BIOCOM

April 6, 2016

Senator Ed Hernandez
State Capitol
Sacramento, CA 95814

RE: SB 1010 (as amended 3/30/16)

Dear Senator Hernandez,

Biocom leads the advocacy efforts of the Southern California life science community with approximately 750 members including medical device, diagnostics, biotechnology and biofuels companies; universities; basic research institutions; and service support firms. As an advocacy organization we are actively engaged in ensuring that the life science industry remains a strong and growing part of the state's economy. In keeping with this mission, we must OPPOSE your SB 1010 (as amended 3/30/16).

SB 1010 seeks to place an unprecedented broad reporting burden on drug manufacturers seeking to make market pricing adjustments in their product lines. The vast majority of Biocom's members, even those with approved products, are relatively small companies. For these small and mid-size companies state by state reporting requirements of any type are a significant and disproportionate burden, diverting valuable resources within companies struggling to survive.

Among other things, SB 1010 appears to require manufacturers to provide information into pricing decisions with the very providers they are negotiating contracts with. This presents an irreconcilable conflict of interest that is anti-competitive at its core. Further, the advance 60 day notice required in the bill, which does not appear to be protected information, also could expose critical business strategy to competitors within the industry as well as to third party payers.

There is also no provision for disclosure of third party payers' rationale for increases in patient share-of-cost for medications similar to that required of manufacturers covered by the bill. If one asserts that pricing rationale is essential for proper public transparency, this would be an absolutely essential part of the public discourse that is missing from this legislation.

Unfortunately, as amended, SB 1010 will not provide a great deal towards transparency, but will impose burdensome and anti-competitive mandates on the industry. Thank you for your consideration of our concerns. If we may answer any questions, please contact me at jjackson@biocom.org or 858-455-0300x102 or BIOCOM's contract lobbyist on this matter, Moira Topp, at 916-930-7197.

Sincerely,

Jimmy Jackson
Senior Vice President of Public Policy
Biocom

April 6, 2016

The Honorable Ed Hernandez
Chair, Senate Health Committee
State Capitol Building, Room 2080
Sacramento, CA 95814

Re: Oppose SB 1010 – Burdensome generic price reporting provision

Chairman Hernandez:

We urge the committee and the legislature to reject the burdensome price reporting requirement for generic drugs in the SB 1010. While we agree that high prices and increasing prices of certain brand and specialty medicines present many issues for payors and consumers alike, generic drugs are the solution, not the problem. A report issued by AARP on March 1 showed that while the average cost of brand name drugs increase 12.9 percent and the average cost of specialty drugs increased 10.6% from 2006-13, the average cost of generic drugs dropped 4%.[1] The reporting requirement for generics should be dropped from this legislation.

Generic drugs are currently 88% of prescriptions dispensed in the U.S., but are only 28% of total drug spending and less than 3% of total U.S. healthcare spend. Generics provided $254 billion in savings for U.S. in 2014. Californians saved a total of $21.5 billion from generic drugs in 2014, including $2.9 billion in savings by Medi-Cal alone.

Mylan is a leading manufacturer of generic drugs and our products currently account for one out of every 13 prescriptions filled in the U.S. We offer a growing portfolio of more than 1,400 separate products, have U.S. operations in seven states and provide medicines in approximately 165 countries and territories.

The market for generic drugs is very different than the brand market. Generics typically operate in a hypercompetitive environment where multiple manufacturers compete primarily on price. Such competition regularly drives the price of generic drugs down to 20% – sometimes to less than 10%– of the price of the corresponding brand drug. As a result of this extreme competition that drives prices to pennies on the dollar, generic manufacturers often have little room to absorb changing costs in production

[1] The use of the words "brand" and "generic" herein are for convenience purposes only as replacements for the use of the terms "innovator" and "non-innovator," respectively, as defined under applicable law.

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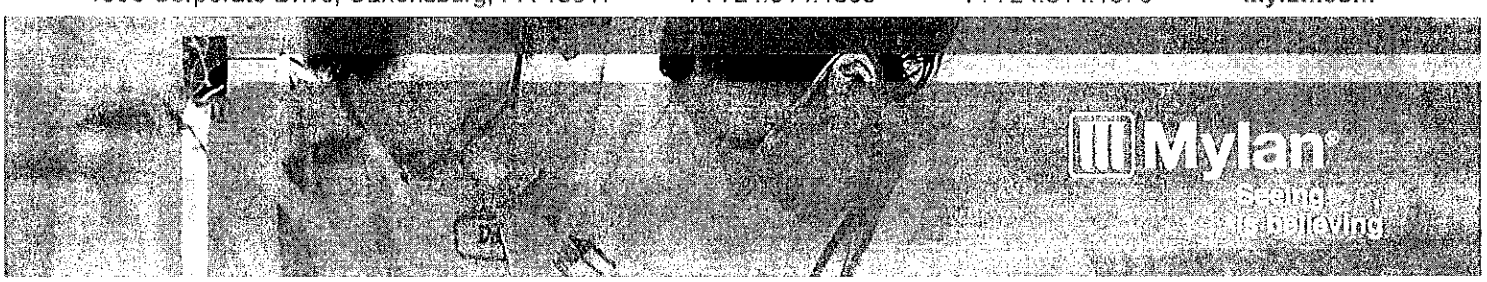

and must adjust prices when there are changes in supply costs, ingredient shortages, regulatory requirements or other factors that drive up production costs.

Under the federal Medicaid program, manufacturers of generics currently provide a 13% rebate, which in some instances means that generic manufacturers actually lose money on products provided to Medicaid and SPAP programs. Prices typically fluctuate up and down much more quickly in the generics market because of the razor thin margins, which would make a requirement for reporting a 10% price increase extremely burdensome and unfair to an industry that represents only 28% of the cost of drugs and ALL of the savings for drugs.

Requiring reporting for temporary price fluctuations could result in higher costs for generics - Medicaid and the private sector - because manufacturers may be reluctant to negotiate such low prices in order to ensure that they have large enough margins built into prices to be able to absorb potential increases in production costs rather than have to endure significant and costly administrative burdens like those included in SB 1010. The unintended consequence of the generic provision could be higher prices for all generics.

We oppose this significant and potentially costly administrative burden and we urge the legislature to reject this provision in SB 1010.

Sincerely,

Bruce Lott

Bruce Lott
Vice President, State Government Relations
Mylan Inc.

Mylan®
Seeing
is believing

April 5, 2016

CLSA
California Life Sciences Association

Senator Ed Hernandez
Chair of the Senate Committee on Health
State Capitol, Room 2080
Sacramento, CA 95814

RE: SB 1010 (HERNANDEZ, ED) – OPPOSE

Dear Chair and Members of the Senate Health Committee:

On behalf of CLSA's more than 750 members spanning the biotechnology, pharmaceutical, medical device sectors of healthcare, among others, I am writing to **oppose SB 1010 (Hernandez, Ed)**. While we understand the intent of the bill, the information being sought under its framework would provide a distorted view of the role medicines play in overall healthcare costs, would pose substantial risks to our members' trade secrets and otherwise proprietary information, and would result in significant costs to the system with no discernible benefit to patients.

First, **the information required of biopharmaceutical companies, health plans, and insurers would create a highly inaccurate picture of how medicines affect overall healthcare costs.** Like other legislative efforts in this area, SB 1010 treats medication costs as solely expenditures, not an investment in more efficient care and better health for patients. The bill ignores all the benefits to patients, the healthcare system, and the economy that the life science sector provides, as well as the benefits to payers and pharmacy benefit managers from oftentimes significantly reduced, negotiated prices. More broadly, the bill appears to ignore the central role pharmacy benefit managers play in the interactions between manufacturers and health plans or insurers.

Health plans, pharmacy benefits managers, and other purchasers of drugs aggressively negotiate with manufacturers for discounts and rebates on the drugs they purchase. This free market negotiation drives down drug prices through competition. It is imperative that any costs disclosed by health plans be based on the net price paid after all discounts, including the rebates they and their pharmacy benefit managers receive.

Regarding the categories of information sought under subdivision (b)(3)(A) of proposed Health and Safety Code section 127675, a number of our members have indicated that making such categories of information drug-specific, where such an allocation is even possible, would be a highly imprecise exercise and provide unreliable information, which could lead to issues with federal regulators as outlined below.

Second, **as we continue to research the extent to which the bill's provisions conflict with, or otherwise negatively interact with, the comprehensive regulatory framework of the United**

States Food and Drug Administration (FDA), we grow increasingly concerned. The bill's requirement of advance notices prior to certain drugs being marketed, being accompanied by a "justification" with "supporting documentation" and an "expected marketing budget," appears to violate FDA restrictions against preapproval marketing or promotion of investigational drugs, because the law and FDA's subsequent guidance only clearly allow for the exchange of scientific information and preclude any form of "commercialization" prior to a medicine's approval for commercial distribution.[1]

All issues related to providing advance notice and "justifications" on a medicine prior to FDA approval are further compounded when the medicine is under an expedited review process. A medicine can receive a special designation from the FDA if it fills an unmet medical need and treats a serious condition or if it offers a major treatment advance or provides treatment where no adequate therapy currently exists. These designations include Fast Track, Breakthrough, Accelerated Approval, and Priority Review. Twenty-seven of the novel drugs approved last year received one of these designations to "expedite the speed of the development and/or approval process and . . . help bring important medications to the market as quickly as possible."[2]

There are also numerous price change "justifications" and "supporting documentation" that may run afoul of FDA law. For instance, in a not uncommon scenario, if a manufacturer raises the price on a medicine because it predicts that the medicine will be approved for a new indication and must begin investing in expanded production capacity, the FDA is clear on the materials that may be distributed permissibly in relation to an unapproved indication and would be concerned about any information disclosure creating a positive impression of an unapproved indication.

Generally, we suspect that the FDA would be concerned about the prospect of SB 1010's advance notice requirements being used as a loophole to or generally creating complications in the monitoring and enforcement of regulations around marketing, promotion, and commercial disclosures. We also have concerns related to legal exposure around federal securities laws on account of the possible circumstances under which our members may be required to make "forward-looking statements" (e.g., in the justifications around advance notices) and potentially "selective disclosures" under the bill's requirements (e.g., in the advance information, which is almost certainly material information, distributed to select parties in California).[3]

Third, the expansive information submission and reporting requirements include a great deal of information that falls within the definition of "trade secret" under California's Uniform Trade Secrets Act (UTSA)[4] or is otherwise considered proprietary information. This is critical because trade secret rights to propriety information within these broad categories are potentially lost with

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[1] 21 CFR § 312.7 (2016) and the relevant Interpreting letters from the FDA Office of Prescription Drug Promotion Letters available at: http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCompanies/default.htm.

[2] U.S. Food and Drug Administration. *Novel Drugs Summary 2015* (January 2016). Available at: http://www.fda.gov/Drugs/DevelopmentApprovalProcess/DrugInnovation/ucm474696.htm.

[3] Private Securities Litigation Reform Act of 1995, Pub. L. 104-67, 109 Stat. 737 (1995); Regulation Fair Disclosure, 17 CFR §§ 243.100 – 243.103 (2010).

[4] California Civil Code §§ 3426 *et seq*.

even aggregate disclosure through legal means such as California's "readily ascertainable" affirmative defense. Many types of information particularly relevant to SB 1010's inquiries have been found to constitute trade secrets, including: research results and related processes or procedures (both successful and unsuccessful); strategic business information regarding pricing, material costs, and suppliers; and financial, marketing, distribution, and manufacturing plans. For instance, a manufacturer justifying a future price increase on account of issues with its raw material supplier would be opening itself up to competitors engaging the only other suppliers of the raw material of interest to put the manufacturer at a competitive disadvantage.

Fourth, **we are also concerned about how the bill potentially conflicts with and negatively interacts with foreign laws and regulators**, as a number of our members are based outside of the United States and many of our members' medicines may be impacted by foreign laws affecting information that originates in those foreign countries, as well as the comprehensive regulatory framework of the European Medicines Agency. We are continuing to research these potential conflicts and interactions and hope to have more to discuss soon.

Finally, both the administrative burdens and the practical effect of producing the information sought under the bill create upward pressure on healthcare costs, as opposed to the downward pressure it intends to create. Information collection, submission, and reporting systems are costly at the scale envisioned by SB 1010. In the Centers for Medicare and Medicaid Services' (CMS) final rule on the "Federal Physician Payments Sunshine Act," CMS estimated that the total burden, falling primarily on manufacturers, was $269 million in the first year and $180 million every year thereafter with no quantifiable benefits to patients or the system overall.[5] While this program was on a national scale, each manufacturer would still have to create unique collection and reporting systems to accommodate the categories of information sought under SB 1010 at a substantial cost – which, again, we assert will lead to no meaningful benefit to patients, as costs are the only focus in this bill.

Again, we thank you for taking the lead on driving the conversation on health care costs in California, but we must oppose SB 1010 in its current form.

For the reasons above, we request an "NO" vote on SB 1010.

Sincerely,

Eve Bukowski, VP of State Government Relations, California Life Sciences Association

Cc: Members of the Senate Health Committee

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[5] Centers for Medicare and Medicaid Services. *Medicare, Medicaid, Children's Health Insurance Programs; Transparency Reports and Reporting of Physician Ownership or Investment Interests*. 78 Fed. Reg. 9457 (8 Feb. 2013). Available at: https://www.federalregister.gov/articles/2013/02/08/2013-02572/medicare-medicaid-childrens-health-insurance-programs-transparency-reports-and-reporting-of.

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OPPOSE

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April 5, 2016

To:	Honorable Ed Hernandez Chair, Senate Health Committee
From:	Pharmaceutical Research and Manufacturers of America (PhRMA)
Re:	Senate Bill 1010 (Hernandez)
PhRMA Position:	Oppose

The Pharmaceutical Research and Manufacturers of America (PhRMA) has adopted an oppose position on your Senate Bill 1010, legislation to, among other things, require prescription drug manufacturers to report certain price increases to state purchasers and private payers of prescription drug products. The bill would also require commercial payers to report to the State of California a number of items to indicate how the plans are spending their resources on prescription medicines.

While we appreciate the early efforts by your office to engage with the pharmaceutical industry on the issues raised, we believe this bill may not fully account for new medicines' crucial contribution to medical advances and the fact that medicines often produce large savings by helping to avoid other types of medical costs.

Though we look forward to continued discussions on drug cost disclosures, we felt it was important to raise our principle concerns with SB 1010, as amended on March 30, 2016:

1. The reporting requirements as established in the bill are extraordinarily broad and would potentially apply to many medicines for which the impact on premiums of a price increase over the threshold of ten percent would be essentially de minimis and would reflect an imperceptible change in the total cost of care.

2. While the information reported by the third party payers is in the aggregate and protected from disclosure by creating specific exceptions to the California Public Records Act (PRA), the data required to be submitted to the state by the pharmaceutical industry includes sensitive proprietary information for specific products that would not enjoy the same PRA disclosure protections provided to the payers – presenting both proprietary and federal antitrust issues.

3. The measure does not include any reference to the significant negotiated rebates and discounts manufacturers provide to payers. Costs disclosed by health insurers should be net of these discounts.

4. Notwithstanding the fact that pharmaceutical companies are required to submit data to justify why a drug's price is increasing, there is no parallel provision to require the third-party payers to disclose their rationale for increasing an enrollee's share-of-cost (co-payment, deductible, out-of-pocket expense, etc.). The bill is silent on what the payers, and their pharmacy benefit managers, do to account for the significant rebates that the drug industry provides. Payers should report the

share of the total net spending for prescription drugs that was paid by the plan and the amount paid out of pocket by enrollees.

5. The requirement for a 60-day advance notice does not appear to be protected information and could thus be anti-competitive, as disclosure of planned pricing changes could have unintended consequences and is generally viewed as extremely disruptive to the competitive marketplace.

Again, we appreciate your efforts to stimulate a meaningful conversation on health care costs in California, and in this case, on prescription drugs, but we must oppose SB 1010 in its current form.

Thank you for your attention to our concerns, and we look forward to discussing the bill in more detail at your convenience.