

BIOCOM CALIFORNIA

2022 FEDERAL POLICY PRIORITIES

Pandemic and Infectious Disease Preparedness

- Support the research and development of products to prevent, diagnose and treat COVID-19, including through **advanced manufacturing and additional public funding**.
- Ensure that the U.S. has an **adequate stockpile of critically needed products** and emphasize the need to **resolve supply chain disruptions**, including of lab supplies and semiconductor chips, to better address current and future pandemics.

Basic Research

- **Increase discretionary funding for the National Institutes of Health (NIH)**, which provide a critical foundation of knowledge that drives innovation across the country. In FY 2021, California received \$5.1 billion from NIH, which has funded over 9,000 grants.
- **Reauthorize the Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) grants** before the program expires at the end of September. The SBIR/STTR program has allowed small businesses and start-up companies to bring innovative ideas to commercialization.

FDA Regulatory Policy

- **Reauthorize the Food and Drug Administration (FDA) user fees agreements (PDUFA, MDUFA and BSUFA)**, with a focus on preserving the accelerated approval pathway, increasing diversity in clinical trials, and enhancing the use of real-world evidence in the approval process.
- **Encourage the development of effective antibiotics** to help fight anti-microbial resistance.
- Provide guidelines to industry on transitioning products approved under the **Emergency Use Authorization (EUA) pathway**.
- **Reject allowing the importation of drugs from foreign markets**, as it would threaten the efficacy and safety of our U.S. drug supply chain and put patients at risk of counterfeit products.

Patient Access to Care

- **Oppose proposals that would establish international reference pricing**, which allows the government to set U.S. prices for drugs based on the prices paid by other countries, effectively importing access restrictions and discouraging the development of new products. Research shows that proposals like H.R.3 would reduce by 90 percent the number of drugs brought to market by small companies.
- **Support lowering out-of-pocket costs for patients**, improving the Medicare Part D drug benefit design, expanding the use of value-based agreements, reforming the rebates to Pharmacy Benefit Managers (PBMs) system so the discounts are passed directly to consumers at the pharmacy counter, and ensuring the availability of broad patient assistance programs.
- **Oppose policies that restrict access to medicines** such as restrictive formularies, increased cost-sharing through specialty tiers, high deductibles and co-pay accumulators, as well as the overutilization of prior authorization and step or “fail first” therapy.
- **Support guardrails around the Center for Medicare and Medicaid Innovation’s (CMMI) demonstration projects** to ensure that the demonstrations are scale-appropriate, voluntary, and transparent.
- **Support changes to the 340B Drug Discount Program that would increase transparency, oversight, and accountability.** Over the years, the 340B program has seen significant growth, surpassing the scope and size that was originally intended by Congress, with the number of participating sites and contract pharmacies nearly doubling in half a decade.
- Support policies that recognize the benefits of precision medicine and **ensure the coverage of next-generation sequencing (NGS) tests, cell and gene therapy products, and pharmacogenomic testing.** Precision medicine helps develop treatments that are more effective, targeted, avoid costly unsuccessful therapies, and prevent adverse patient outcomes.
- **Support the creation of a coverage pathway for medical devices and diagnostics that have been designated as breakthrough** by the Food and Drug Administration (FDA).

Digital Health and Telehealth

- **Support the increased use of digital health technologies**, such as wearables, mobile applications, and artificial intelligence tools, including the integration of patient-generated health data in clinical trials and clinical care settings, the continued work of the FDA to alleviate uncertainties about the regulatory requirements for the use of data in submissions and contexts of use, and the education of physicians and patients about the use and benefits of digital health.
- **Expand the use of current Remote Patient Monitoring codes**, support the development of new codes for additional uses, and accelerate efforts to adapt Medicare Physician Fee Schedule (PFS) methodology to better reflect the growing use of innovative technologies. Reimbursement is one of the most significant barriers to the utilization of digital health technologies.
- **Ensure that patient data is secure and private, empower patients to have reasonable rights over the control of their health information** while distinguishing between traditional consumer data companies and research companies, for which allowing patients to access their clinical trial or post-market study data would fundamentally impair the integrity of the study results, and ensure harmonization of data privacy and ownership frameworks and federal preemption of state laws.
- **Make permanent the telehealth flexibilities created during the COVID-19 public health emergency (PHE)**, such as easing geographic and site of origin restrictions and facilitating cross-state licensure, while ensuring that telehealth serves as a complement to in-person care, which is necessary for many patients and conditions.

Intellectual Property and Trade

- **Oppose legislation that would undermine constitutionally-guaranteed IP protections** by weakening patents, imposing greater requirements on innovators, restricting legitimate patent holders' ability to assert their IP rights, increasing litigation risks, and reversing some of the improvements to the Patent Trial and Appeal Board (PTAB) made by the USPTO in recent years. Undermining the U.S. patent system will be especially detrimental to small companies for which patents are often their only asset and means to attract investors.
- Protect the Bayh-Dole Act of 1980, which has incentivized the development and commercialization of federally-funded research that would not have been developed otherwise, and **oppose allowing the government to take away innovators' patent and exclusivity protections, including invoking "march-in" rights or granting "compulsory licenses"** to generic or biosimilar manufacturers.
- **Oppose waiving IP rights for companies producing COVID-19 vaccines** under the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), as it may weaken existing supply chains, delay access to vaccines, and open the door to counterfeit medicines, while hindering future innovation.
- **Support free-trade agreements and other trade deals that uphold U.S. IP protections** and level the playing field with foreign countries by bringing them closer to our IP standards and limiting foreign "free-riding" on American innovation.

Taxes

- **Preserve the research and development (R&D) tax credit, the current corporate tax rate** of 21 percent which was reduced from 35 percent by the tax reform of 2017, **as well as the territorial tax system** - where the overseas profits of U.S. companies are no longer subject to U.S. tax - also established by the tax reform.
- **Protect the orphan drug tax credit (ODTC)**, which was cut in half by the 2017 tax law and refrain from limiting the availability of the credit for further orphan indications, **allow businesses to deduct their R&D expenses in the same year they were incurred, and remove or increase the cap on SALT deductions**, which was established by the tax law.

Agricultural and Industrial Biotechnology

- **Help promote the development of a biobased economy**, including synthetic biology, advanced and cellulosic biofuels, and plant-based products by increasing manufacturing capacity, growing our supply chain resiliency, and protecting the renewable fuel standard. Continued investment in these innovative technologies is helping us develop clean energy, reduce our dependency on foreign energy sources, protect the environment, and mitigate climate change.
- **Support science-based regulation of agricultural products** that are relevant to health, safety, and nutrition, including the labeling of genetically engineered (GE) foods.

Biocom California is the largest, most experienced leader and advocate for California's life science sector, which includes biotechnology, pharmaceutical, medical device, genomics and diagnostics companies of all sizes, as well as research universities and institutes, clinical research organizations, investors and service providers. With more than 1,500 members dedicated to improving health and quality of life, Biocom drives public policy initiatives to positively influence the state's life science community in the research, development, and delivery of innovative products.