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Testimony in **SUPPORT** of SB 475:
"Health Insurance—Pediatric Autoimmune Neuropsychiatric Disorders—Coverage"
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## A Statewide Coverage Mandate is Urgently Needed

SB 475 is urgently needed. In the absence of a statewide mandate requiring insurance coverage for physician-prescribed and medically indicated PANDAS treatment, health insurers are denying coverage for much-needed medical care. Insurance companies offer two primary justifications for their coverage decisions[1]: (1) the specified treatment is not FDA approved for children with PANDAS and (2) the insurance company considers the specified treatment investigational/experimental, which is categorically excluded from coverage under almost all health insurance plans. These arguments are legally, medically, and ethically problematic—as well as financially shortsighted—for reasons discussed in detail below.

## Insurance Companies' Justifications for Denying Coverage are At Odds with Law, Ethics, and Medical Practice

### (1) Insurers' Requirement of FDA Approval is Inconsistent with Federal Regulations and Existing Insurance Company Practices

Insurance companies that deny coverage of PANDAS treatments, on the ground that those treatments are not FDA approved, operate in a manner inconsistent with FDA regulations. FDA regulations do not require pharmaceutical companies to include children, along with adults, in a request for new drug approval.[2] In fact, FDA regulations allow pharmaceutical companies to defer conducting studies with children (in many cases, for years) because the agency recognizes that conducting "gold standard" research with children is ethically and pragmatically challenging. It is unethical to place sick children in placebo-controlled research, when medical experts have knowledge of effective treatment options, and it is pragmatically difficult to keep sick children in research (attrition rates are high). Absent a legal requirement, drug companies have no incentive to do research related to children generally, but especially in the case of more rare diseases, where conducting the research imposes costs on the pharmaceutical

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[1] Insurance company "denial of coverage" and "rejection of appeal" letters, on file with author of

[2] Joel D. Hudgins, *Pediatric Drug Information Available at the Time of New Drug Approvals*, 27 PHARMACOEPIDEMIOL DRUG SAFETY 161 (2018).

company without the promise of reaping the financial benefit of a drug that is prescribed more widely.

As a consequence, as many as 54% of FDA approved drugs lack pediatric labeling information, and more than three-quarters of children in hospital and outpatient settings are given drugs that are being used "off label."[3] Nevertheless, insurance companies cover those drugs when they are used in children and for indications not specified on the FDA approved label. Insurance companies' decisions not to cover PANDAS treatments, like IVIG and Rituximab, are therefore inconsistent, not only with FDA regulations, but also with insurance companies own payment practices.

(2) Categorizing Certain PANDAS Treatments as Experimental/Investigational Ignores Medical Consensus Guidelines and American Academy of Pediatrics Statements

(a) *Medical Consensus Guidelines.*

Insurance companies that deny coverage of PANDAS-related treatments on the ground that they are experimental/investigational are depriving children of the very medications that expert medical consensus guidelines have established as the standard of care for treating PANDAS. In 2014, the PANS Research Consortium (PRC)—a task force comprised of nationally renowned immunologists, rheumatologists, neurologists, infectious disease experts, general pediatricians, psychiatrists, nurse practitioners, and basic scientists with expertise in neuro-immunology—met at the National Institutes of Health (NIH) to establish Preliminary Treatment Guidelines for PANS and PANDAS.[4] Those guidelines were refined over a 2-year period of time during which they were externally reviewed, revised, and ultimately approved unanimously by the PRC as expressing the standard of care for diagnosing and treating PANS and PANDAS.

The final guidelines were published in 2017 in the highly respected, peer-reviewed *Journal of Child and Adolescent Psychopharmacology.*[5] Those guidelines provide a step-wise plan for treating PANS and PANDAS that accounts for the severity of the disorder, the length of time the child has gone without proper treatment, and the child's medical responsiveness to certain immunomodulatory therapies. Importantly, the expert medical consensus Guidelines recommend IVIG (intravenous immunoglobulin), Rituxan, therapeutic plasma exchange, and MMF (mycophenylate mofetil) as the medically indicated standard of care for children with PANDAS who meet certain specified criteria.[6]

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[3] Id.
[4] Jennifer Frankovich et al., *Clinical Management of Pediatric Acute-Onset Neuropsychiatric Syndrome: Part II—Use of Immunomodulatory Therapies*, 27 J. CHILD & ADOLESCENT PSYCHOPHARMACOLOGY 574, 577 (2017).
[5] *Clinical Management of Pediatric Acute-Onset Neuropsychiatric Syndrome: Parts I-III*, 27 J. CHILD & ADOLESCENT PSYCHOPHARMACOLOGY 556-93 (2017).
[6] Frankovich et al., *supra* note 4, at 581, Table 4.

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(b) American Academy of Pediatrics Statement: "Off-Label Uses of Drugs in Children"

Insurance companies' determination that medically indicated, physician prescribed treatments for PANDAS are experimental/investigation, and are therefore excluded from coverage, is also in substantial conflict with the American Academy of Pediatrics (AAP) formal, published, and current policy statement on "Off-Label Uses of Drugs in Children."[7] The AAP's Policy Statement warns that, in the context of pediatrics, "the term 'off label' does not imply an improper, illegal, contraindicated, or investigational use" of a drug,[8] and that "the absence of [FDA] labeling for a specific disorder does not … signify that therapy is unsupported by clinical experience or data in children."[9] It may simply mean, as discussed above, that randomized controlled studies could not be performed in that patient population.

Recognizing that "for the pediatric population, gold standard clinical trials are often not available," the Policy Statement recommends that health care providers rely on information, "such as expert opinion, …articles in peer-reviewed journals, … [and] consensus statements." Applied to the context of PANDAS treatment, the AAP Policy Statement recommends that physicians tailor their prescribing decisions to the Medical Consensus Guidelines discussed above. But the AAP Policy Statement goes further, and specifically recommends "institutions and payers should not use labeling status as the sole criterion that determines the availability of ore reimbursement status for medications in children."[10] When insurance companies deny coverage for PANDAS treatments that are included in the expert medical consensus guidelines, they are not only doing so in direct conflict with medical experts and the societies that represent them, but they are also denying the standard of care to children whose health is detrimentally endangered by delayed care.

When PANDAS treatments are delayed or never received, because insurance companies denied coverage, the health of children with PANDAS deteriorates. As their condition worsens, they require more physical and occupational therapy, use more school resources, such as IEPs, and require more medication – all at a higher cost to families and the state of Maryland.

For the reasons stated above, I strongly urge you to report favorably on SB 447.

*The views expressed in this testimony are my own and do not necessarily reflect the policies or positions of the academic institutions with which I am affiliated.*

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[7] American Academy of Pediatrics, Committee on Drugs, *Policy Statement: Off-Label Use of Drugs in Children,* 133 PEDIATRICS 563 (2014).
[8] Id.
[9] Id. at 564.
[10] Id. at 566.