



April 7, 2015

Assemblymember Gatto
California State Capitol
Sacramento, CA 95814
VIA FAX: 916-319-2143

Re: AB 170 Newborn Screening Program
AAP-CA Position: Oppose

Dear Assemblymember Gatto,

The American Academy of Pediatrics, California respectfully opposes your proposed legislation AB 170.

The Newborn Screening Program tests all newborns in California at birth for certain genetic and metabolic conditions that are not otherwise apparent at birth. Each year in California, newborn screening identifies about 875 children with a genetic disorder and ensures that they receive treatment as early as possible to prevent disabilities, developmental delays, illnesses, or even death.

AB 170 would create a barrier in the newborn screening process that makes it more likely for screening to not occur and for parents to opt out of screening, putting babies at significant risk of disability and death. Conditions that must be detected shortly after birth will go undiagnosed, resulting in lifelong disabilities and death for newborns, all of which is currently prevented through the universal collection of blood spots at birth.

Further, the current California blood spot database is an internationally recognized public health asset because of its size and diversity. The ability to study rare diseases, diseases contained to small geographical areas or to small subsets of California's genetically diverse population, as well as the ability to link clinical and environmental data (such as pesticides), would not be possible without California's blood spot database. Research studies show that obtaining informed consent from patients regarding participation in registries results in significant selection bias and this would have significant impacts on this vital public health research.

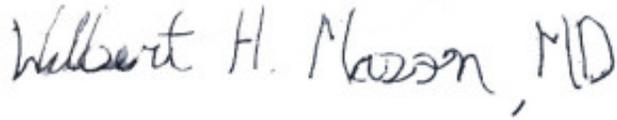
Moreover, implementing such a policy would require significant financial resources to address education of families, training for health care providers in distributing and explaining the consent forms, logistics and follow-up (e.g. destruction of blood spots).

Although there have been no security breaches of data in the current system, if changes are desired it is prudent to wait for federal action on this issue. Federal legislation was passed in December 2014 that will require prior informed consent to be obtained before any newborn blood spot collected after March 17, 2015 could be used in federally funded research. There is a workgroup of newborn screening experts from around the country that is working to determine how informed

consent is defined, the most effective methods and timing to obtain informed consent from parents and to provide resources to states on implementing such a policy. The final regulations around informed consent will be included in an updated Common Rule (relates to federal research using human subjects) that must be finalized by the end of 2016. Given that California will be directly impacted by this policy, it is prudent to delay any changes in the state law until the state has clarity on what will be required by federal laws and regulations.

In the interest of the lives and health of California newborns and children and for the above reasons, AAPCA respectfully opposes AB 170.

Thank you for your public service and leadership.

A handwritten signature in blue ink that reads "Wilbert H. Mason, MD". The signature is written in a cursive style with a comma after the name and "MD" as a suffix.

Wilbert Mason, MD
Governing Board Member
American Academy of Pediatrics, California

cc: AAP-CA Leadership