

SECURING OUR NATION'S BIOTIC FUTURE: TEN INVESTMENTS TO MAKE TODAY

Bio-Strategies & Leadership Hoover Institution at Stanford University Biology is a strategic domain. Biotechnology has significant implications for the US economy, our security, and human flourishing more broadly. Biotechnology is more than pharmaceuticals; it has <u>thousands</u> of applications across all sectors, including entirely new sectors. To have a chance, the United States must increase biotechnology's contributions to our economy overall by a factor of ten. This incredible transformation must be realized within the next fifteen years.

Beyond direct economic and manufacturing power, biotechnology has key national security implications. These appear most acutely in terms of our biosecurity and in competition with China. The US government has yet to realize how far China has advanced in biotechnology from education, to R&D, to translation, to manufacturing. China has taken an all-of-nation approach to biotechnology for the last twelve years, investing billions, whereas the United States continues to log only tepid and incremental victories. China owns vast swaths of the global biotechnology supply chain and is actively engaging and coordinating biotechnology activities globally, on top of the significant domestic investments and platforms operating on the Chinese mainland. At the current level of investment, the United States is not capable of challenging or matching these efforts. Failure to act with urgency and scale will guarantee that the United States will never again be competitive with China in biotechnology.

Here are ten high-leverage and strategic actions the US government should take now to give the United States the best chance of being the world leader in biotechnology. These represent a constellation of strategic investments in our nation's biosecurity.

1. Unlocking Tomorrow

The world's most advanced research facilities for emerging biotechnologies are in <u>Shenzhen</u>, China. To compete effectively, the United States must invest in foundational R&D—at the scale of new national laboratories—for the highest and greatest strategic leverage. However, we must ensure that such investments are not simply supporting the missions of the past. Examples of such future-facing investments include:

Large Language Laboratories (LLLs)

Training the best models requires the best data. For the United States to have the worldleading large language models in biotechnology, we must have the world-leading large language labs. These LLLs should focus on high-throughput automated prototyping and testing with the goal of scaling up our biotechnology abilities. While most of the work of LLLs should be unclassified, there must be a subset of work at the intersection of artificial intelligence and biotechnology that should be carried out at the classified level.

National Biotechnology Accelerator (NBIOTA)

The nation must invest in a National Biotechnology Accelerator whose mission is to relentlessly improve how researchers practice biotechnology and its underlying workflows. Public treasure gains the highest leverage when taxpayer money supports the tools that everyone gets to use. Such world-leading biotechnology tools are a prerequisite to the United States being a world leader. We must support teams making ever-better tools for measuring, modeling, and making biology.



2. Setting the Standards

<u>Article 1, Section 8</u> of the Constitution gives Congress the power and responsibility to "fix the Standard of Weights and Measures." Such standard setting is essential to support reliable reuse of goods and services throughout our economy. For example, how does a farmer know when they fill their pickup truck that a gallon of gas is really a gallon? The hidden work that solves such problems is carried out by the <u>National Institute of Standards and Technology (NIST)</u>. NIST has two major laboratories: the Physical Measurement Laboratory (PML) and the Material Measurement Laboratory (MML). NIST PML pushes the limits of physical measurements: the meter, the kilogram, the second. NIST MML makes reference objects: a standard jar of peanut butter for calibrating your peanut butter factory.

NIST must be resourced to create a third laboratory: the NIST Bio-Measurement Laboratory (BML). The NIST BML should push the limits of measurement science in biology to establish and promulgate the standards that accelerate the US bioeconomy and guarantee that as much of the world as possible is operating on America's biotechnology stack. Securing this future will advantage all US activities globally, from biotechnology regulation to biosafety and biosecurity policy and beyond.

3. Securing Biology with Biology

We need a National Bio-Defense Institute (NBDI) to convene and support the nation's best scientists and engineers in leveraging emerging technologies to secure biology. "Amerithrax," SARS, flu, MERS, and SARS-CoV-2 remind us that biology poses a threat of the highest concern to the United States and its citizens. President Biden's October 2022 <u>National Security Memorandum 15</u> correctly declares that the United States must strive to create a world free from biological catastrophe. The only way to accomplish this goal is to leverage emerging biotechnologies to secure biology. Every American should have the infectious disease diagnostics, treatments, and vaccines they need. But there are significant risks to be navigated in advancing biotechnology to secure biology. The only way to chart a well-led, coordinated, and responsible path is to create a NBDI as a joint project across the government: Health and Human Services (HHS), Department of Homeland Security (DHS), Department of Defense (DOD), Department of Agriculture (USDA), the Intelligence Community, and other agencies.

4. BIOINT: Behind the Molecular Curtain

At the outbreak of the Cold War, observing and understanding the happenings behind the Iron Curtain was essential. This acute need launched the collection of geospatial intelligence (GEOINT). Starting with spy planes and satellites, GEOINT quickly became essential for more than winning the Cold War. Today GEOINT supports not only military and intelligence missions but also provides environmental monitoring, disaster relief, and myriad commercial applications. Now, our security is threatened by what lies behind the molecular curtain. To secure biology we must institutionalize the capacity to surveil the globe at the biomolecular level. Such activities would encompass Biological Intelligence, or BIOINT.

We should start with sequencing and analysis of nucleic acids, the DNA of all living things, which <u>would provide</u> essential information with implications for our security and economy. While several agencies play a role already, we need to grow our current intelligence collection into a national



coordinated program to sustain observation of the living world. Ongoing efforts, while extraordinary and well intentioned, are simply not tasked, coordinated, or resourced at the right scale of need or ambition. A BIOINT Consortium should be established comprising all relevant stakeholders: the Intelligence Community, DOD, Centers for Disease Control and Prevention (CDC), DHS, and the private sector. As an immediate next step, a rapid study should be undertaken to determine an annual budget for BIOINT and the Consortium.

5. BIOINT: Part II

The National Intelligence Council has national intelligence officers (NIO) for various key strategic domains and theaters. US biosecurity requires a standalone NIO for biology to produce valid, high-quality, and comprehensive intelligence informing smart US policies and decision making.

6. Total Biomanufacturing Dominance

The Department of Defense has recently done well by creating a Biodefense Council that serves to coordinate and prioritize needs and actions related to defending against biological threats. In a similar fashion, DOD should create a Biomanufacturing Council (BMC). The mission of the BMC should be to identify, elevate, prioritize, and support all work as needed to guarantee that DOD will have access to the biomanufacturing capacity it requires—from foundational R&D to full-scale manufacturing. This is particularly important for products and materials for which the Defense Department is the only customer (e.g., energetics). Failure to more aggressively advance and integrate next-generation biomanufacturing processes will increasingly leave DOD without the critical resources it needs to protect and defend Americans.

7. Catalytic Capital

Physics and chemistry underlie general-purpose technologies because of sustained public investments over the past eight decades. Biology, however, does not. Transforming biology into a general-purpose technology (see recommendation 1, "Unlocking Tomorrow") will unleash tremendous manufacturing potential across all sectors. Knowing this, we must act now to ensure that the jobs and factories built on these breakthroughs land in the United States. To make this real, funding for factories needs to be widely available, not just at the pilot scale but for full-scale biomanufacturing. One possible solution is "Biobonds for the Biobelt." Rather than asking for direct appropriations to build factories, federal and state governments could incentivize private capital investment by enabling tax-free bonds. These "biobonds" would allow private capital to move more quickly to support the build-out of a robust American biomanufacturing ecosystem at the scale required. Federal and state governments would need to determine the types of biomanufacturing operations most desirable for their jurisdictions and appropriately incentivize private investment through bonds to launch this effort. A good starting assumption is that scaling up from pilot to full-scale production demands ten to a hundred times the investment of the pilot scale.

8. Maximizing Translation

A small adjustment to existing legislation could unlock and promote technological translation and better support US competitiveness against China. The 1980 Bayh-Dole Act gives institutions receiving public funding ownership of any inventions derived from their research. This incentivized universities to patent and license emerging technologies and stimulated advances in technology and the economy. While some inventions need a patent and strong protection, many, if not most,



inventions do not. Congress should clarify that placing inventions in the public domain is also compatible with Bayh-Dole. This recommendation would be made stronger still if any institution receiving federal funding were required to allow a public domain option for translation as a complement to patenting and licensing. By giving inventors and institutions options, we can maximize translation of biotechnology innovations. Because China isn't always perfectly respecting our intellectual property rights process to begin with, adding this option also helps level the playing field for innovators and entrepreneurs in the United States.

One prominent example of this working well can be found at Stanford University, which has among the best track records of invention, translation, and entrepreneurship in the world. Please see paragraph four of Stanford's patent policy: "The inventors, acting collectively where there is more than one, are free to place their inventions in the public domain if they believe that would be in the best interest of technology transfer and if doing so is not in violation of the terms of any U.S. Federal Government grants or any other agreements that supported or related to the work."

9. Building a Biotic America

Becoming the world leader in biotechnology requires an all-of-society effort. All Americans should have the option of participating in the bioeconomy through education, access, and acceleration.

Education: Create and support a national "<u>labrary</u>" network. Similar to public libraries, the nation's public labrary network will enable all Americans to learn about biology and responsibly gain the skills to practice biotechnology.

Access: Grow local, state, and federal support for programs like <u>BioBuilder</u>, which enables localities and regions to build out the infrastructure needed to prepare people for gainful employment in the bioeconomy. Similarly grow support for programs like <u>iGEM</u> that excite, motivate, and equip students to become world leaders and entrepreneurs in emerging biotechnology.

Accelerate: Support a bio-literate workforce in government itself. Increasing pay caps for biology experts in DOD and the Intelligence Community is one example. Policymakers should also consider making bio-education or service a requirement for certain senior positions in government (SES, SIS, and SFS positions).

10. A Star-Spangled Bioeconomy

Policymakers should create "Bio.gov" modeled after <u>AI.gov</u> to serve as a central location for policy experts, allied governments, and the general public to access resources, news, and updates from the government on biotechnology. Currently, biotechnology policies and investments are managed and overseen by as many as <u>ten agencies</u> plus <u>boards</u>, <u>committees</u>, and more. Bio.gov would promote better coordination and visibility as well as elevate biotechnology to its rightful level as a core emerging technology that deserves government attention. The United States needs to announce and lead a biotic future that is informed and inspired by American values.

ADDITIONAL IDEAS

Stayed tuned for more high-impact policy investments, including:

• Prioritizing high-leverage foundational research



- Building and securing a "bionet," enabling manufacturing resilience
- Positioning the Department of Energy to lead in twenty-first-century biotechnologies
- Creating and sustaining geopolitical trust
- Preventing strategic surprise

For more information about these recommendations—including cost estimates—and Bio-Strategies and Leadership at the Hoover Institution at Stanford University, please contact:

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