

Biocom California State Priorities



Health Data | Patient Access to Care | Intellectual Property and Trade | Science, Technology, Engineering and Math (STEM) Education & Workforce | Taxation | Environmental Regulation | Water

Health Data

Data Privacy

As health data is increasingly being used by life science companies to research, test, develop, deliver and monitor products and technologies, it is important to distinguish research companies from traditional consumer data companies when establishing data ownership, privacy, and security frameworks because of their legitimate needs to access and use health care data to advance public health.

As new data privacy legislation is developed, it is important to keep in mind existing frameworks for the regulation of health data and ensure that existing and new frameworks are harmonized and certain entities and data already covered by existing laws are exempt. In addition, as more state legislatures consider privacy laws, it is crucial to enact federal legislation that mandates conformance of state law. A lack of harmonization between existing and new frameworks and between state laws would create uncertainty and widespread disruption to the healthcare system and biomedical research.

Biocom California supports patients being entrusted reasonable rights of control over their health information but believes that it is highly important to exempt biomedical research from such frameworks, including clinical trials, non-interventional research such as observational drug comparative effectiveness and drug safety studies, and real-world evidence, to ensure the validity and integrity of research and post-market surveillance activities and avoid losing data, adding uncertainty, and creating compliance and financial burdens that would make it more difficult for innovators to do business and improve and save lives. Whenever possible, state data privacy statutes must be conformed to accepted standards such as the Health Insurance Portability and Accountability Act (HIPAA).

Digital Health

Health care is at the cusp of a sector-wide transformation due in large part to the development of digital health technologies, such as remote patient monitoring, mobile applications and artificial intelligence. Advances in digital health have enhanced the efficiency of health care delivery, enabled better health care resource utilization, and improved patient outcomes across a wide spectrum of diseases. Wearable devices that monitor a wide range of health data such as blood pressure, glucose levels, blood oxygen levels, heart rate, and electrocardiograms, and devices that deliver medicines directly to patients often reduce the need to physically visit a doctor's office or hospital, allowing patients to receive and transmit health care information instantly in a home setting and be active participants in their care. These technologies, in turn, contain costs, reduce the frequency of visits to medical institutions, and ensure the continuity of care.

Biocom California supports state policies that provide appropriate coverage and payment for new technologies, such as mobile apps, remote patient monitoring and artificial intelligence products, increased use of electronic health records (EHRs) and patient-generated health data.

Patient Access to Care

Access to Medicines, Devices & Diagnostics

Reimbursement policies should encourage innovation and improvement in the standard of care via effective use of therapeutics, medical devices and diagnostics. Unfortunately, many payors and middlemen have implemented policies which increase their profit margins at the expense of the patient's quality of life. These policies interfere with physicians' decisions and effectively prevent patients from using the treatments that are best suited for their condition, delaying access to needed treatments and allowing diseases to progress, which can have irreversible consequences for patients.

Biocom California supports lowering out-of-pocket costs for patients, broad patient assistance and insurance designs that ensure that patients have access to the care they need. Biocom California opposes restrictions 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, among others.

Drug Importation

The practice of importing prescription drugs into the U.S. from foreign locations (many with artificial price controls) creates a serious public health threat. Importation brings with it a significant risk of fraud, as well as significant quality control issues. According to the US FDA's own website, "For example, medicines from outside the legitimate U.S. drug supply chain do not have the same assurance of safety, effectiveness and quality as drugs subject to FDA oversight."

Drug re-importation is not safe because the integrity of the supply chain is not known and cannot be verified. In fact, past federal Health and Human Services Secretaries have been unable or unwilling to issue a safety and cost-saving certification regarding drug importation, despite requirements in federal law that they attempt to do so. This makes clear the risks associated with drug importation.

Biocom California opposes efforts for the State of California to sanction, encourage or somehow facilitate the importation of drugs from other countries.

Precision Medicine

Precision medicine is an innovative approach to disease prevention and treatment that uses individuals' DNA to select the most effective therapies for patients, moving from a traditional one-size-fits-all approach to personalized treatments based on individuals' genetic materials. It holds the promise of revolutionizing the delivery of care as we know it by enabling researchers, providers, and patients to work together to develop more precise, preventive, and individualized treatments. As the cost of healthcare continues to increase, we also look to precision medicine as one way to help develop treatments that are more effective, avoid costly unsuccessful therapies and prevent adverse patient outcomes. Genetic sequencing, still unimaginable a few years ago, has now become one of the most powerful tools in modern medicine.

Biocom California supports policies that recognize the benefits and advance the development of precision medicine, ensure the coverage of next-generation sequencing (NGS) tests, and expand the use and access of genome sequencing for a wide range of patients.

Reference Pricing

Patients in countries with price controls have access to far fewer medicines than in the U.S. and have lower survival rates for most cancers. Price controls also delay the launch of new medicines because of the additional time needed by governments and companies to negotiate prices and lead to less research and development, which risks depriving the sickest patients from potential treatments and cures. At the federal level, Biocom California opposed H.R.3, the Lower Drug Costs Now Act of 2019, after a study found the pricing index proposed in that bill would reduce by 88 percent the number of drugs brought to market by small and emerging companies in California alone.

Biocom California opposes proposals that would impose reference pricing, which allows the government to set U.S. or California prices for drugs based on artificially manipulated prices paid by other countries. Importing foreign price controls on innovative medicines risk importing access restrictions to these medicines, and ultimately discouraging investment in the development of treatments and cures.

Single Payer

While Biocom California is conceptually supportive of healthcare for all, single payer systems decrease covered treatment options available to patients, as well as decrease marketplace competition in general. In 2017, it was estimated that a California-specific single payer system that had been proposed in legislation (SB 562) would cost approximately \$400 billion, twice the total state budget that year. This would result in unacceptable levels of tax increases across all levels of the California economy.

For the reasons above, Biocom California is conceptually opposed to "single payer" healthcare.



Intellectual Property and Trade

The life sciences industry has always had a robust symbiotic relationship with the UC and CSU systems, which has led to a robust revenue stream for the universities in the form of licensing fees and landmark revenues. Key to these relationships are a recognition that all benefit from a system that encourages public-private partnership to insure discoveries can receive the expertise and capital investment it takes to translate them into approved therapies.

Before the 1980s, countless research projects were left on the shelf because there were no incentives to develop the projects. The enactment of the federal Bayh-Dole Act of 1980 allowed research institutes and universities to pursue ownership of an invention derived from federally-funded research and license it to biotech companies, which enabled companies experienced in allowed patients to have access to products and technologies that would never have been developed otherwise. Allowing federal agencies to bypass innovators' rights ("march in") for any reason other than public health emergencies counters the intent of the Bayh-Dole Act.

Biocom California opposes legislation that would allow the government to take away innovators' patent and exclusivity protections, including invoking "march-in" rights or granting "compulsory licenses" to generic or biosimilar manufacturers. Biocom California also opposes legislation which sets a standard for intellectual property issues for California outside of that which is already established in federal law.

Science, Technology, Engineering and Math (STEM) Education & Workforce

Biocom California has consistently supported science, technology, engineering, and math (STEM) education in California. The 501c3 Biocom California Institute supports life science innovation in California by creating opportunities for STEM students, teachers, scientists, and life science companies to work together and grow a diverse community of life science professionals.

The Institute's Veterans Initiative aims to increase career opportunities in the life science industry for transitioning veterans by providing mentoring and networking connections, while promoting advocacy for veteran employment.

The San Diego Festival of Science and Engineering aims at inspiring today's students to become tomorrow's STEM innovators through educational programming and activities for children of all ages during its Festival Week. Along with its signature Expo Day (at Petco Park), the Festival also conducts STEM activities throughout San Diego County.

Biocom California encourages state supported programming in cooperation with the life science industry which will increase exposure and career track interest in science and engineering fields by underrepresented communities, including veterans and children of color.

Taxation

The life science industry is one of the largest economic drivers in California. Accounting for 1.4 million direct, indirect and induced jobs, in 1999 it had an economic impact of \$372B in the state. For context, when compared to national GDP's, that figure would rank in the top 35 economies in the world by the metrics of the IMF, World Bank or United Nations. It historically has been more resilient and less prone to dramatic swings during economic downturns. In fact, during the Great Recession of 2008, the industry continued to grow in California while nationwide it had minimal job loss.

The life science industry has flourished in CA because of a robust research institute network, public and private universities focused on biomedical research, and a highly skilled available workforce. It creates opportunities not only within the industry, but its "multiplier effect" among suppliers, service providers, and new construction opportunities spreads that benefit far beyond the companies themselves.

California itself, however, is a relatively high cost state to operate in, both in terms of taxes, cost of compliance, and cost of living for employees. Other states and countries routinely seek relocation or expansion of companies via economic and regulatory incentives. The State of California, on the other hand, offers little in the way of targeted programs towards the life sciences. Two of the most important tax incentives for life science companies, the state research and development (R&D) credit and the ability to carry forward net operating losses (NOL), have been suspended by the State Legislature to account for budgetary shortfalls caused by the COVID-19 pandemic. There have also been occasional proposals in the legislature to increase per employee payroll taxes or increase corporate income taxes. All of these are detrimental to California maintaining its place as the world's leader in the life sciences.

Biocom California urges the immediate reinstatement of the R&D tax credit and the NOL carryforward. Biocom California also encourages the state to further incentivize companies doing business and having substantial employee presence in California. Biocom California opposes increased payroll or corporate income taxes as they discourage further investment in expanded payrolls or operations within the State of California.

Environmental Regulation

The life sciences are one of the most closely monitored, safety conscious industries anywhere. This is because even the slightest contamination can literally cost a company hundreds of thousands of dollars in recall of product or flawed research findings. Anything used in these facilities, from reagents used in testing and experiments to cleaning products, is very carefully and purposefully chosen and can even be dictated and essential within the FDA or USDA approval process for a drug, device or diagnostic.

At times, well-meaning parties will seek to ban specific chemicals or products from use in California. On rare occasions, these products or chemicals are used in life science facilities.

With the extremely high level of scrutiny of life science facilities by local, state and federal regulators, and with the need for uniformity in conditions and chemicals throughout life science facilities no matter where they are, Biocom California believes that federal law should pre-empt state law in cases of environmental regulation in life science facilities operated under the authority of the US FDA or USDA.

Water

Biocom California was founded out of a water availability crisis, when city leaders were considering rotating water shutdowns akin to the “public safety power shutoffs” known to many Californians. Life science leaders realized the irreparable harm these shutdowns could do to the relatively young industry, and mobilized accordingly. Twenty five years later, having a reliable and uninterrupted supply of quality water is still central to the success of California’s life science industry.

Biocom California supports the development of strong water policies for California to maximize statewide water availability and diversification of sources of water where economically feasible. Biocom California opposes water proposals that will cause undue harm to the industry.

