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Testimony of Janelle Greenlee
IN SUPPORT OF HB 5147, AN ACT CONCERNING NEWBORN SCREENING FOR GLOBOID CELL
LEUKODYSTROPHY AND CYTOMEGALOVIRUS AND ESTABLISHING A PUBLIC EDUCATION PROGRAM FOR
CYTOMEGALOVIRUS
Before the Public Health Committee
February 28, 2014

February 26, 2014

Dear Chairwoman Gerratana, Chairwoman Johnson, and the distinguished Members of the Committee,

This letter is in support of HB 5147 "An act concerning newborn screening for globoid cell leukodystrophy and cytomegalovirus and establishing a public education program for cytomegalovirus".

I serve as the president of Stop CMV, a national CMV advocacy organization, and am also the mother of twins born affected by congenital CMV in 2003. Having worked as a CMV advocate since their birth, I have met with and supported children and families within your state who have had their lives and livelihoods affected by congenital CMV.

So many times crucial CMV prevention information doesn't make its way to those who need it most—pregnant women at risk of acquiring CMV from the bodily fluids of babies, toddlers, and small children. HB5147 is an important and necessary step forward for women and children's health and can result in a decrease of CMV infection during pregnancy and, in turn, a decrease in congenital CMV infection in newborns.

I strongly urge your support of HB 5147 and thank you for your consideration of this issue.

Sincerely,

Janelle Greenlee
President/Founder
Stop CMV – The CMV Action Network
www.StopCMV.org

Many promising strategies for preventing and treating congenital CMV (cytomegalovirus) are available. They include raising awareness, developing behavioral interventions to prevent infection in pregnant women, and improving outcomes in congenitally infected children through early detection and intervention. To be successful, these approaches require adequate surveillance and laboratory capacity. However, prevention and treatment strategies have never been implemented on a wide scale.

CURRENT EFFORTS

Congenital CMV does not receive dedicated federal funding. Fortunately, people have realized a need to address this issue. By using Centers for Disease Control and Prevention (CDC) general funds and external grants, small research activities have been funded, including:

- *Study of the natural history of CMV infection among women*
- *Surveys of women's knowledge, attitudes, and behaviors related to congenital CMV*
- *Laboratory assessments of CMV persistence in the environment and the efficacy of hand washing for removing CMV from hands*
- *Study of long-term outcomes in a group of children born with congenital CMV*

ISSUES NEEDING IMMEDIATE ATTENTION

Awareness - Awareness campaigns are needed to explain the dangers posed by CMV and how it can be prevented

- *Only 13% of women have ever heard of CMV.*
- *Most obstetricians do not discuss CMV or CMV prevention with their patients*

Preventing CMV infection among pregnant women - Behavioral intervention programs need to be developed, implemented, and evaluated

- *A licensed CMV vaccine is unlikely to be available for many years.*
- *A large intervention study in France showed that women who were educated about preventing CMV transmission were able to significantly reduce their rates of infection during pregnancy; a similar intervention needs to be tested in the U.S.*

Evaluating newborn CMV screening - Research and pilot screening programs are needed to determine whether benefits of screening outweigh costs and potential harms

- *Congenital CMV infections are more common than the combined metabolic or endocrine disorders currently in the U.S. core newborn screening panel.*
- *Newborn CMV screening has significant potential for improving children's functional outcomes (e.g., language and educational development) through early detection and intervention.*

Surveillance - Ongoing surveillance is needed to assess the burden of congenital CMV and to make it possible to monitor the effectiveness of future prevention programs

- *There is no ongoing assessment of the occurrence of CMV infection among pregnant women, rates of congenital infection among newborns, or rates of disability among infected newborns.*

Laboratory Capacity - Diagnostic methods are not yet sufficient for universal CMV screening programs

- *Standards and controls need to be developed for quality control of newborn CMV screenings*
- *Improved diagnostic tools are needed for prenatal maternal screening and diagnosis*

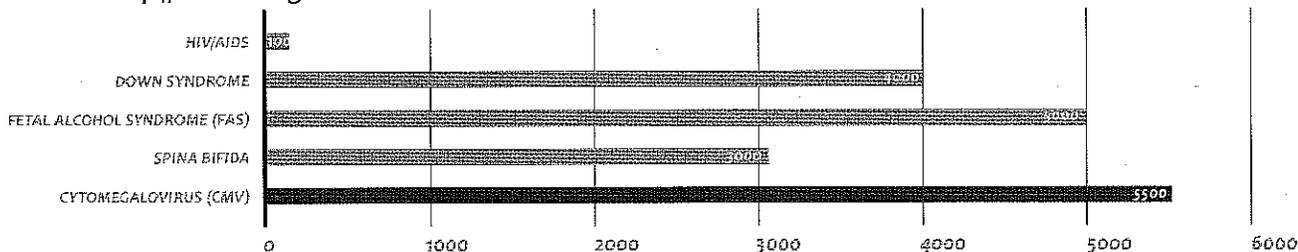


STOP CMV

A 2010 Centers for Disease Control and Prevention (CDC) survey reported that only 13% of women had heard of CMV (cytomegalovirus), and very few were aware of prevention measures against the virus. The American College of Obstetricians and Gynecologists (ACOG) and the CDC recommend that OB/GYNs counsel women on basic prevention measures to guard against CMV infection, but only 44% of OB/GYNs reported counseling their patients about preventing CMV, according to a 2007 survey.

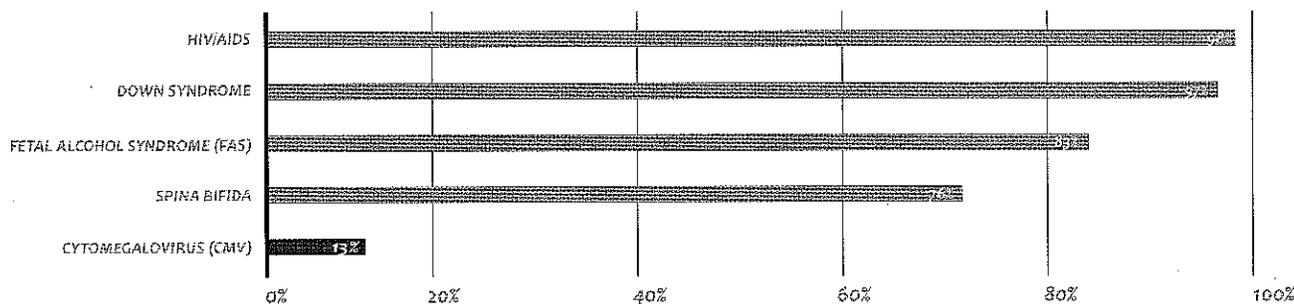
US CHILDREN BORN WITH OR DEVELOPING LONG-TERM MEDICAL CONDITIONS EACH YEAR

Source: <http://www.cdc.gov>



WOMEN'S AWARENESS OF CONDITIONS AFFECTING CHILDREN

Source: <http://www.cdc.gov>



PREVENTING CMV AMONG PREGNANT WOMEN

CMV is a very common virus in young children, and it is estimated that up to 70% of healthy children between 1 and 3 years of age may have CMV.

Simple steps to prevent exposure to saliva and urine might contain CMV:

- Wash your hands often with soap and water for 15-20 seconds, especially after changing diapers, feeding a young child, wiping a young child's nose or drool, and handling children's toys.
- Do not share food, drinks, or eating utensils with young children.
- Do not put a child's pacifier in your mouth.
- Do not share a toothbrush with a young child.
- Avoid contact with saliva when kissing a child.
- Clean toys, countertops, and other surfaces that come into contact with children's urine or saliva.

Through the efforts of Stop CMV to educate national legislators and regulators on the importance of CMV prevention, the United States Senate passed legislation recommending that "more effort be taken to counsel women of childbearing age of the effect this virus can have on their children." The United States Senate designated June as "National Cytomegalovirus Awareness Month" in both 2011 and 2012.



STOP CMV

Since 2003, Stop CMV has been fostering congenital CMV (cytomegalovirus) awareness through the Internet and a variety of public awareness campaigns. The CMV Action Network is comprised of families, friends, and medical professionals personally affected by CMV and committed to public education efforts to prevent future cases of the virus. Since its non-profit incorporation in 2009, Stop CMV has grown to become the world's largest CMV organization.

MISSION

The mission of Stop CMV - The CMV Action Network is to prevent and eliminate congenital CMV and to improve the lives of all people affected by congenital CMV

PREVENT

Stop CMV advocates a comprehensive, dedicated public education campaign surrounding CMV prevention at the Centers for Disease Control and Prevention (CDC), including a Morbidity and Mortality Weekly Report (MMWR), and a Practice Bulletin published by the American College of Obstetricians and Gynecologists (ACOG) specific to CMV prevention.

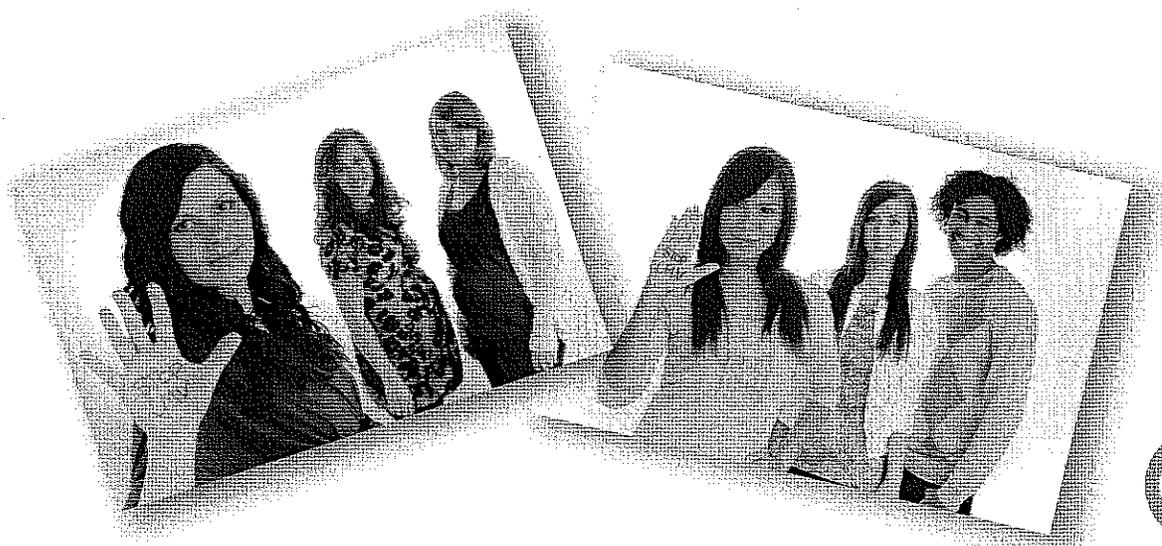
ELIMINATE

Because of cost savings and the human suffering that would be alleviated, in 1999 the National Institute of Medicine (IOM) ranked a congenital CMV vaccine as the first Level 1 priority. CMV vaccines are still in the research and development stage, with the completion of approximately 10 Phase I trials and 2 Phase II trials. Many experts believe a vaccine is possible in the coming decade if there is awareness and support from the general public, the pharmaceutical industry, and the federal government. Stop CMV advocates for a vaccine candidate entering Phase III trial.

IMPROVE

Quality of life for individuals affected by congenital CMV is varied. Stop CMV works toward improving the lives of all affected individuals and families by raising awareness and advocating for further research and education, including an IOM study addressing the state of research of CMV and the gaps that still exist in that research.

Stop CMV has flourished with very low overhead cost thanks to the creativity and agility of the organization and the hard work and commitment of volunteers. All staff, advisors, and board members are volunteers and donate their time and expertise to Stop CMV. Our ability to keep fundraising costs extremely low is a result of leveraging grassroots and online efforts. This has been accomplished through a growing network of talented volunteer fundraisers who believe in Stop CMV's mission and strategy.



STOP CMV

There is no CMV vaccine available to prevent congenital CMV (cytomegalovirus). CMV vaccines are still in the research and development stage, including live vaccines, attenuated vaccines, and subunit vaccines that target individual proteins. Many experts believe that a CMV vaccine could be possible within the next 10 to 20 years, but a CMV vaccine is unlikely to occur without the awareness and support of the general public, the pharmaceutical industry, and the federal government.

CMV VACCINE PROGRESS

There are many pharmaceutical industry-sponsored clinical trials for CMV vaccines, but these focus on other at-risk populations, including HIV patients and organ transplant patients. While important, data from these CMV vaccine trials cannot be applied towards a congenital CMV vaccine.

For a congenital CMV vaccine, there have been approximately 10 phase 1 trials, 2 phase 2 trials, and no phase 3 trials to date.

Vaccine clinical trials costs:

- Phase I trial - less than \$1 million
- Phase II trial - \$5-\$10 million
- Phase III trial - \$10-\$100 million

ECONOMIC BURDEN/COST IMPACT

In the 1990s, the annual cost for caring for children born with congenital CMV was estimated at \$1-\$2 billion for the United States alone.

There have been no recent studies to re-evaluate the cost impact of congenital CMV.

GOVERNMENT RECOMMENDATIONS

In 1999, the National Institute of Medicine (IOM) reviewed 26 conditions with the potential for vaccine prevention. Each different candidate vaccine was ranked from Levels I-IV (highest to lowest) based on cost impact and Quality of Life Adjusted Year (QALY) saved.

A congenital CMV vaccine, given to 12-year-olds, was ranked the first priority in the Level I group because of cost savings as well as the human suffering that would be alleviated by stopping CMV.

Stop CMV presented at the first Food and Drug Administration (FDA) and Centers for Disease Control and Prevention (CDC) sponsored CMV Vaccine Workshop. The two-day event brought together many industry representatives and regulators to discuss paths forward to a viable CMV vaccine. Stop CMV has been active on Capitol Hill, keeping legislators updated on the progress being made towards a CMV vaccine and education policymakers regarding the importance of CMV vaccine development.



STOP CMV

The parents of Stop CMV come from all walks of life and all around the globe. Some of us knew about CMV (cytomegalovirus) very early, and others did not until months or years after our children were born. Our stories are all very different, but there is one commonality between us all: our lives were changed by CMV, for better and for worse. We share our stories, our joys and fears, our struggles and our successes, in hopes that we can help others learn what it's really like to live with this diagnosis.

"The first time I see my daughter, we are baptizing her because she may not live. She is dying. There is no moment where they hand her to me, no moment when I take her face in and know that she is mine. There is, instead, a moment when I look at her and I don't understand what went wrong. Why it is that I expected a healthy baby girl and instead I am looking at a dying neonate? I make myself take pictures of that moment, of us as a family, because I still hope that someday this moment will just be ancient history." – Lauren Grace's Story, Iowa

"I remember sitting in the doctor's office at 22 weeks. They told me if I wanted to terminate, they would set me up with a doctor in another state, since it was no longer legal in mine. I was a single 19-year old sitting in a doctor's office in tears. It was the most important decision of my life. I had no one to talk to. I wish I had known about Stop CMV." – Logan's Story, Connecticut

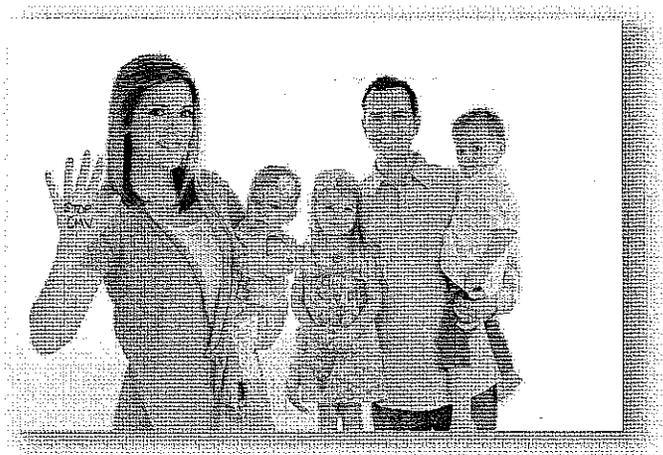
"I received two IV infusions of CMV immunoglobulin and went for another ultrasound at the end of the week. Two perinatologists came in to complete the ultrasound. As they looked at the monitors in silence, I began to cry. The ascites in our baby boy's belly had gotten so much worse. It had also spread to his chest, arms, and legs. His liver was enlarged and damaged. I had barely any amniotic fluid left. I was 23 weeks pregnant. I was induced that night. We understood that our baby would die during the labor and delivery process." – Milan's Story, Illinois

"The ultrasounds were never simple. There was always something wrong - usually something minor, but always something. My amniotic fluid was always low, sometimes dangerously low, and the baby had extra fluid around her heart (pericardial effusion)... By the end of my pregnancy, I was going to bi-weekly ultrasounds and wondering if my baby was going to survive. We had no idea what was going on." – Kaitlyn's Story, North Carolina

"When I looked at him, I noticed he was covered in red dots... I asked the nurse why he was covered in dots, and she said some babies are born like that... When she came back, she had the pediatrician with her. He told us that Dalen would have to stay in the NICU because he had an enlarged spleen and liver. He didn't know what was wrong with him. My heart sank. I felt like I was in a show on the Discovery Health Channel." – Dalen's Story, Mississippi

"He was a very bright boy early on, teaching himself how to read at age two but not learning how to walk until age 2-1/2. At age 5, he was diagnosed with ADHD and takes medication to help him at school. At age 7, Jeb was diagnosed with an autism spectrum disorder, pervasive developmental disorder (PDD-NOS)." – Jeb's Story, Wisconsin

Read more CMV parent stories from around the United States and the world at www.StopCMV.org.



STOP CMV