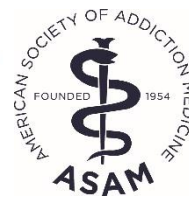


American Academy  
of Pediatrics

DEDICATED TO THE HEALTH OF ALL CHILDREN®



American Association of  
Child & Adolescent  
Psychiatry



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**SAM** Smart  
Approaches to  
Marijuana  
preventing another big tobacco

**SAHM**  
SOCIETY FOR ADOLESCENT  
HEALTH AND MEDICINE

June 21, 2016

The Honorable Brian Schatz  
United States Senate  
Washington, DC 20510

The Honorable Orrin Hatch  
United States Senate  
Washington, DC 20510

The Honorable Thom Tillis  
United States Senate  
Washington, DC 20510

The Honorable Chris Coons  
United States Senate  
Washington, DC 20510

Dear Senators Schatz, Hatch, Tillis, and Coons:

On behalf of the undersigned organizations dedicated to promoting responsible research for the development of safe and effective medical therapies, we write to endorse the *Marijuana Effective Drug Studies (MEDS) Act of 2016*. This legislation aims to significantly reduce the barriers to performing medical research on potential therapies derived from marijuana while keeping in place safeguards needed to prevent marijuana diversion and ensure that medicines available for patients, particularly children, are safe for their use and have evidence of effectiveness.

Currently, marijuana is the most commonly used illicit substance, with 22.2 million Americans aged 12 or older reporting current use of marijuana in 2014. Alarming, 8.4% of children aged 12 to 17 reported past month use of marijuana, a statistically significant increase in use over any of the years from 2002 to 2013.<sup>1</sup> Such an increase in use can be tied to several factors that have normalized marijuana use, including recent state laws legalizing medical, and sometimes recreational, marijuana use among adults. In addition, initiation of marijuana use during adolescence results in a significantly higher risk of marijuana dependence later in life given the vulnerability of the brain during this developmental stage,<sup>2</sup> and consistent use of marijuana during childhood and adolescence has been associated with significant declines in IQ and reduced executive function that can persist for a lifetime.<sup>3</sup> Given these risks, it is imperative that we have more data on the risks and possible benefits of using marijuana-derived compounds as medicine.

Smoking the marijuana plant, which contains more than 400 chemicals and more than 60 individual cannabinoids, for recreational or medical use results in the production of more than 2,000 individual compounds. Therefore, the use of the marijuana plant in its entirety, especially when combusted, is inappropriate for medical use.<sup>4</sup> For marijuana to ever have accepted medical use, marijuana derivatives must be developed and clinical studies must evaluate their safety and efficacy so that the Food and Drug Administration (FDA) can determine their appropriateness for marketing.

Although several small studies have indicated that cannabidiol, a component of marijuana, may have some therapeutic benefit in some children suffering from seizure disorders, including Dravet syndrome and idiopathic epilepsy, these studies have not generated the data needed to conclusively determine the safety and efficacy of cannabidiol extract for children.<sup>5</sup> However, due to these preliminary reports of efficacy and in their desperation to find relief for their children suffering from these diseases, some parents are turning to the use of unapproved therapies, the contents of which are untested and highly variable, putting children at risk of harm. Additionally, despite the medical community's consensus that smoked marijuana is inappropriate for medical use, many states have legalized "medical" marijuana for a number of conditions based on anecdotal reports of benefit or patient demand. Clearly, it is past time for researchers to be able to perform the studies they need to conclusively investigate the effects of these therapies in children and adults.

Currently, researchers performing studies on the potential benefits of marijuana-derived therapies must gain protocol approval through multiple agencies, including the Drug Enforcement Agency (DEA), and changes to these protocols to gain the data needed to develop promising therapies take excessively long and are difficult to obtain. Our organizations believe that the FDA process for determining the safety and efficacy of new therapies is the appropriate pathway for the development of marijuana-derived therapies for children and adults, and are supportive of your efforts to reduce the barriers to investigators gaining the data they need to make meaningful discoveries through this process. Further, this legislation will ensure that if marijuana-derived therapies are approved by the FDA, manufacturers will have the ability to produce these therapies without excessive burdens that would limit the ability of patients across the nation to gain access to these drugs should they prove safe and effective.

The effects of Dravet syndrome and similar neurological conditions are devastating for children, and the need for safe and effective treatments for these illnesses, especially where no other alternatives exist, is crucial for improving child health. Moreover, increased research into the therapeutic effects of marijuana's components may yield benefits for patients suffering from a host of other diseases. This legislation represents a major step forward by providing an effective balance between protecting the nation's youth from access to a harmful and addictive substance while allowing researchers to perform needed medical studies.

We thank you for your work on this important issue and look forward to working with you to ensure that medical research moves forward for the benefit of children and adults.

Sincerely,

American Academy of Pediatrics  
American Association of Child & Adolescent Psychiatry  
American Society of Addiction Medicine  
Child Neurology Foundation  
Child Neurology Society  
Smart Approaches to Marijuana  
Society for Adolescent Health and Medicine

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<sup>1</sup> Center for Behavioral Health Statistics and Quality. Behavioral health trends in the United States: Results from the 2014 National Survey on Drug Use and Health. 2015. Substance Abuse and Mental Health Services Administration.

<sup>2</sup> Chen C., Storr CL, and JC Anthony. Early-onset drug use and risk for drug dependence problems. *Addictive Behaviors*. March 2009. 34(3):319-322.

<sup>3</sup> Volkow ND et al. Adverse health effects of marijuana use. *New England Journal of Medicine*. 5 June 2014. 370:2219-2227.

<sup>4</sup> Sharma P, Murthy P, and MMS Bharath. Chemistry, metabolism, and toxicology of cannabis: Clinical implications. *Iranian Journal of Psychiatry*. Fall 2012. 7(4):149-156.

<sup>5</sup> Porter BE and C Jacobsen. Report of a parent survey of cannabidiol-enriched cannabis use in pediatric treatment-resistant epilepsy. *Epilepsy & Behavior*. Dec. 2013. 29(3):575-577.