DRIVING AMERICAN GLOBAL HEALTH & CLIMATE LEADERSHIP THROUGH BIOTECHNOLOGY

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Bio Biotechnology Innovation Organization

The United States leads the world in developing technologies that will solve the health and economic crises caused by COVID-19, fight climate change, and improve access to nutritious food. Because of cutting-edge science and a growing understanding of biology and genetics, the U.S. biotechnology sector is uniquely valuable in the context of confronting these global challenges. Biotechnology is also a significant contributor to U.S. economic growth and is creating thousands of high paying jobs in cities and towns across the country.

In recent years, however, America's position as the global leader has come under attack. As countries race to secure access to these technologies, governments are working to weaken global rules and international organizations, instead of investing in innovation. Such efforts undermine the core economic incentives needed to advance science, putting American innovation at risk. Government and industry must work collectively to bolster U.S. leadership. BIO recommends several foreign policy actions that will restore our standing as a global leader on biotechnology, enhance economic growth and job creation, and lay the groundwork for leveraging science and American innovation to solve society's biggest and most pressing challenges.

BIO'S GLOBAL LEADERSHIP

CORE ELEMENTS OF AN EFFECTIVE U.S. INTERNATIONAL AGENDA

U.S. leadership in biotechnology is a cornerstone of U.S. economic and national security, and provides a platform from which to exercise global leadership on key issues. To accelerate this process, BIO recommends policies and actions in three categories:

- Enhancing American leadership in global health and pandemic preparedness
- Advancing American trade strategies that enhance the life sciences and grow U.S. bioeconomy jobs
- Driving global climate solutions through American science

GLOBAL HEALTH AND PANDEMIC PREPAREDNESS

COVID-19 underscores the strategic importance of the biotechnology sector. As the world struggles to get control of this virus, we will need a broad array of treatments and vaccines to enable a return to normal. U.S. biotechnology innovators and their durable global partnerships are advancing an unprecedented effort to combat the disease. Multiple breakthroughs have already been commercialized or are close to commercialization, and we are currently witnessing successful vaccine administration across the world. This industry leadership occurred despite the U.S. government's global disengagement, including its withdrawal from the World Health Organization (WHO).

Restore U.S. membership and leadership in the WHO

- Re-engage the U.S. broadly within the WHO to:
  - → Coordinate an international response to the ongoing COVID-19 pandemic, including through efforts like the "ACT-Accelerator" initiative and COVAX Facility.
  - → Drive successful WHO workstreams aimed at applying lessons learned through COVID-19 to future pandemic preparedness, including:
    - Engaging in the review of the WHO's International Health Regulations
    - Enhancing global transparency on outbreaks of new epidemics
    - Removing obstacles to information sharing and data about emerging pathogens
    - Advancing "One Health" collaboration that underscores the connectivity between human, animal, and environmental health
  - → Establish global norms for emerging biotechnologies, including genome editing, that will be instrumental in solving numerous public health, environmental, and nutritional challenges resulting from climate change.
- Work collaboratively with allies to restore the WHO's core mission on public health while streamlining the organization's cumbersome process of engagement with external stakeholders, including the biotechnology sector.

Enhance and expand global access to medicines and related health products

As the originator of most new biomedical innovations in the world, the U.S. has a special responsibility to lead global efforts to provide access to new treatments and cures to patients, while preserving the engine of innovation. U.S. biotech innovators are committed to expanding access to their products globally, but international rules protecting intellectual property rights are critical both to the development of new products and to their launch around the world. The launch of 800 COVID-19 related projects and cross-border collaborations in just a few months demonstrates that commitment and the underlying importance of incentives for innovation, including intellectual property protections. The U.S. should take the following steps to enhance and expand access, with a particular focus on promoting equity:

- Lead efforts to build the capacity and ability to deliver needed medical treatments to underserved populations, including establishing regional centers of excellence.
- Advance global harmonization of efficient, science-based regulatory systems for transformative health products, centered on the U.S. Food and Drug Administration (FDA) "gold standard." Harmonization will lead to faster, more efficient, and safer development of transformative treatments and cures for patients everywhere. To achieve this, the U.S. should:
  - → Partner with leaders of other stringent regulatory agencies to promote broader global harmonization of regulatory best practices through the International Council on Harmonization (ICH).
  - → Use the ICH as the forum for driving the development of regulatory standards for new technologies (e.g., gene and cell therapies, gene editing).
  - → Build capacity for regulatory "reliance" on stringent regulatory agency decisions and effective cross-national pooling of resources within low- and middle-income countries.

TRADE STRATEGIES TO ENHANCE LIFE SCIENCES AND GROW THE U.S. BIOECONOMY

Executing thoughtful and creative trade strategies is among the most effective means to enhance global science-based collaboration while growing the U.S. bioeconomy. An open global trading and investment system benefits innovators and researchers everywhere by establishing a fair, level playing field for all. Trade agreements help to establish national policies that promote the development of and access to disruptive and transformative biotechnologies that will be required to effectively confront serious public health, environmental, and nutritional challenges.

Yet, the United States has backtracked in recent years to protect "defensive" economic interests at the expense of emerging and innovate sectors, such as biotechnology. Further, the United States has ceded much of its leadership and credibility at global institutions such as the World Trade Organization (WTO).

The support for innovation and cross-border collaboration in the world trading system is challenged by inward-looking, nationalistic models based on imitating or even stealing leading technologies. U.S. leadership is essential to preserve and expand the pro-innovation, pro-collaboration nature of that system. To do so, the United States must reassert its influence within the global trading system by leading efforts to place science and technology at the core of its global economic and strategic interests. Doing so will result in the growth of American bioeconomy jobs and better position us to effectively confront big global challenges. We have an obligation – industry and government – to leverage American strengths and work collectively to remove barriers that restrict the development of the global biotech ecosystem. Specific recommendations include:

Recommit to American leadership in global trade

- Reengage within the **WTO**, leveraging American influence to reform the institution and lead efforts to launch new initiatives focused on liberalizing trade and establishing rules to enable a revolution in science and technology.
- Continue to hold **China** accountable, pressing for critical market-based reforms, intellectual property protection and science-based regulation, working with allies as feasible.
- Enforce existing U.S. trade agreements, including implementation of key agricultural biotechnology provisions of the **U.S.-Mexico-Canada (USMCA)** trade agreement.
- Proactively engage **Europe** on science-based climate and sustainable farming, manufacturing, health, and transportation solutions, asserting the valuable and proven role of biotechnology as a means to achieve climate-positive successes in these sectors.

*Leverage the **U.S.-UK trade agreement** to establish a new trade policy model that enhances both nations' life science strengths and bioeconomy growth potential by:*

- → Establishing strong intellectual property and data flow protections
- → Enhancing commitments to science-based regulations and approaches
- → Growing access to transformative biotechnologies and products to underserved communities
- → Partnering to leverage both nations' economic strength to confront anti-innovation efforts in other parts of the world that weaken society's efforts to fight climate change

Leverage Trade Policy to Confront Global Challenges:

- Commit to advancing transformative biotechnologies that are required to meet global public health, environmental, and nutrition challenges through bilateral and multilateral trade agreements and ensuring a fair and level playing field abroad for U.S. innovators.
- Maintain long-standing U.S. trade policy commitments to intellectual property, which is critical to risk-taking and investment in pre-profit companies at the heart of BIO's membership, as incorporated into Trade Promotion Authority.
- Establish rules for digital trade to ensure data related to life-sciences and technology research and development can flow across borders without compromising personal privacy concerns.
- Proactively confront regulatory systems in other countries that do not facilitate access to transformative biotechnologies and products.
- Work creatively with advanced economies to ensure that the world economic system rewards and sustains global incentives for biotechnology innovation in a way that is fair and balanced.

ADVANCING GLOBAL CLIMATE SOLUTIONS

The COVID-19 pandemic is exposing the vulnerabilities in our nation's capacity to respond to crisis, maintain supply chains, and withstand economic downturn. At the same time, this crisis highlights the breakthrough potential of science when it is unleashed. We must apply these learnings as we take bold and drastic action to address climate change, the next imminent threat to our society. From an international standpoint, BIO recommends the following actions:

- Proactively advance biotechnology as a valuable tool to combat climate change through broad trade strategy approaches and efforts to reengage in multilateral forums.
- Build broad global support for the U.S. government's recent regulatory modernization for agricultural biotechnology.
- Build a coalition of countries to push back on international treaties such as the Convention on Biological Diversity and the Nagoya Protocol that tend to stifle the adoption of biotechnology and frustrate research and development.
- Rejoin the Paris Accords and provide active leadership to the United Nations and other global organizations to ensure that science and technology are positioned to overcome climate challenges.

CONCLUSION

U.S. biotechnology innovation will provide significant contributions in our effort to address health, nutrition, and environmental challenges. To protect small innovators and give rise to more American-developed solutions, however, the U.S. must modernize its trade policy objectives to be better positioned within the life-science ecosystem.

Because the U.S. has pulled back its role as the international leader over the past few years, it is critical that the US take steps to restore global leadership, particularly in areas where it has pulled back in recent years.

FACTS AND FIGURES

US Global leadership stats:

- US is still the leader — **57% of new meds**
- In 2019, US represented **66% of global biotech** VC financing (EU — 16%, China 15%) But China is catching up — went from less than 1% of global VC financing in 2010, to almost 15% in 2019 (i.e., a 3000% increase in 9 years)

Threats abroad

- To reduce the potential for trade disruption in agriculture, biotech companies often delay commercialization of new products in the United States until China and Europe have approved the same products. A recent study estimates Chinese delays between 2011 and 2016 reduced farm income by **$5 billion** and U.S. GDP by **$7 billion**.
- Chinese (and potentially other country policies) aim to replace U.S. biotech medicines with locally developed ones by unfair practices such as requiring US companies to do R&D and manufacture locally in order to have access to their market. In addition, while intellectual property laws have improved, enforcement is still weak, so that US developed innovations are being unfairly appropriated abroad.

U.S. crop biotech acreage, US exports of biotech crops, contribution to US GDP (INFORMA REPORT)

- According to the International Service for the Acquisition of Agri-biotech Applications (ISAAA), biotech-enhanced farming systems **saved 452 million acres of lands** from plowing and cultivation, and decreased use of pesticides by **8.2 percent since 1996**.

Climate leadership

- By 2025, California's Low Carbon Fuel Standard, in combination with Cap & Trade, will result in:
  - → Savings of **$8.3 billion** in pollution-related health costs
  - → Prevention of **600 heart attacks** and **880 premature deaths** caused by air pollution
  - → Prevention of **38,000 asthma attacks** and almost **75,000 lost workdays**
  - → Reduction of criteria pollutant emissions by almost **180,000 tons**
- The use of biofuels, primarily used in passenger cars, has resulted in significant greenhouse gas reductions, with cumulative CO2 savings of nearly **600 million metric tons** (mmt) since the RFS was enacted.
- Compared to gasoline, biofuel from energy crops can reduce emissions by **101 to 115 percent**.
- The USDA found that the development of renewable chemicals and biobased products removed **12.7 mmt of CO2** from the manufacturing sector in 2016 alone.
- The USDA estimates that the biobased economy contributes **$393 billion** to the overall U.S. economy, generating **4.2 million jobs**.