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Steve Juarez, Associate Vice President and Director

April 9, 2015

The Honorable Rob Bonta
Chair, Assembly Health Committee
State Capitol Building, Room 6005
Sacramento, CA 95814

RE: ***AB 170 (Gatto), as amended March 25, 2015***
Scheduled for Hearing in the Assembly Health Committee on April 14, 2015
Position: CONCERN

Dear Assembly Member Bonta:

On behalf of the University of California, I am writing to express our concerns regarding AB 170 (Gatto), which would require a revision of the current process under which parents or guardians of a newborn child consent to the retention and use of newborn blood screens for research purposes. The research use of these samples and related data has proven highly beneficial and critically significant to developing new ways to diagnose and treat both genetic diseases as well as illnesses from environmental exposure. We believe that this measure could significantly limit the availability of the valuable data and biosamples collected by the California Newborn Screening Program (NSP) for research use.

One of the greatest values of California's current process for collecting and storing newborn dried blood samples comes from its size and diversity. The samples stored by CDPH reflect California's diverse population and allows us to research how different diseases affect different ethnicities. The sheer number of samples makes research into rare diseases possible, and also facilitates robust studies of regional environmental factors that can cause disease. AB 170's revised consent process for research use of newborn dried blood samples is likely to severely limit the number of samples that may be collected which in turn, would greatly diminish the research value of the current newborn dried blood samples stored by CDPH.

We are also concerned that the bill's research terminology is inconsistent with the Federal Policy for the Protection of Human Subjects, (45 CFR 46) or the "Common Rule." The common rule is utilized by all Human Subject Protection Programs for federally-funded research. We worry that the revised consent process under AB 170 may confuse new parents instead of creating a greater understanding about the benefits of the NSP and the research it supports.

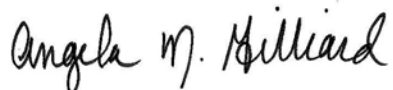
University researchers utilize the data collected by the NSP to develop better diagnostic tests for congenital and heritable diseases, subsequently increasing the number of disorders for which newborn children can be tested and treated at birth. When the NSP program was launched more than twenty years ago, it only screened for three diseases. Today, current screens test newborn babies for more than 80 genetic and congenital disorders. This early diagnosis enables early interventions that lead to successful treatment of these serious heritable diseases and congenital conditions. NSP data is vital to ongoing efforts to improve diagnostic screening tests.

But the University's use of this data also extends beyond heritable and congenital diseases, and we are concerned that AB 170 could jeopardize valuable epidemiological and environmental research that has a significant impact on public health. A project at UCSF, led by Joseph L. Wiemels, Ph.D., uses newborn dried blood spots from the general population to examine how certain contaminants affect a person's cells at the molecular level. Understanding how contaminants can change a person's genetic code and gene expression can help advance methods for the early detection of leukemia. AB 170 may limit the ability of UC researchers to conduct similar research in the future.

Our concerns with this bill reflect our commitment to institutional oversight of our scientific research. We hold the privacy of the patients we serve to the highest standard, and we carefully balance the need for privacy with the need for research that will provide immediate and long term benefits for all Californians. We are concerned that AB 170 will greatly diminish the number of samples available for this critically important research. The University supports additional educational and awareness measures to educate the public and new parents about the benefits of the NSP and the value of the research it supports.

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

Sincerely,



Angela M. Gilliard, JD
Legislative Director – UC Health

cc: Assembly Member Mike Gatto
Vice Chair and Members, Assembly Health Committee
President Janet Napolitano
Senior Vice President Nelson Peacock
Provost and Executive Vice President Aimée Dorr
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