

ORC4731.302 Qualifying Condition request for Autism



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Background

This is a request that Autism to be added to the Ohio Qualifying Conditions list for Medical Marijuana. Even though previous attempts have been made, this request is being made based on “new literature” regarding board practices and methodologies for historical approvals. In particular this “new literature” seeks to highlight bias in the Medical Board approval processes.

During the State Medical Board of Ohio Meeting on May 12, 2021 it was stated that it was both “negligent and unethical” to approve Autism as a qualifying condition for the OHMM program. The specific reasoning revolved around information received from “autism specialists at Nationwide Children’s Hospital, Cincinnati Children’s Hospital, and mental health directors for the State of Ohio”. The State Medical Board of Ohio listed a few summarized “concerns”, and “potential” side-effects from cannabis use as part of the reasoning for the sustained denial. Secondary logic was provided regarding “concerns noted by experts about the minimal rigorous evidence that medical marijuana is beneficial for autism”, alongside a tertiary set of claims that there was a “substantial association of marijuana with the worsening of several psychiatric conditions”. The board went on to further express “alarm”, and highlight “deeply concerned” experts.

It should be noted that The State Medical Board of Ohio also acknowledged that “therapy is challenging and many therapies currently utilized have significant side-effects”. Additionally the board noted “the emotional pain that families manage when there are children in the home with autism”.

Review of Category IV Petitions to Add Qualifying Conditions

Autism Spectrum Disorder: Asperger Syndrome, Autistic Disorder, Pervasive Developmental Disorder

Dr. Bechtel stated that Committee has previously considered autism as a qualifying condition for treatment with medical marijuana. The Committee has reviewed the new literature that was included in the two current petitions for autism. Dr. Bechtel stated that autism is a devastating condition for the patients and their families, noting that therapy is challenging and many therapies currently utilized have significant side-effects. The Committee greatly appreciates the concerns that families have expressed and the sincerity of the petitions.

Dr. Bechtel stated that autism specialists at Nationwide Children’s Hospital, Cincinnati Children’s Hospital, and mental health directors for the State of Ohio have expressed concern with approving medical marijuana for treatment of autism. These concerns including worsening of several psychiatric conditions in pediatric patients, long-term negative effects on cognition, potential long-term negative effects in intelligence quotient, negative effects on concentration and problem-solving, potential obesity, and potential decline in personal engagement later in life.

Dr. Schottenstein appreciated Dr. Bechtel's comments and he also regretted the emotional pain that families manage when there are children in the home with autism. Dr. Schottenstein was also respectful of the concerns noted by experts about the minimal rigorous evidence that medical marijuana is beneficial for autism and the substantial association of marijuana with the worsening of several psychiatric conditions. Dr. Schottenstein observed that experts from the children's hospitals expressed alarm at the prospect of approving medical marijuana for both autism and anxiety. The experts described themselves a deeply concerned and indicated that they felt it would be **negligent and unethical to approve medical marijuana for these conditions** without the results of good studies that are currently underway to support these indications. Dr. Schottenstein regretted that approval of medical marijuana to treat autism seemed premature to him at this time.

Definitions

As a preface, this document will clarify an understanding of the boards role in approval of qualifying conditions for medical marijuana by rehashing definitions within the Ohio Revised Code, as well as statements from The State Medical Board of Ohio itself.

Per ORC 4731.302 "The board shall approve or deny the petition in accordance with any rules adopted by the board under section 4731.301 of the Revised Code."

Per ORC 4731.301 "the board may adopt any other rules it considers necessary to implement sections 4731.30 and 4731.302"

As defined by ORC 4731 Rule 4731-32-05 the relevant Medical Board marijuana rules are as follows:

- ...
- (3) The board shall consult with one or more experts who specialize in the disease or condition.
 - (4) The board shall review any relevant medical or scientific evidence pertaining to the disease or condition.
 - (5) The board shall consider whether conventional medical therapies are insufficient to treat or alleviate the disease or condition.
 - (6) The board shall review evidence supporting the use of medical marijuana to treat or alleviate the disease or condition.
 - (7) The board shall review any letters of support provided by physicians with knowledge of the disease or condition, including any letter provided by a physician treating the petitioner, if applicable.
 - (8) The board shall review any other relevant evidence regarding the disease or condition.

The board was asked via public record request if there were any internal methodologies created, or utilized by The State Medical Board of Ohio Per ORC4371.301 to help ensure that board members adhered to their responsibilities to "review" and "consider" evidence presented to them. The response to the inquiry was: "There are no records responsive to your request". This response confirms that the board has chosen not to implement any specific methodology for "review", or "consideration" by board members in their decision making process.

It could easily be argued that a lack of a dedicated methodology subjects the approval process to inherent bias. There would as such seemingly be nothing stopping a board member with a relationship with TekadaPharma, and a preference for prescribing Guanfacine from outright ignoring evidence, after a taking a moment to "consider" and "review" said evidence.

Observations

ABMS "experts"

The American Board of Medical Specialties (ABMS) is the medical organization that oversees physician certification by developing standards for the evaluation and certification of physician specialists. "It is for this reason that hospitals, health plans, consumers,

and even providers themselves, overwhelmingly select ABMS certification as the gold standard of specialty care". The State Medical Board of Ohio appears to have consulted with the following experts, confirmed as such by their ABMS status.

<https://www.certificationmatters.org/find-my-doctor/?dsearch=1&fname=Craig&lname=Erickson&state=OH&specialty=>
<https://www.certificationmatters.org/find-my-doctor/?dsearch=1&fname=Martine&lname=Lamy&state=OH&specialty=>
<https://www.certificationmatters.org/find-my-doctor/?dsearch=1&fname=Brian&lname=Kurtz&state=OH&specialty=>
<https://www.certificationmatters.org/find-my-doctor/?dsearch=1&fname=Katherine&lname=Lee&state=OH&specialty=>
<https://www.certificationmatters.org/find-my-doctor/?dsearch=1&fname=Cara&lname=Fosdick&state=OH&specialty=>
<https://www.certificationmatters.org/find-my-doctor/?dsearch=1&fname=Drew&lname=Barzman&state=OH&specialty=>
<https://www.certificationmatters.org/find-my-doctor/?dsearch=1&fname=Michael&lname=Sorter&state=OH&specialty=>
<https://www.certificationmatters.org/find-my-doctor/?dsearch=1&fname=Courtney&lname=Cinko&state=OH&specialty=>
<https://www.certificationmatters.org/find-my-doctor/?dsearch=1&fname=Suzanne&lname=Sampang&state=OH&specialty=>
<https://www.certificationmatters.org/find-my-doctor/?dsearch=1&fname=Almeria&lname=Decker&state=OH&specialty=>
<https://www.certificationmatters.org/find-my-doctor/?dsearch=1&fname=Susan&lname=Wiley&state=OH&specialty=>
<https://www.certificationmatters.org/find-my-doctor/?dsearch=1&fname=jennifer&lname=Ehrhardt&state=OH&specialty=>
<https://www.certificationmatters.org/find-my-doctor/?dsearch=1&fname=pankhuree&lname=vandana&state=OH&specialty=>
<https://www.certificationmatters.org/find-my-doctor/?dsearch=1&fname=Anup&lname=Patel&state=OH&specialty=>
<https://www.certificationmatters.org/find-my-doctor/?dsearch=1&fname=Amy&lname>Newmeyer&state=OH&specialty=>

Status for each expert can be queried via the ABMS “verify certification” link, as hosted by “Certification Matters”. “By choosing a physician who is board certified by one of the ABMS Member Boards, you can be confident that he or she is skilled and knowledgeable, an expert in the specialty, and meets a higher standard developed by their peers”. Each specialty and subspecialty can be interpreted based on the ABMS Guide to Medical Specialties in the event that there is concern over any applicability of a particular specialty.

It could be argued that none of the listed doctors are “MOC Part IV, Autism Spectrum Disorder, ACMG/ABMGG” specialists “For geneticists involved in the further evaluation and care of patients diagnosed with Autism” as designated by ABMS. Rather they are all more generalists in similar diseases. ORC 4731 Rule 4731-32-05 section stating that “The board shall consult with one or more experts who specialize in the disease or condition” may not be being adhered to due to the board not consulting an actual “autism” expert.

The ABMS disciplines represented in the papers cited in the Autism denial paper are as follows:

ABMS Specialties - Present

Psychiatry - Specialty

“A psychiatrist specializes in the evaluation and treatment of mental, addictive and emotional disorders such as schizophrenia and other psychotic disorders, mood disorders, anxiety disorders, substance-related disorders, sexual and gender-identity disorders and adjustment disorders.”

Child & Adolescent Psychiatry - Subspecialty

“A psychiatrist who focuses on the evaluation and treatment of developmental, behavioral, emotional and mental disorders of childhood and adolescence”

Forensic Psychiatry - Subspecialty

“A psychiatrist who focuses on the interrelationships between psychiatry and civil, criminal and administrative law. This specialist evaluates individuals involved with the legal system and provides specialized treatment to those incarcerated in jails, prisons and forensic psychiatry hospitals.”

Pediatrics - Specialty

“Pediatricians practice the specialty of medical science concerned with the physical, emotional, and social health of children from birth to young adulthood. Pediatric care encompasses a broad spectrum of health services ranging from preventive health care to the diagnosis and treatment of acute and chronic diseases. Pediatricians understand the many factors that affect the growth and development of children. They understand that children are not simply small adults. Children change rapidly, and they must be approached with an appreciation for their stage of physical and mental development.”

Developmental-Behavioral Pediatrics - Subspecialty

“A pediatrician who specializes in Developmental-Behavioral Pediatrics possesses special skills, training and experience to foster understanding and promotion of optimal development of children and families through research, education, clinical care and advocacy efforts. This physician assists in the prevention, diagnosis and management of developmental difficulties and problematic behaviors in children and in the family dysfunctions that compromise children’s development.”

Neurology with Special Qualification in Child Neurology - Specialty

“Child Neurologists diagnose and treat similar disorders in infants, children, and adolescents. They also have special competence in genetic and metabolic problems, malformation, retardation and other neurodevelopmental problems of childhood.”

Clinical Neurophysiology - Subspecialty

“A psychiatrist, neurologist, or child neurologist who focuses on the evaluation and treatment of central, peripheral and autonomic nervous system disorders using a combination of clinical evaluation and electrophysiologic testing such as electroencephalography (EEG), electromyography (EMG) and nerve conduction studies (NCS), among others.”

Epilepsy - Subspecialty

“A neurologist or child neurologist who specializes in Epilepsy focuses on the evaluation and treatment of adults and children with recurrent seizure activity and seizure disorders. Specialists in Epilepsy (Epileptologists) possess specialized knowledge in the science, clinical evaluation and management of these disorders.”

Neurodevelopmental Disabilities - Subspecialty

"A child neurologist or pediatrician who specializes in Neurodevelopmental Disabilities focuses on the evaluation and treatment of chronic conditions that affect the developing and mature nervous system such as cerebral palsy, mental retardation and chronic behavioral syndromes or neurologic conditions."

American Board of Psychiatry and Neurology

American Board of Pediatrics

ABMS Specialties - Not present

The applicable ABMS discipline that is not represented in the papers submitted to The State Medical Board of Ohio is:

Medical Genetics and Genomics - Specialty

Medical geneticists specialize in medicine that involves the interaction between genes and health. They are trained to evaluate, diagnose, manage, treat and counsel individuals of all ages with hereditary disorders. This specialist uses modern cytogenetic, molecular, genomic and biochemical genetic testing to assist in specialized diagnostic evaluations, implement needed therapeutic interventions and provide genetic counseling and prevention through prenatal and preimplantation diagnosis. The Medical Geneticist plans and coordinates screening for genetic diseases involving single gene and chromosomal disorders, congenital anomalies, inborn errors of metabolism, multifactorial conditions, and common disorders with hereditary factors.

American Board of Medical Genetics and Genomics

Potential Bias

FSMB recommendations

As noted in a recent FSMB webinar titled "Ensuring Fairness in Medical Regulation: Can Implicit Bias Be Overcome?" (Dec. 16, 2020)", "Research has shown that implicit bias is prevalent among health care professionals, it has harmful effects on patient health, and it is a contributing factor to health disparities."

The paper "Implicit Bias and Mental Health Professionals: Priorities and Directions for Research" supports the FSMB outlook on bias: "Implicit bias pervades the mental health system. Mental health systems have unique threats to the equitable delivery of services and thus deserve research attention. These biases affect every aspect of the mental health care continuum, from screening to treatment, and additional research should further consider how implicit biases may affect health service delivery and subsequent outcomes". It further mentions "Implicit bias can preclude certain groups from accessing mental health services. Unlike other types of health care that use an interprofessional, team-based approach, mental health services are frequently provided on a one-on-one basis, so that a single provider is the gatekeeper to accessing care."

On the specific topic of Marijuana the Federation of State Medical Boards Model Guidelines for the Recommendation of Marijuana in Patient Care seemingly disagree with Ohio's medical board position on Autism. Rather than inflating "potential concerns", the FSMB suggests that "The decision to recommend marijuana should be a shared decision between the physician and the patient. The physician should discuss the risks and benefits of the use of marijuana with the patient. Patients should be advised of the variability and lack of standardization of marijuana preparations and the effect of marijuana".

The Ohio Medical Board in general opposition to FSMB is on the other hand allowing letters from Childrens Hospital, and Cinci Childrens to act as provider that are "the gatekeeper to accessing care", potentially impacting marginalized groups, and preventing them from accessing relief of their ailment through Marijuana.

Evidence supporting the use of medical marijuana

Cincinnati Children's went out of their way to point out they felt a lack of "rigorous scientific evidence" was a reason to deny Autism.



State of Ohio Medical Board
30 East Broad
Columbus, Ohio 43215

Dear Medical Board,

As Ohio experts in the diagnosis and clinical care of autism spectrum disorder we are writing in response to the petition pursuant to Ohio Administrative Code 4731-32-05 to add autism as a qualifying condition or disease for treatment with medical marijuana in the State of Ohio.

First, we want to make it clear to the Board that no rigorous scientific evidence exists to date supporting marijuana (cannabis) use in persons with autism. While a few studies of cannabis for treatment of autism have been published, they are seriously

Cincinnati Children's additionally claimed that the "few studies of cannabis for treatment of autism" are all "seriously flawed". One reason cited is because they are "open-label studies", and another reason that "no placebo control was utilized".

~~studies to date supporting therapeutic cannabis, use in persons with autism varies greatly.~~
studies of cannabis for treatment of autism have been published, they are seriously flawed. First, they are all open-label studies, meaning that no placebo control was utilized. The gold standard for assessing clinical effectiveness of any drug is the randomized, placebo-controlled study. Studies that are open label are more likely to report positive response rates due to placebo effect where the caregiver desires positive outcomes of the treatment in question.

Despite citing a "gold standard" as being necessary, Children's went on to use a study that didn't even adhere to their own expectations as justification to deny Marijuana as a Qualifying Condition. The cited paper "[THC exposure of human iPSC neurons impacts genes associated with neuropsychiatric disorders](#)" by Guennewig does not mention or directly reference "placebo" anywhere, similarly the word "blind" can not be found in the paper at all.

Translational Psychiatry, Guennewig et al. (2018) reported that THC exposure in induced pluripotent stem cell-derived neurons results in blunted brain cell responses from persons with schizophrenia. They also found that gene expression changes induced by THC in these neurons mimics the genetic alterations characteristic of autism. ~~The conclusion from Guennewig et al. (2018) is one of caution when considering use of cannabis in autism as THC may actually exacerbate the core symptoms and brain features of autism, rather than having a beneficial treatment effect.~~

The double standard presented in their own paper highlights bias on the part of Cincinnati Children's at the very least, and by proxy that of the Ohio Medical Board, for blindly following their advice sans a methodology to evaluate the advice for soundness. One could easily call the double standard "unethical", and "negligent".

The Cincinnati Children's paper seemingly unintentionally acknowledges that Autism is a disease of ***intractable mental pain***, while simultaneously showing their bias, and refusing to act on treatment options due to the previously mentioned double standard when compared to previously approved conditions.

SYMPOMS AND BRAIN FEATURES OF AUTISM, LARGER THAN HAVING A BENEFICIAL THERAPEUTIC EFFECT.

We recognize that autism is a lifelong disorder associated with significant communication, social and behavioral challenges that can greatly impact daily life for children and their families. We also recognize there is need to develop additional treatments that target these challenges. Cannabis is one of innumerable treatments proposed and discussed among autism researchers and families of children with autism each year. To determine the true clinic impact of cannabis for children with autism, a well-designed clinical investigation utilizing placebo-control approach and validated outcome measures is needed. Further, autism is a heterogeneous condition with

A paper titled "[The Concept of Mental Pain](#)" outlines that "Mental pain is no less real than other types of pain related to parts of the body, but does not seem to get adequate attention". This statement could not be more right with regard to Autism, and how Ohio Medical Board both acknowledges that the pain exists, but refuses to give it the adequate attention of an approval in qualifying condition status.

NIH documents a similar construct in the paper "[Is There Such a Thing as Psychological Pain? and Why It Matters](#)" by writing that "Medicine regards pain as a signal of physical injury to the body despite evidence contradicting the linkage and despite the exclusion of vast numbers of sufferers who experience psychological pain".

The Mayo Clinic also documents that "Chronic pain and mental health disorders are common in the general population, and epidemiological studies suggest that a bidirectional relationship exists between these 2 conditions" in their paper "[Chronic Pain and Mental Health Disorders Shared Neural Mechanisms, Epidemiology, and Treatment](#)".

In a further show of implicit bias Cincinnati Children's falsely claims that somehow approving Marijuana as qualifying condition will contaminate future research opportunities. The claim is flat out fallacious. Research efforts are parallel in nature to any sort of existing patient use.

centers with autism specialty clinics who are in a position to conduct the studies required to evaluate the efficacy of cannabis for children with autism. Adding autism as an indication for medical marijuana use without compelling scientific evidence will undermine any efforts of autism researchers in Ohio to rigorously study efficacy of cannabis for children with this disorder. This, in turn, will prevent providers and families from obtaining accurate, scientifically-based information from which to make clinical decisions about cannabis use for children with autism.

I astly, the psychoactive effects of THC pose significant threats for our population

It is unclear why Autism is being discriminated against, but the implicit bias showed by Cincinnati Children's shines through when the exaggerated importance of side effects are brought into the picture once again. It is very unfortunate that Cinci Children's does not appear to respect the patient-doctor relationship that many Autistic individuals, and families have established with their caregivers, and caretakers. It is both insulting, unethical, and negligent to imply that Marijuana would be any less safe than Guanfacine for example with regard to "communication deficits", and the ability to "report internal states of displeasure". Several substances that Ohio doctors are free to prescribe have documented known side-effects such as "suicidal ideation", yet Ohio doctors and patients are free to consult with each other, and make the determination if that risk is worth the reward of potential relief provided.

decisions about cannabis use for children with autism.

Lastly, the psychoactive effects of THC pose significant threats for our population of persons with autism, in particular, those with communication deficits who cannot self-report internal states of displeasure, confusion, or psychosis induced by THC. Given this, it is of paramount importance to study cannabis use in autism in a controlled clinical trial setting with sufficient observation for safety and tolerability. There is no available understanding of how to dose cannabis in autism or what the impact combining THC containing cannabis and prescribed drugs will have in this vulnerable population. Many youth and adults with autism take other psychoactive FDA-approved drugs to treat interfering and symptoms such as anxiety, irritability, and ADHD and the impact of combining cannabis with such medications in this population is unknown.

NIH commentary on supporting evidence

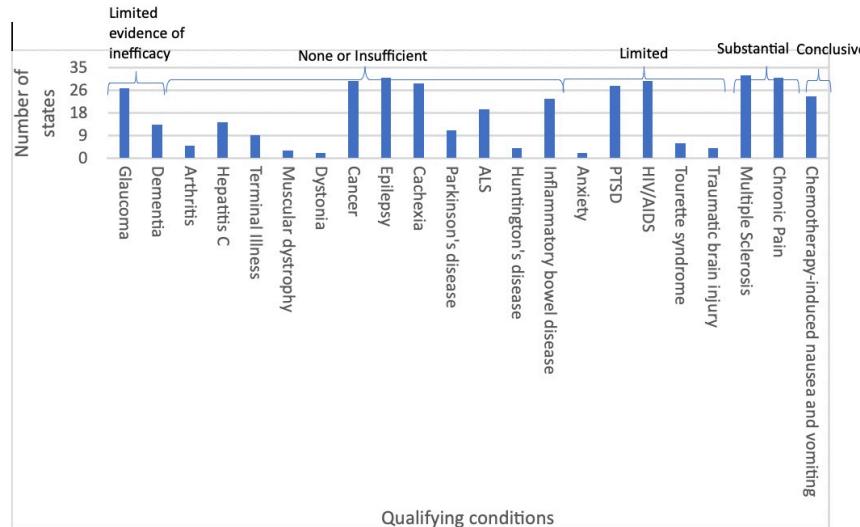
The NIH has done a study titled "Qualifying Conditions of Medical Cannabis License Holders in the United States" in which they claim that "85.5% of conditions for which patients are licensed to use medical cannabis have either substantial or conclusive evidence of efficacy according to the categories outlined in the 2017 NASEM report".

Overall, 85.5% of patient-reported qualifying conditions are supported by conclusive or substantial evidence of therapeutic effectiveness according to the 2017 NASEM report – i.e., chronic pain, chemotherapy-induced nausea and vomiting, and multiple sclerosis spasticity symptoms. This percentage is quite consistent across the time-frame of available registry data (mean=87.8%, SD=6.2%). However, there are many other, less well-supported qualifying conditions, including some for which there is either no/insufficient evidence for efficacy (Hepatitis C, muscular dystrophy) or even evidence suggesting that cannabis is ineffective (glaucoma) for treating them ([Exhibit 4](#)). See [Appendix Exhibit A3](#) for a visualization of the number of states that allow medical cannabis licensure for each qualifying condition.

(7)

The verbose detail on inefficacy from the NIH report is shown below:

Appendix Exhibit A3. Number of states allowing each NASEM qualifying condition in 2016.



Notes. SOURCE: Author's analysis of qualifying conditions allowed under state law as of 2018. The level of evidence from the 2017 NASEM report is displayed in brackets at the top of the exhibit.

If you classify Ohio's approved conditions vs the NIH concerns the discrepancies, and biases immediately show themselves.

Limited evidence of inefficacy

- Glaucoma
- terminal illness

None or insufficient

- Hepatitis C
- Amyotrophic lateral sclerosis
- Parkinson's disease
- Cachexia
- Epilepsy or another seizure disorder
- Cancer
- Inflammatory bowel disease

Limited

- AIDS
- Positive status for HIV
- Tourette syndrome
- Post-traumatic stress disorder

Substantial

- Multiple sclerosis
- Pain that is either chronic and severe or intractable
- Traumatic brain injury

Exhibit A2: Consolidation of qualifying conditions into 2017 NASEM report categories, and estimated number of affected Americans¹

NASEM 2017 report categories	State categories combined under NASEM categories	Level of evidence from NASEM report	Estimated number of affected Americans
Amyotrophic lateral sclerosis	ALS, lateral sclerosis	None or Insufficient	20,000 ^{2,3}
Antiemetics for chemotherapy-induced nausea and vomiting	nausea, moderate to severe vomiting	Conclusive	70-80% of people with cancer undergo chemotherapy, ⁴ chemotherapy prevalence varies based on type of cancer ⁵
Cancer	Cancer	None or Insufficient	15,112,098 ⁶
Cancer-associated anorexia cachexia and anorexia nervosa	Cachexia, wasting syndrome, Chemotherapy induced anorexia	None or Insufficient	1.67 million ⁷
Chronic pain	Chronic pain, severe and chronic pain, neuropathic pain, painful peripheral neuropathy, chronic regional pain syndrome 1+2, causalgia, Chronic Inflammatory Demyelinating Polyneuropathy, fibromyalgia, interstitial cystitis, Reflex Sympathetic Dystrophy, Chronic Regional Pain Syndrome Type I, Residual Limb pain	Substantial	100 million adults ⁸
Dementia	Alzheimer's or agitation of Alzheimer's	Limited evidence of ineffectiveness	5.7 million ⁹
Dystonia	Dystonia, Spasmodic torticollis (cervical dystonia)	None or Insufficient	250,000 ^{10,11}
Epilepsy	Epilepsy, seizures	None or Insufficient	3.4 million ¹²

Glaucoma	Glaucoma	Limited evidence of ineffectiveness	2.9 million ¹³
Huntington's Disease: chorea and symptoms	Huntington's Disease: chorea and symptoms	None or Insufficient	30,000 ^{14,15}
Increasing appetite and decreasing weight associated with HIV/AIDS	Increasing appetite and decreasing weight associated with HIV/AIDS	Limited	1.1 million ¹⁶
Irritable Bowel Syndrome	Crohn's disease, ulcerative colitis	None or Insufficient	3.1 million ¹⁷
Multiple sclerosis: 1) Clinician measured MS spasticity symptoms, 2) Depressive symptoms in chronic pain and MS, 3) Patient-reported Multiple sclerosis spasticity symptoms	Multiple sclerosis, sclerosis, muscle spasms, intractable skeletal spasticity	Substantial (patient reported spasticity)	400,000 ¹⁸
Not mentioned	Terminal illness, Neurobiological, Chronic Pancreatitis, chiari malformation, fibrous dysplasia, hydrocephalus, myasthenia gravis, myoclonus, Sjorgen's syndrome, spinocerebellar ataxia, syringomyelia, Tarlov cysts, One or more injuries, muscular dystrophy, Hepatitis C, Nail Patella, Inflammatory autoimmune-mediated arthritis, Lupus	None or Insufficient	Did not look up
Outcomes of traumatic brain injury	Outcomes of traumatic brain injury	Limited	3.32 million ¹⁸
Parkinson's disease or levodopa-induced dyskinesia	Parkinson's disease	None or Insufficient	500,000 ¹⁹
Post-traumatic stress disorder	Post-traumatic stress disorder	Limited	5.2 million aged 18-54 ²⁰
Spasticity in patients with paralysis due to spinal cord injury	Spasticity in patients with paralysis due to spinal cord injury	None or Insufficient	236,000-327,000 ¹⁸
Tourette's syndrome	Tourette's syndrome	Limited	200,000 ²¹

Notes. Consolidation of conditions allowed by states into categories of evidence under the 2017 NASEM report. The first column shows the conditions listed in the 2017 NASEM report. The second column shows all of the conditions allowed in each state that were consolidated under each of the NASEM report categories. The third column shows the

For three quick comparative examples, under Ohio law, Hepatitis C, HIV, and IBD are qualifying conditions, however, as noted by NIH "There have been no RCTs (Rigorous Randomized Controlled Trial) examining the use of cannabinoids on HCV infection".

Similarly "Findings from human studies have resulted in an increase in publicity regarding the efficacy of cannabis use in IBD therapy; however, the flaws of these studies are rarely mentioned", and specifically "The population studies discussed in this article lack objective parameters showing improvement in IBD activity with cannabis use."

Even with HIV, it can be stated that some studies claim "there was no statistically significant association between marijuana use and viral suppression".

Nearly every qualifying condition will have conflicting studies, or lack or, or limited "supporting evidence", historically this has not prevented approval of a condition into Ohio's Medical Marijuana Program. It should be clearly noted that the same level of professional scrutiny given to Autism, has not been afforded to other qualifying conditions. It is also poignant to point out bias in funding mentioned in the NIH paper "Qualifying Conditions of Medical Cannabis License Holders in the United States". "there is a funding bias, as government funding has typically been used to examine harm due to cannabis use and abuse rather than therapeutic benefits", as such leaning heavily on research as part of the approval process will subject the process to implicit bias.

Fallacious claims in documents used by board response for Autism

The most egregious bias is presented by the decision to repeat flat out false, and inaccurate tropes in the decision making process.

Schleider paper rejected?

The Cincinnati Children's letter misrepresents the "Schleider" paper in a negative light by claiming that it was "rejected for publication" due to "shortcomings and weaknesses of the study".

Looking more specifically at the few studies of cannabis for treatment of autism, in a recent paper written by Schleider et al. (2019), 30.1% of patients with autism were described as significantly improved and 53.7% moderately improved after open-label treatment with cannabis at a variety of doses and formulations. However, of the 188 patients treated with cannabis, only 60% (n=93) were evaluated, meaning 40% (n=62) were excluded from analysis. This is not how rigorous, systematic open-label drug studies are done and has the potential to result in biased and/or misleading findings. Further, the outcome measures utilized in the Schleider paper to assess treatment effectiveness are not standardized for use in individuals with autism and likely have little clinical utility. The authors themselves note that their results are based on subjective caregiver reports and may be reflective of "inflated expectations of the novel treatment 'miracle' effect." Finally, the Schleider paper was rejected for publication at autism-focused journals with editors who were aware of the shortcomings and weaknesses of this study.

The paper can be found on Nature.com just fine, the site is not noted for shying away from an “autism focus”.
<https://www.nature.com/articles/s41598-018-37570-y>

Researchgate has no issue hosting it, and they can be considered a more traditional host of approved academic “journal” content.
https://www.researchgate.net/publication/330450360_Real_life_Experience_of_Medical_Cannabis_Treatment_in_Autism_Analysis_of_Safety_and_Efficacy

The paper is also cited by other psychiatric journals just the same.
<https://www.psychiatrictimes.com/view/medical-marijuana-for-autism>

Likewise it is cited by universities.

https://medicalcannabis.utah.gov/wp-content/uploads/2020/04/QMC_Autism.pdf

Undermines research efforts?

Cincinnati Children’s accidentally admits a conflict of interests by stating they their “signatories” include academic license holders that are poised to study medical marijuana use and autism. It is flat out fallacious to suggest that empirical evidence would not be increased as a result of patient access, even if the data collection method isn’t favored. Denying approval would absolutely be in the favor of a group that was poised to do research that is being deemed essential by the paper cited by the board for moving forward with approval. This claim is a cyclical self-perpetuating bias sitting out plain as day.

LEGAL OPPORTUNITY TO RIGOROUSLY STUDY THE CLINICAL EFFECTIVENESS OF CANNABIS FOR CHILDREN WITH AUTISM
with autism. Our signatories include Schedule 1 DEA license holders at academic centers with autism specialty clinics who are in a position to conduct the studies required to evaluate the efficacy of cannabis for children with autism. Adding autism as an indication for medical marijuana use without compelling scientific evidence will undermine any efforts of autism researchers in Ohio to rigorously study efficacy of cannabis for children with this disorder. This, in turn, will prevent providers and families from obtaining accurate, scientifically-based information from which to make clinical decisions about cannabis use for children with autism.

No evidence, can’t move forward?

For some reason, possibly the previously mentioned conflict of interests, Cincinnati Children’s also claims that progress can not be made until they do work that they’ve deemed to be essential in the process. This simply isn’t true, there are other routes that The State Medical Board of Ohio is refusing to take. Perhaps a methodology for approvals would help? See for example FDA review process “Sometimes, though, questions arise that require additional consideration. In these cases, FDA may organize a meeting of

one of its Advisory Committees to get independent, expert advice and to permit the public to make comments". The board could choose to use a similar process to obtain more information, but it quite simply has opted not to, arguably out of negligence.

~~Impact of combining cannabis with other medications in this population is unknown.~~

We appreciate the efforts and interests of family and other stakeholders who are seeking to expand treatment options in autism. We appreciate the potential medical benefits of cannabis for certain indications. With that said, there is no compelling, scientifically sound evidence to support general use of marijuana in persons with autism. This is a topic that requires more study. Autism researchers in Ohio and nationwide are poised to rigorously study the potential role cannabis may have for treatment of autism. This work needs to be done before the State of Ohio Medical Board

In another confusing act of bias this time on the part of Nationwide Childrens Hospital, it could easily be argued that acting like "Accelerated Approval" isn't a normal process generally speaking is similarly negligent, and unethical. There several options available for moving forward, unfortunately NCH has chosen to misrepresent their desired path at the only path forward, and has as such contaminated the opinion of The State Medical Board of Ohio.

It would be, not only negligent but also unethical to approve medical cannabis as an indication of ASD and anxiety prior to the completion of these studies which is the standardized process to seek approval for drugs. We strongly request that the State of Ohio wait for solid, reliable information from these studies to make decisions on what products are safe for our children to be exposed to, instead of utilizing information which is being pushed by biased stakeholders.

Inability to address “potential” concerns?

Why is The State Medical Board of Ohio in lockstep with Nationwide Children's, and Cincinnati Children's in unethically acting like patients in conjunction with their doctors can't track, and address “potential” concerns within the normal approval process, using the FDA Drug review rules as an example: "Because premarket review can't catch all potential problems with a drug, the FDA continues to track approved drugs for adverse events through a post-marketing

surveillance program". The entire point of a Postmarketing Surveillance Program is to handle "potential" concerns with substances that are in patients hands. Why does the board feel that this process standard is inadequate for Marijuana?

"The Quality of Clinical Data" described in "FDA's Drug Review Process: Continued" mentions that sometimes inspections need to be performed on clinical data, and "At the conclusion of each inspection, FDA investigators prepare a report summarizing any deficiencies". One could easily argue that the medical board is seemingly avoiding similar responsibility in preparing a report fully summarizing the deficiencies in the various requests for Autism that they have chosen to deem insufficient.

If such a summary was created the obvious biases would show up immediately when compared to historic approvals. If one were to 1:1 compare the "documented" risks of an Autistic child using Guanfacine to the "potential" risks of a child using Cannabis this conversation with The State Medical Board of Ohio immediately becomes farcical.

Take for example that the FDA continues to "monitor adverse effects, including suicidal ideation and behavior" with Guanfacine variants, but it is all good and considered "ethical" as far as The State Medical Board of Ohio is concerned to prescribe it to an Autistic child. Guanfacine isn't to be taken lightly you are literally hooked on something that you have to be weaned off of, at risk of an immediate health episode (blood pressure), yet the board sees no limitation, or issue in using it for Autism?

The double standard is unethical, and negligent.

No Placebo tests performed?

Per the NIH paper Randomized double blind placebo control studies, the "Gold Standard" in intervention based studies, studies follow a hierarchy in terms of the quality of evidence that they can provide. Randomized double blind placebo control (RDBPC) studies are considered the "gold standard" of epidemiological studies"... "the major advantage of trial over and observational study is the ability to demonstrate causality i.e., cause-effect relationship. When RDBPC is compared with other research designs, the level of evidence given by RDBPC is nearly 100% and hence it is considered "gold standards" for comparison."

NIH article "Understanding and misunderstanding randomized controlled trials" points out that "Based on the features below, the reality is that DB studies may sometimes be flawed, or may be largely irrelevant clinically. Moreover, other studies that are not DB may be clinically far more useful."

The article “Are we blind to the limits of double-blind medical studies?” Notes that unblinded studies are actually by “far the most common study in psychology, for example”

There are different kinds of blind studies (Table 1)

- a. **Unblinded study:** A study in which both the patient/ subject and the doctor /investigator knows what is being administered. It is far the most common study in psychology, for example, where tests and scoring is obvious to the subject and the tester. It is also the way physicians practice medicine in a clinical setting, except they may not perceive such practice as “research”, but a clinical attempt to make the patient better. There is a special psychology involved here and the doctor-patient relationship may play a key role. But the object is to get the patient better, though we still might not know how well the drug works compared with the psychology of the relationship between the therapist or doctor and the patient.
- b. **Single blind studies:** When only one of the subject or patient OR the investigator is blind to

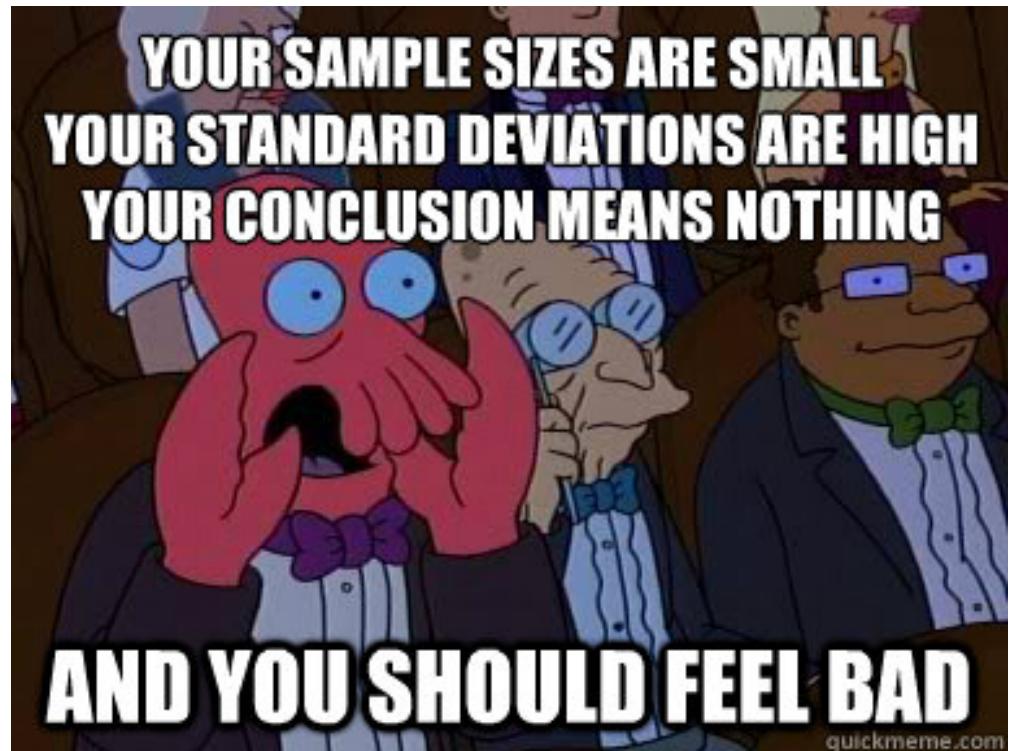
“There is a special psychology involved here and the doctor-patient relationship may play a key role. But the object is to get the patient better, though we still might not know how well the drug works compared with the psychology of the relationship between the therapist or doctor and the patient” is certainly something that shouldn’t be missed, keeping in mind again that The State Medical Board of Ohio is currently gatekeeping this relationship.

Conclusion

While we strongly support research and development of pharmaceutical cannabinoids and THC products for the treatment of chronic debilitating conditions, interpreting current research as indicative of clinical effectiveness and safety of cannabis in treating conditions such as autism and anxiety disorders is concerning and raises several medical, ethical and legal questions. As aforementioned, there is not a single published randomized, double-blind, placebo-controlled trial to specifically study the safety and efficacy of cannabis in ASD, which is the gold standard for FDA-approval of medications for use in the clinical setting. Almost every published study reviewed reports that there is lack of strong evidence to support the use of cannabinoids in ASD and that further randomized, double-blind, placebo-controlled trials are necessary to validate the efficacy and safety of cannabinoids in ASD (3,4,10,11). We request the Board oppose the inclusion of autism spectrum disorder and anxiety as qualifying conditions or disease for treatment with medical marijuana in Ohio.

Speaking again to the specific implicit bias mentioned before it should be noted that the NIH paper ["Effectiveness studies: advantages and disadvantages"](#) states specifically “inadequate sample size increase the risk of a β -error (failure to detect a difference although there is one)”

Table II. Advantages and disadvantages of using an active control or placebo in clinical studies.		
	Advantages	Disadvantages
Placebo-controlled studies	<ul style="list-style-type: none"> Allow estimation of the assay sensitivity and thus internal validation of the study Allow better evaluation of the clinical relevance Smaller sample size Lower study costs 	<ul style="list-style-type: none"> Perhaps higher risk from “nontreatment” Perhaps more limited generalisability of the results to the general population
Studies with an active control	<ul style="list-style-type: none"> Supply data on relative efficacy and tolerability At least theoretically no inactive treatment Fewer dropouts due to lack of efficacy May be more acceptable to an ethics commission Tendency to minimize efficacy differences Larger sample sizes Higher study costs 	<ul style="list-style-type: none"> Risk of false studies because assay sensitivity is lacking Equivalence/noninferiority not suitable as proof of efficacy Active comparator may not be standard therapy More dropouts due to adverse events



After claiming that all example cannabis studies were “deeply flawed”, and subsequently attempting to use their negative qualities to bolster the claims it was further stated that in fact no studies at all used placebo. Even though the logic presented attempts to use RCTs as some sort of infallible technology [“Findings from RCTs may not be valid beyond the study population”](#) per [“Evidence for Health Decision Making — Beyond Randomized, Controlled Trials”](#). This of course makes the inflated focus on this type of testing questionable in context of approval of Marijuana for Autism.

The stance presented that "To determine the true clinic impact of cannabis for children with autism, a well-designed clinical investigation utilizing placebo-control approach and validated outcome measures is needed", is simply false.

proposed and discussed among autism researchers and families of children with autism each year. To determine the true clinic impact of cannabis for children with autism, a well-designed clinical investigation utilizing placebo-control approach and validated outcome measures is needed. Further, autism is a heterogeneous condition with significant individual variation in quality and severity of symptoms. Treatment studies o

The paper "Evidence based medicine: what it is and what it isn't" states that "Criticism has ranged from evidence based medicine being old hat to it being a dangerous innovation, perpetrated by the arrogant to serve cost cutters and suppress clinical freedom". It is unclear why The State Medical Board of Ohio chose to ignore these obvious lines of bias in their decision making process.

There is no shortage of criticism from NIH, and other entities on this standard that is being propped up by The State Medical Board of Ohio with the help of Cincinnati Childrens, and Nationwide Children's. "Even so-called "gold-standard" RCT's can be undermined by poor study design" according to NIH paper "Identifying and Avoiding Bias in Research". The board seems to want to hide behind the two papers as a means to absolve itself of the responsibility of further "review", and "consideration" of evidence.

The largest population of Ohio patients is Post-traumatic stress disorder with upwards of 48,322 patients, somehow however as noted above by the NIH stidues, Marijuana efficacy for treatment of PTSD is only supported by weak evidence, and it is similarly not supported for use by "double blind" studies. Why is it that PTSD can be approved on such a weak foundation, but Autism must be held to a higher standard for some reason?

Everyone is clueless!?

Statements made on the "vulnerable population", and the "understanding" of Marijuana in this population being "unknown" is another fine piece of negligent unethical hyperbole that has been consumed by The State Medical Board of Ohio in their decision making process.

It should be again noted that the same level of professional scrutiny being applied to marijuana is not afforded to other drugs like Guanfacine. The exaggeration of psychosis below for example can easily be compared to the NIH paper

“Psychosis associated with guanfacine”. How does the board handle Guanfacine, certainly not a wholesale denial of its use? It does so with reasonable measures that are put in place to monitor the side-effects, and communicate with the patient through shared responsibility, and informed decision making.

Lastly, the psychoactive effects of THC pose significant threats for our population of persons with autism, in particular, those with communication deficits who cannot self-report internal states of displeasure, confusion, or psychosis induced by THC. Given this, it is of paramount importance to study cannabis use in autism in a controlled clinical trial setting with sufficient observation for safety and tolerability. There is no available understanding of how to dose cannabis in autism or what the impact combining THC containing cannabis and prescribed drugs will have in this vulnerable population. Many youth and adults with autism take other psychoactive FDA-approved drugs to treat interfering symptoms such as anxiety, irritability, and ADHD and the

Deny the whole thing because of “children”?

One final fallacy associated with the denial of Autism as a qualifying condition is that the entire denial seems to hinge on fear, uncertainty and doubt aka FUD around minors using marijuana. Both papers put an unnatural focus on children, however coming out of two Children’s hospital organizations in this case excuses the bias partially. Where the bias is inexcusable is when it is used to deny everyone access, as opposed to just children.

We continue to support and hope for high quality unbiased research on this topic, however, do have significant concerns about prematurely approving medical cannabis for treatment of serious developmental and psychiatric conditions. We are closer than ever in our ability to systematically study the benefits vs. risks of these products on the brains of our kids. There are several well designed, randomized, double-blind placebo-controlled trials currently underway at several leading institutions

The problem with this logic being used for a denial is that patients that are “under 18” only represent 0.20% of the OHMM population. Wholesale denying Autism as a qualifying condition for adults because of fears in a small population of minor patients within the OHMM program is “unethical”, and “negligent”.

We recognize that autism is a lifelong disorder associated with significant communication, social and behavioral challenges that can greatly impact daily life for children and their families. We also recognize there is need to develop additional treatments that target these challenges. Cannabis is one of innumerable treatments proposed and discussed among autism researchers and families of children with autism each year. To determine the true clinic impact of cannabis for children with autism, a well-designed clinical investigation utilizing placebo-control approach and validated outcome measures is needed. Further, autism is a heterogeneous condition with significant individual variation in quality and severity of symptoms. Treatment studies of autism should more systematically aim to determine what subgroups or specific characteristics of autism are best targeted by the treatment in question. In Ohio, there is clear opportunity to rigorously study the clinical effectiveness of cannabis for children with autism. Our signatories include Schedule 1 DEA license holders at academic centers with autism specialty clinics who are in a position to conduct the studies required to evaluate the efficacy of cannabis for children with autism. Adding autism as an indication for medical marijuana use without compelling scientific evidence will undermine any efforts of autism researchers in Ohio to rigorously study efficacy of cannabis for children with this disorder. This, in turn, will prevent providers and families from obtaining accurate, scientifically-based information from which to make clinical decisions about cannabis use for children with autism.

Autism should be treated the same as “Chronic Pain” that is intractable.

It is clear that The State Medical Board of Ohio has a lack of methodology for consideration, and review of qualifying conditions. In order to make things less complicated for the board it is suggested that the board embrace the mental pain that Autism patients experience, and allow them to relieve their chronic intractable mental pain via Marijuana.

"The Concept of Mental Pain", that in the case of Autism is obviously intractable as acknowledged by the board, simply can not be ignored further. It is negligent, and unethical to do so.

<https://www.karger.com/Article/FullText/343003>

All parties involved seem to acknowledge the parameters around mental pain, and recognize by nature that this pain is intractable.

Dr. Bechtel stated that Committee has previously considered autism as a qualifying condition for treatment with medical marijuana. The Committee has reviewed the new literature that was included in the two current petitions for autism. Dr. Bechtel stated that autism is a devastating condition for the patients and their families, noting that therapy is challenging and many therapies currently utilized have significant side-effects. The Committee greatly appreciates the concerns that families have expressed and the sincerity of the petitions.

obesity, and potential decline in personal engagement later in life.

Dr. Schottenstein appreciated Dr. Bechtel's comments and he also regretted the emotional pain that families manage when there are children in the home with autism. Dr. Schottenstein was also respectful of the concerns noted by experts about the minimal rigorous evidence that medical marijuana is beneficial for autism and the substantial association of marijuana with the worsening of

Summary

The State Medical Board of Ohio has shown obvious bias in the decision making process. Autism is not subject to the same freedoms that other approved conditions have been afforded. The board unfortunately lacks a methodology which will continue to exacerbate subjective decision making processes around qualifying conditions for Marijuana. In order to remove bias, and discrimination against Autism patients the board should treat the condition as intractable (mental) pain, and allow the doctor-patient relationship to regulate any "potential" concerns.



in·träc·ta·ble

/,in'traktəb(ə)l/

adjective

hard to control or deal with.

"intractable economic problems"

Similar:

unmanageable

uncontrollable

ungovernable

out of control

out of hand



- (of a person) difficult or stubborn.

Similar:

stubborn

obstinate

obdurate

inflexible

unadaptable

unmalleable

