



Massachusetts Coalition for PANS/PANDAS Legislation  
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November 4, 2020

The Honorable Robert A. DeLeo, Speaker  
 Massachusetts House of Representatives  
 State House, Room 356  
 Boston, MA 02133

The Honorable Karen E. Spilka, President  
 Massachusetts State Senate  
 State House, Room 332  
 Boston, MA 02133

Dear President Spilka and Speaker DeLeo:

We are compelled to respond to the [recent letter](#), dated October 29, 2020, from health plan and business representatives regarding the PANDAS/PANS legislation. We are joined by clinicians and researchers from the fields of pediatrics, infectious disease, psychiatry, immunology, neuroethics, neuroscience, and nursing to demonstrate, with evidence from current literature and international guidelines, the safety and efficacy of PANDAS/PANS treatment.

The authors’ arguments against the bill are based on inaccurate statements refuted by the [Medical Efficacy Update](#) and recent diagnostic and treatment studies. Claims that this legislation could be costly are inaccurate – true costs are estimated between a fraction of a penny to a few pennies at most. It is also important to note that MassHealth already covers these treatments (including IVIG) for PANDAS/PANS.

Below, we highlight evidence from the literature in response to their claims.

Claim	Evidence-Based Response
<p><b><i>The following statement is inaccurate:</i></b>  <i>“More invasive procedures, including IVIG, plasmapheresis, tonsillectomies, and the long-term use of antibiotics are NOT evidence-based treatments for PANDAS/PANS.”</i></p>	<p>“The efficacy of immunomodulatory treatment has been rigorously examined since 2015. Recent evidence overwhelmingly supports inclusion of IVIG in the levels of treatment available for children with PANDAS and PANS. Based on extensive systematic reviews from several specialty areas, treatment studies, and the consensus guidelines of the PRC and PPN, IVIG is indicated for the treatment of a small but significant subset of children who meet the criteria.”  <a href="#">PANDAS Medical Efficacy Update</a></p> <p>Additionally, please see further research done over the past two years:</p>

	<ul style="list-style-type: none"> <li>• <a href="#">Yale Study Finds Antibodies in PANDAS</a></li> <li>• <a href="#">Th17 Lymphocytes Drive Vascular and Neuronal Deficits in a Mouse Model of Postinfectious Autoimmune Encephalitis</a></li> <li>• <a href="#">Treatment of Pediatric Acute-Onset Neuropsychiatric Disorder in a Large Survey Population</a></li> <li>• <a href="#">Benefits of IVIG in Pediatric Acute-Onset Neuropsychiatric Syndrome</a></li> <li>• <a href="#">Guidelines on the Use of Therapeutic Apheresis in Clinical Practice – Evidence-Based Approach from the Writing Committee of the American Society for Apheresis: The Eighth Special Issue</a></li> <li>• <a href="#">Pediatric Autoimmune Neuropsychiatric Disorder Associated with Streptococcus Immunology</a></li> <li>• <a href="#">Treatment of PANDAS and PANS: a systematic review</a></li> <li>• <a href="#">Clinical-Serological Characterization and Treatment Outcome of a Large Cohort of Italian Children with Pediatric Autoimmune Neuropsychiatric Disorder Associated with Streptococcal Infection and Pediatric Acute Neuropsychiatric Syndrome</a></li> </ul> <p>Please also refer to:</p> <ul style="list-style-type: none"> <li>• Written Testimonies given by medical professionals (Table 1 below)</li> <li>• Video Testimonies (Table 2 below)</li> </ul>
<p><b><u>The following statement is inaccurate:</u></b>  <i>“Less conventional treatments, such as plasmapheresis and IVIG, are considered experimental when used to treat PANDAS/PANS.”</i></p>	<p>“The American Society for Apheresis (ASFA) included PANDAS in its guidelines published in the Journal of Clinical Apheresis (JCA) in its last two editions. ‘In severely symptomatic patients with PANDAS or SC, immunomodulatory therapies, such as IVIG...or TPE, have been shown to be effective in reducing symptom severity or shorten the course.’”</p> <p>“A 2018 review published in the official journal of the European Paediatric Neurology Society...classified IVIG as a first line therapy in the treatment of PANDAS. ‘...there are general themes that broadly apply including: early diagnosis and treatment is better, minimise the severity of disease, escalate treatment if the patient is not responding to initial treatments, and minimise relapse.’”</p> <p><a href="#">PANDAS Medical Efficacy Update</a></p> <div style="display: flex; justify-content: space-around; align-items: center;">   <div style="text-align: center;"> <p>EUROPEAN PAEDIATRIC NEUROLOGY SOCIETY</p> </div>  </div>
<p><b><u>The following statement is inaccurate:</u></b>  <i>“...no defined diagnostic criteria exist- confirmation of the condition is based on subjective evaluation - and that ‘Research regarding the effectiveness of treatment for either PANDAS or PANS is not yet complete, nor is it conclusive.’”</i></p>	<p>“In 2017, the PANS Research Consortium (PRC) published a guideline series in four parts with contributing experts from more than two dozen academic institutions across the United States. Researchers and clinicians from the National Institute of Mental Health (NIMH), Harvard, Yale, Georgetown, Columbia, Stanford and other academic institutions pooled their data and clinical experience with more than 1000 PANDAS and PANS patients to develop best practice recommendations. These can be summarized as: Treat the SYMPTOMS, remove the SOURCE, and modulate the IMMUNE</p>

	<p>SYSTEM to reduce neuroinflammation.”  <a href="#">JCAP 2017 Guidelines for treating PANS/PANDAS</a></p> <p>Please also see:</p> <ul style="list-style-type: none"> <li>• <a href="#">PANDAS Medical Efficacy Update</a></li> <li>• <a href="#">PANDAS Physicians Network</a></li> <li>• <a href="#">Massachusetts Child Psychiatry Access Program (MCPAP)</a></li> </ul> <div style="display: flex; justify-content: space-around; align-items: center;">   </div>
<p><b><u>The following statement is inaccurate:</u></b>  <i>“...national organizations including the American Academy of Pediatrics and the National Institute of Mental Health (NIMH) do not support IVIG...”</i></p>	<p>Please see the following:</p> <p>This legislation provides access to immune treatment in a manner consistent with NIMH recommendations:</p> <p><a href="#">NIMH website: What about treating PANDAS with plasma exchange or immunoglobulin (IVIG)?</a>:  “Plasma exchange or immunoglobulin (IVIG) may be a consideration for acutely and severely affected children with PANDAS. Research suggests that both active treatments can improve global functioning, depression, emotional ups and downs, and obsessive-compulsive symptoms. [Given side effects and risk of infection,] the treatments should be reserved for severely ill patients and administered by a qualified team of healthcare professionals.”</p> <p>Further, the Massachusetts Child Psychiatry Access Program (MCPAP), which is funded by the Department of Mental Health, substantiates these guidelines:</p> <p><a href="#">Massachusetts Child Psychiatry Access Program (MCPAP) NEWS: Clinical Conversation: November 20, 2018</a>  “Immune therapies – used when there is clear evidence of neuroinflammation or postinfectious autoimmunity...In moderate to severe cases, intravenous immunoglobulin (IVIG) may be used.”</p>
<p><b><u>The following statement is inaccurate:</u></b>  <i>“Existing published studies are limited and have a high risk of bias.”</i></p>	<p>Organizations such as the American Academy of Allergy, Asthma, and Immunology; the American Society for Apheresis; and the European Paediatric Neurology Society endorse the use of IVIG for children with severe PANDAS.</p> <p>Please refer to studies referenced above.</p>
<p><b><u>The following standard has been met:</u></b>  <i>“As evidence regarding the diagnosis and treatment efficacy continues to evolve, only those specific treatments that have been adopted as generally accepted professional medical practice should be performed.”</i></p>	<p>Again, please refer to the research links above and below for diagnostic and treatment guidelines and supportive literature:</p> <ul style="list-style-type: none"> <li>• <a href="#">JCAP 2017 Guidelines for treating PANS/PANDAS</a></li> <li>• <a href="#">PANDAS Physicians Network</a></li> <li>• <a href="#">PANDAS Medical Efficacy Report</a></li> </ul> <p>Further, please see research from Columbia University this year,</p>

	<p>which confirms the need for such treatments:</p> <p><a href="#">How Immune Response to Strep Infection Triggers BGE Breakdown of Blood Brain Barrier PANDAS/PANS</a></p>
<p><b><u>The following statement is inaccurate:</u></b>  <i>“Specifically, the membership of the Advisory Council, as detailed in House Bill 4916, is not representative of the broad medical community, and is inclusive of only those few physicians in the state that have experience diagnosing and treating children with a PANDAS or PANS diagnosis.”</i></p>	<p>We worked with the Senate and House to craft this language to ensure this was an inclusive council.</p> <p>A PANDAS/PANS Advisory Council would logically have doctors who have treated the disorder to provide guidance as to best practices for support of children in the Commonwealth.</p> <p>Also please refer to <a href="#">Autism Commission</a> of Massachusetts as we feel PANDAS/PANS Advisory Council follows similar guidelines already established:</p> <p>In 2014, the Commonwealth of Massachusetts enacted legislation that established a permanent Autism Commission composed of 35 members, including representatives of a dedicated autism treatment center, state agencies and advocacy organizations, as well as parents and a self- advocate. Ch.226 of the Acts of 2014 states, “members of the commission shall be persons with demonstrated interest, experience and expertise in autism and related services...”</p>
<p><b><u>The following standard has been met:</u></b>  <i>“We recommend that the diagnosis criteria, screening protocols, and treatment guidelines for PANDAS/PANS to be utilized in making coverage determinations must be: • evidence-based, • representative of generally accepted professional medical practice based on input from practicing physicians and participating providers, and • in accordance with the standards adopted by national accreditation organizations.”</i></p>	<p>The research and information listed in this document confirms that diagnostic and treatment guidelines meet these important criteria. We worked with the Senate and House to craft language to ensure the advisory council addresses this.</p>
<p><b><u>The following statement is inaccurate:</u></b>  <i>“...it is essential that any legislatively established PANDAS/PANS Advisory Council that will play a leading role in the development of state medical guidelines for treatment be unbiased and include input from a greater range of practicing physicians and providers.”</i></p>	<p>We worked with the Senate and House to ensure the advisory council is interdisciplinary.</p> <p><b>Physician</b> specializing in infectious diseases; <b>pediatrician</b>; <b>child psychiatric practitioner</b>; <b>two health care providers/ medical specialists</b>; <b>medical researcher</b>; <b>representative</b> of a Massachusetts non-profit PANDAS/PANS Advocacy Organization; <b>representative</b> from the Massachusetts Coalition on PANDAS/PANS Legislation; <b>representative</b> of a professional organization in this State for school nurses; <b>two parents</b> with children who have been diagnosed with PANDAS or PANS; <b>social worker</b>; <b>special educator administrator</b>; <b>member</b> of Department of Mental Health appointed by the Secretary of Health &amp; Human Services; <b>member</b> of the General Assembly appointed by the Speaker of the House of Representatives; <b>member</b> of the General Assembly appointed by the President of the Senate; <b>member</b> of the General Assembly appointed by the Minority Leader of the House of Representatives; <b>member</b> of the General Assembly appointed by the Minority Leader of the Senate.</p>

***The following statement is missing critical data from the 2015 CHIA report:***  
*“State-mandated health care benefits add to the cost of health care.”*

The costs of implementing An Act Relative to Insurance Coverage for PANDAS/PANS, calculated by the [2015 CHIA report](#), were summarized in the [PANDAS Medical Efficacy Update](#) provided to your Joint Committee in November, 2019:

“Given the narrow subset of patients requiring IVIG...coverage of treatment would result in a slight increase in premiums for insurance holders in the Commonwealth of Massachusetts. According to the report, ‘requiring coverage for this benefit by fully-insured health plans would result in an average annual increase, over five years, to the typical member’s monthly health insurance premiums of between \$0.003 (0.001%) and \$0.039 (0.008%) per year.’”

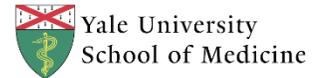
Also of note, MassHealth has designated immunotherapies (such as IVIG) as medically necessary when authorizing physician-ordered treatment for children with PANDAS and PANS.

As you know, Massachusetts was the first state to file a PANDAS/PANS coverage bill (2013) and is the only state to commission a CHIA report (2015). The original language of that bill and the actuarial assessment have since been used by seven other states to pass insurance legislation.

That this bill stands at the threshold of passage in the Commonwealth is a testament to your work to understand these disorders. Both the Senate and the House have asked hard, critical, insightful questions and challenged our coalition and the expert medical professionals to ensure you had the answers as the bill and advisory council moved through the legislative process. The time the Senate and the House of Representatives have taken to learn about this illness, its levels of treatment, and the necessity of this legislation shows true dedication our legislators have to their constituents.

With continued gratitude,

**Sheilah Gauch, LICSW, M.Ed, and Jennifer Vitelli, MBA**  
Co-Leaders, Massachusetts Coalition for PANS/PANDAS Legislation



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**Kyle Williams, MD**

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cc: Joint Committee on Financial Services  
 Joint Committee on Health Care Finance  
 Senate Ways and Means  
 Representative Josh Cutler  
 Senator Jason Lewis

**Table 1**

<b>Written Testimonies</b>
<a href="#">Dr. Mark Pasternack, Chief of Pediatric Infectious Disease, Massachusetts General Hospital</a>
<a href="#">Dr. Jennifer Frankovich, Assistant Professor of Pediatric Rheumatology, Co-Director, PANS Clinic</a> <a href="#">Dr. Kiki Chang, Professor of Psychiatry, Director, Pediatric Bipolar Disorders Program &amp; Co-Director of PANS Clinic</a>
<a href="#">Dr. Kyle Williams, Director, Pediatric Neuropsychiatry and Immunology Clinic, Massachusetts General Hospital</a>
<a href="#">Dr. Melissa L. McCormack, MD, PhD, Pediatrician</a>
<a href="#">Margaret Chapman, CNS, BC</a>
<a href="#">Dr. Yujuan Julia Zhang, Floating Hospital for Children at Tufts Medical Center, Division of Pediatric Rheumatology</a>
<a href="#">Madeleine W. Cunningham, Ph.D. George Lynn Cross Research Professor Presbyterian Health Foundation Presidential Professor Microbiology and Immunology Director, Immunology Training Program University of Oklahoma Health Sciences Center</a>
<a href="#">Dr Margo Thienemann, Child and Adolescent Psychiatrist</a>
<a href="#">Dritan Agalliu, PdD, Associate Professor, Columbia University</a>
<a href="#">PANDAS Network</a>

**Table 2**

<b>Video Testimonies</b>
<a href="#">Dr. Susan Swedo, Scientist Emerita, Intramural Research Program National Institutes of Health</a> (13 minute mark)
<a href="#">Dr. Mark Pasternack, Chief, Infectious Pediatric Infectious Disease, Massachusetts General Hospital</a> (65 minute mark)
<a href="#">Dr. Melissa L. McCormack, MD, PhD, Pediatrician</a> (49 minute mark)
<a href="#">Margaret Chapman CNS, BC</a> (39 minute mark)
<a href="#">Legislative Video Testimony: RISE UP</a>