Free markets. Real solutions.

EXPLAINER

How a Drug's Schedule I Status Restricts Research

July 2023

Introduction

From laboratory studies to randomized controlled trials, drug research is essential to elucidate the potential effects—both therapeutic and harmful—of known and novel substances. However, scientists report barriers when it comes to studying a particular class of drugs: those that are classified as Schedule I under the Controlled Substances Act (CSA). In fact, the director of the National Institute on Drug Abuse (NIDA), Nora Volkow, explained in an interview with *Marijuana Moment* that the multi-level, highly bureaucratic process "detracts [from] researchers who want to investigate because it's just much more cumbersome than doing studies with other substances."

Schedule I drugs are subject to the most restrictions, including when it comes to research. Examples of Schedule I drugs include heroin, cannabis and psilocybin.

What are Schedule I drugs?

The CSA classifies drugs into five progressive "schedules," according to two primary criteria:

Criteria One	**Potential for abuse or dependency (abuse is undefined)** • Schedule I* deemed most potential for abuse/dependency • Risk for abuse/dependency declines as schedule increases
Criteria Two	**Degree of established medical utility** • Schedules II-V all have established medical utility

** Schedule I drugs are subject to the most restrictions, including when it comes to research.*

Why study scheduled drugs?

Although Schedule I drugs do not currently have established medical utility, that does not mean they lack medical potential. For example, cannabis and psilocybin are Schedule I drugs, but recent research suggests they have therapeutic effects. Studying scheduled substances can also result in discovering new medicines. For example, the overdose reversal drug, naloxone, is chemically similar to morphine, which is a Schedule II drug. Another reason to study scheduled drugs is to understand how they affect people without the dangers of adulterants found in the illicit drug supply.

How does Schedule I status affect research?

- **Red Tape**

  Scholars must receive permission from their institution, state and the Drug Enforcement Administration (DEA) for any research in which they obtain, synthesize or distribute a Schedule I drug. Some studies, such as clinical trials, may also require approval through the U.S. Food and Drug Administration. This process can be time consuming. DEA approval alone takes several months, while institutional review boards often take extra time to evaluate the research ethics of a Schedule I study, and may be reluctant to permit the research at all.

R Street

Free markets. Real solutions.

EXPLAINER

How a Drug's Schedule I Status Restricts Research

July 2023

- **Funding Restrictions**
  The federal government does not fund research that "promotes the legalization of any drug or other substance included in schedule I" unless substantial data already supports its therapeutic value. Non-government funders, on the other hand, often hesitate to cover research on Schedule I drugs as they are believed to be "dangerous."

- **Substance Access**
  Schedule I drugs must be synthesized by approved researchers or obtained via NIDA. In the case of cannabis, it must be obtained from a handful of approved growers. Because federally approved growers do not produce the diversity of products available in the real-world supply, this requirement limits the external validity of findings.

By the Numbers

750 lbs
The minimum weight of a Schedule I drug storage safe unless it's attached to the ground or a wall

$296
Annual fee for DEA registration in 2023

250+
The number of Schedule I substances

750
DEA-approved Schedule I researchers as of 2019

For perspective, there are

~300
Substances listed on schedules II through V combined

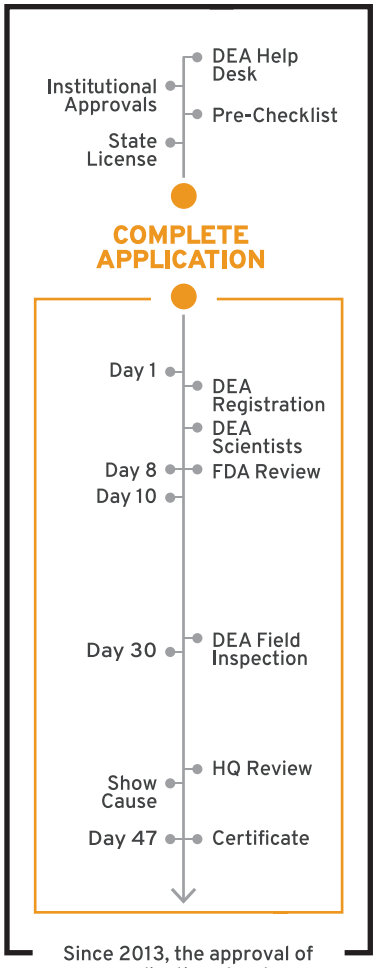
In 2019,

8,079
United States scholars received DEA approval to study them

95 days
Average number of days to approval once complete application is received
See DEA Regulatory Timeline

3-14 months
Time that a DEA research license is good for

DEA Regulatory Timeline



Since 2013, the approval of new applications has been reduced from 161 days.

Descheduling and Rescheduling Potential

Even if researchers are able to conduct research on a Schedule I substance and show that there are medical uses for the substance, rescheduling or descheduling the drug remains difficult to accomplish. The executive and legislative branches of government have the authority to change a drug's schedule, but the president is bound by the criteria set forth by the CSA, while Congress can change schedules with an amendment to the CSA. Non-governmental entities can also petition the DEA to change a drug's schedule; however, attempts to use this process for cannabis have failed.

Contact us

For more information, please contact:

Stacey McKenna
Resident Senior Fellow
Integrated Harm Reduction
smckenna@rstreet.org

Chelsea Boyd
Research Fellow
Integrated Harm Reduction
cboyd@rstreet.org