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Mandating coverage or reimbursement of non-FDA-approved cannabis products would be bad public policy

The *International Academy on the Science and Impact of Cannabis (IASIC)*, an organization comprised of physicians and researchers who educate on cannabis based on scientific and medical literature, is a nonpartisan group created to facilitate informed decisions when considering policy and law.

We wish to express our **strong opposition to** state-funded reimbursement of dispensary-sold cannabis products that have not demonstrated safety and efficacy through the U.S. Food and Drug Administration (FDA) review process. Joining other respected medical societies, including the *American Medical Association*, the *Medical Society of New Jersey*, the *New Jersey Orthopaedic Society, the New Jersey Society of Interventional Pain Physicians*, the *Mid-Atlantic Regional chapter of the American College of Occupational and Environmental Medicine*, it is IASIC's position that reimbursement of dispensary cannabis products will ultimately put patients at increased risk by encouraging use of *unproven* cannabis products that have not been demonstrated safe or effective.

The implications of reimbursement of cannabis products purchased for medical purposes include:

- 1. Favoring a drug product category with known serious safety risks and for which there is not credible evidence to support its use, especially when used as a substitute for an FDA-approved therapy
- 2. Encouraging the marketing of dispensary cannabis products with unsubstantiated claims of therapeutic valueⁱ, and encouraging their use by vulnerable patients based on pseudoscience and misleading promotion, and
- 3. Requiring society to bear the costs of these products, as well as the foreseeable consequences associated with their harmful effects and widespread use.

In written testimony submitted to the FDA regarding the health impacts of cannabidiol (CBD), Dr. Robert L. DuPont, former director of the National Institute on Drug Abuse (NIDA) and member of IASIC's Physician Council, stated, "Patients and their clinicians have fought for and deserve the ability to rely upon the FDA's regulatory process and enforcement mechanisms when making decisions about what they ingest to improve their health and treat disease. We have a century of experience that shows the societal benefits of having an independent FDA safeguard the health of our society." ii

published on the harms of cannabis and its derived products. For example:

- Research suggests that "parental cannabis use has the potential to produce intergenerational effects on brain development, thus impacting children with prenatal or pregestational parental cannabis use." This evidence prompted the American College of Obstetricians and Gynecologists (ACOG) to advise against "prescribing or suggesting the use of marijuana for medicinal purposes during pre-conception, pregnancy, and lactation."
- Regarding Post Traumatic Stress Disorder (PTSD) (a common "qualifying condition in state medical cannabis programs), according to the *American Psychiatric Association* (APA): the APA Council on Addiction Psychiatry, the Council on Research, and the Council on Quality Care reviewed available evidence regarding the use of cannabis in the treatment of PTSD and concluded that no published evidence of sufficient quality exists in the medical literature, and...[the] APA does not endorse cannabis for treatment of PTSD at this time, as further study is needed." The Veterans Administration/Department of Defense "recommends against treating PTSD with cannabis, [noting] preliminary evidence [that] cannabinoids could improve PTSD symptoms...is offset by the significant side effects including tolerance, dependence, withdrawal syndrome, psychosis, cognitive deficits, and respiratory symptoms if smoked."
- The Alzheimer's Association explains why manufacturers' claims of cannabis' benefits for people with neurodegenerative disorders are misleading, stating, "Although some of the chemical components of cannabis have been studied in relationship to Alzheimer's and dementia, most of this research has been conducted in animal models and cell cultures, not in people, [and] research findings to date have been inconclusive and contradictory.

Reimbursement of dispensary cannabis products before there is robust scientific evidence supporting their use puts patients' health and lives at risk. Such reimbursement policy would essentially turn the entire concept of medical insurance on its head. Now, instead of paying for a scientifically validated therapy, a commercial or publicly funded payer would be paying for a purported 'treatment' despite the absence of rigorous clinical evidence demonstrating a therapeutic benefit, an effective dosage, and long-term safety.

IASIC members share the hope that cannabis demonstrates therapeutic benefit for diseases or conditions where there are no treatments that the FDA considers safe and effective. But when a product is marketed and sold outside the regulatory process, there are no standards for purity, or for what dosing or delivery methods are safe and effective; patients are just getting a "pig in a poke" -- it's an unknown entity being packaged and sold to vulnerable consumers.^{iv}

We urgently need smart public health policies that follow the science, prevent addiction, and decrease mental illness, including psychosis, depression, and suicide. Reimbursement for non-standardized, non-FDA-regulated products sends the wrong message and will take us in the wrong direction.

Sincerely,

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ⁱ American Academy of Neurology 2021 Position Statement on Use of Cannabis for Medical Purposes; Theodore Caputi, PhD: "The Use of Academic Research in Medical Cannabis Marketing: A Qualitative and Quantitative Review of

Theodore Caputi, PhD: "The Use of Academic Research in Medical Cannabis Marketing: A Qualitative and Quantitative Review of Company Websites," Journal of Studies on Alcohol and Drugs, Jan 2022

ii Docket No. FDA-2019-N-1482, Scientific Data and Information about Products Containing Cannabis or Cannabis-Derived Compounds; Public Hearing; Request for Comments; https://www.ibhinc.org/blog/2019/5/31/robert-dupont-cbd-fda-testimony iii Deepak Cyril D'Souza, Marta DiForti, Suhas Ganesh, Tony P. George, Wayne Hall, Carsten Hjorthøj, Oliver Howes, Matcheri Keshavan, Robin M. Murray, Timothy B Nguyen, Godfrey D. Pearlson, Mohini Ranganathan, Alex Selloni, Nadia Solowij & Edoardo Spinazzola (2022) Consensus paper of the WFSBP task force on cannabis, cannabinoids and psychosis, The World Journal of Biological Psychiatry, 23:10, 719-742, DOI: 10.1080/15622975.2022.2038797

iv Excerpted from interview with IASIC President Eric Voth, "Marijuana is focus of international academy," What's Up Woodbridge, Oct 2021, https://whatsupwoodbridge.com/marijuana-use-focus-international-academy