



December 1, 2021

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Acting Administrator
Office of Regulatory and Information Policy
725 17th Street, NW
Washington, DC 20503

Re: Request for OIRA to Resolve Interagency Disagreement Concerning IQA Implementation About Medical Marijuana

The Competitive Enterprise Institute (CEI) requests that OIRA resolve a dispute between two different agencies concerning responsibility for ensuring compliance with the Information Quality Act. This involves a scientific evaluation of medical marijuana which was done by HHS at the request of the DEA. HHS sent this evaluation to the DEA, which then published it in the Federal Register (81 FR 53690–738, 2016) and relied upon it to deny rescheduling of medical marijuana from its classification as a Schedule I drug.

The problem is that no peer review was ever conducted on this scientific evaluation, because each agency says the other agency was responsible for arranging it. HHS claims DEA was responsible for IQA compliance because DEA disseminated the evaluation without HHS approval. DEA claims compliance was HHS’s responsibility because the evaluation was performed by HHS.

We request that OIRA ensure coordination between these two agencies, so that that the underlying document meets the criteria of the Information Quality Act (“IQA”).

I. Background

Under the IQA, Section 515 of Public Law 106-554, Congress instructed OMB to develop rules to ensure the quality, objectivity, utility, and integrity of information disseminated to the public by agencies. To accomplish this, OMB established rules for all agencies requiring peer review of influential scientific information and a process of correction if an agency fails to do so. OMB’s Final Information Quality Bulletin for Peer Review, 70 FR 2664 (2005). “OIRA, in consultation with OSTP, is responsible for overseeing agency implementation” of these rules. 70 FR 2674. Additionally, according to the White House, “OIRA also coordinates agency implementation of the Information Quality Act, including the peer-review practices of agencies.” The White House, <https://www.whitehouse.gov/omb/information-regulatory-affairs/>. It is for that reason that we are contacting OIRA to resolve the conflict between the agencies.

Even if an agency disagrees, it is ultimately up to the OIRA Administrator to determine whether the peer review requirements are triggered. This is especially true for a Highly Influential Scientific Assessment (“HISA”) such as this one, and OIRA should make it clear when sending this back to the agencies that this document is a HISA. 70 FR 2676 (“This section applies to influential scientific information that the agency *or the Administrator* determines to be a scientific assessment that: (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.”).

II. Disagreement Between HHS and DEA Concerning Responsibility For IQA

A. CEI’s Initial Request for Correction to HHS

CEI submitted its initial request for correction to HHS on June 12, 2019. See Attachment A. We explained in detail why the Scientific Evaluation of Marijuana is a “scientific assessment” under the OMB Guidelines for Peer Review, which define the term to include “state-of-science reports” along with “weight-of-evidence analyses; meta-analyses; health, safety, or ecological risk assessments; toxicological characterizations of substances; integrated assessment models; hazard determinations; or exposure assessments.” 70 FR 2666.

In this case, the statute required a “scientific... evaluation,” 21 U.S.C. 811(b), and the HHS evaluation claimed to assess, for instance, “Scientific Evidence of [Marijuana’s] Pharmacological Effects” (81 FR 53692), and “The State of Current Scientific Knowledge Regarding [Marijuana]” (81 FR 53698).

CEI’s request for correction based its claim that the document was a HISA on two facts. First is the fact that the federal government spent about \$4 billion per year on marijuana prohibition, the state and local governments spent another \$6 billion with 660,000 arrests for marijuana possession per year. This easily met the HISA requirements of at least a \$500-million dollar impact.

Second is the fact that the claim that cannabis lacks medical use is widely contradicted by, among others, 33 states, four U.S. territories, and the District of Columbia, along with the World Health Organization’s Expert Committee on Drug Dependence, American Nurses Association, American Academy of Family Physicians, American Public Health Association, American Medical Student Association, Epilepsy Foundation, Leukemia & Lymphoma. This makes the claim controversial, and thus is another reason for why the scientific evaluation must be considered a HISA.

CEI argued that HHS had failed to follow OMB guidelines by failing to perform a peer review as required by OMB rules. We cited the OMB’s April 24, 2019 Memorandum, M-19-15, which in Implementation Update 2.1 explicitly required each agency to be responsible for the quality of the information it contributed.

HHS’s General Counsel Robert Charrow provided the initial response of HHS on September 24, 2019. See Attachment B. Charrow claimed that as IQA only applies to information

“disseminated by the agency” and as FDA rather than HHS disseminated it, so his opinion was that HHS was not required to ensure compliance with the IQA.

CEI appealed his decision on October 24, 2019, noting that Charrow had failed to consider Implementation Update 2.1. That update requires the agency that created the information to be responsible for it. See Attachment C. We also challenged the decision because under Implementation Update 4.4, HHS had initiated the distribution and that distribution, in OMB’s words, gave the “appearance of having the information represent agency views.” This follows closely the example given by OMB of “a risk assessment prepared by the agency to inform the agency’s formulation of possible regulatory or other action.” 67 FR 8454. That is, of course, exactly how the DEA used the report.

HHS’s Eric Hargan, who at the time was the Deputy Secretary before later became the Acting Secretary, provided the final response of the agency on February 7, 2020. See Attachment D. According to Hargan, HHS’s did not initiate the distribution by transmission of information to DEA. Thus, DEA was “the agency that released information that was subject to the IQA.” Hargan also claimed that HHS did not “sponsor” the distribution because it was FDA, rather than HHS, that “determined the content and presentation of the dissemination.” Hargan rejected the notion that there had been any “cross-agency dissemination” under Implementation Update 2.1. His reasoning was based this on HHS not choosing to make it public (again that was DEA).

B. CEI’s Request for Correction to DEA

On the basis of HHS’s response, CEI petitioned DEA for correction on October 25, 2019. See Attachment E. As with HHS, we explained to DEA that this was a scientific evaluation and should be considered a HISA and thus required peer review.

DEA’s Terrence Boos, Chief of the Drug & Chemical Evaluation Section of the Diversion Control Division of the DEA, provided the agency’s initial response on January 31, 2020. See Attachment F. According to Boos, “DEA has reviewed CEI’s request and has determined that because this request concerns HHS’s information, it is not subject to an Information Quality Act request direct to the DEA.” No further explanation was given.

CEI submitted its appeal to DEA on March 16, 2020. Attachment G. CEI noted that OMB had not been notified of the initial decision as required by OMB guidelines, the initial decision did not include a point-by-point response nor any explanation of its reasoning as required by OMB guidelines, that DEA had a responsibility to ensure the quality of the information it disseminates even if that information was originally created by other parties, and that HHS had already disclaimed any responsibility to ensure IQA compliance. That last requirement is due to OMB guidelines which state that “Agencies shall treat information quality as integral to every step of an agency’s development of information, including creation, collection, maintenance, and dissemination.” That rule is in addition to the requirement that “agencies should not disseminate substantive information that does not meet a basic level of quality.” CEI also noted that “if an agency, as an institution, disseminates information prepared by an outside party in a manner that reasonably suggests that the agency agrees with the information, this appearance of having the

information represent agency views makes agency dissemination of the information subject to these guidelines.” 67 FR 8454. This applies because DEA had made five separate statements that it agreed with the HHS evaluation and that this evaluation represented DEA’s views. CEI also attached a copy of the final decision by HHS, which contended that it was FDA that was responsible for the evaluation.

We were informed that OMB had instructed DEA and HHS to “get on the same page” as to the IQA requirements during our appeal. But as shown below, DEA decided not to do that.

On July 28, 2021, Matthew Strait, Deputy Assistant Administrator of the DEA Diversion Control Division, provided FDA’s final answer concerning our appeal. See Attachment H. Strait characterized DEA’s initial response as follows: “DEA had determined that because CEI’s request concerns HHS’s information, it was not subject to an Information Quality Act request directed to DEA.” Strait concluded that, “After careful consideration, DEA affirms its position that the IQA is not applicable to this request.” According to Strait this is because the “The 2015 medical and scientific evaluation for marijuana was originated by HHS, and is not DEA’s information.” Strait also claimed that this is also because HHS’s “medical and scientific recommendations are binding on DEA under the statute.” No further explanation was given by Strait.

CEI believes that the response provided by DEA is in direct conflict with the response provided by HHS. This means that it is OIRA’s responsibility to resolve that conflict.

III. OIRA Should Require One of the Agencies to Ensure Compliance With the IQA

It is OIRA’s responsibility to ensure that FDA and HHS are, in OMB’s words, “on the same page” concerning peer review requirements. One of the two agencies should be ordered by OIRA to consider the document a HISA and to conduct the required peer review. HHS should then re-evaluate the properties of marijuana in light of that scientific peer review.

Our view is that both agencies failed in their duties under the act. HHS should have peer reviewed the information before it sent the report to FDA, given that HHS knew that information would be disseminated and relied upon for regulatory action by FDA as required by statute. And DEA should not have published the HHS evaluation without first ensuring that the IQA requirements had been met (arranging for the peer review itself if HHS would not).

Even though both agencies failed in their duties under IQA, it makes the most sense to require HHS to do the HISA peer review in this case. This is because Implementation Update 2.1 puts primary responsibility on the agency that created the information, in this case HHS, and because HHS needs to re-evaluate its conclusions in light of the peer review results.

Finally, to prevent such a situation from occurring again, further clarification should be provided in a public memorandum for agencies in general.

For the last five years, marijuana has been entirely prohibited based on incorrect scientific

information. OMB rules required independent scientific experts to evaluate highly influential scientific information disseminated and relied upon by agencies, and yet that was not done by either agency. President Biden has pledged to “follow the science.” And that is all we have asked for that independent scientific experts be asked to follow the science and report on if they believe the scientific claims of HHS are accurate. We believe once that is done, those scientific experts will agree, along with the vast majority of states and medical organizations, that marijuana does have some medical uses and as such cannot properly be classified as a Schedule I drug.

Sincerely,

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