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June 11, 2008

Assemblywoman Sally Lieber
State Capitol, Room 3013
Sacramento, CA 95814

RE: Assembly Bill 515
CHI Position: **Oppose, as amended 9/07/07**

Dear Assemblywoman Lieber:

On behalf of the California Healthcare Institute, whose more than 250 members include our state's premier life sciences companies, I am writing to indicate our continued opposition to AB 515. This legislation would require the Occupational Safety and Health Standards Board (Standards Board) to duplicate its rulemaking for hundreds of chemicals that already have permissible exposure limit (PEL) standards. The bill is unnecessary and would have a significant negative impact on California's life sciences industry.

California is the worldwide headquarters for biomedical research and development. More than 2,600 biomedical companies and 100 public and private research institutions are devoted to solving major unmet medical needs such as cardiovascular and respiratory disease, cancer, diabetes, AIDS/HIV and other infectious diseases. Many CHI member companies and academic research institutions utilize hazardous chemicals in their research and development, as well as manufacturing processes. These chemicals are always used in accordance with OSHA standards for occupational exposure, which are very stringent and protective.

The Current Process for Setting PEL's is Not Broken

The current robust PEL-setting process in California has already resulted in the most stringent workplace chemical exposure limits of any state in the nation, with limits far more comprehensive and stringent than those required by Federal OSHA. The current law requires the Standards Board to adopt a PEL standard which most adequately assures, to the extent feasible, that no employee will suffer material impairment of health or functional capacity even if the employee has regular and prolonged exposure to the hazard for the period of his or her working life (Labor Code Section 144.6). To set the PEL standard, the Standards Board utilizes an administrative process in which an advisory committee reviews scientific information and makes recommendations. The advisory committee takes input from labor representatives, industry and nationally recognized experts in the occupational health field, then reviews the available scientific information. This process includes sufficient worker protections and there is no evidence that employees are harmed by the current PEL settings for workplace chemicals. There is no reason to require the Standards Board to go through the whole process again. The changes recently undertaken were spurred by your AB 815 of the 2005-06 legislative session. These changes were a collaborative effort in which all stakeholders, including the sponsors of the bill and your staff participated.

WWW.CHI.ORG

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The Amendments of 09/07/07 Do Not Address Concerns of Biomedical Industry

Although we appreciate the author's attempt to address some of the concerns of the biomedical industry, the last set of amendments in the bill fail to adequately address the problem. The amendments fail to recognize the complexity involved in determining whether a biological license might have to be changed due to the provisions of this bill. After a long process, if a company determines that an amendment to the FDA is necessary for the license then it would have to ask the Board to consider that information with the uncertainty of what the result would be. Meanwhile, a manufacturer of a biologic therapy or a medical device could experience significant disruption in its research and development and manufacturing in California, and deprive thousands of patients access to life-saving products until such trials are completed.

The life sciences industry's first priority is public health, and we support PEL standards for hazardous chemicals that are based on the best available science, worker safety and considerations for the costs and benefits of changing current PEL standards. Unfortunately your measure will have the effect of denying public input and consideration of the best science. If your proposal were implemented, it would add tremendous cost to researching, developing and manufacturing life-saving products for our member companies and additionally, could mean huge costs to the state to implement this unnecessary bill.

We must express our continued strong opposition to AB 515. Thank you for your consideration

Sincerely,

A handwritten signature in black ink, appearing to read "Sandra Pizarro". The signature is fluid and cursive, with a long horizontal stroke at the end.

Sandra Pizarro
Vice President, State Government Affairs

cc: Chair, Senator Joe Simitian
Members, Senate Environmental Quality Committee
Bruce Jennings, Consultant, Senate EQ
Dane Wadle, Consultant, Senate Republic Caucus