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CALIFORNIA HEALTHCARE INSTITUTE

September 5, 2012

The Honorable Edmund G. Brown, Jr.
Governor of California
State Capitol, Room 1173
Sacramento, California 95814

RE: Assembly Bill 1277 (Hill/Perea) – SUPPORT

Dear Governor Brown:

On behalf of the California Healthcare Institute (CHI), whose more than 270 members include our state's premier life sciences companies and academic research institutions, I write to respectfully request that you sign AB 1277, a bill that addresses duplicative regulation of drug and medical device manufacturers in California.

This legislative session, legislative leaders and your office set a goal of reducing redundant or onerous state regulations. The biomedical industry responded with a perfect example of overregulation in California – the duplicative regulation of drug and medical device manufacturers. U.S. drug and device companies are subject to oversight, approval, and inspection by the federal Food and Drug Administration (FDA). The FDA performs stringent oversight of drug and device manufacturers, with approvals required and inspections taking place throughout the development process and on a regular basis thereafter. This oversight is the same for all 50 states in the U.S.

California is the only state that has duplicate regulations requiring state-level permitting and inspection of drug and medical device facilities. The California Department of Public Health's Food and Drug Branch licenses, approves and inspects drug and medical device manufacturers in California.

Duplicative state regulation creates additional hurdles to drug and device business' ability to manufacture and create jobs in California. For example, drug and device businesses in California are required to be licensed by the state prior to initiating manufacturing or distribution of specified commodities, even though their products, including their manufacturing processes, have already been approved by the FDA. This results in a delay of manufacturing activities in California.

Duplicative state oversight and inspections also place an increased financial burden on manufacturers in California. Manufacturers expend hundreds of thousands of dollars for similar and overlapping inspections. For example, a company spent over $200,000 and had over 40 staff members involved in a state Food and Drug Branch inspection that took eight days to complete. This was a routine inspection that did not find any health or safety problems, which was conducted less than six months after a comprehensive FDA inspection.

Given the significant cost involved in duplicative state inspections and approvals, and the federal oversight and regulation of manufacturers, CHI believes that state and federal drug and medical device laws should be harmonized. AB 1277 would allow companies that have met FDA requirements to bypass state inspections. AB 1277 would still allow the state Food and Drug Branch to perform state inspections in specified situations, such as when the public may be at risk or the FDA has requested the state's assistance in carrying out a recall.

Duplication of the FDA regulatory standards at the state level has the potential to cause extra expenses due to duplication of permits and inspections, business disruption and possibly different interpretation on the same laws at the state and federal level. This may result in drug and medical device manufacturers moving to other states that do not require state regulation of their facilities, creating more jobs and boosting the economy in those states that do not require state regulation. AB 1277 would move us in the direction of reducing the regulatory burden on California's biomedical manufacturers.

The biomedical industry believes that regulation and inspection are necessary. However, they are counterproductive when they become duplicative. Eliminating duplicative regulations would support innovation and job growth in California. For this reason and the reasons stated above, we have sponsored and strongly support AB 1277. Please feel free to contact me at Hernandez@chi.org or 916-443-5576 if you have any questions or concerns.

Sincerely,

Consuelo Hernandez
Vice President – State Government Affairs