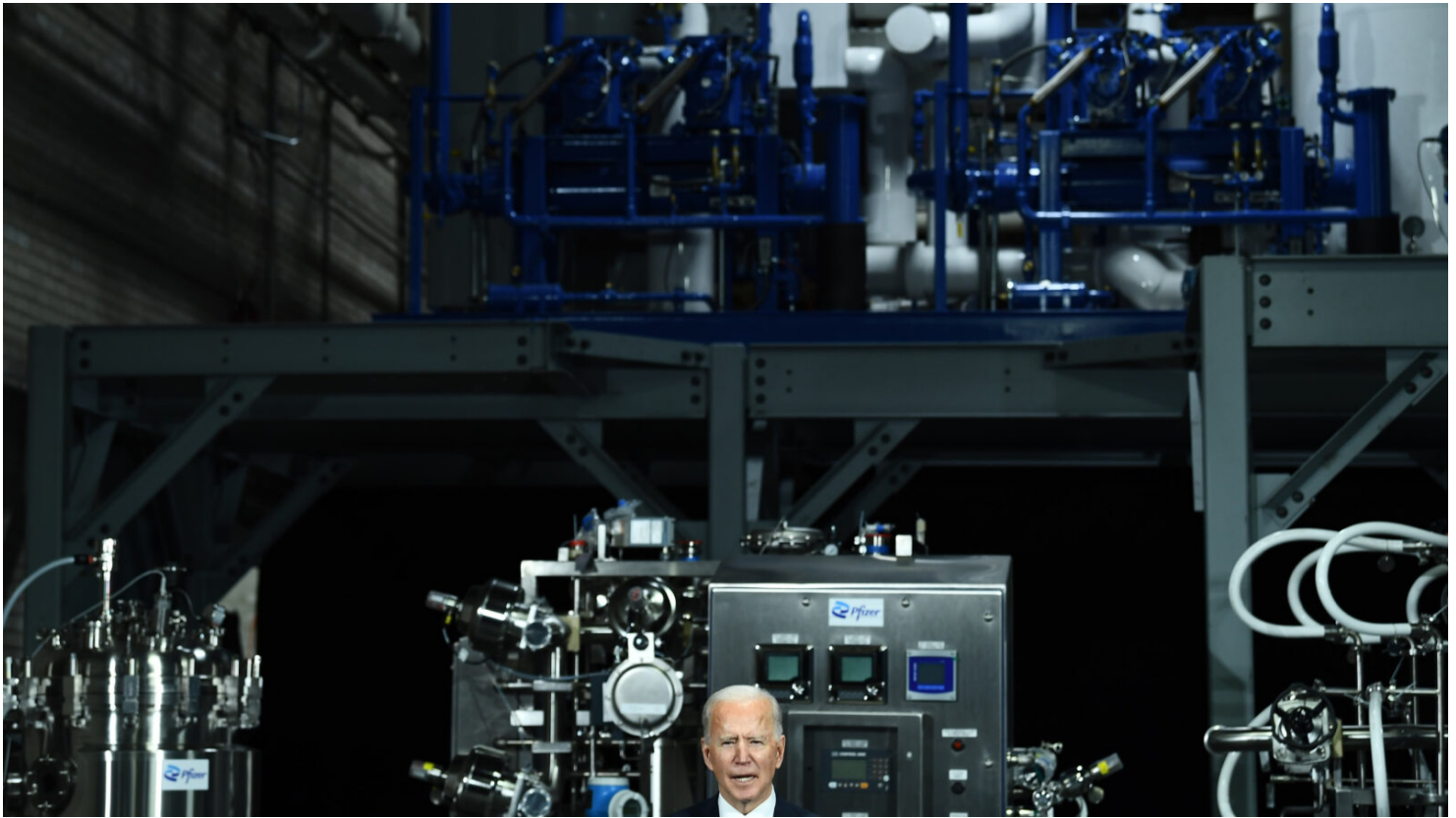


STAT⁺₁

A Biden-Harris Biomanufacturing Initiative could increase supplies of vaccines, therapeutics in one fell swoop

By Krishanu Saha March 24, 2021



President Biden speaks at the Pfizer Covid-19 vaccine manufacturing site in Portage, Mich., on Feb. 19.
BRENDAN SMIALOWSKI/AFP via Getty Images

The coronavirus pandemic is generating pressure on the manufacturing of [vaccines](#)³ and [therapeutics](#)⁴.

Every day that passes with inadequate production leads to excessive suffering and even death for thousands of Americans. We can do so much better — and we must — by maximizing advances in biomanufacturing, a field that uses biological systems to efficiently create drugs, tissues, and even products that go into foods and beverages.

As factories produce vaccine components — mRNA, proteins, and attenuated viruses — the U.S. and the world desperately await the finished vaccines. At the

same time, tens of thousands of people are waiting for cell therapies to treat their cancers, for gene therapies to address their inherited diseases, and for immunotherapies to relieve their autoimmune disorders. For advanced therapeutics like these, factories make similar products — constituent RNA, proteins, and necessary viral components.

With structural and policy-driven support, the U.S. could ramp up the supply of products to meet the current shortages, both during the pandemic and beyond.

Preparation for the future must consider the growth of the vaccines and therapeutics sectors together, in part because the scale-up and modernization of vaccine biomanufacturing will have spillover effects for therapeutics.

Compared to the variable demand curve associated with infectious diseases, the demand for advanced therapeutics is more consistent. As the need for any particular vaccine wanes, a common, integrated biomanufacturing infrastructure could be seamlessly used to make therapeutics instead, eliminating lulls in production. And any excess capacity that may be generated in 2021 would provide surge capacity for the next pandemic.

Biomanufacturing of both vaccines and therapeutics relies heavily on common knowledge, supply chains, and workforces that are [potentially interchangeable](#)⁶. [BioNTech](#)⁷, for example, which had initially aimed its mRNA technology at cancer, was able to quickly pivot to vaccines soon after the emergence of Covid-19 in early 2020. Both therapeutics and vaccines leverage advances in programmable biology by modifying DNA or RNA within the manufacturing process or product. Today's processes are built upon decades of steady innovation in gene synthesis, genomic sequencing, genetic engineering, and genome editing.

Even before the pandemic, there was a disconnect between vaccine and therapeutics manufacturing. [Yearlong queues](#)⁸ in manufacturing viral vectors have persisted since 2017. With rare exceptions, biomanufacturing efforts continue to be siloed, mainly within specialized companies focused on either field.

The Biden-Harris administration could prioritize a deeply integrative approach across vaccine and therapeutics industries with a Biomanufacturing Initiative. A precursor, of course, is the Obama-Biden administration's [Cancer Moonshot Initiative](#)⁹. It increased data sharing and partnering across the public-private continuum for cancer research, but only a sliver of that effort focused on biomanufacturing.

With the continuing pandemic, Covid-19 and cancer — and more — could be addressed within a single effort. Stronger connections across vaccine and therapeutics manufacturing would increase resilience and preparedness to increase the supply of these essential products.

Vaccines are seen as being closer to public goods, and therapeutics closer to private goods. And that's part of the problem. Vastly different business models are used to finance the development and manufacturing of these products. A Biomanufacturing Initiative could help bridge this divide with the development of new technologies, incentives, and regulatory policy to promote flexible manufacturing.

Platform technologies — like the [Platform Vector Gene Therapies Project](#)¹⁰, rapid response platforms for so-called [Disease X](#)¹¹ by the Coalition for Epidemic Preparedness Innovations, and proprietary platforms such as [Moderna's](#)¹² — can be tailored to quickly produce many different vaccines and therapeutics. Incentives, along with corresponding changes in regulatory policy, that allow firms to switch seamlessly between various business models would lead to a more flexible biomanufacturing base.

Facilities within this base could quickly pivot from the centralized manufacturing of a single product to regional or point-of-care production of different products. In the U.S., for example, if Covid-19 surges on the East and West Coasts were to lead to lockdowns, facilities in the Midwest could ramp up production — and vice versa.

A Biomanufacturing Initiative could also address a current blind spot in health care: the disconnected digital infrastructure. Detailed manufacturing information on products administered to patients is rarely linked to patient outcomes, which means losing out on the insights of data science and artificial intelligence into biomanufacturing. With a robust digital infrastructure, differences in product formulation and dosing could be correlated to patient outcomes, and even permit long-term monitoring for adverse events when it comes to issues that could take [years to develop](#)¹⁴ after treatment with vaccines or therapeutics.

Perhaps most compelling, a Biomanufacturing Initiative could keep the nation better prepared and stocked to fight new viral variants and other dangers. The [U.S. Strategic National Stockpile](#)¹⁵ of therapeutics already exists, preparing us for nuclear or chemical attack. The Biomanufacturing Initiative could augment and diversify this stockpile to address other threats. The international [Coalition for Epidemic Preparedness Innovations](#)¹⁶, [Catapult](#)¹⁷ in the United Kingdom, the [Centre for Commercialization of Regenerative Medicine](#)¹⁸ in Canada, and the [National Institute for Innovation in Manufacturing Biopharmaceuticals](#)¹⁹ and [Advanced Regenerative Manufacturing Institute](#)²⁰ in the U.S. have all gained significant momentum and provide various models for incentivizing flexible manufacturing and stockpiling of vaccines and other biopharmaceuticals across an interconnected public-private biomanufacturing infrastructure.

Stockpiling and incentives can go only so far without an appropriately trained workforce. A Biomanufacturing Initiative could establish a kind of “National Guard” for biomanufacturing, galvanizing the resurgent [public service ethos](#)²¹ and [collaborative spirit](#)²² in the scientific community during the pandemic. [Next-generation training](#)²³ supported by a Biomanufacturing Initiative could educate this workforce in the latest advances in platform technologies, [automation](#)²⁴, flexible manufacturing, and data science.

The Covid-19 pandemic has revealed both the extraordinary demand for vaccines and therapeutics and the heartrending consequences of having a patchy, sluggish supply of them. As we anticipate the post-pandemic world, our response should

be visionary, providing strategic integration and modernization of the country's rapidly evolving biomanufacturing base.

We've never needed it more, and we will almost certainly need it again.

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Links

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