



FAACT.Iowa@gmail.com

Petition for Addition of Adult Autism
with Aggression and/or Self-injury

RECEIVED

FEB 04 2019

Office of Medical CBD
Iowa Dept. of Public Health



BEFORE THE IOWA MEDICAL CANNABIDIOL BOARD

F.A.A.C.T. (Families and Autism Advocates for Cannabis Treatment)

Petition by (Your Name)

for the (addition or removal) of

Adult Autism with Aggression and/or Self-Injury



PETITION FOR ADDITION or REMOVAL (Circle one)

(medical condition, medical treatment or debilitating disease) to the list of debilitating medical conditions for which the medical use of cannabidiol would be medically beneficial.

Petitioner's Information form with fields for Name, Home Address, City, State, Zip Code, Telephone Number, Email Address, and a Yes/No question.

Representative's Information form with fields for Name, Mailing Address, City, State, Zip Code, and a Yes/No question.

RECEIVED

FEB 04 2019

Rev. 03/2018



Telephone Number: (319) 855-3287		Email Address: robertsmaryj@icloud.com	
1. Please provide the name of the specific medical condition, medical treatment, or debilitating disease you are seeking to add to or remove from the list of debilitating medical conditions for which patients would be eligible to receive a medical cannabidiol registration card. <i>Please limit to ONE condition, treatment, or debilitating disease per petition.</i>			
Recommended Action		Condition or Disease	
<input checked="" type="checkbox"/> Add <input type="checkbox"/> Remove		Adult Autism with Aggression and/or Self-Injury	

2. Please provide a brief summary statement that supports the action urged in the petition. *Attach additional pages as needed.*

See attached



3. Please provide a brief summary of any data or scientific evidence supporting the action urged in this petition. *Attach additional pages as needed*

See attached

4. Please provide a list of any reference material that supports your petition.

See attached



5. Please provide a list of subject matter experts who are willing to testify in support of this petition (if any). The list of subject matter experts must contain names, background, email addresses, telephone numbers, and mailing addresses. *Attach additional pages if needed.*

Name	(1) Suzanne Bartlett Hackenmiller MD	(2) Alyson Beytien	(3) Tom Braverman
Background	See attached	See attached	See attached
Email address	sbartlett@cfu.net	abeytien@gmail.com	bravezeus@yahoo.com
Telephone number	319-883-9183	563-585-0560	319-541-3739
Mailing address	1724 Whispering Pines Circle, Cedar Falls, IA. 50613	1235 Arrowhead Rd. Dubuque, IA. 52003	428 S. Summit St. Iowa City, IA. 52240

6. Please provide the names and addresses of other persons, or a description of any class of person, known by you to be affected by or interested in the proposed action which is the subject of this petition. *Attach additional pages if needed.*

See attached



7. Please indicate whether you have attached a brief in support of the action urged in the petition.	Yes	No X
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8. Please indicate whether you are asking to make an oral presentation of the contents of the petition at a board meeting following submission of the petition.	Yes X	No
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9. Acknowledgement and Signature

By signing this document, I certify that the information provided in this petition is true and accurate to the best of my knowledge.


Signature

01/30/2019
Date (mm/dd/yyyy)

- Please fill out each section that is applicable to your petition. Failure to conform to what is required in this petition may result in a denial of consideration by the board.
 - You do not need to fill out sections asking for your representative's information if you do not have one.
 - For section 2, please provide a short, essay-like summary of your argument.
 - For section 3, please provide a short, essay-like summary of the articles and evidence that supports your position (if any).
 - For section 4, please provide a list of articles that are in support of your position (if any).
 - For section 5, please provide a list of experts that would be willing to testify in support of your position (if any). In the background section, please provide the reasons why they should be considered experts in the area: education, credentials, field of study, occupation, etc. This section is optional but will greatly aid in helping the board consider your petition.
 - For section 6, please provide information about groups of people that will be affected if the petition were approved. This could include people suffering from a specific disease, advocacy groups, local government officials, etc.
 - Sections 7 and 8 are optional but may aid the board in considering this petition.
- Please be aware:
 - The board may request that you submit additional information concerning this petition. The board will notify you of the requested materials in the event that more information is needed.
 - The board may also solicit comments from any person on the substance of this petition.
 - The board may also submit this petition for a public comment period where any interested person may comment.
 - The board has six months after you submit this form to either deny or grant the petition. If approved, you will be notified in writing that the board has recommended the addition or removal of the medical condition, treatment, or debilitating disease to the board of medicine. If denied, the board will notify you in writing the reasons for denial.



- If the board denies your petition for failure to conform to the required form, you will be allowed to correct the errors and resubmit for consideration.
- **After you have completed this petition, please make sure that you sign, date it, and email, mail, or hand deliver to:**

**Iowa Department of Public Health
Office of Medical Cannabidiol
Lucas State Office Building
321 E. 12th Street
Des Moines, IA 50319-0075
Email: iamedcbd@idph.iowa.gov
Phone: (515) 281-7996**

Attachments

Section 2 - Summary Statement:

Adults with autism face myriad challenges in their homes, in their communities, and in the healthcare system. Many of those struggles can be attributed to a lack of access to residential services, experienced and confident prescribers, employment, evidence-based therapies like applied behavior analysis, and other luxuries often afforded to children with the same disorder.

The Iowa Cannabidiol Board and Iowa Medical Board recently included “severe pediatric autism” as a qualifying condition for access to medical cannabis. This petition posits that the same logic used to include children with autism should be applied to adults with the same condition. The difference between a 17 year-old and an 18 year-old with autism can be as arbitrary as a single day. The need for effective treatment spans the lifetime, arguably becoming more important as a person engaging in self-injury and aggression grows bigger and stronger.

The importance of the first step to include “severe pediatric autism” cannot be overstated—neither can its potential analogue for adults.

Section 3 - Scientific Evidence:

Please see enclosed packet entitled “Medical Studies and Scholarly Articles”

Section 4 - Reference Material:

Please see enclosed packets entitled “Medical Studies and Scholarly Articles” and “Letters of Support”

Section 5 - Subject Matter Experts:

1. Suzanne Bartlett Hackenmiller, MD, FACOG, ABOIM

Background: Parent of an 18-year old with autism, Autism Society of Iowa board member and past board president, OB-Gyn and Integrative Medicine physician.

2. Alyson Beytein

Background: Parent of three young adult sons with autism, one of whom has severe autism. Board Certified Behavior Analyst, author, consultant, international speaker on autism behavior, advocate.

3. Tom Braverman

Background:

"My name is Tom Braverman and I have been an at-risk and special education teacher for over 30 years. The students I have worked with range from those with significant intellectual disabilities, autism spectrum disorders, learning disabilities, behavioral disabilities and some have been non-verbal and sight impaired. I have also been a direct care professional working with this same population, as well as a job coach for people with barriers to employment. At the same time I have served on boards of organizations dedicated to providing services to people with disabilities. I do this because I believe it is important to serve as an advocate for those who are often unable to advocate for themselves. Currently I serve as the board president for Eastern Iowa's largest supporting living, day habilitation and supported employment organization who serves people with intellectual, behavioral and physical disabilities. I am also the faculty sponsor of our high schools chapter of Best Buddies International, an organization dedicated to improving the lives of people with intellectual disabilities by providing socially inclusive opportunities where they interact with their non-disabled peers.

As a lifetime resident of Iowa City, Iowa (428 S. Summit St.) I have witnessed a large influx of people with intellectual disabilities, physical and behavioral disabilities to our community who are in search of the necessary supports that they require in order to live as independently as possible. Most often, their towns or cities do not have agencies or trained personnel who can provide the services they need. As Iowa City becomes a destination for this population, a myriad of agencies

have come into existence in our area, and as board president of one of those agencies I am committed to making it more consumer friendly and to making it an agency that is able to provide for the needs of all people, regardless of how energy intensive and costly those supports are. At the same time I am an advocate for the hundreds of people who we employ so that they can earn a living wage doing work that is often physically and psychologically taxing. Iowa has the lowest unemployment rate in the nation and we need to make sure we are justly compensating our employees and that we are making the many settings in which they work as safe and inviting as we possibly can.

With shrinking funding streams available for our most vulnerable population, it is imperative that we seek out new, economically feasible and innovative methods for addressing the needs of the people we serve. With that being said, some of my students and people served by the agency I am president of regularly display behaviors of concern, and despite ABA and traditional pharmacological approaches designed to address those behaviors, they persist. We therefore need to be open to trying new approaches including those involving products derived from marijuana in an effort to help people reduce or extinguish behaviors which serve as barriers to healthy and productive lives. It is for this reason that I have agreed to serve on this panel.

*Sincerely,
Tom Braverman”*

Section 6 - Other Affected and Interested Parties:

Please see enclosed packet entitled “Letters of Support”

Letters of Support

1. Autism Society of Iowa - Stakeholder Organization
2. Olmstead Consumer Taskforce - Stakeholder Organization
3. Suzanne B. Bartlett Hackenmiller, MD, FACOG, ABOIM - Physician, Parent
4. The Village Community - Stakeholder Organization
5. Alyson Beytien, BCBA - Parent
6. Deb Scott-Miller - Autism Consultant
7. Brenda Kurtz - Co-founder, Executive Board, The Village Community
8. Ned Szumski - Community Services Provider
9. Marc Hines - Community Services Provider
10. Sarah Schrader - Parent
11. Iowa City Autism Community - Stakeholder Organization
12. Brian Hagmeier - Parent
13. Brittany Hodge, MS, CCC-SLP - Provider, Speech-Language Pathologist
14. Elizabeth Friedrich - Parent
15. Mallory McWilliams - Community Services Provider
16. Jason Matiyow - Registered Nurse, Family Member
17. Jody Schiltz - Parent
18. Margaret Dunn, PhD - Supporter
19. Laura Striegel - Parent
20. Ann D. Benge - Community Member

 **AUTISM SOCIETY**
Improving the Lives of All Affected by Autism
Iowa

Iowa Board of Medicine 400 SW 8th Street, Suite C Des Moines, IA 50309

11/19/18

To Whom it May Concern,

The Autism Society of Iowa Board of Directors has approved submission of this correspondence, encouraging approval by the Iowa Board of Medicine for the addition of autism as a qualifying condition for the Iowa Medical Cannabidiol Program.

Autism spectrum is a set of complex neuro-developmental disorders defined behaviorally by impaired social interaction, delayed and disordered language, repetitive or stereotypic behavior, and a restricted range of interests. Many individuals with autism have symptoms of associated medical conditions, including seizures, sleep problems, metabolic conditions, and gastro-intestinal disorders, which have significant health, developmental, social, and educational impacts. The disorder can often include severe behavioral presentations, including significant self-injury, aggression, and property destruction. The impingement of autism on autistic individuals, their families, and society is extensive.

There are currently eight states which have autism as a qualifying condition for medical cannabis, including Delaware, Utah, Georgia, Louisiana, Michigan, Minnesota, Pennsylvania, and Rhode Island. Six other states are considered "autism friendly" because their laws allow for a doctor's discretion to recommend medical cannabis for debilitating conditions. These include California, Florida, Oklahoma, Oregon, Massachusetts, and Washington DC.

The fact that the Iowa Medical Cannabidiol Board on 11/2/18 voted to recommend that Iowa add autism to the list of qualifying conditions was unexpected yet fantastic news. Having cannabidiol as an option for individuals with autism will offer a safe yet therapeutic option, especially for those with more significant behaviors, including self-injury and aggression. These behaviors severely limit the quality of life for the individual, as well as their caregivers, teachers, medical staff, and other providers. The addition of cannabidiol may mitigate many of these dangerous behaviors and allow the individual to have a more fulfilling, inclusive quality of life.

Studies have shown the efficacy and safety profile of cannabidiol outweighs many of the alternative psychotropic medications currently allowable and prescribed to this population. Having access to a safer yet effective medication will lead to fewer crisis situations, hospitalizations, increases in antipsychotics with long term problematic side effects, and other dangerous PRN medications.

Currently, only two atypical antipsychotic drugs are approved by the Food and Drug Administration to treat symptoms of autism in the United States. However, like many medications, they do not work for all patients and can have serious side effects including significant weight gain and altered hormone production.

 **AUTISM SOCIETY**
Improving the Lives of All Affected by Autism
Iowa

Points of relevance:

- There is abundant science, research and anecdotal evidence that points to the efficacy of cannabidiol in autism • The US government has a patent on certain cannabinoids for their medicinal properties • Cannabis has an unparalleled safety record and there is little risk of dangerous side effects • Cannabis is used medicinally in pediatric epilepsy, cancer, and other qualifying conditions in states where it is legal • Many existing qualifying conditions are co-morbid with autism • There is great versatility of strains and delivery methods for cannabis treatment • Medicinal cannabis has the potential to be both palliative and curative • There are now eight states that allow direct access for autism

Some recent/relevant articles:

1) Aran A1, Cassuto H2, Lubotzky A3, Wattad N3, Hazan E3.

"Cannabidiol-Rich Cannabis in Children with Autism Spectrum Disorder and Severe Behavioral Problems- A Retrospective Feasibility Study."

Journal of Autism and Developmental Disorders. 2018 Oct 31. doi: 10.1007/ s10803-018-3808-2.

Neurology Apr 2018; 90 (15 Supplement) P3.318

"Following the cannabis treatment, behavioral outbreaks were much improved or very much improved in 61% of patients. This preliminary study supports feasibility of CBD

based cannabis trials in individuals with ASD. This retrospective study assessed the safety, tolerability, and efficacy of cannabidiol (CBD) based medical cannabis, as an adjuvant therapy, for refractory behavioral problems in children with ASD. Following the cannabis treatment, behavioral outbreaks were much improved or very much improved in 61% of patients. The anxiety and communication problems were much or very much improved by 39% and 47% respectively. Disruptive behaviors were improved by 29% following the treatment. Parents reported less stress as reflected in the APSI (Autism Parenting Stress Index) scores, changing by 33%."

2) <https://health.ucsd.edu/news/releases/Pages/2018-04-26-study-to-explore-whethercannabis-compound-eases-severe-symptoms-of-autism.aspx>

"Study to Explore Whether Cannabis Compound Eases Severe Symptoms of Autism"

"Considered the most promising study about the relationship between cannabis and autism, this project was kickstarted with a donation of \$4.7 million to the Center for Medicinal Cannabis Research (CMCR) at the UC San Diego School of Medicine. (This is considered the largest private donation to date for medicinal cannabis research in the US) The goals of the study include whether cannabis treatment is safe, tolerable, and effective in children with autism. The scientists predict research using the CBD for treatment, the substance of the plant that does not cause psychoactive effects and is most suitable for

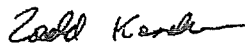
 **AUTISM SOCIETY**
Improving the Lives of All Affected by Autism
Iowa

medical purposes. In addition, they seek to conclude whether the CBD alters the chemical messengers known as neurotransmitters, and how this process occurs, whether it can improve brain connectivity and whether there is any change in biomarkers of brain inflammation, a symptom also associated with autism.”

In closing, the Autism Society of Iowa is in favor of including autism as a qualifying condition for the Iowa Cannabidiol Program. We are happy to answer questions, provide additional information specific to autism, connect the Board to families and other stakeholders, or anything else that might be helpful in reaching your decision.

Sincerely,





Kris Steinmetz, Autism Society of Iowa Executive Director

Todd Kopelman, Ph.D., Autism Society of Iowa President



Iowa's Olmstead Consumer Task Force

12/7/18

To the Iowa Board of Medicine,

The Olmstead Consumer Taskforce is a statewide advocacy group charged by Executive Order to monitor Iowa's response to the 1999 Supreme Court's Olmstead Decision, shifting focus and resources from institutions to home and community-based settings.

Our activities support the full inclusion of people with disabilities in housing, employment, transportation, healthcare, and other areas. We work with consumers and families, state agencies, providers, and others to ensure that legislation, changes in administrative rule, and other public policies and programs promote the full inclusion of individuals with disabilities in all aspects of life in the community.

Our Board has voted to support community initiatives and the recent Iowa Cannabidiol Advisory Board's recommendation promoting cannabidiol access to individuals with autism.

One of the Iowa Olmstead Taskforce's primary strategic priorities is to ensure choice to our citizens with disabilities. Having the option to access a safe, therapeutic product to help maintain an individual's ability to remain in a community-based setting certainly falls within our purview and we advocate for access.

Many individuals with autism experience significant incidences of aggression and self-injury, due to overstimulation, pain of unknown etiology, inability to self-regulate, and many other reasons. At this point, families are left with the choice of harmful psychotropic medications carrying aberrant immediate and long-term side effects, hospitalizations, out-of-home placements, and other adverse options.

There is also an increasing rate of "medical refugee" families. Those choosing to leave the state (their *home*) to move to an area they can access a broader range of care options, including medical cannabis, for their affected loved one.

We as a state can do better. The OCTF respectfully recommends that you strongly consider approving autism to the list of qualifying conditions for the Iowa Cannabidiol program.

Thank you for your consideration.

Sincerely,

A handwritten signature in cursive script that reads "Dawn E. Francis".

Dawn E. Francis
Chair
Iowa Olmstead Consumer Task Force

VAN DIEST MEDICAL CENTER

Suzanne Bartlett Hackenmiller, MD, FACOG, ABOIM
2350 Hospital Drive
P.O. Box 430
Webster City, IA 50595

December 12, 2018

Iowa Board of Medicine
400 SW 8th Street
Des Moines, IA 50309

Dear Members of the Medical Board:

I am writing to support the recommendation by the Iowa Medical Cannabidiol Board that autism be added to the list of conditions that are approved for treatment with medical cannabis. Given the difficulties in treating severe autism with physically aggressive behaviors, I believe this to be a very appropriate decision by the Iowa Medical Board.

By way of introduction, I am a board-certified obstetrician gynecologist currently practicing in Webster City, Iowa. I am also the parent of an 18-year-old son with autism and, as such, have served on the board of the Autism Society of Iowa for 15 years and am a Past President of the organization. I currently serve on the University of Iowa Autism Center Advisory Council, among other autism-related advocacy roles. Partly because of my son's condition, I completed a two-year highly rigorous fellowship in integrative medicine through the University of Arizona and remain one of the only (if not the only) fellowship-trained and board-certified physicians in integrative medicine in the state of Iowa. Integrative medicine combines conventional medicine with *evidence-based* complementary and alternative treatment modalities. I believe my medical training and personal experience with autism offers me a uniquely qualified perspective in this discussion.

You are receiving a letter of endorsement from the Autism Society of Iowa (ASI) therefore I will not repeat the points of relevance or resubmit the research that was contained in that letter, other than to say that I completely support ASI's position.

In my training and ongoing continuing education, I have studied and worked with a number of physicians who are pioneers in the realm of medical cannabis use. These include Donald Abrams, MD, renowned Integrative Oncologist at UCSF who presents on the topic and has written extensively on the use of medical cannabis, and Danielle Gordon, MD, who works and speaks internationally on the subject of medical cannabis, among other leaders in the field. In preparation for this letter, I spoke with Dr. Gordon. While we all acknowledge that research is in its infancy, I found it helpful to hear from Dr. Gordon that she belongs to a closed group of



December 7, 2018

I am writing on behalf of The Village Community to express our support of adding autism as a qualifying condition for Iowa's Cannabidiol program.

The Village Community is a non-profit, 501c3 organization located in Johnson County with the mission of supporting individuals with developmental and intellectual disabilities so that they can maintain good health, quality of life and increased independence. The majority of our program participants are on the autism spectrum and therefore struggle to be appropriately social and functionally communicative. Their inability to do so often leads to challenging behaviors that includes aggression against themselves and others. For many of these individuals, traditional medications have been ineffective at reducing or eliminating these behaviors. Other times, despite their effectiveness, the medications have been discontinued due to the adverse side effects experienced by the individual. In some instances, individuals have required out of home placement, in either a hospital or institutional setting, so that the individual can be sufficiently sedated, restrained, or isolated leading to increased trauma and stress to the individual and their family and caregivers. If it were not for the challenging behaviors these individuals could more functionally, appropriately, and successfully participate in their daily lives.

In other states where access to cannabis is less limited, people with autism have seen improvement in attention and functional communication and therefore a reduction in challenging behaviors, most importantly those behaviors that cause harm to self and others. It seems only right and fair that citizens of Iowa be given the same access to medical care as is afforded citizens of other states. The use of cannabis can potentially improve the effectiveness of other evidence-based practice approaches such as ABA and positive behavior supports, because the individual will be better able to focus and attend to the instruction and be less agitated by external stimuli. Since the negative side effects of cannabis are minimal to non-existent, the individual's medical and educational teams will have fewer variables to consider when evaluating overall program effectiveness.

In closing, it is my hope that the members of the Iowa Board of Medicine will vote in favor of adding autism to the list of qualifying conditions, therefore giving the opportunity for improved quality of life to the citizens of our state who suffer from the debilitating symptoms of autism.

Thank-you for your consideration,

Ann Brownsberger.

Executive Director, The Village Community

The Village Community
5305 Herbert Hoover Highway
West Branch, Iowa 52358-9543

thevillagecommunity@post.com
www.thevillagecommunity.org

Iowa Board of Medicine
400 SW 8th Street
Des Moines, IA 50309

November 28, 2018

Dear Iowa Board of Medicine,

This letter supports the inclusion of individuals with autism in the Iowa Medical Cannabidiol Board recommendation of qualifying conditions. Autism is a very complex disorder, which can often result in significant self-injurious behavior to the individual and physical aggression to family members and support staff. This has been true for my son, [REDACTED]

[REDACTED]; significant physical aggression has led to an out-of-state placement from 2007-2011, placement at Woodward Resource Center from 2011-2012, and placement in a community-based, 24/7, 1:1 staff support environment from 2012 through today. The physical aggression has caused him to have 5 broken bones in the past 2 years; surgery, casts, and permanent physical impairment. The high-level of medication caused a Neuroleptic Malignant Syndrome episode in 2012 that nearly cost him his life. His physicians have prescribed everything from anti-depressants to anti-seizures to anti-psychotics. He has experienced EVERY medication known by his physicians including nicotine patches and a 2-week Oxycontin trial. Despite significant investment in best practice strategies and financial support from the state of Iowa, NOTHING has given him relief from anxiety, frustration and constant agitation. The best support team and the best physicians that Iowa can provide has not made a difference. He is miserable and unhappy. The availability of Cannabis as another treatment option would hopefully relieve these significant symptoms without the use of increasingly toxic and dulling medical drugs.

Individuals with autism deserve the chance to access Cannabis to relieve significant symptoms of distress, self-injury and aggression. Please consider including individuals with autism in the Iowa Medical Cannabidiol Board recommendation of qualifying conditions. Consider giving families of individuals the autism the opportunity to choose a drug that will not cause severe side-effects.

Thank you,

Alyson Beytien
1235 Arrowhead Dr.
Dubuque, IA 52003
abeytien@gmail.com

Iowa Board of Medicine
400 SW 8th Street
Des Moines, IA 50309

November 28, 2018

Dear Iowa Board of Medicine Members,

This letter supports the inclusion of individuals with autism in the Iowa Medical Cannabidiol Board recommendation of qualifying conditions. Over the past forty-four years, I have worked as a special education teacher and consultant in Michigan, Wisconsin, and Iowa supporting students with autism. Autism is a very complex disorder, which can sometimes result in significant self-injurious behavior to the individual and physical aggression to family members and support staff. As a result, individuals and their families are unable to access the support services needed, and at times, may be at a safety risk.

Despite significant investment in best practice strategies for working with individuals with autism, there are times when anxiety and overstimulation become too much for both our adults and children. At these times, behavior interventions and accommodation supports simply can't relieve the pain that these people are experiencing. Parents, caregivers, teachers, and support staff are unable to keep these individuals safe or keep others safe. Medical intervention is the only option and the availability of cannabis would relieve these significant symptoms without the use of increasingly toxic and dulling medical drugs.

Individuals with autism deserve the chance to access cannabis to relieve significant symptoms of distress, self-injury and aggression. Please consider including individuals with autism in the Iowa Medical Cannabidiol Board recommendation of qualifying conditions. It would save lives.

Thank you,

Deb Scott-Miller
1820 Rochester Court
Iowa City, Iowa 52245
319-331-4026

Iowa Board of Medicine
400 SW 8th Street
Des Moines, IA 50309

December 7, 2018

Dear Members of the Board,

I am writing today to request that the Iowa Board of Medicine strongly consider the recent recommendation by the Iowa Medical Cannabidiol Advisory Board to add autism to the list of qualifying conditions.

As an Executive Board member and co-founder of The Village Community in Iowa City, I regularly witness the difficulties faced by parents of children with autism diagnoses. As our organization serves young adults (as opposed to children), by the time these families are seeking our services, they have literally "tried everything." Some of these families have endured years (even decades) of the stress which accompanies guardianship responsibilities for an individual with a severe autism diagnosis. There is often self-harm or otherwise injurious or unsafe behavior, which puts the individual – as well as their family members and support providers – at risk.

And yet, with what instruments do we equip these families to keep themselves, their loved ones, educators, and care providers safe? A long list of "approved" pharmaceuticals that illicit serious side effects. And many of those side effects will eventually preclude the individual's ability to continue a medication.

Take, for example, antipsychotics – routinely prescribed for individuals with autism who exhibit severe mental health disturbances (unable to be treated with less-harmful medications). For most patients, antipsychotics are a drug of last resort, due to significant and harmful side effects. Many individuals must eventually discontinue these meds due to adverse effects, such as rapid or uncontrolled weight gain (eventually causing secondary high blood pressure/cholesterol, sleep apnea, heart disease, or diabetes). In addition, antipsychotics may induce tardive dyskinesia, which can become yet another permanent debilitating condition.

As parents/guardians, we are faced with an impossible choice: do I treat my child's severe and debilitating mental health issues at the expense of their physical health and longevity? In other words, "Do I want my child to live a physically unhealthy (and potentially shortened) life in order to relieve a bit of their mental anguish? Or do I forgo the physically unhealthy pharmaceutical so that my child may live a longer, albeit tortured, life?" Please note: there is presently no such thing as a "long and happy life" for our kids who suffer serious mental health issues that are not alleviated by currently-available, low-side-effect drugs.

However – you have the enviable power to change this outlook. With its low side-effect profile and potentially high efficacy, Cannabidiol could be an answered prayer to many Iowa families. I respectfully ask that you seriously consider the inclusion of autism as a qualifying condition, as recommended by the Iowa Medical Cannabidiol Board. No doubt, the Board did not arrive at this decision lightly. Whatever drawbacks there may be (I cannot think of any for a population that is currently over-medicated on harmful pharmaceuticals), they are far outweighed by the benefits of this important inclusion.

Respectfully,

Brenda Kurtz
3442 Donegal Court
Iowa City, IA 52246

Ned Szumski
2061 Kountry Ln. SE #2
Iowa City, IA 52240
(319) 321-0456

December 12, 2018

TO THE IOWA BOARD OF MEDICINE

A Letter In Support of the Approval of CBD Treatment for Individuals with Autism Spectrum Disorder

I write to encourage the board to approve cannabidiol (CBD) as a treatment for behavioral and mental-health symptoms in individuals with Autism Spectrum Disorder (ASD).

For 19 years, I've provided/overseen supported community living (SCL) services for individuals with disabilities. I have worked with more people with ASD than I could possibly count. I teach classes within my company—one includes a primer for understanding and helping meet the needs of people with ASD; another teaches how to prevent behavior crises and/or respond when they occur.

Life is disproportionately and perpetually stressful for many individuals with autism. Many are constantly exposed to a barrage of amplified sensory input they can't readily process. Many have demands placed on them by caretakers that frustrate their abilities and patience. Many often might feel like they're snorkeling through a mire of life events—frequently surprised, confounded, and battered by what they encounter; and never achieving much sense of control.

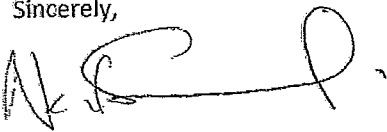
All of these stressors and more, for so many people I've known, have a way of piling up and contributing to crisis behavior that can quickly bring on a lifetime of labels, ostracism, contemptuous treatment—and even, sadly, abuse.

Psychotropic polypharmacy is not just common, it's pretty much the rule. Anxiolytics are probably the most common. Some take anti-depressants, or even antipsychotics or mood stabilizers. A troubling number of them take a combination of several drugs across categories, as physicians struggle to find ways to help patients cope. The willingness to add another new drug treatment always outstrips the will to discontinue one that isn't working well enough to justify the side effects. None of them is ever especially effective.

While there does need to be more research on the benefits of CBD (and other cannabis treatments) for individuals with ASD, early research has been quite promising in significantly reducing anxiety and challenging behavior. The side effects of CBD are all but negligible when compared the side effects of almost any category of psychotropic drug (antipsychotics in particular, as you are no doubt aware).

I hope you will agree there is scarcely any downside to adding CBD as a far more benign—and more effective—tool in a box full of blunt instruments.

Sincerely,



Ned Szumski

FAACT
P.O. Box 5284
Coralville, IA 52241

December 11, 2018

Dear Iowa Board of Medicine:

My name is Marc Hines. I have spent the last 13 years of my life working with people on the autism spectrum across the state of Iowa in schools, day programs, supported community living homes, and hospitals. I've worked with children as young as 3 and adults as old as 85. For the entirety of my career, I've focused on people with significant behavior and mental health needs—specifically people who engage in severe self-injury, aggression, and property destruction.

The road to stability for these individuals is paved with misdiagnoses, pain, rotating casts of caretakers, and ever-changing medication regimens. Children with ASD are exposed to antipsychotics, mood stabilizers, and stimulants early and often. They become adults with decades of exposure to side effects—weight gain, cognitive slowing, tardive dyskinesia, and cumulative effects on livers and kidneys.

A growing body of anecdotal evidence shows that cannabis can be an effective treatment for the symptoms of autism. I've seen firsthand what cannabis can do. I've listened to parents talk about their life-changing experiences: the vast improvements, the elimination of toxic interventions, and the shrieks turned to smiles.

Cannabis is not the answer for everyone, but it might be the answer for some—one with far fewer deleterious effects on a patient's body. People with ASD, especially children, deserve a chance to find out if it's their answer.

In advocacy,

Marc Hines

Iowa Board of Medicine
400 SW 8th St.
Des Moines, IA. 50309

12/1/18

Dear Board Members,

There are many families anxiously awaiting Christmas right now. Parents are anticipating their children's joy when they finally get to wake up and tear into all the wrapping paper. Kids are staring at wrapped boxes with equal parts exhilaration and impatience, trying to guess if anything from their list made it under the tree. Finally getting the chance to rip apart those presents leaves smiles on everyone's faces. Most people are excited for the gatherings with their extended families and the favorite foods, jokes, songs, games, and so on that accompany them. For the majority of families, Christmas revolves around traditions, celebrations, excitement, and joy.

For families like ours, Christmas brings mounting trepidation and anxiety. The joy of wrapping your daughter's present is absent because the sound of paper ripping only leads to sensory overload, which guarantees a meltdown. Surprises are often not welcomed with joy to many kids on the spectrum because of the anxiety that frequently tags along co-morbidly. The thought of "what is in that box?!" cycles on constant repeat until it turns from a wonder to a terror. Even once given permission to open his gift, my son is so anxious that he doesn't want to go near it, let alone see what is inside. Trying to have gatherings with extended family is another guarantee for sensory over-stimulation. Grandma's perfume smells too strong, Auntie is sitting on the couch in the spot that Dad always sits in and she doesn't belong there. The cousins are playing a game and **THEY ARE SO LOUD THAT HIS HEAD FEELS LIKE IT WILL EXPLODE!** The Christmas music playing in the background, everyone talking and catching up on the family gossip, the lights on the tree are constantly blinking, the mix of all the different smells coming from the kitchen overwhelming a sensitive nose and stomach, the usually predictable actions and routines from family members seem to have become absolute chaos in a matter of minutes.....it all adds up to an experience that no one wants to attempt again. That is, obviously, only a fraction of a glance at how autism truly impacts every single facet of our life.

My name is Sarah Schrader and my husband is Brandin Schrader. We have eight children, ranging in ages from twelve years old down to 8 months old. Three of our children have been diagnosed as moderate to severe autism, and are also nonverbal. We live in the tiny town of Eddyville, Iowa. We genuinely believed that raising up our kids in the proverbial "small town, America", right smack in the middle of the heartbeat of the Midwest, was going to give our kids their best chance at their futures. We envisioned close-knit communities that would help us instill the values we wanted our kids to have, while posing a somewhat smaller risk for some of the atrocities you might see more frequently in the bigger areas. I was working as a geriatric nurse, with a passion for providing hospice care, while my husband was the actual definition of a cowboy. He trained colts and problem horses, and also did farriery work. We started our family and thought that was it now we get to raise our babies and make the memories we can look back on when we are old together. We never dreamed autism would be a word we would have to ever be familiar with and we certainly didn't ever think it would impact our every single day, in every single way. We didn't realize it would change how we looked at and planned for our futures, as well as theirs.

Living in Iowa has had many benefits but while we do our best to appreciate those, we also can't help but face the grim truth with every doctor's appointment, phone call, therapy appointment, school meeting, etc. Iowa, as a whole, is severely lacking in resources and competent, holistic care for spectrum families all across the board. When I have to take my children to the doctor or therapist and I have to explain to them what autism is, as well as what it isn't.....that is an unacceptable disservice to ASD individuals and their families. Autism seems to be the diagnosis that no one, including most medical professionals, wants to have to know much about, simply because there aren't many answers or options out there for families that have struggles like ours and more. The vast majority of the people fighting for this cause are either on the spectrum themselves, or are a family member of someone who is, because the people who experience the struggles of autism firsthand know that it is, without a doubt, cruel to deny relief to these individuals, to the ones who will bang their head on anything they can find, regardless of the injury that incurs. It is inhumane to ask a mother to watch her daughter pull her own hair out or bite herself. As a parent, when you see your child struggling in ways that leaves your heart physically aching, there is no feeling as

helpless or infuriating, especially when you know there is an option out there that could very well improve their quality of life.

I have had to search, research, dig, and practically harass the professionals to get any answers for my kids, and when I finally found a doctor who agrees that self-injurious behaviors need to be addressed, he prescribes my three year old son Risperdal. An ANTIPSYCHOTIC!!! Prescribed by a GENERAL pediatrician. I dropped the prescription off at the pharmacy and then headed home to do my own research on the medication. After reading about the medication, I had already decided that this was not a medication I felt comfortable giving my little boy. The very next day, I received a phone call from the pharmacy stating that this medication wasn't appropriate for this use in children this young so insurance was denying to fill it.

I feel like I need to state the very obvious facts. It is perfectly acceptable and legal for a pediatrician, with minimal-to-no experience in pediatric mental health or behavioral disorders and their treatment, to prescribe my child a medication that has side effects that include metabolic, neurological, and hormonal changes that can be permanent and harmful, as well as substantial weight gain, BUT it is considered taboo, unacceptable, and ILLEGAL to allow the use of medical cannabis, even though it does not cause side effects to any degree of what is listed above. The "best" arguments against allowing the use of it medicinally are that it can potentially have "negative effects" on a developing brain, such as attention, memory, and decision making skills that could last for days after it leaves the system. It is an unspeakably indignant feeling to know that its okay for a doctor, completely ignorant about autism, to give my child an antipsychotic medication that can cause permanent neurological changes, but parents are being denied the right to give their child an option that could cause temporary symptoms that they are generally already experiencing anyways. If my child already has poor decision making skills due to his autism and is also injuring himself, but there is an option for treatment out there that might not help the already poor decision making skills, but has a great chance at decreasing the self-harm?? I fail to see the logic in the argument against it.

I understand that this isn't a personal issue for majority of the people who might read my statement so it is fairly easy for this plea to be brushed aside, but PLEASE understand that we are educated. We are hard-

working. We obey the law. Most of all, we would do anything to help our kids. When it's just words on a page like mine, it's easy to forget that each of these letters belongs to a PERSON, and each person belongs to a struggle. We aren't nameless or faceless. I am Sarah and I am asking you to please allow this to happen for my six year old daughter, [redacted], my five year old son, [redacted], my four year old son, [redacted]; and all of the other kids with stories similar. The rate of incidence of kids being diagnosed with autism isn't going to slow down any time soon and as the rates increase, so do the voices of the parents desperate for something to offer their children some relief. This could literally be life-changing for all of us and you could help us turn Iowa into a state that finally has something to offer to families with autism.



Thank you for your time!
Sarah Schrader
sjschrader@live.com
(319)-795-6095
21361 Power Plant Rd., Ottumwa, IA 52501

November 16, 2018

Dear Iowa Board of Medicine,

The Iowa City Autism Community supports making CBD oil a legal option for Iowans on the autism spectrum, as recently recommended by the Iowa Medical Cannabidiol Board.

However, we are concerned that the recommendation is limited to pediatric patients. Autistic adults would also benefit from having more choices when it comes to addressing some of the challenges of autism.

If CBD oil is approved only for pediatric patients then we are likely to see autistic individuals who have benefited therapeutically from its use be denied continued access to this medication upon turning 18 years of age.

We urge you to work on behalf of all Iowans on the autism spectrum – whether they are children or adults - by giving families the freedom to have expanded therapeutic options beyond the currently available psychotropic drugs, many of which are known to have a myriad of serious and troubling side effects for patients.

Regards,

Dina Bishara and Jessie Witherell

Co-Founders, ICAC (Iowa City Autism Community)



Iowa Board of Medicine
400 SW 8th St., Suite C
Des Moines, IA 50309

12/4/18

To the Iowa Board of Medicine,

I'm a parent of 2 adults with significant autism and am writing this letter asking you to include autism, per the recommendation of the Iowa Medical Cannabidiol Board, as a qualifying condition for the Iowa Cannabidiol Program.

Autism is not a condition that improves with age, so as my children have grown to adults some of the medications that used to help them with their anxiety and self injury are no longer effective at a safe dose. Working with our doctors we have tried multiple combination of psychiatric medications over many years to help but each come with their own set of complicating and detrimental side effects.

I have visited with friends/families who have adult children on the very affected end of the autism spectrum who are "cannabis refugees" (moved their family to a state where the medication is legally accessible). While visiting, I witnessed first hand the calming effects of cannabis on both behavior (aggression and self-injury) and rigidity. I was astounded when the parents told me that not only were they being treated effectively with cannabinoids, but they were also free of harmful side effects.

Please include autism as a qualifying condition, this could be a life changing medication for my children.

Thank you for your consideration,

Brian Hagmeier
1901 13th St. Coralville, IA. 52241
behagmeier@gmail.com
(319) 855-3289

FAACT-Iowa
P.O. Box 5284
Coralville, Iowa 52241
November 28, 2018

Dear FAACT-Iowa Staff,

This letter supports the inclusion of individuals with autism in the Iowa Medical Cannabidiol Board recommendation of qualifying conditions. Over the past six years, I have worked as a speech-language pathologist and have had the opportunity to work closely with children and adults diagnosed with autism. The symptoms of autism vary greatly from person to person, but may sometimes manifest in physical and aggressive behavior, both toward the individual themselves and to their family members and other caregivers. As a result, individuals and their families are often unable to access the support services needed.

Behavioral strategies have been a great treatment approach for controlling and limiting the negative symptoms of autism, however, at times both children and adults suffering from this debilitating disorder still become overstimulated and aggressive. In these instances, when all other treatment approaches have failed, medical intervention is the only option to improve the safety and well-being of the patient. Availability of Cannabis would relieve these significant symptoms without the use of increasingly toxic and dulling medical drugs.

Individuals with autism deserve the chance to access Cannabis to relieve significant symptoms of distress, self-injury and aggression. Please consider including individuals with autism in the Iowa Medical Cannabidiol Board recommendation of qualifying conditions. It would save lives.

Thank you,

Brittany Hodge, MS, CCC-SLP

Iowa Board of Medicine
400 SW 8th Street, Suite C
Des Moines, IA 50309

December 5, 2018

Dear Iowa Board of Medicine,

I am writing to support the inclusion of individuals with autism in the Iowa Medical Cannabidiol Board recommendation of qualifying conditions. Of my six children, two have autism with other developmental disabilities. As a result, I am personally ingrained in the lives of many individuals with autism and see how profoundly beneficial the availability of medical cannabis would have on their quality of life.

Medical cannabis would be a safe, natural, effective alternative to many of the toxic drugs currently being prescribed, most of which carry a hefty burden of dangerous side effects that can further complicate an already complicated neurological situation. Many individuals with autism can experience tremendous levels of anxiety and extreme overstimulation placing them into a mental state that has the potential to be dangerous for themselves and their caregivers.

Please consider including individuals with autism in the Iowa Medical Cannabidiol Program, per the recommendation of the Advisory Board as a qualifying condition. Doing so will give these remarkable people an opportunity at a better and a safer quality of life.

Thank you for your time and consideration,

Elizabeth Friedrich
843 Devonshire Rd
Stoughton, WI 53589
920-202-2540

Dear FAACT Staff,

This letter supports the inclusion of individuals with autism in the Iowa Medical Cannabidiol Board recommendation of qualifying conditions. I worked with adults with disabilities for eight years. Much of my time was focused on supporting adults with autism in an enhanced day program, designed to better suit those with high behavioral needs. Despite frequent training and use of best practice strategies, the gentlemen served in the program often displayed significant self-injurious behaviors and physical aggression directed toward support staff and their peers.

The individuals I speak of and many individuals on the autism spectrum face significant barriers in regards to the services they can access, due to of the safety risk they may pose. The use of cannabis to relieve symptoms of anxiety and instances of self-injury and aggression would allow individuals with autism to improve the quality of their daily lives.

Please consider including individuals with autism in the Iowa Medical Cannabidiol Board of recommendation of qualifying conditions.

Thank you,

A handwritten signature in cursive script that reads "Mallory McWilliams". The signature is written in black ink and is positioned above the printed name.

Mallory McWilliams

FAACT-Iowa
P.O. Box 5284
Coralville, Iowa 52241
December 11, 2018

Dear FAACT-Iowa Staff,

I am writing this letter in support of the inclusion of autism as a qualifying condition by the Iowa Medical Cannabidiol Board. Over the last 15 years since meeting her, I have witnessed my sister-in-law (and Iowa resident) devote her life to the care of her two autistic children. She has more love and patience for her children than anyone I have ever known. Entirely new ways of learning and communication were created by her to help them grow and get the most out of life despite their challenges.

While the successes are numerous, I have also witnessed the helpless feeling when her child has outbursts of frustration that can result in harm to themselves or those caring for them. Many times, it is unknown what the trigger is, and the behavior can spiral downward lasting days or weeks. I cannot even begin to imagine watching your child be this distraught and not being able to help them. When all non-medical interventions have been exhausted, current caregivers are left with benzodiazepines to sedate their children.

As a registered nurse, I know first-hand how addictive these medications can be. Chronic use of these drugs has many adverse effects. Many of these drugs also take away the child's personality the parents know and love. A safer option with fewer side effects is available with medical cannabis. It is only fair that autistic individuals and their caregivers have every tool available to manage this complex condition. Please consider adding autism as a qualifying condition for the use of cannabis.

Jason Matiyow
255 Hidden Pond Lane
North Barrington, IL 60010
773-851-7977

Iowa Board of Medicine
400 SW 8th Street
Des Moines, IA 50309

12/3/18

Hello,

I'm writing our story to help you understand how much cannabis can change the life of a child with Autism Spectrum Disorder.

Our son's name is [redacted] is [redacted] years old and has diagnoses of Autism, Anxiety, OCD, ADHD and Tourette's.

His biggest autism issue has been his anxiety. For most of his life he has lived in a constant state of defense mode because of his autism, always in a flight or fight state of mind. He was unable to pay attention, communicate properly, or just be comfortable in his own skin. Think of it as a soldier always under attack: the soldier can't think about anything but his own survival. That's the constant state of mind for a person with autism.

[redacted] has been under a psychiatrist's care and in therapy since he was three. He was on six pharmaceuticals and they barely helped him.

In February 2018 we introduced cannabis. Thankfully we live in a state where autism is a qualifying condition. Cannabis has changed his life. His anxiety is under control, he is no longer a raw nerve. Now that his anxiety is decreased his other, autism co-morbid conditions (ADHD and OCD) have decreased as well. His Tourette's tic is controlled.

He uses several cannabinoids, CBG, CBD, THCa and THC.

He is no longer on ANY pharmaceuticals.

Cannabis has changed our lives. It's a plant. I can't get over that, a plant has changed [redacted] life and, as a result, our whole family's life.

Please approve autism as a qualifying condition for medical cannabis. It is letterlife changing.

Thank you,

Jody Schiltz

Iowa Board of Medicine
400 SW 8th St. Suite C
Des Moines, IA 50300

December 4, 2018

To the Iowa Board of Medicine

As a former resident of Iowa, I have always been proud of the state's leadership in social and medical issues. Having seen the ravages on a family that autism can cause, I would urge you to include individuals born with autism in the Iowa Medical Cannabidiol Board recommendation of qualifying conditions.

Sincerely,

Margaret Dunn, PhD
14021 Gilchrist Road
Mount Vernon, OH 43050

Iowa Board of Medicine
400 SW 8th Street
Des Moines, IA 50309

12/1/18

To the Iowa Board of Medicine,

I'm asking as a parent of a young adult with autism to please qualify the condition of autism for medical cannabis.

Autism is a lifelong condition and most of the standard psychotropic medications currently used to treat various symptoms have terrible side effect profiles.

Cannabidiol does not have these side effects and I have seen how CBD oil can calm anxiety and make life a little easier for the individual on the autism spectrum

Thank-you for your consideration,

Laura Striegel
319 Sycamore St.
Riverside, IS. 52327
(319) 648-4520

Iowa Board of Medicine
400 SW 8th Street, Suite C
Des Moines, Iowa 5030

December 4, 2018

To the Iowa Board of Medicine

Individuals afflicted with autism should be allowed to have the option to use cannabis to alleviate their negative symptoms. These can include self-injury, aggressive behavior, excessive anxiety, etc.

Please include autism in the Iowa Medical Cannabidiol Board recommendation of qualifying conditions.

Thank you.

Ann D Bengé
3179 Province Circle
Mundelein, IL 60060

Medical Studies and Scholarly Articles

A Selection of Studies Relevant to the Treatment of Autism with Medical Cannabis

Underlying deficiency in anandamide (i.e. endogenous version of THC) Plasma Anandamide Concentrations are Lower in Children with Autism Spectrum Disorder (Stanford University 2018). Anandamide concentrations significantly differentiated ASD cases from controls, such that children with lower anandamide concentrations were more likely to have ASD. These findings are the first empirical human data to confirm a link between plasma anandamide concentrations in children with ASD. Although preliminary, these data suggest that impaired anandamide signaling may be involved in the pathophysiology of ASD.

Core symptoms of autism

Real Life Experience of Medical Cannabis Treatment in Autism: Analysis of Safety & Efficacy (Israel, January 2019) Analysis of data collected as part of the treatment program of 188 ASD patients treated with medical cannabis between 2015 and 2017. 30.1% reported a significant improvement, 53.7% moderate, 6.4% slight and 8.6% had no change in their condition. Study concludes: Cannabis as a treatment for autism spectrum disorders patients appears to be well-tolerated, safe and seemingly effective option to relieve symptoms, mainly: seizures, tics, depression, restlessness and rage attacks. The reported side effects at one month were: sleepiness (1.6%), bad taste/smell of the oil (1.6%), restlessness (0.8%), reflux (0.8%) and lack of appetite (0.8%).

Oral Cannabidiol Use in Children with ASD to Treat Related Symptoms and Co-morbidities (Israel, January 2019) The use of cannabidiol for 53 autistic children between the ages of 4 and 22 brought improvement in the following symptoms and co-morbidities: self injury, rage attacks, hyperactivity, sleep problems and anxiety. The adverse effects were mild somnolence and a change in appetite.

Cannabidiol Based Medical Cannabis in Children with Autism – A Retrospective Feasibility Study (Israel, April 2018) Preclinical study using a 20:1 ratio of CBD:THC. Here, the feasibility of CBD based medical cannabis as a promising treatment option for refractory behavioral problems in children with ASD is investigated. Following the cannabis treatment, behavioral outbreaks were much improved or very much improved (on the CGIC scale) in 61% of patients.

Oral Cannabis Extracts as a Promising Treatment for the Core Symptoms of ASD: Preliminary Study (Chile 2017) Most cases improved at least one of the core symptoms of ASD, including social communication, language, or repetitive behaviors. Additionally, sensory difficulties, food acceptance, feeding and sleep disorders, and/or seizures showed improvement.

Improvement in self-injury and mood

Dronabinol (Marinol) in the Management of Treatment-Resistant Self-Injurious Behavior (Missouri 2006) According to this study, Marinol [synthetic THC, schedule 3] reduced self-injurious behavior. "Seven of the ten subjects had a significant improvement in self-injurious behaviors and their overall mood/well being as reported by caregivers."

First do no harm (i.e. the problem with atypical antipsychotics for behavioral issues)

Abilify & Risperidol: These are the only 2 FDA approved pharmaceuticals for "irritability" in autism. Both come with black box warnings and a myriad of other significant, and possibly permanent side effects such as gynecomastia, tardive dyskinesia, pathological gambling or other compulsive behaviors, seizures, cognitive impairment, ...

Characteristics of Children Prescribed Antipsychotics: Analysis of Routinely Collected Data (UK 2018) It was found that antipsychotics are prescribed predominantly to those with intellectual difficulty/autism, not psychotic diagnoses. Children in special schools, those with autism and those with aggression, are especially likely to be prescribed an antipsychotic. Side effects included: increase rates of respiratory disease, epilepsy, diabetes, hospital-admitted depression and injury. **This study concludes that the use of antipsychotics for behavioral management is likely to have increased cost implications to the healthcare system.**

Long-term antipsychotic treatment and brain volumes (NIH 2010) Viewed together with data from animal studies, this study suggests that antipsychotics have a subtle but measurable influence on brain tissue loss over time, suggesting the importance of careful risk-benefit review of dosage and duration of treatment as well as their off-label use.

Cannabidiol Based Medical Cannabis in Children with Autism- a Retrospective Feasibility Study (P3.318)

ADI ARAN, Hanoch Cassuto, Asael Lubotzky
First published April 9, 2018

Abstract

Objective: This retrospective study assessed safety, tolerability and efficacy of cannabidiol (CBD) based medical cannabis, as an adjuvant therapy, for refractory behavioral problems in children with ASD.

Background: Anecdotal evidence of successful cannabis treatment in children with autism spectrum disorder (ASD) are accumulating but formal studies are lacking.

Design/Methods: Sixty children with ASD (age = 11.8 ± 3.5 , range 5.0–17.5; 77% low functioning; 83% boys) were treated with oral CBD and tetrahydrocannabinol (THC) at a ratio of 20:1. The dose was up-titrated to effect (maximal CBD dose – 10mg/kg/d). Tolerability and efficacy were assessed using a modified Liverpool Adverse Events Profile, the Caregiver Global Impression of Change (CGIC) scale, the Home Situations Questionnaire–Autism Spectrum Disorder (HSQ-ASD) and the Autism Parenting Stress Index (APSI).

Results: Following the cannabis treatment, behavioral outbreaks were much improved or very much improved (on the CGIC scale) in 61% of patients. The anxiety and communication problems were much or very much improved in 39% and 47% respectively. Disruptive behaviors, were improved by 29% from 4.74 ± 1.82 as recorded at baseline on the HSQ-ASD to 3.36 ± 1.56 following the treatment. Parents reported less stress as reflected in the APSI scores, changing by 33% from 2.04 ± 0.77 to 1.37 ± 0.59 . The effect on all outcome measures was more apparent in boys with non-syndromic ASD. Adverse events included sleep disturbances (14%) irritability (9%) and loss of appetite (9%).

Conclusions: This preliminary study support the feasibility of CBD based medical cannabis as a promising treatment option for refractory behavioral problems in children with ASD. Based on these promising results, we have launched a large, double blind, placebo controlled cross-over trial with 120 participants (NCT02956226).

Link: http://n.neurology.org/content/90/15_Supplement/P3.318

Plasma Anandamide Concentrations are Lower in Children with Autism Spectrum Disorder

Debra S. Karhson,¹ Karolina M. Krasinska,² Jamie Ahloy Dallaire,³ Robin A. Libove,¹ Jennifer M. Phillips,¹ Allis S. Chien,² Joseph P. Garner,^{1,2} Antonio Y. Hardan,¹ and Karen J. Parker¹

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Abstract

Background

Autism spectrum disorder (ASD) is a neurodevelopmental disorder characterized by restricted, stereotyped behaviors and impairments in social communication. Although the underlying biological mechanisms of ASD remain poorly understood, recent preclinical research has implicated the endogenous cannabinoid (or endocannabinoid), anandamide, as a significant neuromodulator in rodent models of ASD. Despite this promising preclinical evidence, no clinical studies to date have tested whether endocannabinoids are dysregulated in individuals with ASD. Here, we addressed this critical gap in knowledge by optimizing liquid chromatography-tandem mass spectrometry methodology to quantitatively analyze anandamide concentrations in banked blood samples collected from a cohort of children with and without ASD ($N = 112$).

Findings

Anandamide concentrations significantly differentiated ASD cases ($N = 59$) from controls ($N = 53$), such that children with lower anandamide concentrations were more likely to have ASD ($p = 0.041$). In keeping with this notion, anandamide concentrations were also significantly lower in ASD compared to control children ($p = 0.034$).

Conclusions

These findings are the first empirical human data to translate preclinical rodent findings to confirm a link between plasma anandamide concentrations in children with ASD. Although preliminary, these data suggest that impaired anandamide signaling may be involved in the pathophysiology of ASD.

Link

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5848550/>

Scholarly Articles

- Use of dronabinol (delta-9-THC) in autism: A prospective single-case-study with an early infantile autistic child (full-2010) http://www.cannabis-med.org/data/pdf/en_2010_04_1.pdf
- Can autism be triggered by acetaminophen activation of the endocannabinoid system? (link to PDF-2010) <http://www.ncbi.nlm.nih.gov/pubmed/20628445>
- Variation in the human Cannabinoid Receptor (CNR1) gene modulates gaze duration for happy faces (full-2011) <http://www.molecularautism.com/content/pdf/2040-2392-2-10.pdf>
- Consequences of cannabinoid and monoaminergic system disruption in a mouse model of autism spectrum disorders (full-2011) <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3137184/>
- Moderation of antipsychotic-induced weight gain by energy balance gene variants in the RUPP autism network risperidone studies (full-2013) <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3693401/>
- Autism-Associated Neuroligin-3 Mutations Commonly Disrupt Tonic Endocannabinoid Signaling (full-2013) <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3663050/>
- Evidence for a Common Endocannabinoid-Related Pathomechanism in Autism Spectrum Disorders (link to full-2013) <http://www.sciencedirect.com/science/article/pii/S0896627313003619>

- Cannabinoid Receptor Type 2, but not Type 1, is Up-Regulated in Peripheral Blood Mononuclear Cells of Children Affected by Autistic Disorders (abst-2013) <http://www.ncbi.nlm.nih.gov/pubmed/23585028>
- Alterations in the endocannabinoid system in the rat valproic acid model of autism (abst-2013) <http://www.ncbi.nlm.nih.gov/pubmed/23643692>
- The in vitro GcMAF effects on endocannabinoid system transcriptionomics, receptor formation, and cell activity of autism-derived macrophages (full-2014) <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3996516/>
- Defects in fatty acid amide hydrolase 2 in a male with neurologic and psychiatric symptoms (full-2015) <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4423390/>
- Increased Cortical Inhibition in Autism-Linked Neuroligin-3R451C Mice Is Due in Part to Loss of Endocannabinoid Signaling (full-2015) <http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0140638>
- Endocannabinoid signaling mediates oxytocin-driven social reward (full-2015) <http://www.pnas.org/content/112/45/14084.full>
- Medical marijuana: review of the science and implications for developmental-behavioral pediatric practice (abst-2015) <http://www.ncbi.nlm.nih.gov/pubmed/25650954>
- Endocannabinoid Signaling in Autism (abst-2015) <http://www.ncbi.nlm.nih.gov/pubmed/26216231>

- Endocannabinoids and Mental Disorders (abst-2015) <http://www.ncbi.nlm.nih.gov/pubmed/26408164>
- The basolateral amygdala γ -aminobutyric acidergic system in health and disease (abst-2015) <http://www.ncbi.nlm.nih.gov/pubmed/26586374>
- β -Neurexins Control Neural Circuits by Regulating Synaptic Endocannabinoid Signaling (abst-2015) http://www.cell.com/cell/abstract/S0092-8674%2815%2900826-0?_returnURL=http%3A%2F%2Flinkinghub.elsevier.com%2Fretrieve%2Fpii%2FS0092867415008260%3Fshowall%3Dtrue
- Oxytocin Enhances Pleasure of Social Interactions by Stimulating Production of “Bliss Molecule” (news/abstract-2015) <http://neurosciencenews.com/oxytocin-anandamide-2926/>
- p21-activated kinase 1 restricts tonic endocannabinoid signaling in the hippocampus (full-2016) <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4907698/>
- Endocannabinoid signaling in social functioning: an RDoC perspective (full-2016) <http://www.nature.com/tp/journal/v6/n9/full/tp2016169a.html>
- Targeting anandamide metabolism rescues core and associated autistic-like symptoms in rats prenatally exposed to valproic acid (full-2016) <http://www.nature.com/tp/journal/v6/n9/full/tp2016182a.html>
- Acetaminophen Use for Fever in Children Associated with Autism Spectrum Disorder (full-2016) <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5044872>

March 1, 2017

Christian Bogner, MD
Microglia & Cannabinoid Research in Autism
Plant-Based Nutrition Certified,
Cornell University
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Detroit, MI
Email: christian@drbogner.com

Autism & Cannabis – Physician Support

This brief summary is meant as “additional supportive evidence” for Texas lawmakers to justify autism as qualifying condition for the medical marijuana program. Please refer to the first document entitled “The Endocannabinoid System as it Relates to Autism” to appreciate further scientific evidence.

Recommendation

Dear Colleagues, I am the father of a 12 year old son who has autism. I have found great interest in pursuing possible etiologies in the development of the condition and explore safe alternatives to conventional pharmaceutical intervention. I am a speaker at multiple national conferences, specifically focused on autism and cannabis. I have provided testimony in several other states about this same issue at hand. As you know, several states have autism as qualifying diagnosis and more and more are to follow in the coming years.

Since I am sure you are aware, cannabis is non-lethal to humans. There are no reported deaths in recorded history that are attributed to cannabis as the cause of death.

The only question that really should be asked is if chronic cannabis exposure to the developing brain can be harmful. I share the same passion to protect our children. I am a father of four and am caught in the health-nut movement, where everything I offer them is safe to consume, free of refined sugars, genetically modified foods and more of such nature. Recommending cannabis to this subpopulation comes with a great deal of research.

I am giving my full support for giving parents the choice to choose cannabis as treatment modality in autism spectrum disorders. The reason is because

- I have seen countless parents' success stories with it,
- I have seen parents with their treated children for several years without adverse effects,
- I have researched this thoroughly. Cannabis is not only safe, but therapeutic (evidence below),
- this is not meant to change novel treatment recommendations for autism in any way. This is meant simply to be a legal choice for those parents that desire to choose cannabis for their child. It offers them legal protection from prosecution,
- many "do it" without having "cannabis-cards" anyways. This causes additional stress for already struggling families.

I have personally consulted with Professor Grinspoon, who is a renowned Harvard Psychiatrist for 40 years and was reassured that cannabis is not toxic in the developing brain. I have also consulted Professor Mechoulam, who discovered the THC molecule. In fact, he is still active as professor in Israel and is involved in the first human trial with cannabis and autism [out of all diseases].

If you see the powerful transformation yourself, when you listen to powerful parent testimony, it is our duty to protect these parents from state or federal interference. We must protect these very brave, yet vulnerable parents.

Thank you for your time to hear these parents and physicians and thank you for your time researching this subject as thoroughly as I have.

Scientific evidence

Highlights

- “These alterations in endocannabinoid signaling may contribute to autism pathophysiology (Földy 2013, Krueger 2013, Onaivi 2011, Siniscalco 2013).”
- “Endocannabinoids regulate stress responses, in part via the modulation of the 5-HT system (Haj-Dahmane 2011).”
- “**Neurogenesis** (Galve-Roperh 2007, Jiang 2005, Avraham 2014, Campos 2013)”
- “**Neuroprotection** (Hampson 2003, Lara-Celador 2013, Sanchez 2012)”
- “**Antioxidants** (Borges 2013, Pertwee 2010, Hampson 1998, Hampson 2003)”
- “**Neuromodulation** (Davis 2007, Lara-Celador 2013, Pertwee 2010, Youssef 2012)”
- “**Anti-inflammatory** (Pertwee 2010, Izzo 2009, Nagarkatti 2009, Klein 2005)”

Direct Links

- NL3 mutations inhibit tonic secretions of endocannabinoids
- ECS is suggested target for fragile X treatment
- CB2 upregulated and is suggested target for ASD treatment
- PPAR alpha/gamma and GPR55 downregulated
- CB1 is key element of perception of basic emotions (like happy faces)

Correlations

- Modulation of GABA efflux via CB1 and CB2
- ECS and 5-HT system closely interrelated
 - eCBs via CB1 modulate 5-HT release
 - 5-HT regulates the release of eCBs via 5-HT_{2a}
 - AEA reduces 5-HT binding
 - THC, THCA, CBD, CBDA are all 5-HT_{1a} agonists
 - THC increases 5-HT_{1a} receptor expression and function
 - Cannabinoid agonists inhibit 5-HT₃
 - CBD tryptophan degradation suppressor
- Cannabinoid signaling suppresses cytokine proliferation/release via CB1/CB2 dependent and independent mechanisms
- CB1 regulates synaptic plasticity at synapse onto Purkinje cells
- ECS target for modulating neuronal and glial cell function in epileptogenic developmental pathologies
- Tonic eCBs regulate GI functions (including metabolism)

Phytocannabinoids are compounds that are useful as tissue protectants, such as neuroprotectants. The compounds and compositions may be used, for example, in the treatment of neurological insults due to inflammation, such as autism spectrum disorders.

Cannabinoid receptor type 1 (CB1) receptors are thought to be one of the most widely expressed G protein-coupled receptors in the brain, making cannabinoids an integral part in brain homeostasis. CB2 receptors are mainly expressed on T cells of the immune system, on macrophages and B cells, and in hematopoietic cells, making cannabinoids an integral part in human immune function.

Cannabinoids as antioxidants and neuroprotectants – US Patent 6630507 B1

United States Patent 6630507 by the Department of Health and Human Services, 'Cannabinoids as antioxidants and neuroprotectants'. Cannabinoids have been found to have antioxidant properties, unrelated to NMDA receptor antagonism. This new found property makes cannabinoids useful in the treatment and prophylaxis of wide variety of oxidation associated diseases, such as ischemic, age-related, inflammatory and autoimmune diseases. The cannabinoids are found to have particular application as neuroprotectants.

"It has surprisingly been found that cannabidiol and other cannabinoids can function as neuroprotectants..." "No signs of toxicity or serious side effects have been observed following chronic administration of cannabinoids to volunteers..." "It is an object of this invention to provide a new class of antioxidant drugs..."

The Shafer Commission Report Evidence

The Controlled Substances Act created the Presidential Commission on Marijuana and Drug abuse specifically to advice on the proper scheduling on cannabis. Thus was born a council that would become one of the most legendary fact-finding bodies ever conceived: the Shafer Commission.

In the early 1970s, President Nixon appointed Gov. Raymond P. Shafer of Pennsylvania, a former prosecutor with a "law-and-order" reputation, to run a commission that would demonstrate enough evidence to re-affirm Marijuana to the "most dangerous" list, Schedule I.

The Shafer Commission "recorded thousands of pages of transcripts of formal and informal hearings, solicited all points of view, including those of public officials, community leaders, professional experts and students. They conducted separate surveys of opinion among district attorneys, judges, probation officers, clinicians, university health officials and 'free clinic' personnel. They commissioned more than 50 projects, ranging from a study of the effects of marijuana on man to a field survey of enforcement of the marijuana laws in six metropolitan jurisdictions."

Shafer brought his report to the White House March 21, 1972. It was **1,184 pages** long.

A short summary of the Shafer Commission for pertinent points relating to the Public hearing on Autism as qualified diagnosis for the Texas Medical Marijuana Program in Texas:

"No significant physical, biochemical, or mental abnormalities could be attributed solely to their marihuana smoking... No valid stereotype of a marihuana user or non-user can be drawn... Young people who choose to experiment with marihuana are fundamentally the same people, socially and psychologically, as those who use alcohol and tobacco... No verification is found of a causal relationship

between marihuana use and subsequent heroin use.... Most users, young and old, demonstrate an average or above-average degree of social functioning, academic achievement, and job performance...

"The weight of the evidence is that marihuana does not cause violent or aggressive behavior; if anything marihuana serves to inhibit the expression of such behavior... Marihuana is not generally viewed by participants in the criminal justice community as a major contributing influence in the commission of delinquent or criminal acts... Neither the marihuana user nor the drug itself can be said to constitute a danger to public safety... Research has not yet proven that marihuana use significantly impairs driving ability or performance..."

-Shafer Commission report 3/21/1972

Cytokine levels higher in autism

Cytokines are small secreted proteins released by cells that have a specific effect on the interactions and communications between cells. Pro-inflammatory cytokines are involved in the up-regulation of inflammatory reactions. [1] Elevated pro-inflammatory cytokine levels are associated with autism spectrum disorders (ASD) [1]. In ASD, as well as a number of conditions, the expression level of CB2 receptors increases in response to the inflammatory nature of the condition. [2][3] Given that CB2 is up-regulated, and that it's believed to play a neuroprotective role, CB2 is being investigated as a potential target for treatment of ASD. [3] CB1 variations modulate the striatal function that underlies the perception of signals of social reward, such as happy faces. This suggests that CB1 is a key element in the molecular architecture of perception of certain basic emotions. This may have implications for understanding neurodevelopmental conditions marked by atypical eye contact and facial emotion processing, such as ASC. [4] Endocannabinoids are key modulators of synaptic function. [5] Endocannabinoids regulate stress responses, in part via the modulation of the 5-HT system. [6][7] Additional targets of endocannabinoids (and exogenous cannabinoids), PPAR α , PPAR γ , and GPR55 expression levels have shown reductions in a valproic acid model of autism in rats.[8]

Toxicity

No signs of toxicity or serious side effects have been observed following chronic administration of cannabidiol to healthy volunteers (Cunja et al., Pharmacology 21:175-185,1980), even in large acute doses of 700mg/day (Consroe et al., Pharmacol. Biochem. Behav. 40:701-708,1991) but cannabidiol is inactive at the NMDA receptor [9], indicating that THC is warranted. According to US patent 6630507, safety is demonstrated by stating that in the presence of glutamate alone, and in the presence of glutamate and cannabidiol (CBD) or THC, it was demonstrated that CBD and THC were similarly protective.

Government patents on cannabinoid safety

United States patents specifically demonstrating evidence of safety:

NMDA receptor antagonism can be achieved with a subset of cannabinoids.
U.S. Pat. No. 5,538,993 (3S,4S-delta-6-tetrahydrocannabinol-7-oic acids),
U.S. Pat. No. 5,521,215 (stereospecific (+) THC enantiomers), and
U.S. Pat. No. 5,284,867 (dimethylheptyl benzopyrans)
have reported that these cannabinoids are effective NMDA receptor blockers.

Terpenes

Phytocannabinoids aid in neuroprotection against oxidative stress in patients affected with neurological diseases. In addition to the cannabinoids, terpenes have been found to be helpful in providing CB2 activation. Caryophyllene is the only terpene known to interact with the endocannabinoid system (CB2). β -caryophyllene selectively binds to the CB2 receptor and that it is a functional CB2 agonist. Further, β -caryophyllene was identified as a functional non-psychoactive CB2 receptor ligand in foodstuff and as a macrocyclic anti-inflammatory cannabinoid in cannabis. [16]

Many of the other cannabinoids, terpenoids and flavonoids found in medical marijuana play a role in boosting the therapeutic effect of cannabis. **The FDA and other agencies have generally recognized terpenes as “safe.”**

For example, humulene and caryophyllene displayed comparable anti-inflammatory responses to steroid alternatives. [17] Humulene was simultaneously effective in reducing inflammation and offering pain relief. [18] The oral effects of humulene were analyzed and the results suggested that again, this terpene was highly effective at reducing inflammation, proving its usefulness as a topical or oral supplement. [19]

Conclusion

There is evidence that aggressive autism behaviors can be explained by chemical imbalances in the body leading to a multitude of health concerns, including neuro-inflammation. Cannabinoids such as CBD and THC were found to be neuroprotective according to United States Patent #6630507 by the Department of Health and Human Services and many studies as presented above. Rather than causing harm to the developing brain, phytocannabinoids appear to aid in brain neuropsychiatric homeostasis. A strong support towards approval in this case will create relief on many levels.

Please call me directly for questions or concerns or further opportunities to clarify uncertainties,

Sincerely,

Christian Bogner, MD

References

- [1] Zhang, Jun-Ming, and Jianxiong An., et al. "Cytokines, Inflammation and Pain." *International anesthesiology clinics* 2 (2007): 27–37. PMC. Web. 11 June 2015.
- [2] Fernández-Ruiz, Javier, et al. "Prospects for cannabinoid therapies in basal ganglia disorders." *British journal of pharmacology* 163.7 (2011): 1365-1378.
- [3] Siniscalco, Dario, et al. "Cannabinoid receptor type 2, but not type 1, is upregulated in peripheral blood mononuclear cells of children affected by autistic disorders." *Journal of autism and developmental disorders* 43.11 (2013): 2686-2695.
- [4] Chakrabarti, Bhismadev, and Simon Baron-Cohen. "Variation in the human Cannabinoid Receptor (CNR1) gene modulates gaze duration for happy faces." *Molecular autism* 2.1 (2011): 10.
- [5] Castillo, Pablo E., et al. "Endocannabinoid signaling and synaptic function." *Neuron* 76.1 (2012): 70-81.
- [6] Di Marzo, V., and F. Piscitelli. "Gut feelings about the endocannabinoid system." *Neurogastroenterology & Motility* 23.5 (2011): 391-398.
- [7] Li, Chen, Peter M. Jones, and Shanta J. Persaud. "Role of the endocannabinoid system in food intake, energy homeostasis and regulation of the endocrine pancreas." *Pharmacology & therapeutics* 129.3 (2011): 307-320.
- [8] Kerr, D. M., et al. "Alterations in the endocannabinoid system in the rat valproic acid model of autism." *Behavioural brain research* 249 (2013): 124-132.
- [9] Cannabinoids as antioxidants and neuroprotectants, US patent 6630507, US dept. of Health
- [10] Microbe Inotech test report 03/14/2016, Invoice # GLYPH312
- [11] *Chemosphere*. 2013 Apr;91(4):545-51. doi: 10.1016/j.chemosphere.2012.12.036. Epub 2013 Jan 18.
- [12] *Toxicology*. 2014 Jun 5;320:34-45. doi: 10.1016/j.tox.2014.03.001. Epub 2014 Mar 15.
- [13] Great Planes Laboratories, requisition # 467141, 10/18/2016
- [14] *Neuropsychopharmacology*. 2016 Nov 21. doi: 10.1038/npp.2016.260. [Epub ahead of print]
- [15] *J Pharmacol Exp Ther*. 2008 Nov;327(2):538-45. doi: 10.1124/jpet.108.141796. Epub 2008 Aug 12.
- [16] *Proc Natl Acad Sci U S A*. 2008 Jul 1;105(26):9099-104. doi: 10.1073/pnas.0803601105. Epub 2008 Jun 23. Beta-caryophyllene is a dietary cannabinoid.
- [17] *Eur J Pharmacol*. 2007 Aug 27;569(3):228-36. Epub 2007 May 22. Anti-inflammatory effects of compounds alpha-humulene and (-)-trans-caryophyllene isolated from the essential oil of *Cordia verbenacea*.
- [18] *Planta Med*. 2008 Nov;74(14):1678-83. doi: 10.1055/s-0028-1088307. Epub 2008 Oct 24. Pharmacokinetics and tissue distribution of the sesquiterpene alpha-humulene in mice.
- [19] *Br J Pharmacol*. 2009 Oct; 158(4): 1074–1087. Preventive and therapeutic anti-inflammatory properties of the sesquiterpene α -humulene in experimental airways allergic inflammation