



STATE LEGISLATIVE YEAR IN REVIEW 2006

In many ways, 2006 marked a year of transition for both BIOCOM and the California Legislature. The Public Policy Unit was revamped, and this was the first full legislative session of our relationship with our contract lobbyists, the firm of Sloat, Higgins, Jensen & Associates. In Sacramento, the Governor and Democratic leadership engaged in an almost unprecedented level of bipartisan cooperation.

Although we endured one high profile defeat, overall this was an incredibly successful legislative year for BIOCOM. As noted below, 70% of BIOCOM-endorsed bills were signed into law, only one was vetoed. Just as importantly, when the two bills which were substantially amended are removed from the count, BIOCOM enjoyed an 86% success rate in defeating legislation identified as harmful to the industry.

Total bills supported: Ten (one priority), seven of which were signed into law (70% success rate)

Total bills opposed: Nine (seven priority), one of which was signed into law in the form BIOCOM opposed, two were signed after significant amendments which addressed the primary concerns of BIOCOM (86% success rate).

Health Care

AB 2911 (Nunez)—BIOCOM oppose ****Priority****

In the final days of this year's state legislative session, the state Legislature approved and the Governor signed into law the California Discount Prescription Drug Program, a compromise plan between Governor Arnold Schwarzenegger and the Democratic leaders of both houses. Authored by Assembly Speaker Fabian Nunez, this bill enacts a form of prescription price controls in California. The program is available to anyone making 300% of the federal poverty level (this is currently \$60,000 for a family of four) and members of other specific groups (see [link for further information](#)).

This bill allows a three year period in which companies are "encouraged" to negotiate discounted prescription pricing with the state. Effective August 1, 2010, a manufacturer must be at or below at least one of three benchmarks: Medicaid Best Price, the lowest price offered to private payers, or the average manufacturers' price minus 15 percent. If the negotiations fail to produce discounts meeting at least one of these benchmarks, the state may require prior authorization for all products from that manufacturer for any Medi-Cal patient being started on a medication (patients already under treatment with a particular medication are exempted). Although many organizations (including the Western Center on Law and Poverty, Huntington's Disease Society of America, and the National Alliance for the Mentally Ill California) opposed leveraging access to medications for the poor as a negotiating chip, this bill passed 47-31 in the Assembly and 25-12 in the State Senate.

AB 2877 (Frommer)—BIOCOM Oppose

This bill started as a bill which would have established a state-sponsored website for certified drug importation sources, and in that form was a priority bill for BIOCOM. As such, it also was a focus of our advocacy efforts. In the face of overwhelming opposition by much of the biotech and pharmaceutical industries, the bill was substantially amended just before the end of session and it became a bill which is intended to help CA consumers find the lowest available domestic price, as well as include information about prescription assistance programs operated by industry. In this weakened form, the bill was signed by the Governor.

Environmental Health & Safety

AB 2155 (Wolk)—BIOCOM Support

This bill, which was signed by the Governor, exempts specified pharmaceutical neutralization procedures from having to meet requirements for hazardous waste control and from having to obtain permits for same.

AB 2335 (Saldaña)—BIOCOM Support

This bill, sponsored by the County of San Diego, made several technical changes which the County argued would benefit both regulators and waste generators by clarifying current law. It was brought to the attention of the Public Policy Committee by BIOCOM's Environmental Health & Safety Committee, which recommended support. This bill was signed into law by the Governor.

AB 2582 (Mullin)—BIOCOM Support

Under current law, the CA Secretary for Environmental Protection operates the CALGOLD (CA Government Online to Desktops) program, which is an online permit assistance center. According to the author, this site is outdated as it gives no recognition to the biotechnology industry. This bill, which was signed into law, requires the program to be reviewed periodically and updated as necessary.

SB 1379 (Perata)—BIOCOM Oppose

This bill establishes a California Biomonitoring program. Through the efforts of a coalition led by the American Chemistry Council (which BIOCOM participated in), SB 1739 went from a priority bill that would have been based more on popular fear and sensationalism to a program based in and guided by science and scientists. Although BIOCOM's opposition was not removed due to limited concerns, most other opponents, including the American Chemistry Council, withdrew their opposition to the bill after the last amendments.

Regulatory

SB 1476 (Figueroa)—BIOCOM Support

Among many other things, this bill extended the deadline for the CA Board of Pharmacy to implement an electronic pedigree system for tracking biologics and pharmaceuticals to January 1, 2009 (from Jan 1, 2007). The current state of available technology is such that the 1/1/07 deadline would NOT have been practical, a fact acknowledged by Board of Pharmacy staff. This bill was passed by the Legislature and signed by the Governor.

AB 71 (Chan)—BIOCOM Oppose ****Priority****

This bill would have mandated that manufacturers pay into a fund (based on total sales, with a cap of \$3.5 million) for a website that was to be created by the University of California. This website would contain previously released data which purportedly would give physicians and consumers information on the safety and effectiveness of prescription drugs in CA. Defeat of this bill was a high priority for the biotechnology and pharmaceutical industries, and in the closing days of the legislative session this bill was defeated twice. BIOCOM worked very actively to kill this bill through both our lobbyist and internal staff. San Diego area Senators Christine Kehoe and Denise Ducheny were critical in standing with the life science industry in defeating this bill.

Tax Reform

AB 1037 (Frommer)—BIOCOM Support ****Priority****

BIOCOM was actively involved in trying to pass this legislation, from lobbying efforts to the testimony of Joe Panetta before the Senate Revenue and Taxation Committee. In its initial form, it would have established a “single sales factor” whereby sales would be the sole determinant for corporate income tax in California. Later amendments would have changed California’s formula from the present 50% weighting of sales (property and payroll each being the other 25%) to one where sales would have been approximately 2/3 of the apportionment with sales and property accounting for 1/6 of the weighting each. BIOCOM partnered with members of the biotechnology, entertainment, and destination industries in working towards this legislation, but ultimately the bill failed in the final days of the session when legislative leadership agreed no tax legislation would be brought forward.

AB 2182 (Mullin)—BIOCOM Support

This bill will require a study, subject to funds being appropriated, by the Board of Equalization in conjunction with the CA Assessors Association and representatives of the semiconductor and biopharmaceutical industries of the valuation tables used by assessors in determining property tax values,. This bill also requires that this study be published upon its completion and provides a rebuttable presumption that the values established by the study are those that should be used by Assessors going forward. This bill was needed because in current practice, Assessors throughout the state use different valuation tables, some more current than others, which creates a system by which the same piece of capital equipment may be taxed at two entirely different valuations in two different counties. This bill was signed into law by the Governor.

Workforce & Education

AB 2595 (Arambula)—BIOCOM Support

In its original form, this bill would have established a manufacturing equipment tax incentive program which would have allowed the deduction of the entire cost of specified equipment over 3 years, and a sales and use tax offset against the tax liability on qualified manufacturing equipment. It also mandated that the Office of the Secretary of Labor and Workforce Development and the California Workforce Investment Board shall establish a logistics worker training initiative for the purpose of making California workers more skilled in the competitive global manufacturing value chain. The final version, which was signed into law, was limited to the logistics worker training initiative.

AB 2423 (Wyland)—BIOCOM Support

This bill, in its original form which BIOCOM supported, would have required the integration of experimental science into elementary school science education, which is already required. In both its original and final form, the author asserted it would encourage school districts to designate specific teachers to be science coaches and provide a framework to do so. This bill, however, was vetoed by the Governor as unnecessary and possibly inadvertently excluding available funds that could be used to fund such positions.

MEDI-CAL

AB 2631 (Laird)—BIOCOM Support

This bill, which was signed into law, will require that Medi-Cal establish a utilization policy for an injectable therapeutic (not self-administered by the patient) within 180 days of being notified by the manufacturer of the therapeutic of approval by the FDA. If Medi-Cal does not develop a utilization policy within that 180 day window, it shall use as its utilization policy standards approved by the FDA via information in the package insert. This bill is important to the industry as Medi-Cal has often lagged in establishing utilization guidelines for new drugs, and without these guidelines there was no mechanism to establish an interim policy. This bill allows such interim guidelines after a reasonable period for Medi-Cal to implement its own policy, thereby expediting new drugs to needy patients.

SB 452 (Alarcon)—BIOCOM Oppose ****Priority****

Under current law, a select few people within the Medi-Cal division have access to the negotiated pricing information companies have agreed to. This bill would have extended this access to the Governor in the form of a “confidential” report comparing current Medi-Cal pricing to the lowest available published federal price. The Governor would then have to make a determination as to whether to seek additional rebates, and would require the Governor to make that determination public via a finding in the Governor’s annual budget. Medi-Cal pricing is considered equivalent to a trade secret, and any breach in confidentiality would put companies at a tremendous competitive disadvantage. This bill assumes the Governor has the expertise to solely make such determinations. Again, BIOCOM participated in a broad-based coalition and contributed significantly to successfully defeating this bill.

MISC

SB 1683 (Scott)—BIOCOM Oppose ****Priority****

This bill was one of the strongest victories for the industry this session. This bill would have required publishing of every clinical trial except Phase I, regardless of outcome, for all therapeutics. It further would have required an explanation for any discontinued clinical trial. These reports would have to be in “plain english” when possible. BIOCOM and other groups and company representatives worked together to defeat this legislation, which would have duplicated much information already available through the federal government or through PhRMA’s voluntary compliance vehicle.

SB 163 (Scott)—BIOCOM Oppose ****Priority****

After the defeat of SB 1683, Senator Scott amended SB 163 to contain identical provisions to SB 1683. Despite having to mobilize on very short notice, the coalition that had mobilized against SB 1683 was successful in defeating this bill.

SB 1056 (Florez)—BIOCOM Support

This bill would have created a state pre-emption in the regulation of bio-engineered seed. Currently, this is left to cities and counties, and has resulted in a patchwork where neighboring counties have different and sometimes conflicting statutes. This bill would have “grandfathered” all local bans enacted before July 1, 2006. Although this bill passed the Assembly, it was held by the Senate Rules Committee, where it died.

AB 2721 (Mullin)—BIOCOM Oppose ****Priority****

This bill would have created a California Office of Intellectual Property. This agency would be responsible for negotiation of all intellectual property rights for discoveries and inventions made using state funds. The bill as written included permissive march-in rights, a requirement for access plans for the uninsured, as well as a price cap. BIOCOM worked with a coalition that included CHI, BIO and both the state and national offices of PhRMA in defeating this bill, although we have pledged to work with the author, who chairs the Assembly Select Committee on Biotechnology.

SB 1763 (Figueroa)—BIOCOM Oppose ****Priority****

This bill would have created a compulsory licensing program for the state of California whereby, upon declaration of a “state of necessity” by the Governor, a company’s intellectual property rights would be suspended in California and the state would be able to allow other manufacturers to produce a product with “just compensation” (as determined by the state) going to the holder of the patent. Defeat of this unprecedented foray by a state into federal patent law was a top priority for BIOCOM, and we and our strategic partners were able to defeat this bill in its first committee hearing.