

June 12, 2019

ADM Brett P. Giroir, M.D.  
Assistant Secretary for Health  
Office of the Assistant Secretary for Health  
U.S. Department of Health and Human Services  
200 Independence Ave, S.W.  
Washington, D.C. 20201  
Via Email: [ash@hhs.gov](mailto:ash@hhs.gov)

**Re: Information Quality Act Correction Request Regarding the HHS Scientific Assessment That Marijuana Has No Accepted Medical Use (81 FR 53690 (2015))**

The Competitive Enterprise Institute (CEI) submits this request for correction of this agency’s 2015 scientific evaluation of medical marijuana. We submit this under the Information Quality Act (IQA), 114 Stat. 2763, section 515, as implemented through HHS and Office of Management and Budget (OMB) guidelines. These guidelines were expanded by OMB in a [memorandum](#) issued on April 24, 2019. This request concerns the scientific evaluation of marijuana performed by HHS without a peer review—specifically, the attachment to a June 25, 2015 letter from Karen B. DeSalvo, Acting Assistant Secretary for Health, to Chuck Rosenberg, Acting Administrator of the Drug Enforcement Administration, (81 FR 53690–738). This letter formed the basis for the DEA 2016 decision to keep marijuana under Schedule I of the Controlled Substances Act.<sup>1</sup>

Under OMB’s new requirements, **“agencies will not take more than 120 days to respond to an RFC without the concurrence of the party that requested the request for correction.”** For this reason, we expect a response to this request for correction (RFC) within 120 days. In addition, the new OMB guidelines require that, “The agency response should contain a point-by-point response to any data quality arguments contained in the RFC and should refer to a peer review that directly considered the issue being raised, if available.” Furthermore, “Agencies should share draft responses to RFCs and appeals with OMB prior to release to the requestor for assessment of compliance with the above norms.” Thus, responses to correction requests now need to be reviewed in advance by OMB sufficiently in advance of the 120-day deadline.

The attachment to the HHS letter to DEA was titled “Basis For the Recommendation for Maintaining Marijuana in Schedule I of the Controlled Substances Act” [hereafter referred to as

---

<sup>1</sup> DEA, Denial of Petition To Initiate Proceedings To Reschedule Marijuana, 81 FR 53687 (2016), <https://www.federalregister.gov/documents/2016/08/12/2016-17954/denial-of-petition-to-initiate-proceedings-to-reschedule-marijuana>.

the HHS Scientific Evaluation]. We ask HHS to determine that this document does not meet the quality requirements of the Information Quality Act.

The document was disseminated via the Federal Register at 81 FR 53690–738. It concluded that “currently marijuana does not have any accepted medical use, even under conditions where its use is severely restricted.” 81 FR 53702. Based on the scientific evaluation attached to this letter, DEA decided to not reschedule marijuana out of Schedule I, and that continues to be its position.<sup>2</sup>

### **The HHS Scientific Evaluation of Marijuana Is a Highly Influential Scientific Assessment**

On November 30, 2011, the governors of Rhode Island and Washington, petitioned DEA to remove marijuana from Schedule I of the Controlled Substances Act. In accordance with the 21 U.S.C. 811(b), upon receiving this petition, DEA requested “a scientific and medical evaluation” of marijuana from HHS.

On June 25, 2015 HHS responded to DEA via a letter, with its Scientific Evaluation of Marijuana attached. DEA published the letter and attachment in the Federal Register at 81 FR 53689.

HHS failed to explain whether the attachment was a “highly influential scientific assessments” (HISA) or whether instead it merely contained “influential scientific information.” As is shown below, the document is in fact a HISA. This triggers a number of Information Quality requirements that HHS failed to follow. But even if the document was not a HISA and contained only “influential scientific information,” HHS still would have failed to follow the OMB guidelines.

*The HHS Scientific Evaluation of Marijuana is a scientific assessment.*

According to OMB’s [Final Information Quality Bulletin for Peer Review](#), 70 FR 2664 (2005), (“OMB 2005 Final Memo”), the “term ‘scientific assessment’ means an evaluation of a body of scientific or technical knowledge, which typically synthesizes multiple factual inputs, data, models, assumptions, and/ or applies best professional judgment to bridge uncertainties in the available information. These assessments include, but are not limited to, **state-of-science reports**; technology assessments; **weight-of-evidence analyses**; **meta-analyses**; **health, safety, or ecological risk assessments**; **toxicological characterizations of substances**; integrated assessment models; **hazard determinations**; or **exposure assessments**.” *Id.* at 2666 (emphasis added).

The Controlled Substances Act, 21 U.S.C. 811(b), requires a “scientific... evaluation” by HHS. The HHS attachment purported to fulfill this function. It attempted to assess, for instance, the

---

<sup>2</sup> *Id.*

“Scientific Evidence of [Marijuana’s] Pharmacological Effects” (81 FR 53692), “The State of Current Scientific Knowledge Regarding [Marijuana]” (81 FR 53698) and other evaluations which are considered under the OMB guidelines to be scientific assessments.

*The HHS Scientific Evaluation of Marijuana is highly influential due to its social and economic impacts and its controversial nature.*

The OMB 2005 Final Memo defines a “highly influential scientific assessment” (HISA) as a scientific assessment which “(i) Could have a potential impact of more than \$500 million in any year, or (ii) Is novel, controversial, or precedent-setting or has significant interagency interest.” 70 FR 2671.

The Federal Government spent about \$4 billion in 2016 on marijuana prohibition, the state and local governments spent another \$6 billion.<sup>3</sup> There were almost 660,000 arrests for marijuana in 2017.<sup>4</sup> The total impact of spending on police, courts, jails other costs by the federal, state and local governments substantially exceeds \$500 million in impacts per year. Last year the marijuana industry<sup>5</sup> was a \$10.4 billion industry in the U.S.<sup>6</sup> The potential impact is far beyond the \$500 million minimum requirement for the scientific evaluation to be considered a HISA.

The HHS Scientific Evaluation is also controversial and as such, it is a HISA on that basis as well. The following major national or international medical organizations have substantially disagreed with evaluation’s conclusion that marijuana has no accepted medical use:

- World Health Organization’s Expert Committee on Drug Dependence.<sup>7</sup>
- American Nurses Association “support for the review and reclassification of marijuana’s status from a federal Schedule I controlled substances.”<sup>8</sup>
- American Academy of Family Physicians: “The AAFP recognizes that there is support for the medical use of marijuana...”<sup>9</sup>

---

<sup>3</sup> Jeffrey Miron, Cato Institute, The Budgetary Effects of Ending Drug Prohibition (2018), <https://object.cato.org/sites/cato.org/files/pubs/pdf/tbb-83.pdf>.

<sup>4</sup> Calculated from 1,632,921 total drug abuse arrests according to <https://ucr.fbi.gov/crime-in-the-u.s/2017/crime-in-the-u.s.-2017/tables/table-29>. 3.7% of those are for sale/manufacturing of marijuana (60,418 arrests) and 36.7% of which are for possession (599,282 arrests) according to <https://ucr.fbi.gov/crime-in-the-u.s/2017/crime-in-the-u.s.-2017/tables/arrest-table>.

<sup>5</sup> Federal law for medical marijuana is not currently being enforced due to the Rohrabacher–Farr appropriation rider.

<sup>6</sup> AP, Legal marijuana industry had banner year in 2018 (Dec. 27, 2018), <https://www.cnbc.com/2018/12/27/legal-marijuana-industry-had-banner-year-in-2018.html>

<sup>7</sup> 84 FR 7067 (March 1, 2019) (“preparations of cannabis have therapeutic advantages for treatment of conditions such as certain forms of pain and epilepsy”), <https://www.federalregister.gov/documents/2019/03/01/2019-03662/international-drug-scheduling-convention-on-psychoactive-substances-single-convention-on-narcotic>

<sup>8</sup> <https://www.nursingworld.org/~49a8c8/globalassets/practiceandpolicy/ethics/therapeutic-use-of-marijuana-and-related-cannabinoids-position-statement.pdf>

<sup>9</sup> <https://www.aafp.org/about/policies/all/marijuana.html>

- American Public Health Association: “cannabis/marijuana was wrongfully placed in Schedule I of the Controlled Substances Act depriving patients of its therapeutic potential.”<sup>10</sup>
- American Medical Student Association: “there is support for the medical use of marijuana.”<sup>11</sup>
- Epilepsy Foundation: “Calling on the Drug Enforcement Administration to implement a lesser schedule for marijuana so that it can be more easily accessible for medical research.”<sup>12</sup>
- Leukemia & Lymphoma Society: “remove criminal and civil sanctions for the doctor-advised, medical use of marijuana by patients with serious physical medical conditions.”<sup>13</sup>
- National Multiple Sclerosis Society.<sup>14</sup>

Additionally, while HHS found no medical use for cannabis, cannabis has been recognized to have a medical use by 33 states, four U.S. territories, and the District of Columbia.<sup>15</sup>

As further evidence of its controversial nature, there have also been several petitions submitted requesting rescheduling of marijuana:

- **The 1974 Petition.** The National Organization for the Reform of Marijuana Laws (NORML) filed a rescheduling petition in 1972, which the precursor to DEA refused to process until ordered to do so in 1974 by the D.C. Court of Appeals.<sup>16</sup> In 1986 the DEA administrator initiated public hearings on cannabis rescheduling that lasted two years. The DEA’s chief administrative law judge Francis Young ruled that cannabis did not meet the legal definition of a Schedule I drug, until he was overruled by DEA Administrator John Lawn.
- **The 1995 Petition.** High Times Magazine and Jon Gettman filed a petition in 1995 petitioning for rescheduling. In response to this petition the White House Office of National Drug Control Policy (ONDCP) asked the Institute for Medicine to conduct a study and in 1999 it recommended “Short-term use of smoked marijuana (less than six months) for patients with debilitating symptoms (such as intractable pain or vomiting).”<sup>17</sup>

<sup>10</sup> <http://druglibrary.org/schaffer/hemp/medical/apha.htm>

<sup>11</sup> <http://www.amsa.org/wp-content/uploads/2015/05/A8-Principles-Regarding-Illegal-drugs-alcohol-and-tobacco-1.pdf>

<sup>12</sup> <https://www.epilepsy.com/article/2014/2/epilepsy-foundation-calls-increased-medical-marijuana-access-and-research>

<sup>13</sup> <https://maps.org/research-archive/mmj/lnls-res.pdf>

<sup>14</sup> <https://www.nationalmssociety.org/Treating-MS/Complementary-Alternative-Medicines/Marijuana/Marijuana-FAQs#question-What-is-the-Society’s-position-on-the-use-of-marij>

<sup>15</sup> The following states and U.S. territories have recognized that marijuana has a medical use: Alaska, Arizona, Arkansas, California, Colorado, Connecticut, Delaware, District of Columbia, Florida, Guam, Hawaii, Illinois, Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Missouri, Montana, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Dakota, N. Mariana Islands, Ohio, Oklahoma, Oregon, Pennsylvania, Puerto Rico, Rhode Island, U.S. Virgin Islands, Utah, Vermont, Washington, West Virginia.

<sup>16</sup> *Nat’l Org. for Reform of Marijuana Laws (NORML) v. Ingersoll*, 497 F.2d 654, 659 (D.C. Cir. 1974).

<sup>17</sup> <https://web.archive.org/web/20000815232249/http://books.nap.edu/html/marimed/ch4.html>.

Despite this, DEA denied the petition, and the D.C. Circuit held that the petitioners lacked standing to challenge the decision.

- **The 2009 and 2011 Petitions.** In 2009, Rev. Bryan A. Krumm, CNP, filed a rescheduling petition for cannabis. And in 2011 Washington State Governor Christine Gregoire and former Governor of Rhode Island Lincoln Chafee filed a petition with DEA to reschedule cannabis. These petitions were denied on August 12, 2016. The letter sent by HHS to DEA concerning these petitions is the subject of this correction request.

Lastly, the American people also accept the medical potential of marijuana, with 93% supporting “allowing adults to legally use marijuana for medical purposes if their doctor prescribes it.”<sup>18</sup>

This demonstrates that a determination by HHS that marijuana has no medical use is, at the very least, controversial. As such, its Evaluation must be considered a Highly Influential Scientific Assessment according to the OMB guidelines.

### **Even if it is not a HISA, the HHS Evaluation Is Clearly Influential Scientific Information**

A lower standard set of peer review requirements is applied information that is not a HISA, but is instead categorized as “influential scientific information.” The definition of this is “scientific information the agency reasonably can determine will have or does have a clear and substantial impact on important public policies or private sector decisions.” OMB 2005 Final Memo, Section I, Part 6. Even if HHS properly determined that the Evaluation is not a HISA, it is at least “influential scientific information.” It was the basis of the HHS decision, required by 21 U.S.C. § 811(b), that was “binding on the Attorney General as to such scientific and medical matters.” As such, it clearly had, and continues to have, a substantial impact on these important public priorities.

### **HHS Failed to Follow the OMB Guidelines By Ignoring the Peer Review Requirement**

HHS did not perform a peer review, as required for all HISA and ISI information. OMB 2005 Final Memo, Section II, Part 1 (“To the extent permitted by law, each agency shall conduct a peer review on all influential scientific information that the agency intends to disseminate.”); Section II, Part I (“To the extent permitted by law, each agency shall conduct peer reviews on all information subject to this Section.”). As such, none of the peer review requirements for HISA or ISI by OMB were followed by HHS.

Because no peer review was done, the requirements of OMB concerning selection of reviewers, independence, choice of peer review mechanism, opportunity for public participation in the peer review process, and certification of compliance were all violated by HHS.

Additionally, the new 2019 Memo states that “When an agency makes information originally collected or developed by other Federal agencies available to the public in a cross-agency dissemination, each agency is responsible for the quality of the information they contribute.” As

---

<sup>18</sup> U.S. Voters Believe Comey More Than Trump, Quinnipiac University National Poll Finds; Support For Marijuana Hits New High, Quinnipiac (April 26, 2018), <https://poll.qu.edu/national/release-detail?ReleaseID=2539>.

such, HHS is responsible for the quality of the information it sent to DEA, even if HHS did not directly disseminate it.

The failures by HHS to do a proper peer review as required by the OMB and HHS guidelines for the HHS Scientific Evaluation of Marijuana undermine the quality of the information disseminated.

**HHS Should Inform DEA and the Public that the 2015 HHS Scientific Evaluation of Marijuana Should Not Be Relied Upon Due to Lack of Peer Review**

The Information Quality Act guidelines require an agency to follow the proper peer review process before a scientific assessment can be disseminated or used in a regulatory process. No valid peer review process was done for the HHS Scientific Evaluation of Marijuana. Until such a peer review process is validly completed, under the OMB guidelines, HHS should formally withdraw its evaluation through a notice in the Federal Register inform the public that the information disseminated should not be relied upon for regulatory or other purposes until a proper peer review has been completed. Additionally HHS should inform DEA that the 2015 Scientific Evaluation of Marijuana did not follow the proper procedures for being relied upon in such a regulatory proceeding.

HHS should then start the process of peer reviewing the HHS Scientific Evaluation of Marijuana. Lastly, HHS will have to reconsider the Evaluation's findings in light of this new peer review process, taking into account objections and problems raised by the peer reviewers and the public. The public is required to be involved in a HISA peer review through the opportunity to submit comments for evaluation by the peer reviewers under OMB guidelines.

By withdrawing the HHS Scientific Evaluation of Marijuana and then restarting the peer review process for it, HHS can ensure that there is confidence in the quality of the information being disseminated.

Sincerely,

Devin Watkins, Attorney  
devin.watkins@cei.org  
Sam Kazman, General Counsel  
sam.kazman@cei.org  
Competitive Enterprise Institute  
1310 L Street NW, 7th Floor  
Washington, DC 20005  
(202) 331-1010