FLOOR ALERT
SB 606 (Scott) – Clinical Trials
CHI Position: Oppose

CHI and its member companies have had discussions with Senator Scott on our concerns with SB 606 and our reasons for opposing the measure. We understand Senator Scott will offer amendments; however, we remain opposed on two critical areas:

**Issue #1**

The provision in SB 606 requiring the posting of clinical trial data within 90 days of the date a drug is first sold, delivered, offered for sale, or given away within the state.

**Progress**
Industry advised Senator Scott it could meet this requirement if clinical trial data could be posted within 1 year of the date the drug is first sold, etc. Ninety days from the last patient visit (the end of a trial) is an impossible deadline to meet as it takes time to resolve all the study site report queries and conduct the analysis of the data. Manufacturers typically post results within one year following the completion of the study. The one-year proposal was rejected in favor of a lesser time period and, for the reasons mentioned, this is not acceptable to Industry.

**Issue #2**

The potential for proprietary information being disclosed by SB 606’s mandates.

**Progress**
Industry recommended an amendment to SB 606 that would not require a manufacturer to submit, disclose, or post publicly any trade secret or confidential commercial information. That amendment was rejected in favor of an amendment referring to the definition of a trade secret in California Civil Code Section 3426.1. Industry’s concern with referring to the trade secret definition is that some company information, while confidential, will nonetheless not meet the definition of “trade secret.” For example, the work product of scientists, clinicians and statisticians that worked on the clinical trials, including their notes, internal communications, correspondence and other working papers are not trade secrets, but are nonetheless confidential. Not only does this work product have economic value, but its disclosure as part of the clinical trials data will be misleading and subject to manipulation. It is essential this work product be protected. More specifically, Section 130652(f) of SB 606 requires the posting of the outcomes of the clinical trial, including all time points at which outcome data were measured. The time points of measurement are a proprietary detail of a company’s clinical trial protocol; however, it may not be considered a “trade secret.”

The life sciences industry remains concerned that sensitive proprietary and confidential information will mandated by SB 606 and thus, must remain opposed to the measure.