OSTP Open for Business & Seeks Input

SynBio Panel @ JPM Healthcare Provides Policy Outlook and Opportunities

- **Capitol Street co-hosted a panel at JPM featuring Synthetic Biology (SynBio) policy updates and partnerships** The panel discussed emerging technologies (DNA, Inscrypta, IFF) federal opportunities from the White House Office of Science & Technology (OSTP), 2022 policy direction, and the future of synthetic biology. Participants included:

    - Max Bronstein, Asst. Director, WH Office of Science & Technology Policy (OSTP)
    - Jason Kelly, CEO, Ginkgo Bioworks
    - Sri Kosaraju, President & CEO, Inscripta
    - Greg Yep, EVP, Chief R&D, Global Integrated & Sustainability Officer, International Flavors & Fragrances

- **The WH Office of Science & Technology (OSTP) is the President's advisory board on scientific, engineering, and technology initiatives impacting the economy and homeland security.** The OSTP is led by geneticist and former lead of the NIH's National Genome Project Eric Lander. He is a pioneer in the mapping of the human genomic blueprint. Biden has elevated his role to a position within his Cabinet. Biden sent Lander a letter outlining his goals for the OSTP including ensuring accessible, data driven public health measures and addressing competition from China, specifically pertaining to advances in synthetic biology and artificial intelligence. See here for full text.

- **White House's Max Bronstein encouraged innovators to share ideas with OSTP.** Bronstein issued an open invitation from OSTP to early and late stage developers to share their interests as OSTP defines its partnership and research strategy. Specifically, he gave an overview of ARPA-H and OSTP's public private partnerships pipeline**.** Bronstein noted cancer therapeutics, biosecurity and bio-economy (biology and agricultural science collaborations) are key priorities for the OSTP. He is not an expert by any stretch in SynBio per se.

- **OSTP has no desire to pick technologies or winners and losers**. The OSTP is technology agnostic**.** Specifically the OSTP will prioritize innovative platform technologies that demonstrate nimble adaptation capabilities. OSTP contact information is here.

- **ARPA-H is a DARPA inspired investment to fund high risk, game-changing investments in public health.** Recall DARPA is noted for bringing the internet to scale and accelerating investment in artificial intelligence. ARPA-H is designed to be vehicle for accelerating innovation that doesn't fall into a specific "public" or "private" investment category. ARPA-H will re-define previously siloed investment strategies by creating a hybrid model leveraging public private partnerships that bring scientific discovery to market. Congress is finalizing the ARPA-H budget ($3 B is the current allocation), enabling OSTP to begin work this year.

- **What's needed to scale synthetic biology field?** Could we see a Syn Bio project akin to a "mini" Human Genome Project? CEOs Kosaraju (Inscripta) and Kelly (Ginkgo) emphasized the need for industry to cooperate with the government and academia to catalyze future innovation. Kelly spoke specifically to investment in technology on the backend that enables agile manipulation of existing DNA strands. Similar to the NIH's "Shark Tank" inspired Rapid Acceleration of Diagnostics (RADx) program to fund innovation in COVID testing, we could see a similar program over time focused on various types of government-backed venture funding for synthetic biology innovators perhaps through ARPA-H or other means.

- **2022+ policy catalysts, in our view**

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- The OSTP is led by geneticist; Dr. Eric Lander, and member of the President's cabinet indicating high priority in this Administration
- HHS released a RFI (request for information) in 2020 to update Screening Guidance for Synthetic Double Stranded DNA, including whether to incorporate new developments in Synbio. An updated guidance document – if released -- could be an opportunity for industry.
- Biden's ARPA-H Cancer Moonshot was initially envisioned to be $6.5 B, and the likely smaller but significant project ($3 B) is likely to be refined in Cures 2.0 legislation in 2022. It's a way for innovators, venture capitalists, scientists, foundations & others to work with the government on critical projects.
- *Endless Frontier* legislation moving forward (passed by the Senate 68-32) is a 2021 bill to out-compete China in key emerging tech areas critical to national security. Could pass the House this year (biosecurity).

- **What's Next:** Synbio is a controversial space. We can see investments in synthetic biology paving the way for implementing key lessons learned from COVID & PHE. We enter a pivotal year where the Biden administration will lay out its plans to address the dynamic pandemic, and Congressional Committees discuss COVID lessons learned for inclusion likely in a Q3 2022 bill (Cures 2.0, Supply Chain, FDA User Fee Bills). We will outline OSTP actions and priorities as they become available.

Background

Ginkgo Bioworks announced it will utilize Inscripta's Onyx genome engineering technology to accelerate new applications. Onyx is a pioneering benchtop genomic engineering platform that will enable more agile product development across Ginkgo's products. Specifically, the Onyx synthetic biology platform will increase performance and productivity in Ginkgo's foundries, enabling new applications in pharmaceutical products and other industries including agriculture, food, and industrial chemicals.

Max Bronstein's Bio: Max G. Bronstein is the Assistant Director for Health Innovation in the White House Office of Science & Technology Policy (OSTP). At OSTP, Max is helping to lead efforts in launching the Advanced Research Projects Agency for Health (ARPA-H) and works on a variety of health and life science policy issues. Previously, he ran a boutique consulting firm, serving clients in the biotechnology and non-profit sectors. While in the private sector, Max was the Senior Director of Health Policy & Corporate Affairs at Audentes Therapeutics, leading company interactions with state and federal policymakers, while driving various coalitions to advance patient-focused policies for gene therapy and regenerative medicine. In particular, Max was a leader of legislative efforts to promote payment model innovation for gene therapy products and ensuring the strongest possible standards in the US for diagnosis of rare diseases. Previously, Max was the Chief Advocacy & Science Policy Officer at the EveryLife Foundation for Rare Diseases where he led the Foundation's policy initiatives to close the innovation gap for rare diseases and to enhance newborn screening in America.

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