Representative Hank Vaupel

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Representative Abdullah Hammoud
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Representative Kevin Hertel
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Representative Aaron Miller
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Representative Karen Whitsett
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Representative Matt Koleszar
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Re: House Bill 5465

Dear Representatives Vaupel, Hammoud, Hertel, Miller, Whitsett, and Koleszar:

I am writing on behalf of the Michigan Chapter of the Alexander Graham Bell Association for the Deaf and Hard of Hearing (MI AG Bell) **in support of HB 5465.** Thank you for being the sponsors of this important bill!

HB 5465 creates a rare disease review committee to provide information to the legislature and make recommendations as to legislation. Importantly, Cytomegalovirus is one of the six rare diseases listed; other rare diseases will be listed as well by the committee.

The MI AG Bell is particularly concerned about Cytomegalovirus.

Congenital Cytomegalovirus (CMV) affects 1 in every 150 babies in Michigan. Congenital CMV is the most common cause of nonhereditary hearing loss in children, and in the United States it causes about 400 deaths a year and in Michigan about 12 deaths a year.

Congenital CMV is preventable to a significant extent and it is treatable.

CMV is preventable, yet very few women have heard of it or know how to prevent it. The knowledge of simple hygiene measures taken during pregnancy could save a significant number of infants lives and hearing in addition to saving the state millions of dollars yearly for special education and Children's Special Health Care Services funds for this high needs group.

The Michigan Early Hearing Detection and Intervention Program (MI EHDI) of the Michigan Department of Health and Human Services (MDHHS) has produced a brochure entitled "Pregnant or Planning Pregnancy? Learn how to protect your baby from birth defects caused by CMV" (Ml EHDI brochure-CMV). There is a lot of important information in that brochure that is quoted in this letter.

This informational brochure should be provided not only to medical personnel and to expectant mothers, but also to those programs and persons who are in direct contact with parents and young children. That is why we are strongly recommending that dissemination of information about CMV include: programs for early childhood education, midwives, childcare programs and childcare providers, including private and religious programs for children. Young women teachers and other professionals in these early childhood programs are at risk for CMV, because the virus can remain alive on an item for six hours. (Ml EHDI brochure-CMV)

Utah in its Cytomegalovirus (CMV) public education and testing statute (Section 26-20-10) lists those persons and organizations that should be provided this information about CMV, and we recommend that a similar list be included in future legislation in Michigan.

The MI A.G. Bell supports universal newborn CMV screening, and in a nutshell this is why. CMV is a leading cause of preventable birth defects and developmental delays in newborns, and it’s the most common cause of nonhereditary Deafness and Hearing Loss in newborns and infants. Congenital CMV can only be detected by screening in the first 3 weeks of a newborn’s life. Delayed onset hearing loss very often results from CMV, and delayed onset hearing loss from CMV is missed by newborn hearing screening. Universal newborn CMV screening is inexpensive at $10 per newborn screening, and effective medical treatment and early intervention services are available in Michigan. This public health initiative is based on scientific studies that are discussed later in this letter.

MI A.G. Bell supports CMV screening of all newborns (universal screening) by saliva swabs as inexpensive at $10 per newborn, accurate at 97%, and extremely important to the lives of newborns and their parents. CMV is a leading cause of preventable birth defects and developmental delays in newborns, and the most common cause of nonhereditary Deafness and Hearing Loss in newborns and infants. Congenital CMV can only be detected by screening in the first 3 weeks of a newborn's life. Delayed onset hearing loss often results from CMV, and delayed onset hearing loss from CMV is missed by newborn hearing screening.

These children with CMV can be effectively medically treated and also receive early intervention services that are available in Michigan under the federal Individuals with Disabilities Education Act (IDEA).

Universal CMV screening is similar to universal newborn hearing screening and universal screening for PKU, sickle cell disease and the 6 other designated diseases under MCL 333.5431 in all of our Michigan hospitals. The creation of the rare disease review committee will allow input from hospitals, pediatric infectious disease specialists, audiologists, speech and language pathologists, teachers of the deaf and hard of hearing, other medical and educational professionals, professional organizations, and parent organizations.

In Michigan Hutzel Hospital and Sparrow Hospital have begun doing targeted CMV screening of newborns that failed the newborn hearing screening. Other Michigan hospitals are in the planning stages.

Emerging national consensus. In the United States and in Michigan there is an emerging national consensus supporting universal newborn screening for congenital cytomegalovirus (c CMV). This is reflected in the nomination on March 27, 2019 by the National CMV Foundation of congenital cytomegalovirus infection for inclusion on the Recommended Uniform Screening Panel (RUSP). Here is the link.

https://www.nationalcmv.org/getattachment/about-us/advocacy/RUSP_CMV_Nomination_Final.pdf.aspx

This nomination was <u>supported by the Directors of Speech and Hearing Programs in State Health and Welfare Agencies</u>, medical school professors, and researchers in this area. The published scientific studies that are cited in the nomination application and letters of support are included within the nomination application; please see the link.

Legislation in Utah and Connecticut

Both Utah and Connecticut in their respective statutes require testing of newborns for CMV for those newborns that fail the newborn hearing screening. This is targeted CMV screening and will identify and benefit (by treatment and early intervention) the majority of newborns with CMV but will also miss a significant percentage of newborns with CMV for the reason that congenital CMV very often causes late onset hearing loss that is not detected by hearing screening of newborns. This is discussed later in this letter.

Connecticut has a statute for testing newborns for PKU (phenylketonuria), sickle cell disease, and other listed diseases that is very similar to our Michigan statute at MCL 333.5431 that also tests for these diseases. Connecticut in 2015 enacted a statute entitled "An Act Concerning Cytomegalovirus" (Public Act No. 15-10) that added a paragraph to their newborn screening statute requiring the birthing hospitals to administer for *"any newborn infant who fails a newborn hearing screening, a screening test for cytomegalovirus...*
Such screening tests shall be administered as soon after birth as is medically appropriate." At subsection d) the hospital has a duty to "report any case of cytomegalovirus that is confirmed as a result of a screening test" to their Department of Public Health.

*Michigan could enact a similar statute for testing newborns for CMV when they have failed the newborn hearing screening or in the alternative enact a statute that requires universal CMV screening by adding CMV to the list of conditions that the hospitals are required to test for under our M*ichigan statute MCL 333.5431.

<u>Information from the MI EHDI</u>

It is important that the CMV test be done at the birthing hospital. As per the cited MI EHDI brochure, "Babies born with CMV may show no symptoms of the virus until they are older. *A child can only be diagnosed with CMV within the first 3 weeks of life.* A child is sometimes diagnosed much later, through the symptoms of CMV rather than a test." (MI EHDI brochure-CMV- attached)

Where there is testing of the newborns for CMV at the hospital, this also eliminates potential loss to follow up.

"CMV is a common virus that a woman may get during pregnancy and pass to her unborn child. It causes about 400 deaths a year. The mother may not know she is sick or may assume she has a common cold. <u>CMV is a leading preventable cause of birth defects and developmental disabilities. For the unborn child, CMV can damage the ears, eyes, brain, and/or other organs in the body</u>." (MI EHDI brochure-CMV)

“CMV affects 1 in 150 babies per year in the U.S. (about 30,000 children…. Congenital CMV is the most common cause of nonhereditary hearing loss in children” (MI EHDI brochure-CMV)

The National CMV Foundation Nomination Application at page 2 - <u>Incidence</u> states:
“In developed countries including the United States, congenital CMV is estimated to occur in ~ 5 to 7 per 1000 live births. A recent multi-center, hospital-based study screening of 100,332 newborn infants for congenital cytomegalovirus and the overall prevalence was 4.5 per 1000 live births.
Approximately 10% of infants with congenital CMV will have clinical findings at

birth (symptomatic infection). The vast majority of infected infants (~90%), however, will have no clinical manifestations present during the newborn period (asymptomatic infection). Approximately 40% to 60% of symptomatic infants will manifest permanent sequelae, with sensorineural hearing loss (SNHL) being the most common, followed by cognitive impairment, retinitis, and cerebral palsy. Asymptomatic infants are also at risk for CMV related disabilities, and ~10 to 15% of asymptomatic infants will develop SNHL. In the United States, disabilities from symptomatic and asymptomatic congenital cytomegalovirus infection are more common in children than other more recognized diseases such as Down syndrome, fetal alcohol syndrome, or spina bifida."
https://www.nationalcmv.org/getattachment/about-us/advocacy/RUSP_CMV_Nomination_Final.pdf.aspx

Numbers of newborns in Michigan with CMV and resulting sensorineural hearing loss, cognitive impairment, retinitis, and cerebral palsy. In Michigan 112,000 babies are born each year. Utilizing the incidence percentages from the National CMV Nomination Application, I calculate that 672 newborns will be born with congenital CMV and 110 newborns will have serious disabilities resulting from CMV with "sensorineural hearing loss (SNHL) being the most common, followed by cognitive impairment, retinitis, and cerebral palsy." National CMV Foundation Nomination Application, p. 2. Out of the 110 newborns with disabilities, 76 newborns will be asymptomatic (no clinical symptoms present during newborn period) and have late onset sensorineural hearing loss and may also have these other disabilities.

Reported Large Scale Investigation as to Targeted versus Universal Newborn CMV screening

A five-year study of almost 100,000 infants born at 7 US medical centers over a 5-year time period received both NHS (newborn hearing screening) and screening for congenital cytomegalovirus c CMV). This was the result. "A targeted CMV approach that tests newborns who fail their NHS (newborn hearing screen) identified the majority of infants with CMV-related SNHL (sensory neural hearing loss) at birth. However, 43% of the infants with CMV-related SNHL in the neonatal period and cCMV (congenital cytomegalovirus) infants who are at risk for late onset SNHL (sensory neural hearing loss) were not identified by NHS (newborn hearing screening)." "A Targeted Approach for Congenital Cytomegalovirus Screening Within Newborn Hearing Screening" by Karen Fowler, et al. was reported in Pediatrics Vol. 139 no. 2, February 2017. Here is the link.

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5260148/

Cost Effectiveness of Universal and Targeted Newborn Screening for Congenital Cytomegalovirus

The MI A.G. Bell is in favor of universal CMV screening as compared to CMV targeted screening based in large part on this study reported in 2017 in Pediatrics as well as "*Cost-effectiveness of Universal and Targeted Newborn Screening for Congenital Cytomegalovirus Infection*" by Dr. Soren Gantt, MD, MPH, et al. published in JAMA Pediatrics /2016; 170(12):1173-1180. *This reported study will be quoted from extensively in pages 7-9. Here is the link.* https://jamanetwork.com/journals/jamapediatrics/fullarticle/2557388

"Approximately 10% to 25% of all childhood sensorineural hearing loss (SNHL) can be attributed to congenital cytomegalovirus." *Id*, page 1174.

"…All infants with congenital cytomegalovirus, symptomatic or asymptomatic, may benefit from early diagnosis for anticipatory guidance, early identification of late -onset hearing impairment, and appropriate support. Treatment of newborns with symptomatic congenital cytomegalovirus infection with the antiviral drug valganciclovir hydrochloride for 6 months also results in improved hearing and developmental outcomes." *Id*, page 1174.

"Targeted congenital cytomegalovirus screening based on failed newborn hearing screens would not capture infections that result in late-onset hearing loss." Supra, page 1174. This is the primary reason that the MI A.G. Bell favors universal CMV screening. Universal CMV screening will identify all of the infants with CMV compared to targeted CMV screening that will miss the substantial number of infants with CMV (43%) that will develop late-onset hearing loss, cognitive impairment, loss of vision, and cerebral palsy.

For those newborns infected with CMV at birth who pass the newborn hearing screen, the standard of practice is "to have audiologic testing every 6 months to monitor for late-onset hearing impairment; this follow-up was assumed to lead to earlier identification of hearing loss by a mean of 24 months." *Id*, page 1174

The oral swab for saliva has 97% accuracy for CMV; "…97% sensitivity and 99 % specificity". *Id*, Page 1174

"*Discussion*- Convenient, accurate, and inexpensive testing for congenital cytomegalovirus in newborns with the use of oral swabs is now available. In addition, randomized clinical trial data indicate that oral antiviral therapy for symptomatic congenital cytomegalovirus infection is safe and effective. Available evidence indicates that current approaches to identification of newborns with congenital cytomegalovirus infection will not receive timely and appropriate care in the absence of some type of screening program." *Id*, page 1176

In "Conclusions: We found that screening newborns for cCMV infection is generally associated with cost savings or is essentially cost neutral from the perspective of net public spending, across a wide range of assumptions. These results, combined with the reported clinical benefits and high parental acceptance, appear to satisfy accepted criterial for newborn screening. Thus, in the absence of a vaccine or other effective methods to prevent cCMV infection, newborn cCMV screening appears warranted in the United States." *Id*, page 1179

The cost analysis in these 2 reported scientific studies in Pediatrics does not include the benefit to the newborn of preventing untreated CMV resulting in death, intellectual disability, damage to vision, and cerebral palsy. "Ganciclovir treatment might also improve neurodevelopmental outcome." National CMV Foundation Nomination Application, supra at page 4.

Available Audiological testing, Hearing Aids, Cochlear Implants, Early Intervention Services are available in Michigan

In addition to medical treatment, early identification of late onset hearing loss from CMV occurs through periodic and repeated audiological hearing assessments. Early intervention through appropriate fitting of hearing aids and cochlear implants are available. Early intervention services including assessments and services of speech and language pathologists and teachers of the deaf and hard of hearing and teachers of the cognitively impaired are available and required under the federal Individuals with Disabilities Education Act.

Our Organization – The MI AG Bell is a Michigan nonprofit corporation. Our membership is made up of parents of children who are deaf and hard of hearing, teachers of the deaf and hard of hearing, audiologists, speech and language pathologists, and adults who are deaf and hard of hearing. Our President, Stacey Lim, Ph.D., utilizes cochlear implants, is a professor of audiology at Central Michigan University and has authorized me to write this letter.

Please feel free to write me at: sidkraizman@sbcglobal.net or at my law office at 645 Griswold St., Suite 2200 Penobscot Building, Detroit, MI 48226. My cell is (248) 921-0687; feel free to call me.

Best Regards,

/Sidney Kraizman/
Sidney Kraizman
Representative of the MI A.G. Bell

Cc Stacey Lim, President of the MI A.G. Bell