

Endocannabinoids and Autistic Spectrum Disorders: Facts, not Hype

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Autism spectrum disorder (ASD) has been added to the list of qualifying medical conditions for Minnesota Medical Cannabis. Patients certified to have ASD will be eligible to enroll in the program on July 1, 2018 and receive cannabis extracts from the state's approved vendors beginning August 1, 2018.

Minnesota joins only Pennsylvania and Georgia in specifically including autism among their lists of qualifying conditions for young people. In Delaware, autism is a qualifying condition for adults only.

The Science Behind the Law

What are the facts and current state of the science behind this law? Let's do a basic review. We do have an endocannabinoid system (ECS) in our bodies and brains. The endogenous ligands are not products of cannabis plants, but rather are eicosanoid products of the arachidonic acid system in our bodies. The ECS appears to be involved in cellular signaling underlying multiple processes, including, but not limited to, inflammatory and neuromodulatory.

Data regarding cannabinoids and ASD can be found in the Minnesota Department of Health's research brief: <http://www.health.state.mn.us/topics/cannabis/rulemaking/autismbrief2.pdf>

It is up to the individual provider to determine if the evidence in this brief provides enough support to justify certifying a patient with ASD. In summary, there are promising data that support the continued study of ECS in ASD and related conditions, and clinical trials may soon produce a medication. For example, purified cannabidiol (CBD) is undergoing clinical trials in pediatric seizure and a number of other indications, including ASD. There is likely to be a vetted, regulated drug in the foreseeable future.

Valid Concerns

However, the bulk of the studies cited in the research brief come from predominantly rat models, which are enlightening but not a substitute for human study. The small remainder highlighted are human studies, but cannot be equated namely because they do not all investigate the same cannabinoids.

It is worth noting that in 2015, ASD was rejected as a qualifying condition in Michigan because the state's Director of the Department of Licensing and Regulatory Affairs expressed concern that approval applies not just to more severe cases, but to any in the spectrum. He further stated that even though parents applying to the program would need the approval of two medical doctors, there was no

requirement that either doctor be experienced in treating autism. His final determination was based in part on corroborating testimony by Dr. Harry Chugani, chief of pediatric neurology at Children's Hospital of Michigan and recognized national authority on autism.

Yet, the same scenario is true here in Minnesota.

Finally, there is a problem equating the state's medical cannabis programs with clinical trials. The products are not subject to the same regulatory scrutiny as those undergoing the FDA testing and regulatory process. There is no scientific rigor in patient selection, inclusion/exclusion criteria, data collection or analyses, or safety monitoring. For example, there is evidence of a clinically significant drug-drug interaction between CBD and the anti-seizure drug, clobazam. That discovery was the result of a rigorous research study.

To certify or not?

Regardless of how one interprets the science, we now have "medical cannabis" available for people with ASD in Minnesota. What is a pediatrician to do? Should you certify? Do you have to certify? The overall, probably unsatisfying answer is, except where limited by your own clinic or system policies, the decision is between you and your patients/caregivers. You are under no legal or other obligation to either register as a provider, or certify any patients.

Whether you certify or not, we are all increasingly faced with multiple challenges, including requests for information/education, upset caregivers and colleagues who may disagree with a provider's decisions, and others providing certification even while we remain the bona fide treatment provider for a child's ASD-related condition.

When contemplating the use of the extracts of the cannabis sativa plant as contained in Minnesota Medical Cannabis products, keep in mind that there are multiple cannabinoids, most of whose functions are incompletely understood, much less combinations thereof. There is not one discrete diagnosis of "autism," but rather a range of severity, symptoms, and co-morbidities.

Is there liability concern for those who certify patients? The most recent answer to that question is, possibly. Check out <http://onlinelibrary.wiley.com/doi/10.1002/cpu.30204/full> for more information.

If you are considering certifying a patient, be an expert in the ASD field with a bona fide treatment relationship who is truly following the child's progress, not the generalist just "helping the family out".

Sometimes helping is hurting.