U N I V E R S I T Y O F C A L I F O R N I A

BERKELEY • DAVIS • IRVINE • LOS ANGELES • MERCED • RIVERSIDE • SAN DIEGO • SAN FRANCISCO SANTA BARBARA • SANTA CRUZ

OFFICE OF THE PRESIDENT

DANIEL M. DOOLEY
Senior Vice President – External Relations

Office of State Governmental Relations
1130 K Street, Suite 340
Sacramento, California 95814
(916) 445-9924
Steve Juarez, Associate Vice President and Director

April 16, 2013

The Honorable Noreen Evans
Chair, Senate Judiciary Committee
State Capitol, Room 2187
Sacramento, CA 95814

Re: SB 222 (Padilla), as amended April 1, 2013
Scheduled to be heard in the Senate Judiciary Committee on April 23, 2013
Position: OPPOSE

Dear Senator Evans:

The University of California (UC) has reviewed SB 222, as amended April 1, 2013, which would add a new provision to the Confidentiality of Medical Information Act (CMIA), and regretfully must oppose the bill. We understand the complexity of developing policy on this topic and UC supports the authors efforts to protect the privacy of personal genetic information and to prevent the surreptitious collection, analysis and disclosure of this information. However, UC is concerned that in its current form, the vague provisions of SB 222 would be deleterious to California's patient care and research, and would put the state's biomedical industry at a distinct economic disadvantage.

Broad Provisions

SB 222 broadly applies to all entities and would prohibit the collection, storage, analysis and disclosure of genetic information without the written authorization of the individual to whom the information pertains. Despite the declared intent of SB 222 to enact legislation that would promote the use of genetic information for legitimate reasons, including, but not limited to, health care research, advancement of medicine, and educational purposes, no mention of research, health care, or any other legitimate use of genetic information appears within the statutory provisions of the bill.

SB 222 assumes a standard of appropriate practice (written authorization for any release) that is not based in evidence. The bill does not make distinctions between clinical, scientific and commercial uses of genetic information with the understanding that different best-practices may apply in these arenas. Additionally, it does not define genetic information, and without a clear understanding of what information is to be protected, the requirements of the bill could apply to hundreds of UC research studies involving tens of thousands of research participants, as well as all patient medical records.

Body of Existing Laws

SB 222 recognizes neither the vast body of existing federal and state laws and regulations governing the privacy of medical information, nor the laws and regulations governing human subject research. The Health Insurance Portability and Accountability Act (HIPAA) and its regulations have been in effect for nearly a decade and protect the privacy and security of protected health information, including genetic information. At the state level CMIA also protects this information. However, both laws intentionally allow the sharing of information for treatment and other medical center operations without specific written authorizations. Additionally, all human subjects research conducted at UC is subject to the federal Common Rule for human subject research. These federal regulations mandate review by an Institutional Review Board (IRB), which is a critical body of scientific and ethics experts responsible for ensuring that all research involving human subjects meets nationwide ethical and privacy standards. Given the broad and vague provisions of SB 222. it is unclear how the requirements of the bill interact with these existing laws and regulations.

Impact to Hospital/Patient Care

UC is concerned that written authorization provisions of SB 222 could adversely affect patient care by inhibiting necessary, rapid exchange of critical course of treatment information among health care providers, and the bill will significantly increase UC hospital patient record-keeping costs and other administrative costs. Other important hospital operations could be affected by the need to obtain written authorizations for the storage and disclosure of genetic information such as conducting peer reviews, quality of care and patient safety reviews, coding and billing activities, releasing information requested by health insurance agencies, and reporting to public health agencies such as the California State Cancer Registry, which is mandatory.

Secondary Research

UC's ability to conduct secondary research using genetic data, including data that has been stripped personally identifiable health information, would be severely limited by SB 222. Many of the discoveries we have today were the products of unexpected results that inspired new studies – that is secondary research – are not planned at the onset of a research project. The exploration of these serendipitous discoveries would be prevented by the bill's requirement to obtain authorizations for subsequent research use. A few examples of discoveries from secondary research use include hormone replacement therapy which resulted from samples collected for other purposes; initial AIDS transmission findings that were derived from research on hepatitis; and findings that obese individuals were at a high risk for liver disease. Further, the most powerful genetic research often depends on obtaining data obtained from large numbers of participants. It would be virtually impossible to obtain authorizations and reauthorizations needed for the tens of thousands of research participants needed to perform these types of research activities.

Financial Impact

UC may simply not be able to participate in federally-funded multi-center research studies of archival or retrospective tissue samples, cancer research, personalized medicine research or other cutting edge genetic science that requires large-scale data sharing. California has been a national leader in health care research such as statewide approval and funding for stem cell research. The requirements of SB 222 run contrary to advancing research in these areas.

UC is concerned that the disclosure penalty provisions in the bill could result in costly litigation and fines for accidental or unintentional disclosures of genetic information that are made without authorization during the course of legitimate research and patient care activities. These provisions could result in millions of dollars of penalties and litigation costs regardless of whether an individual suffered, or reasonably could have suffered, actual harm from the disclosure.

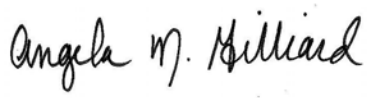
Conclusion

UC recognizes that protecting the privacy of genetic information while simultaneously promoting the use of genetic information for research, health care, the advancement of medicine and educational purposes is a complex issue. The findings and declarations of SB 222 refer to the Presidential Commission for the Study of Bioethical Issues report and the commission's recommendation that federal and state governments ensure a consistent floor of privacy protections. The commission further recommends that in considering such a floor that a panel of experts be convened to engage in further discussion because implementation of such options are unclear.

The Senate has approved Senator Padilla's request for a select committee to review complex science policy issues such as those presented by genomics research. UC believes that it would be most appropriate for that committee to first hold hearings to carefully consider the policy-making on this subject, rather than prematurely take action on SB 222.

As always, the University appreciates your consideration of our views. Should you have any questions on the University's position on SB 222, please do not hesitate to contact me at (916) 445-9924.

Sincerely,



Angela M. Gilliard, JD
Legislative Director

cc: Senator Alex Padilla
Members, Senate Judiciary Committee
President Mark G. Yudof
Provost Aimée Dorr
Senior Vice President John Stobo
Senior Vice President Daniel Dooley
Vice President Steve Beckwith
Associate Vice President and Director Steve Juarez