Duke | MARGOLIS CENTER *for* Health Policy

Exploring Policy Options for Establishing Cannabidiol Safety Surveillance

July 17, 2020 | 11:00am-3:00pm

Meeting Agenda Day 1

Since the passage of the Agriculture Improvement Act of 2018, consumers have experienced increased access to products containing cannabidiol (CBD); however, there remains a lack of information about the safety of CBD. Establishing a CBD safety surveillance system would allow regulators to obtain a better understanding of the risks of CBD, and would enable them to quickly identify and respond to emerging public health threats related to CBD. This workshop, convened under a cooperative agreement between the Robert J. Margolis, MD, Center for Health Policy at Duke University and the U.S. Food and Drug Administration (FDA), will explore opportunities to develop systems and approaches to gain better insight into the safety of CBD with the goal of informing policymakers and public health professionals. Key topics for discussion include:

- Exploring existing CBD safety surveillance efforts;
- Identifying key data and methodological challenges when studying CBD safety;
- Considering which data sources could be used to assess CBD safety; and,
- Identifying potential policy approaches and next steps to improve understanding of CBD safety.

11:00 a.m. **Welcome and Introductions**

Marta Wosińska, Duke-Robert J. Margolis, MD, Center for Health Policy

11:10 a.m. **Opening Remarks**

Douglas C. Throckmorton, Center for Drug Evaluation and Research, U.S. Food and Drug Administration

11:20 a.m. **Session I: Introduction to CBD and Monitoring Risks of Consumer Products Regulated by FDA**

Moderator: Marta Wosińska

Objective: This session will provide an overview of emerging trends in the consumer use of CBD products, as well as foundational challenges and opportunities around the monitoring of such trends. Discussions will draw from recent experience with products such as e-cigarettes and vaping. Discussion will also consider how safety is assessed in non-drug products, such as dietary supplements.

Presenters:

- Stephanie Jack and Clarke Olsen, Health Canada
- Jonathan Miller, U.S. Hemp Roundtable

Discussants:

- Larry Walker, National Center for Natural Products Research
- Terry Alsup, California Department of Public Health
- Douglas C. Throckmorton, CDER, FDA

Open Discussion

12:20 p.m. **Break**

12:50 p.m. **Session II: Existing Efforts to Track CBD Utilization and Potential Health Safety Risks**

Moderator: Adam Kroetsch, Duke-Margolis Center for Health Policy

Objective: This session will delve into the current landscape of efforts to track the utilization and safety of CBD. Discussion will consider key trends in consumer behavior around these products as well as product distribution, which will provide context around the formative research requirements of surveillance activities underway. Secondly, discussion will consider approaches being developed to detect signals, refine signal strength, and evaluate potential adverse events.

Panelists:

- Elyse Contreras, Colorado Department of Public Health & Environment
- Janetta Iwanicki, Rocky Mountain Poison & Drug Safety

Discussants:

- Jacqueline French, Epilepsy Foundation
- Gillian Schauer, Consultant

Open Discussion

1:50 p.m. **Break**

2:00 p.m. **Session III: Leveraging Potential Data Sources to Assess CBD Safety**

Moderator: Marta Wosińska

Objective: This session will explore data sources that can be leveraged to gain a better understanding of CBD safety. Both traditional public health data sources (e.g., surveys, poison center data, claims data) and non-traditional surveillance data sources (e.g., social media data and websites that track illicit substance abuse) will be discussed. It is likely that no one data source can comprehensively address all questions of interest and discussion will consider the strengths and weaknesses of each data source to answer key surveillance questions.

Panelists:

- Julia Dilley, Multnomah County and Oregon Public Health Division

- Robert Walsh, National Institute on Drug Abuse (NIDA)
- Ryan Moog, Cerner Corporation
- Rich Maturo, Nielsen
- Oded Netzer, Columbia Business School

Open Discussion

3:00 p.m. **End of Day 1**

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July 20, 2020 | 10am-1pm

Meeting Agenda Day 2

10:00 a.m. **Recap of Day 1 and Opening Remarks**

Marta Wosińska, Duke-Robert J. Margolis, MD, Center for Health Policy

10:15 a.m. **Session IV-A: Establishing Key Goals and Capabilities for Establishing a National CBD Safety Surveillance Network**

Moderator: Marta Wosińska

Objective: This session will discuss next steps to establish a sustainable CBD safety surveillance system. Discussion will consider the cost and feasibility of different surveillance system approaches, and will explore the strengths and weaknesses of these approaches to answer different surveillance questions of interest.

Discussants:

- Nancy Dryer, IQVIA
- William Crown, OptumLabs

Open Discussion

11:25 a.m. **Break**

11:45 a.m. **Session IV-B: Exploring Potential Policy Options for Establishing a National CBD Safety Surveillance Network**

Moderator: Marta Wosińska

Discussants:

- Robert Ball, Center for Drug Evaluation and Research, U.S. Food and Drug Administration
- Janetta Iwanicki, Rocky Mountain Poison & Drug Safety

Open Discussion

12:55 p.m. **Closing Remarks**

Marta Wosińska**,** Duke-Robert J. Margolis, MD, Center for Health Policy

1:00 p.m. **Adjournment**

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