



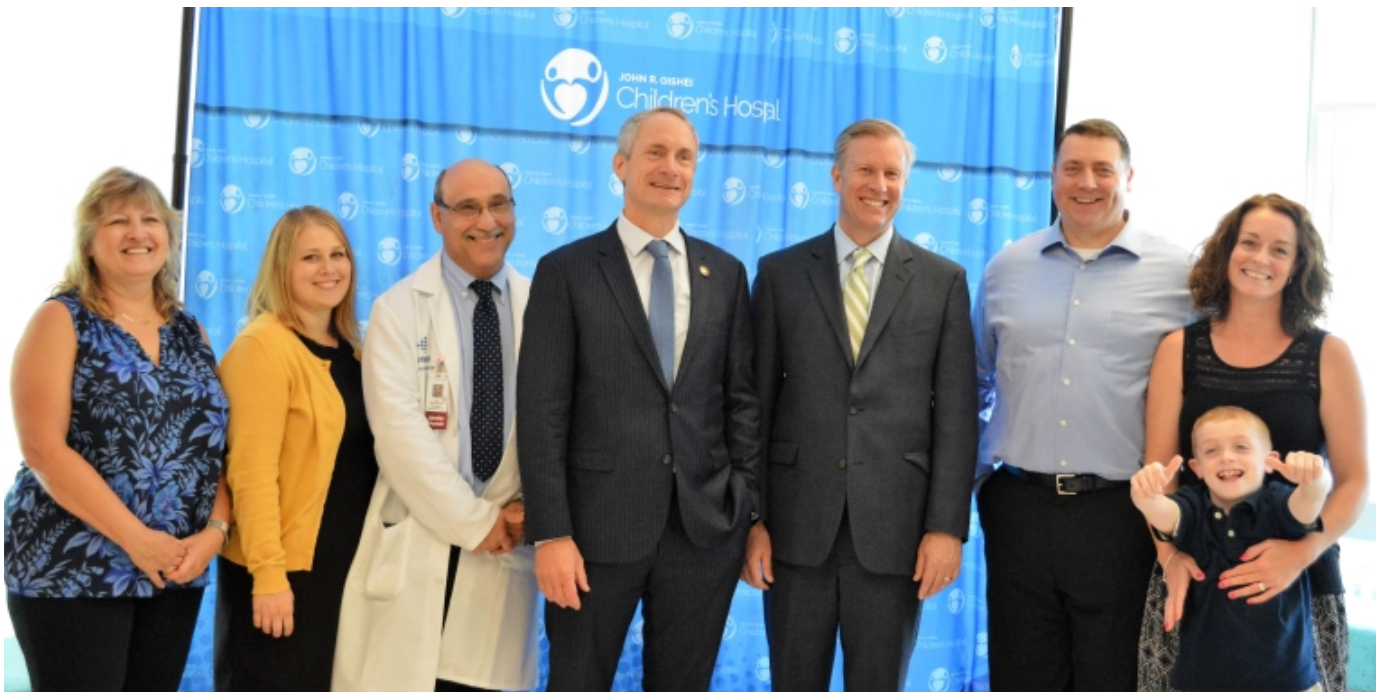
NEW YORK STATE SENATOR

Chris Jacobs

Jacobs, Ryan Call for Governor to Sign Their Bill That Will Allow Patients to Maintain Access to Critical Medications

SENATOR JACOBS June 29, 2018

| ISSUE: **EPILEPSY, NYS DEPARTMENT OF HEALTH, CONTROLLED SUBSTANCES**



(Buffalo, NY) – New York State Senator Chris Jacobs joined State Assemblyman Sean Ryan joined to call for Governor Andrew Cuomo to sign a bill they sponsored that will allow the New York State Commissioner of Health to reschedule drugs consistent with Food & Drug Administration (FDA) approvals and changes made by the Drug Enforcement Agency (DEA). Ordinarily the rescheduling of a drug in New York State would require both houses of the legislature to vote on a measure to change the classification. The Ryan-Jacobs bill will allow

doctors to continue to prescribe medications to patients without interruption.

The bill is particularly important here in Western New York where the University at Buffalo Medical School in partnership with Oishei Children's Hospital has been participating in a trial program with the drug Epidiolex. Proven effective in treating seizures with two rare and severe forms of epilepsy, Dravet and Lennox-Gastault syndromes, Epidiolex is a purified form of the drug Cannabidiol (CBD). Despite recently becoming the first plant-derived cannabinoid product to be federally approved, the life changing drug will not be available to New Yorkers if the bill is not signed into law.

"Giving the Commissioner of Health the authority to reclassify drugs consistent with Federal Drug Administration classifications is a common sense reform that enhances the provision of care in New York State without compromising safeguards designed for patient safety," said **Senator Chris Jacobs**. "I am pleased that Assemblyman Ryan and I could secure passage of this legislation in our respective houses. When this bill becomes law patients at Children's Hospital in Buffalo, or anywhere in New York State, will be able to continue to have access to the medications they need to sustain their health and well-being."

"This bill will help to allow patients in New York State to have access to the latest advancements in medical care" said **Assemblyman Sean Ryan**. "Allowing the Commissioner of Health to reschedule drugs in accordance with FDA classifications will allow the state to move quickly when new medications are approved, and that is in the best interest of our patients. The great medical research being done in Western New York is providing new options for our patients, and we need to do everything we can to grant them access to the medication that works for them."

Dr. Arie Weinstock, Professor of Clinical Neurology and Medical Director of the Child Neurology Division at the University at Buffalo Jacobs School of Medicine & Biomedical

Sciences said “Epidiolex has substantially reduced seizures in patients with two rare forms of epilepsy, and the study we've participated in will help thousands of patients across New York and the United States. We're conducting studies that bring new hope to patients, and the fact that we're able to do them here in Buffalo is a testament to the commitment the University at Buffalo, the Jacobs School of Medicine and Biomedical Sciences at UB and Oishei Children's Hospital have made to leading medical innovations.”

“The Epilepsy Foundation actively advocates for changes to state scheduling laws that would allow therapies derived from cannabidiol and approved by the FDA to become available in a timely manner to people living with epilepsy,” said **Philip Gattone**, President and CEO of the Epilepsy Foundation. “For those living with intractable seizures caused by LGS and Dravet syndrome, therapies such as EPIDIOLEX®, represent a true medical advancement; but, even with FDA approval, any new therapies derived from CBD would not be available unless states, like New York, implement changes to state scheduling laws.”

“We are extremely pleased that the state of New York has passed this law to enable children with two types of severe, childhood-onset epilepsies to have access to the first and only FDA-approved CBD medication, EPIDIOLEX, very soon after it is rescheduled by the Drug Enforcement Administration,” said **Justin Gover**, GW’s Chief Executive Officer. “These patients suffer from devastating types of seizures, and they and their families are in great need of new medications. Epidiolex offers an important and novel treatment option for these patients, and this new law ensures that their access will not be delayed as a result of state law obstacles.”

Epidiolex uses CBD, a chemical component of the Cannabis sativa plant, but does not cause the intoxication or euphoria that comes from tetrahydrocannabinol (THC). The study that the University at Buffalo Medical School and the Oishei Children’s Hospital participated in

was a part of the FDA “Compassionate Use” program that gives expanded access to investigational drugs for treatment use.

ABOUT DRAVET SYNDROME:

Dravet syndrome is a rare genetic condition that appears during the first year of life with frequent fever-related seizures (febrile seizures). Later, other types of seizures typically arise, including myoclonic seizures (involuntary muscle spasms). Additionally, status epilepticus, a potentially life-threatening state of continuous seizure activity requiring emergency medical care, may occur. Children with Dravet syndrome typically experience poor development of language and motor skills, hyperactivity and difficulty relating to others.

ABOUT LENNOX-GASTAUT SYNDROME

Lennox-Gastaut syndrome begins in childhood. It is characterized by multiple types of seizures. People with Lennox-Gastaut syndrome begin having frequent seizures in early childhood, usually between ages 3 and 5. More than three-quarters of affected individuals have tonic seizures, which cause the muscles to contract uncontrollably. Almost all children with Lennox-Gastaut syndrome develop learning problems and intellectual disability. Many also have delayed development of motor skills such as sitting and crawling. Most people with Lennox-Gastaut syndrome require help with usual activities of daily living.

RELATED LEGISLATION

2017-S8275B

-
- Introduced

 - - In Committee Assembly
 - In Committee Senate

 - - On Floor Calendar Assembly
 - On Floor Calendar Senate

 - - Passed Assembly
 - Passed Senate

 - Delivered to Governor

 - Signed By Governor

 -

Relates to authorizing the reclassification of controlled substances by regulation

April 26, 2018

Senate Floor Calendar

Sponsored by **Chris Jacobs**

Do you support this bill?