



May 22, 2012

Senator Alex Padilla
State Capitol, Room 4038
Sacramento CA 95814

Dear Senator Padilla,

On behalf of CHI, BayBio and BIOCOM, we regretfully write to oppose your SB 1267, the Genetic Information Privacy Act. CHI, BayBio and BIOCOM represent the biomedical industry statewide and in the Bay Area and Southern California. Our membership includes California's premier life sciences companies and academic research institutions. As an industry, we account for over 2300 companies that generate approximately \$115 billion in revenue. Biomedical companies employ almost 270,000 Californians and pay \$20 billion in wages and salaries.

California can directly attribute its status as the country's leading site of research and development, job and investment opportunities in the life sciences to the basic research that is conducted at the state's universities. This basic research fuels the innovation that leads to breakthrough treatments for patients. It is our understanding that SB 1267 seeks to protect the privacy of genetic information against surreptitious use. However, the bill as currently drafted is overly broad and adds more regulation without providing additional privacy safeguards. As a result, the bill could have a chilling effect on research and the provision of health care in California. Below are our areas of concern. Given the breadth and potential reach of the bill we anticipate that there are other problems which may come to light later.

- There currently exists a comprehensive set of federal and state legal requirements that already protect genetic information privacy.
- Essential activities such as quality improvement reviews, peer reviews, fundamental education of medical residents and other caregivers in California would be precluded unless individual written consent is secured.
- Public health reporting to state and federal agencies, including routine reporting for surveillance as well as public health emergency reporting, could not occur without the specific consent outlined in the bill.
- Proposed amendments seek to exempt HIPAA covered research. However, there are other activities that are not governed by HIPAA but are covered by other state and federal laws which would be subject to the provisions of the bill.
- The bill would require information to be re-identified, which is a violation of privacy.

- The FDA has the authority to require a Risk Evaluation and Mitigation Strategy (REMS) from manufacturers to ensure that the benefits of a drug or biological product outweigh its risks. For example, the FDA can require manufacturers to conduct post-marketing research using public databases such as states' cancer registries. If SB 1267 were to pass, it could preclude companies from using California's databases which contain genetic information. Failure to comply with REMS can lead to the revocation of approval for a therapeutic and deny patients access to needed therapies.
- SB 1267 could prohibit information sharing between a health care professional who tests patients for genetic mutations and payers who determine whether to reimburse for testing.

For the reasons stated above, and our general concern about the overly broad reach of SB 1267, we must oppose the bill. As the bill is currently drafted, and after reviewing proposed amendments, we have determined that the bill can't be amended to address the numerous concerns it raises. Please feel free to contact us with any questions.

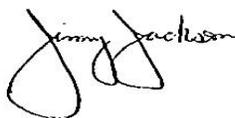
Sincerely,



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