

Key Findings from ASA report: *Denial of Existing Medical Cannabis Research: A Peer-Reviewed Comparative Analysis of DEA's "Denial of Petition to Initiate Proceedings to Reschedule Marijuana"*

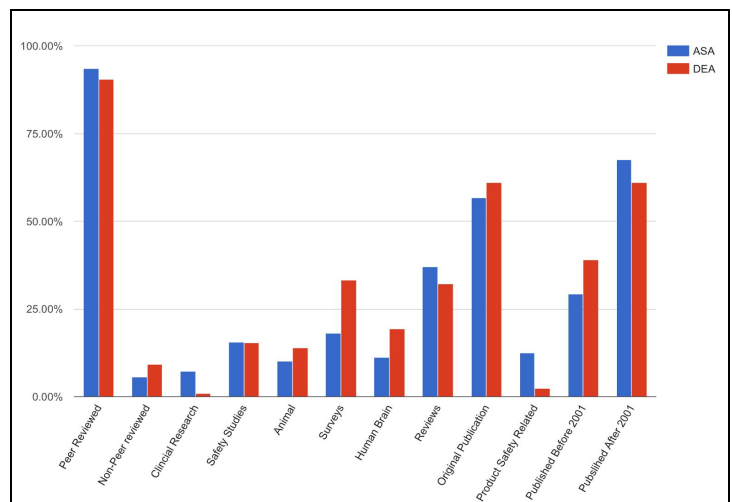
On August 11, 2016, the Drug Enforcement Administration (DEA) issued a report concluding that "marijuana" (cannabis) should remain in Schedule I of the Controlled Substances Act due to the following 3 factors:

1. Marijuana has a high potential for abuse;
2. Marijuana has no currently accepted medical use in treatment in the U.S.; and
3. Marijuana lacks accepted safety for use under medical supervision.

Americans for Safe Access (ASA) has organized scientific evidence that the DEA decision is flawed, and cannabis should be removed from its Schedule I status, in a report entitled [Denial of Existing Medical Cannabis Research: A Peer-Reviewed Comparative Analysis of DEA's "Denial of Petition to Initiate Proceedings to Reschedule Marijuana."](#) This report compares the non-peer reviewed Health and Human Services 8-Factor analysis (which DEA used to make its decision to keep cannabis in Schedule I) with the peer-viewed 8-Factor analysis prepared by ASA. Note: page numbers in parentheses refer to pages in ASA's Denial report.

Source Material Comparison (page 8)

- DEA's report: 207 citations, ASA's: 558.
- ASA's report was submitted for peer-review; there is no evidence that the DEA report was peer reviewed, lacks accountability due to no listed authors.
- DEA's report is deficient in addressing clinical trials with existing standardized cannabis-based medicines (2 citations; representing <1% of their citations).
- Nearly 1/10th of the DEA report comes from non-peer reviewed sources.
- Fully 1/3rd of the DEA's report comes from epidemiologic and survey based research, many of which do not bare clinical. significance or do not demonstrate long term harm.
- The DEA's report was deficient in its analysis and reporting of medical cannabis products, i.e., 9,000 patient/years of placebo-controlled clinical research with nabiximols (i.e., cannabis extracts) was not even mentioned.
- While the DEA devoted a higher proportion of citations to the human brain (19%), it represents only 40 citations. While ASA cited 62 studies on the subject, which represents about 11% of ASA's 558 citations.



See the report at: <http://www.safeaccessnow.org/deareport>

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Commonground (page 5)

- ASA agrees with DEA that cannabis satisfies Factors 1b, 1d, 2, 3, 6, and 8 of the 8-factor analysis
- Even the federal government admits the Gateway Theory is not supported by science

DEA claim that Marijuana has a high potential for abuse (page 11)

- If medical cannabis and related products had a high potential for abuse, there would exist a significant black market for both FDA and State regulated medical cannabis products
- U. Mississippi has been producing whole plant 300 cannabis cigarettes per/patient each month to federal IND patients since 1970, yet no report exists of finding these on the blackmarket
- Europe has no report of any significant black market for medical cannabis products such as Sativex, Marinol, or pharmaceutical grade cannabis produced by Bedrocan®
- Cannabis is physiologically non-toxic, there is no known LD₅₀ (lethal dose) for cannabis, and is not associated with causing any long-term negative health consequences

DEA claim of no currently accepted medical use in treatment in the U.S. (page 13)

While DEA claims the cannabis does not meet the federal 5-element test to determine accepted medical use, ASA has found significant evidence to the contrary.

1. the drug's chemistry is known and reproducible;
 - The chemistry of cannabis is both known and reproducible. Complete cannabis monographs have been published, including one by the *American Herbal Pharmacopoeia* (AHP), which is based on FDA guidelines (page 13)
2. there are adequate safety studies;
 - Based on toxicity research (sedation, cytotoxicity, genotoxicity, etc.) cannabis and its components have a uniquely wide safety margin (page 18)
3. there are adequate and well-controlled studies proving efficacy;
 - A 2009 review of clinical studies conducted over a 38-year period found that out of 33 U.S. published controlled clinical trials, almost all demonstrated significant and measurable benefits in subjects receiving medical cannabis treatment (page 19)
4. the drug is accepted by qualified experts; and
 - Statements from 14 medical organizations urging rescheduling (page 21)
5. the scientific evidence is widely available.
 - There are tens of thousands of peer reviewed articles available online, including: Springer, Wiley, Pubmed, and websites of expert groups such as ASA, theAnswerpage.org, and the International Cannabis and Cannabinoid Institute

DEA claim that marijuana lacks accepted safety for use (page 24)

- DEA analysis excluded nearly 100 clinical trials completed with cannabis products
- HHS 8-Factor analysis included only 2 clinical trials

Conclusions/Recommendations (page 27)

- Only option for moving forward is Congressional Action: Pass the CARERS Act (H.R. 1538/S. 683)
- Update out of date information on the DEA's website and education materials

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