Oregon's House Bill 2390
Evidence-Based Response to Common Oppositional Arguments

Common Oppositional Claims	**Evidence-Based Response**
The following statement is inaccurate. "It takes decision making out of the hands of medical providers".	Just the opposite. A 2017 American Medical Association survey of 1,000 physicians found that 84% of those surveyed felt the burdens imposed by insurers to obtain care were high/extremely high and 92% surveyed indicated that these barriers can have a **negative impact on patient's outcomes.** HB 2390 removes these barriers **allowing the physician to determine the most clinically appropriate treatment for their patient**. In the words of an Oregon pediatrician, 'The lack of insurance coverage absolutely impacts my prescribing practices for children with PANDAS/PANS'.
The following statement is inaccurate. All of the estimated 4,300 children affected by these disorders will require IVIG and/or Plasmapheresis.	It is estimated that only a small sub-set, those with moderate-severe severity, will require IVIG and/or Plasmapheresis. According to the 2017 Journal Child and Adolescent Pharmacology guidelines, "A small but significant subset, estimated to be 10-15% of referred children, fail to improve with these conventional measures and require immunomodulatory therapy with intravenous immunoglobulin (IVIG), therapeutic plasmapheresis (also known as plasma-exchange), or other modalities". The National Institute of Mental Health confirms this small subset as well indicating that immunotherapies are reserved for the sickest children. The correct estimate of those who would need immunotherapy is 433-645 children and that is assuming every child with PANDAS/PANS has been diagnosed accurately in our state.
The following statement is inaccurate. IVIG and plasmapheresis, are NOT evidence-based treatments for PANDAS/PANS and should be considered experimental and/or investigational.	IVIG has been used for over 70 years and has well established anti-inflammatory and immunomodulatory properties (Annals of American Thoracic Society). The efficacy of immunomodulatory treatment in PANDAS/PANS 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 national consensus guidelines of the PANS Research Consortium and PANDAS Physician Network, "IVIG is indicated for the treatment of a small but significant subset of children who meet the criteria." 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.'" As you will see by the medical efficacy update and studies linked below, IVIG is the gold standard of care for a specific severity of P/P children and has been researched extensively. PANDAS Medical Efficacy Update by Dr. Sue Swedo (NIMH Emerita) and Dr. Mark Pasternack of Harvard can be found in uploaded written testimonies for HB 2390. Published research findings over the last two years: • Yale Study Finds Antibodies in PANDAS • Th17 Lymphocytes Drive Vascular and Neuronal Deficits in a Mouse Model of Postinfectious Autoimmune Encephalitis • Treatment of Pediatric Acute-Onset Neuropsychiatric Disorder in a Large Survey Population • Benefits of IVIG in Pediatric Acute-Onset Neuropsychiatric Syndrome • 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

	• Pediatric Autoimmune Neuropsychiatric Disorder Associated with Streptococcus Immunology • Treatment of PANDAS and PANS: a systematic review • 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 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, minimize the severity of disease, escalate treatment if the patient is not responding to initial treatments, and minimize relapse.'
The following statement is inaccurate. There is not consensus on diagnostic and treatment guidelines, including the use of immunotherapies.	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 SYSTEM to reduce neuroinflammation. In December of 2020, PANDAS Physician Network, national expert body, released updated diagnostic and treatment guidelines further clarifying diagnostic and treatment guidelines via clinical algorithm. JCAP 2017 Guidelines for treating PANS/PANDAS Please also see: • PANDAS Medical Efficacy Update • PANDAS Physicians Network • Massachusetts Child Psychiatry Access Program (MCPAP)
The following statement is inaccurate. The National Institute of Mental Health (NIMH) does not recognize PANDAS/PANS and does not support IVIG and Plasmapheresis.	The original research regarding PANDAS/PANS originated in the NIMH with Dr. Sue Swedo's revelation that strep caused OCD. Dr. Sue Swedo is now recognized as a NIMH Emerita. This legislation provides access to immune treatment in a manner consistent with NIMH recommendations: NIMH website: What about treating PANDAS with plasma exchange or immunoglobulin (IVIG)?: "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." Further, the Massachusetts Child Psychiatry Access Program (MCPAP), which is funded by the Department of Mental Health, substantiates these guidelines: Massachusetts Child Psychiatry Access Program (MCPAP) NEWS: Clinical Conversation: November 20, 2018 "Immune therapies – used when there is clear evidence of neuroinflammation or postinfectious autoimmunity...In moderate to severe cases, intravenous immunoglobulin (IVIG) may be used."
The following statement is inaccurate. There is not sufficient research and/or the published research that exists is too limited, without control groups.	As stated above, IVIG 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 and is agreed upon by a national body of medical experts and given as a treatment option listed by the NIMH. Randomized clinical trials are not always feasible in every population, especially in vulnerable populations. The very sickest patients (and their parents) may not consent to a trial with a placebo just because the risk of not getting potential treatment is too high. There is controversy even amongst researchers when it comes to the inclusion of pediatric subjects in clinical trials because of their inability to consent for themselves and when receival of a placebo could delay much needed treatment for a child who is already severely ill. Please refer to studies referenced above.
The following statement is inaccurate. Insurance mandates add to the cost of healthcare for plan members, insurers and the state.	Massachusetts did a cost analysis in 2015, updated in 2019, that reflected the negligible cost impact to plan members which is highlighted in the 2015 CHIA report, and summarized in the PANDAS Medical Efficacy Update. "Given the narrow subset of patients requiring IVIG (an estimated 10-15%) ...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**.'" The upstream cost of not treating the most severely affected PANDAS/PANS children in our state could result in costs related to lifetime mental illness, social security disability, education costs (504s, IEPs, 1:1 tutors, special education), Medicaid enrollment, psychiatric residency and hospitalization, homelessness, and suicide. The lifetime burden of serious mental illness estimated to be 1.84 million per patient.
The following statement is inaccurate. There isn't an ICD code for PANDAS/PANS	Effective 10/1/2020, ICD 10 has assigned a corresponding code for PANDAS which is 89.89 (Other specified disorders involving the immune mechanism, not elsewhere classified), and the new version of the ICD-11 will include a specific code for PANDAS (8E4A.0 Paraneoplastic or autoimmune disorders of the central nervous system, brain or spinal cord). ICD codes are developed by the World Health Organization and maintained by the National Center for Health Statistics (NCHS) of the Centers for Disease Control and Prevention (CDC).
The following statement is inaccurate.	According to the Hospital for Sick Kids, IVIG is a safe treatment for children. Most side effects (headache, nausea, dizziness) are mild and easy to control. The process of administering is as

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IVIG and PE is invasive and expensive.	simple as placing a hollow needle into a vein in your child's hand or arm to infuse healthy antibodies. According to the UT Southwestern Medical Center, "plasma exchange is a safe procedure with a few side effects". The total cost of IVIG therapy ranges from $5000 to $10,000, depending on the patient's weight. The private pay cost of these therapies is cost prohibitive for most Oregon families however, the cost to insurers is much lower due to contracted rates and their practice of passing costs on to their plan members. Despite this practice, a 2015 Massachusetts financial analysis of member impact by the inclusion of IVIG treatment resulted in less than pennies a month even at the highest utilization (20%). Meanwhile Oregon insurers post revenue and profitability in the multi-millions.
The following statement is inaccurate. Oregon's Health Evidence Review Commission sets the precedent for commercial insurers and HB 2390 should be paused until HERC has reviewed their coverage guidelines.	In 2018, correspondence with the Health Evidence Review Commission of Oregon, both their Director and Medical Director, confirmed coverage of IVIG and Plasmapheresis for PANDAS children with the caveat that ultimately a Coordinated Care Organization (CCO) could approve or deny the claim. In addition, the Policy Manager for the Oregon Dept. of Consumer & Business Services informed us in 2018 that HERC decisions, while providing some model of coverage, don't typically have any bearing on medical necessity calls in commercial plan (Rick Blackwell, now Director of Govt. Relations for Pacifisource). Per HERC's Medical Director, "Currently, based on the Prioritized List, PANDAS (coded with ICD10 D89.89, Other specified disorders involving the immune mechanism, not elsewhere classified) is paired with IVIG and plasmapheresis on line 313 DISORDERS INVOLVING THE IMMUNE SYSTEM. Therefore, **a patient with PANDAS should be covered for either of these treatments if clinically appropriate**." HERC has already confirmed coverage for these treatments. While they are currently re-examining new evidence on the treatment of PANDAS/PANS/AE, this should not stall legislation that seeks to create pay parity amongst commercial insurers. And as stated above, HERC decisions don't have any bearing on medical necessity calls in commercial plans.
The following statement is inaccurate. "It's telling that the bill allows for billing of another condition rather than PANS/PANDAS; it is a tacit acknowledgement that we may be racing ahead of the medical evidence".	House Bill 2390 states **"..**may be coded as autoimmune encephalitis until the American Medical Association and the Centers for Medicare and Medicaid Services create and assign a specific billing and diagnostic code for PANDAS/PANS". Autoimmune encephalitis is NOT another condition. Recently, a number of studies have proven that PANS/PANDAS is a form of autoimmune encephalopathy. Research published in 2020 specifically identifies that PANDAS, Sydenham Chorea, including basal ganglia and/or dopamine receptor encephalitis all have findings of autoimmunity and neuroinflammation. The inclusion of 'autoimmune encephalitis' is reflective of the growing consensus that PANDAS/PANS is a form of encephalitis that the emerging scientific evidence supports.