Key Priorities for FDA’s Controlled Substances Program

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The **Controlled Substance Program (CSP)** aims to help CDER take a more proactive approach to limit problematic use while enabling appropriate access to controlled substances.

**CSP Mission**

To promote the *public health* through strategic programs and policies to help *enable appropriate access* to controlled substances for medical use and identify, mitigate and manage emerging issues with controlled substances to *minimize risks associated with problematic use* of these products.

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**Controlled Substance Program (CSP)**

*Marta Sokolowska, Associate Director for Controlled Substances*

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**Controlled Substance Staff (CSS)**

*Dominic Chiapperino, Director, CSS*

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**Controlled Substance Initiatives (CSI)**
CSP Core Functions

**Scientific Expertise**
- Provide consultation services and medical science-based assessment and management of drug abuse risks

**Identify and Analyze**
- Proactively identify emerging issues in controlled substances and related strategy and initiatives to drive appropriate access

**Manage and Influence**
- Effectively coordinate CDER/FDA controlled substances efforts and facilitating intra- and inter-agency interactions

**Rapid Response**
- Provide rapid response to internal and external inquiries related to controlled substances

**Strategic Engagement**
- Communicate with and engage stakeholders on emerging issues/ongoing activities (with internal strategic partners)
This is a non-exhaustive list of the internal and external stakeholders for CSP.
CSP Portfolio

Opioids
- Opioid data warehouse
- SUPPORT Act
- Overdose reversal

Benzodiazepines
- Assessment of abuse and withdrawal

Stimulants
- Assessment of abuse
- Development of treatment for stimulant use disorder

Cannabis

NMEs
CSP and COVID-19

CSP is broadly working across CDER to assess the **public health consequences of COVID-19 on drug abuse**, as well as the potential actions that FDA can or should proactively take.

- **What are you most concerned about regarding the potential impact of COVID-19 on substance abuse?**
- **Who should CSP be engaging to better understand and prepare for the potential public health consequences of COVID-19 on substance abuse?**
Thank you

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