# 2023 Federal Policy Priorities

Biocom California



## Research & Pandemic Preparedness

### Priority 1

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 2022, California received $5.3 billion from NIH, which has funded over 9,000 grants.

### Priority 2

Build and actively engage in a coalition to apply for an Advanced Research Projects Agency for Health (ARPA-H) hub in California.

### Priority 3

Support the timely reauthorization of the Pandemic and All-Hazards Preparedness Act (PAHPA), which authorizes funding for the Biomedical Advanced Research and Development Authority (BARDA) and the Project BioShield Special Reserve Fund (SRF).

### Priority 4

Support further research and development of next-generation products to prevent, diagnose and treat COVID-19, including through advanced manufacturing and additional public funding, and ensure that the U.S. has an adequate stockpile of critically needed products to address future pandemics.

## Intellectual Property & Trade

### Priority 1

Oppose legislation that would undermine constitutionally-guaranteed IP protections by weakening patents, impose greater requirements on innovators, restrict legitimate patent holders' ability to assert their IP rights, increase litigation risks, and reverse 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.

### Priority 2

Protect the Bayh-Dole Act of 1980, which 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.

### Priority 3

Oppose waiving IP rights for companies producing COVID-19 vaccines and therapeutics 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.

### Priority 4

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.

## Patient Access to Care

### Priority 1

Educate members on the Inflation Reduction Act's Prescription Drug Pricing Reform and help mitigate the impact of implementation on industry.

### Priority 2

Support lowering out-of-pocket costs for patients, including reforming the rebates to Pharmacy Benefit Managers (PBMs) system so discounts are passed directly to consumers at the pharmacy counter, expanding the use of value-based agreements, and ensuring the availability of broad patient assistance programs.

### Priority 3

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.

### Priority 4

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.

### Priority 5

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.

### Priority 6

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 and avoid costly unsuccessful therapies, and prevent adverse patient outcomes.

### Priority 7

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).

### Priority 8

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.

### Priority 9

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.

### Priority 10

Engage in data privacy legislation to ensure that patient data is secure and private while not compromising data collection and management of health research companies, and fostering the harmonization of data privacy and ownership frameworks at the state and federal levels.

## Taxes

### Priority 1

Reverse the R&D amortization provision in the 2017 Tax Law to allow businesses to deduct their R&D expenses in the same year they were incurred.

### Priority 2

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.

### Priority 3

Protect the orphan drug tax credit (ODTC), which was cut in half by the 2017 Tax Law and, and advocate against limiting the availability of the credit for further orphan indications.

## Regulatory

### Priority 1

Ensure the proper implementation of the FDA user fee agreements passed in 2022, including the Prescription Drug User Fee Act (PDUFA), Medical Device User Fee Act (MDUFA), and the Biosimilar User Fee Act (BsUFA).

### Priority 2

Protect the Accelerated Approval Pathway.

### Priority 3

Encourage the development of effective antibiotics to help fight anti-microbial resistance.

### Priority 4

Provide clarity to industry on transitioning products approved under the Emergency Use Authorization (EUA) pathway after the end of the Public Health Emergency.

### Priority 5

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.

### Priority 6

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.

## Agricultural & Energy Biotechnology

### Priority 1

Support the timely reauthorization of the Farm Bill, which provides funding for Energy Title programs, including the BioPreferred Program, Biobased Markets Program, Biorefinery, Renewable Chemical, and Biobased Product Manufacturing Assistance Program, and the Biomass Crop Assistance Program (BCAP).

### Priority 2

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.

### Priority 3

Support science-based regulation of agricultural products that are relevant to health, safety, and nutrition, including the labeling of genetically engineered (GE) foods.

Since its founding in 1995, Biocom California has emerged as the most respected association voice for the state's life science industry in regional government, the State Capitol, and Washington, D.C.

Please direct any questions to:

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