFA passage in the next few months, and possibly as soon as this month with a budget (CR), due by Sept 30.