BIOCOM
accelerating life science

Federal POLICY PRIORITIES

- **BIOMEDICAL RESEARCH FUNDING**
- **FDA REGULATORY POLICY**
- **REIMBURSEMENT AND PATIENT ACCESS TO CARE**
- **TAXES**
- **DIGITAL HEALTH AND GENOMICS**
- **SCIENCE, TECHNOLOGY, ENGINEERING, AND MATH (STEM) EDUCATION & WORKFORCE**
- **AGRICULTURAL AND INDUSTRIAL BIOTECHNOLOGY**
- **INTELLECTUAL PROPERTY AND PATENT LAW**

Biocom is one of the largest statewide life science associations in the world, representing more than 1,000 member companies in California. The association focuses on initiatives that positively influence the region's life science community in the development and delivery of innovative products that improve health and quality of life.

BIOMEDICAL RESEARCH FUNDING

>>NATIONAL INSTITUTES OF HEALTH (NIH)
By supporting basic research, the NIH provides a critical foundation of knowledge and technologies that drive private biomedical investment and innovation across the country, and especially in California. In FY 2017, California received $3.7 billion from NIH, which has funded over 7,500 grants. Among those, Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) grants have allowed small businesses and start-up companies to bring innovative ideas to commercialization. However, NIH funding has been flat for the past decade and has not kept pace with inflation, which has resulted in the NIH losing nearly 25 percent of its purchasing power. Decreased investments in innovation could affect existing research, erode the U.S. global leadership in medical innovation, and lead some scientists to pursue their research in other countries.

Congress allocated $32 billion to the NIH in FY2016 and $34 billion in FY2017, increases highly welcomed by Biocom. In December 2016, Congress passed the 21st Century Cures Act, which aims at bringing new treatments and cures to patients faster, a top priority for Biocom. The bill adds funding for the NIH, with dedicated funding for major executive initiatives, including the Precision Medicine Initiative, BRAIN Initiative, and Cancer Moonshot. But Congress must continue to invest in medical innovation to enable the development of breakthrough treatments and cures. **Biocom is urging the House and the Senate to increase funding for the NIH in FY2018 and FY2019.**

>>BIODEFENSE
Biocom continues to advocate for biodefense and pandemic research funding. Recent outbreaks, such as Ebola and Zika, have revived a nationwide debate over U.S. preparedness for emerging infectious diseases and emphasized the need for robust public-private partnerships. Biocom supports additional funding for the Project BioShield Special Reserve Fund (SRF), which incentivizes companies to develop medical countermeasures (MCMs), and the Biomedical Advanced Research and Development Authority (BARDA), which develops vaccines and treatments for chemical, biological, radiological, and nuclear (CBRN) threats, through partnerships with industry. **In particular, Biocom is urging Congress to reauthorize the Pandemic and All-Hazards Preparedness Act (PAHPA), set to expire on September 30, 2018, which authorizes funding for BARDA and SRF programs.**

Please direct any questions to
Biocom's Director of Federal Policy and Government Affairs,
Laure Fabrega at lfabrega@biocom.org or 202.449.3962.

BIOCOM
accelerating life science

Federal POLICY PRIORITIES

FDA REGULATORY POLICY

>>REGULATORY POLICY
Biocom is dedicated to improving the drug and device review and approval process, communication between industry and FDA, and transparency and accountability within the agency. Biocom will continue to monitor and engage on important regulatory matters on behalf of the California life science community, including the regulatory pathway for the approval of biosimilar products established by the Biologics Price Competition and Innovation Act (BPCIA) in 2010, the regulation of compounded products, mobile apps, laboratory-developed tests (LDTs), Next-Generation Sequencing (NGS) tests, and the new drug tracing and UDI (Unique Device Identification) systems, among others. **In particular, Biocom will engage with Congress and federal agencies to ensure the proper implementation of two newly-enacted laws that have been top priorities for Biocom:**

>>21ST CENTURY CURES
Biocom applauded the passage of the 21st Century Cures Act in Congress in December 2016.The measure makes much needed changes to our regulatory environment to improve our innovation ecosystem, from discovery to development to delivery, and includes provisions to enhance efficiency, hiring, and training at the NIH and FDA, improve electronic health records (EHRs), a priority review pathway for breakthrough medical devices, a limited population approval pathway for antibiotics, an expansion of the priority review voucher program for rare pediatric diseases, clear standards for biomarker acceptance and qualification, as well as provisions to advance the use of modern trial designs and real-world evidence, among others.

>>USER FEES REAUTHORIZATION
In August 2017, President Trump signed the FDA Reauthorization Act (FDARA) of 2017 into law.The legislation reauthorizes the prescription drug, medical device, generic drug, and biosimilar user fee agreements.The agreements are negotiated every five years by the FDA and industry and amended and approved by Congress. Industry agrees to pay higher fees to the FDA to supplement the agency's review and approval activities in exchange for FDA's commitment to reviewing products faster and meeting performance goals. FDA will build upon provisions included in the 21st Century Cures Act, including incorporating patient perspectives into the drug development process, facilitating the use of innovative clinical trial designs and real-world evidence, and improving communication, accountability and predictability.

REIMBURSEMENT AND PATIENT ACCESS TO CARE

Biocom is committed to ensuring that patients have access to the care they need and supports reimbursement policies that provide appropriate and inclusive coverage, coding, and payment for biopharmaceutical, medical device, and diagnostic products. Coverage and coding limitations, outdated Medicare regulations, restrictive formularies, and increased cost-sharing such as specialty tiers and high deductibles, among others, inhibit both the development of breakthrough technologies and their use by providers, which in turn limits patients' access to life-enhancing and life-saving products. Reimbursement systems should reward innovative modes of health care delivery that result in quality improvement and cost reduction and, most importantly, save lives.

>>MEDICARE PART B
Biocom has strongly opposed the $3 billion cuts to Medicare Part B reimbursements to physicians mandated by the sequester, and continues to oppose proposals that would cut the current market-based average sales price reimbursement system for physicians (ASP+6 percent), which has successfully reduced Medicare costs since its inception. Further cuts to Medicare Part B will increase the likelihood that physicians will stop providing critical treatments to the most vulnerable patients.

>>MEDICARE PART D
Biocom is opposed to cuts and changes to the Medicare prescription drug benefit program (Medicare Part D), a successful program covering more than 90 percent of Medicare beneficiaries with comprehensive drug coverage. Proposals to impose rebates and price controls to Medicare Part D will likely destabilize the program and decrease industry incentives to invest in new drugs' research and development.

BIOCOM
accelerating life science

Federal POLICY PRIORITIES

TAXES

>>TAX REFORM
In December 2017, Congress passed and the President signed into law tax legislation, which reforms our corporate and individual tax code. Biocom applauded Congress for permanently reducing the corporate tax rate to 21 percent from 35 percent and moving the U.S. to a territorial tax system, where the overseas profits of U.S. companies would no longer be subject to U.S. tax, two provisions that had been top priorities for Biocom. These landmark provisions will help make California companies more successful and competitive at home and abroad. The bill also retained the research and development (R&D) tax credit, which incentivizes companies to invest in R&D and is essential to the sustainability and growth of life sciences innovation. However,

On the other hand, Biocom had repeatedly expressed concerns about provisions that reduced the orphan drug tax credit from 50 percent to 25 percent and limited State and Local Tax (SALT) deductions for income and property. **Biocom will work to ensure that these provisions do not disproportionately disadvantage Californians and will continue to support policies that promote research, innovation, and advanced manufacturing, stimulate job creation and economic activity, and sustain America's global leadership.**

>>MEDICAL DEVICE EXCISE TAX
Biocom applauded the two-year retroactive delay (2018-2019) of the medical device tax that was signed into law in January 2018 and adds to a previous two-year suspension of the tax, enacted in 2015. The bill ensures that medical device manufacturers will continue to be exempt from paying the 2.3 percent excise tax on medical device sales, which first took effect on January 1, 2013, and has put serious budget constraints on medical device companies.

The tax is expected to cost manufacturers nearly $30 billion over the next ten years, putting 43,000 jobs at risk, stifling R&D investments and medical innovation, eroding U.S. global leadership, and jeopardizing patient access to breakthrough devices and therapies. Similar excise taxes are levied by the federal government on products such as alcohol and tobacco to discourage their use. In addition, the tax is assessed on revenue and, therefore, is particularly burdensome for many innovative start-up companies, which are not yet profitable. **Biocom is committed to working with Congress and stakeholders to fully repeal the medical device tax.**

DIGITAL HEALTH AND GENOMICS

Health care is at the cusp of a sector-wide transformation due in large part to the development of digital health technologies, from genomic testing and sequencing to mobile applications to remote patient monitoring. 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.

Digital health technologies often reduce the need to physically visit a doctor's office or hospital, allowing patients to communicate with their physicians and receive and transmit health care information instantly in a home setting, thus containing costs, preventing the deterioration of conditions, reducing the frequency of visits to medical institutions, and ensuring the continuity of care. Digital health also empowers patients to be active participants in their health care decision-making process.

Biocom will continue to support reimbursement policies that provide appropriate and inclusive coverage, coding, and payment for new technologies, platform-agnostic regulations of digital health technologies, increased use of electronic health records (EHRs) and patient-generated health data, as well as educational efforts to help patients, providers, and caregivers better understand the benefits and usage of digital health technologies and genomics, among others.

BIOCOM
accelerating life science

Federal POLICY PRIORITIES

SCIENCE, TECHNOLOGY, ENGINEERING, AND MATH (STEM) EDUCATION & WORKFORCE

Biocom has consistently supported science, technology, engineering, and math (STEM) education in the United States. The Biocom Institute supports life science innovation in Southern 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 San Diego Festival of Science and Engineering aims at inspiring today's students to become tomorrow's STEM innovators through a week of educational programming and activities for children of all ages. The 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.

In addition, Biocom will continue to support immigration reform that provides American employers with greater access to the world's best talents by allocating green cards and H-1B visas to high-skilled foreign graduates and graduates with STEM degrees.

AGRICULTURAL AND INDUSTRIAL BIOTECHNOLOGY

>>GE FOOD LABELING

In July 2016, Congress passed and the President signed into law legislation that created limited mandatory disclosure requirements for genetically engineered (GE) foods. **While Biocom supports voluntary food labeling that communicates science-based information relevant to health, safety, and nutrition to consumers, we will work to ensure the proper implementation of the law so that it does not discriminate against GE foods and mislead consumers.**

>>ENERGY PROGRAMS

In February 2014, Biocom applauded the enactment of the Agricultural Act, also known as the Farm Bill, which provides $881 million in mandatory funding for Energy Title programs, including the Biorefinery, Renewable Chemical, and Biobased Product Manufacturing Assistance Program, the Biomass Crop Assistance Program (BCAP), and the Biomass Research and Development Initiative (BRDI), as well as eligibility for renewable chemicals. Farm bills commonly refer to legislation authorizing funding for programs within the U.S. Department of Agriculture (USDA) in five-year increments. Since 2002, Farm Bills have funded energy programs (under "the Energy Title"), which have facilitated the development of biorenewable energy, including biofuels and biobased products. **Biocom will work with Congress this year to ensure the timely reauthorization of the Farm Bill, which is set to expire in September 2018.**

>>RENEWABLE FUEL STANDARD (RFS)

Biocom will continue to support preserving the RFS and oppose any attempts to weaken or eliminate it. The RFS has enabled the development of advanced and cellulosic biofuels and helps support continued investment in these innovative technologies, which in turn helps reduce our dependency on foreign energy sources, generates economic activity, creates jobs, and protects the environment.

INTELLECTUAL PROPERTY AND PATENT LAW

>>PATENT REFORM

Biocom has vehemently opposed and will continue to oppose legislation that imposes greater requirements and penalties on patent holders, such as costly pleading and reporting requirements, restrictions on additional discovery requests, and burdensome fee shifting provisions, among others. Such limitations undermine the U.S. patent system by restricting legitimate patent holders' ability to assert their patent rights and increasing litigation risks, which would in turn lower the value of patent assets and reduce investment in early innovation.

Several recent and major judicial and administrative developments in patent law have fundamentally changed the landscape under which patent legislation should be considered, and made some proposed measures irrelevant or unnecessary. Should Congress resume consideration of such ill-written proposals, Biocom will engage with House and Senate committees and leaderships to find reasonable ways to address abusive practices by specifically targeting bad actors, commonly referred to as "patent trolls". Biocom will only support measures that protect the constitutionally-guaranteed intellectual property rights of innovators.

>>USPTO USER FEES

Biocom continues to work to ensure that the Patent and Trademark Office (USPTO) has access to the entirety of user fees collected and is advocating against user fee diversion. Over the past twenty years, PTO user fees diversion has led to more than 600,000 unexamined patent applications and more than 28 months in the average patent pendency time.