

Center for Regulatory Effectiveness

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September 12, 2016

Charles P. Rosenberg
Administrator (Acting)
Drug Enforcement Administration
Lincoln Place-West
700 Army Navy Drive
Arlington, VA 22202

Re: Kratom

Dear Mr. Rosenberg:

Having worked as a regulatory official in [five](#)¹ Presidential Administrations, I understand that regulatory policy is not and should not be determined via plebiscite; however, in the instance of Kratom, when 100,000 ²members of the public express outrage with a regulatory decision, it deserves a second look. Consequently CRE, in its role as a nationally³ recognized regulatory watchdog, is going to investigate this matter.

In addition CRE has received hundreds of letters—not form letters—from concerned citizens which we have posted on the *Kratom Policy Forum*⁴ on this [page](#). We realize the time involved in reading a regulatory docket. It is for this reason we compiled these first hand stories for easy viewing by policymakers; no need to visit a website, then input docket numbers and take other actions. All is needed is a simple click on the aforementioned link.

The Resolution of Interagency Conflicts Is Within the Jurisdiction of OMB

The Office of Information and Regulatory Affairs (OIRA) has been described as the cockpit of the regulatory state. It is an organization that has a statutory mandate to manage and oversee the flow of regulatory actions taken by federal agencies. In the discharge of these duties OIRA is often involved in one-on-one discussions with agency personnel to resolve potential conflicts with OMB personnel.

However in this instance, the DEA action to ban Kratom, the conflict is considerably wider in scope. In this instance there is a sharp disagreement among a number of federal agencies. Consequently if there were ever a time for an OMB intervention this is it.

¹ http://thecre.com/pdf/20160228_tozzi.pdf

² http://www.huffingtonpost.com/entry/petition-kratom-ban-dea_us_57d051e7e4b06a74c9f2177a

³ <http://thecre.org/emerging/seven.htm>

⁴ <http://www.thecre.com/forum11/>

The DEA's August 31, 2016 *Federal Register* notice placing Mitragynine and 7-Hydroxymitragynine into Schedule I⁵ highlights the out of context observation that the "consumption of kratom individually, or in conjunction with alcohol or other drugs, is of serious concern as it can lead to severe adverse effects and death." The FR notice, however, left out the crucial supporting data that is necessary to understand the information provided by DEA and to place it in a policy context. Earlier this year, the peer-reviewed neuroscience journal *Brain Research Bulletin* published a survey of the literature on traditional and non-traditional uses of Mitragynin which found that,

*"While several cases of toxicity and death have emerged in the West, such reports have been non-existent in South East Asia where kratom has had a longer history of use. We highlight the possible reasons for this as discussed in the literature. More importantly, it should be borne in mind that the individual clinical case-reports emerging from the West that link kratom use to adverse reactions or fatalities frequently pertained to kratom used together with other substances. Therefore, there is a danger of these reports being used to strengthen the case for legal sanction against kratom. This would be unfortunate since the experiences from South East Asia suggest considerable potential for therapeutic use among people who use drugs."*⁶

Thus, one federal agency--law enforcement agency--DEA, is in the process of making the possession of kratom a felony at the same time that a journal edited by the Principal Investigator of another federal agency, the National Institute of Child Health & Human Development, published an article which concluded that "more scientific clinical human studies are necessary to determine [kratom's] potential therapeutic value."⁷

Furthermore, USDA's Agricultural Research Services conducted a major Discovery and Development of Natural Products for Pharmaceutical and Agrochemical Applications research project that financed scientific research into kratom; USDA's research supported "future clinical studies." The research project's focus was developing "novel products, compounds and materials needed for specialized products in biotechnological, agrochemical, and pharmaceutical applications."⁸ The USDA/ARS research into kratom, which was published in a peer reviewed journal, explained that,

"The current study focuses on studying the absorption, distribution, metabolism, and excretion (ADME) properties of these three compounds using in vitro based assays. This will enable us to understand their drug-like properties for future clinical studies. This is the first report to compare the ADME properties of three

⁵ 81 FR 59929.

⁶ [Singh D](#)¹, [Narayanan S](#)², [Vicknasingam B](#)³ "Traditional and non-traditional uses of Mitragynine (Kratom): A survey of the literature" [Brain Res Bull.](#) 2016 May 10. Abstract, RESULTS. Available at <http://www.ncbi.nlm.nih.gov/pubmed/27178014>. [Emphasis added.]

⁷ Id., Abstract, CONCLUSION.

⁸ See, <https://www.ars.usda.gov/research/project/?accnNo=423803>.

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major compounds present in Kratom. The results show that mitragynine had superior ADME properties compared to the other two compounds.”⁹

The research footprint in favor of exploring the beneficial uses of kratom continues to grow. Research on kratom has developed to the point that two nationally recognized research institutions, the University of Massachusetts Medical School and the University of Mississippi not only received a grant from the parent institution, NIH, but also from two of its operating entities to study the beneficial uses of kratom. The grants were from:

- NIH
- National Institute for Drug Abuse
- National Center for Research Resources

The research is focused on the fact that “Kratom (*Mitragynia speciosa* korth) is recognized increasingly as a remedy for opioid withdrawal by individuals who self-treat chronic pain and/or generalized substance abuse.”

The kratom footprint grows even further. The research was so well conducted and received by the scientific community that the aforementioned institutions applied for a patent. How much more additional evidence is needed to demonstrate that the DEA has acted arbitrarily in issuing a ban on kratom?

In short, without going through a notice-and-comment process, DEA is obviating another agency’s research that was conducted with appropriated funds. With its action, DEA is also obviating the progress and promise of kratom research to boosting the American bio-sciences industry.

In short the arbitrary cancellation of Kratom by DEA without any public input suggests that OMB must reassert itself with respect to the regulatory actions of the agency. In addition where have been the officials the Office of Legal Counsel in the Department of Justice whose job is to review regulatory actions taken by the components of the agency before they are submitted to OMB?

DEA’s Action on Kratom Violates the US-Canada Regulatory Cooperation Council (RCC) Agreement

DEA is unilaterally outlawing the possession of kratom at the same time that Health Canada, a regulatory agency with which the US coordinates closely, lists kratom as a permitted Natural Health Product (NHP).¹⁰ DEA’s action is particularly problematic since earlier this year the FDA recognized Canada as having a comparable food safety system to the US.¹¹ DEA’s unilateral actions to declare illegal a botanical that is recognized by Health Canada as a Natural Health Product threatens the

⁹ See, <https://www.ars.usda.gov/research/publications/publication/?seqNo115=302305>.

¹⁰ See, <http://webprod.hc-sc.gc.ca/nhp/nd-bdipsn/ingredReq.do?id=6743&lang=eng>.

¹¹ Food and Drug Administration, Constituent Update, “FDA Recognizes Canada as Having a Comparable Food Safety System to the U.S.” May 4, 2016. Available at <http://www.fda.gov/Food/NewsEvents/ConstituentUpdates/ucm498611.htm>.

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FDA's regulatory recognition of Canada and with it the basis of US and Canadian regulatory cooperation.

DEA states in its *Federal Register* notice that it sent a letter to HHS stating its intent to place kratom in Schedule I more than three months ago, it is a letter that DEA has apparently chosen not to publicly disseminate. The *Federal Register* notice reports HHS's response to the DEA letter but does not indicate what questions prompted the answers nor does it indicate whether DEA called the violation of the RCC agreement to the attention of HHS. CRE looks forward to reviewing DEA's supporting documents; to this end we would appreciate your timely response to an earlier request¹² for a copy of the letter written by DEA to HHS regarding its intent to place kratom in Schedule I.

Former Deputy FDA Commissioner Taylor, in his statement on the US-Canadian regulatory recognition agreement, explained that it "establishes a framework for regulatory cooperation in a variety of areas that range from scientific collaboration to outbreak response."¹³ The Deputy Commissioner further explained that:

"this arrangement is part of the US-Canada Regulatory Cooperation Council in which the countries intend to better align their food safety regulatory systems, reduce unnecessary duplication, enhance information sharing, and to the extent possible, leverage resources so that the agencies can better meet their public health objectives."

DEA's action creates the impression that it has the authority to veto any agreement reached by the US-Canada Regulatory Cooperation Council (RCC).

CRE also notes that the White House's Strategy to Combat Transnational Organized Crime (TOC) states that one of its "five overarching policy objectives" is breaking "the economic power of transnational criminal networks and protect[ing] strategic markets and the U.S. financial system from TOC penetration and abuse."¹⁴ Unfortunately, the DEA's scheduling action on kratom undermines the Strategy's policy objective because it would create large financial opportunities for transnational criminal organizations by declaring illegal a substance which is in widespread and growing use in the US and which is legally available on the other side of our very long Northern border.

A Fact Sheet released by the White House earlier this year on the state of US-Canadian relations noted that the "United States and Canada share a longstanding commitment to cooperation. . . . We work closely together in areas such as counter narcotics..."¹⁵ It is difficult for the US and Canada to

¹² <http://www.thecre.com/forum8/?p=294>

¹³ Food and Drug Administration, "Statement by Michael Taylor, Deputy Commissioner for Foods and Veterinary Medicine, on Systems Recognition Arrangement with Canada" May 4, 2016. Available at <http://www.fda.gov/Food/InternationalInteragencyCoordination/InternationalCooperation/ucm499063.htm>

¹⁴ The White House, National Security Council, "Strategy to Combat Transnational Organized Crime" Available at <https://www.whitehouse.gov/administration/eop/nsc/transnational-crime/strategy>.

¹⁵ The White House, Office of the Press Secretary, FACT SHEET: United States – Canada Relationship, March 10, 2016. Available at <https://www.whitehouse.gov/the-press-office/2016/03/10/fact-sheet-united-states-%E2%80%93-canada-relationship>.

work together closely and effectively in combatting narcotics when we do not have agreement, or even consultation, on what constitutes a narcotic.

The focal point of our government's regulatory cooperation with Canada is the RCC. We are calling your attention to the RCC's Joint Forward plan which has been put through a notice-and-comment process in both the *US Federal Register* and in *Canada Gazette*.¹⁶ In the Joint Forward Plan, the US and Canadian government make a series of mutually-developed, formal, Department-to-Department commitments to each other.¹⁷ It is under these Department-to-Department commitments that the regulatory agreement between the FDA and Health Canada's Canadian Food Inspection Service was reached.

DEA's efforts to place kratom into Schedule I without going through a notice-and-comment rulemaking is a clear and flagrant abuse of discretion.

DEA Violates The Information Quality Act In That It Did Not Designate Its Schedule I Classification of Kratom As A HISA, Highly Influential Scientific Assessment

The OMB Peer Review Guidelines, which govern the Information Quality responsibility of all federal agencies, define a Highly Influential Scientific Assessment (HISA) as follows:

“A scientific assessment is considered “highly influential” if the agency or the OIRA Administrator determines that the dissemination could have a potential impact of more than \$500 million in any one year on either the public or private sector or that the dissemination is novel, controversial, or precedent-setting, or has significant interagency interest”

The aforementioned information most certainly demonstrates that the Schedule I listing is controversial and has significant interagency interest. Consequently DEA is required by law to conduct a HISA. Either DEA or OMB can designate a scientific study as a HISA.

CRE has notified another agency¹⁸ regarding compliance with HISA; these comments are equally applicable to DEA and its parent. The Department of Justice ¹⁹has informed the courts that OMB has the authority to make the final comments with respect to IQA.

Substantively complying with the HISA requirements of the IQA are of particular import because the said compliance will ensure that DEAS benefits from the rich talent through the entire Executive Branch.

¹⁶ United States – Canada Regulatory Cooperation Council, Joint Forward Plan, August 2014, p. 15.

¹⁷ Id.

¹⁸ http://www.thecre.com/emerging/20160828_quality_act.htm

¹⁹ <http://www.thecre.com/oira/?p=4124>

The Effective Date of the Schedule I Listing Can Be Extended Because There Is No Imminent Hazard As Defined By the Controlled Substances Act

The Controlled Substances Act states (21 U.S.C. 811(h)(1) that the Attorney General may act without adherence to established administrative processes “If the Attorney General finds that the scheduling of a substance in Schedule I on a temporary basis is necessary to avoid an imminent hazard to the public safety.” With respect to established administrative processes the statute states: “Rules of the Attorney General under this subsection shall be made on the record after opportunity for a hearing..”

Kratom has been in use for decades, if not centuries. What compelling documentation does the DEA, a law enforcement agency, have in its possession that would support a finding of an *imminent* hazard? DEA did present arguments in the Federal Register in which they claim kratom poses a threat to public health, but none so convincing that it is an imminent threat to public health. The public, including a wide range of experts, should have been given the opportunity to comment on DEA’s findings. The DEA chose to bypass the preferred listing process in the Controlled Substances Act, which allows for public comment, by claiming that kratom is an "imminent hazard." By taking this action without providing sufficient detail of the factual predicate justifying its determination that kratom is somehow an imminent hazard, the DEA inappropriately revoked any rights of the public to comment on the agency's findings.

Conclusion

The bottom line is that DEA will have to overcome the work of three preeminent governmental research organizations as described below if it is going to sustain its claim that kratom poses an imminent threat to public health.

First, since kratom is a legal product in Canada, its scientists would have acted if in fact an imminent threat to public health of existed. "Second, Canada choosing not to take prohibitory action concerning kratom is underscored by a similar posture at the US Department of Agriculture. In its own extensive studies of kratom, the USDA did not note any "imminent hazards" posed by its homeopathic uses." And third, the world’s premier health research agency---NIH-- as noted above, has not only sponsored an in-depth study of kratom, and has never suggested that kratom poses an imminent threat to public health (page 2) but has also sponsored related research in support of patent(page 3) for the beneficial use of kratom.

In its rush to judgment DEA has violated several of the most fundamental statutes which” regulate the regulators”, including the Data (Information) Quality Act, Executive Order 12866 and OMB’s Peer Review guidelines.

Lastly, and somewhat surprising for a law enforcement agency, it failed to disclose any analysis of the likelihood that a ban on kratom in the United States would create an environment for transnational crime linked to the funding of organized crime and terrorist organizations since kratom is a legal product in Canada. It would behoove DEA to spend as much time on the criminal implications of its position as it did on the claimed health consequences.

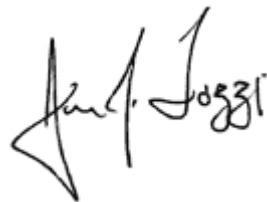
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Relief Requested

CRE is requesting that the DEA take the following actions, none of which prejudice the final status of Mitragynine and 7-Hydroxymitragynine:

1. Extend the effective date for placing kratom into schedule I until July, 1, 2017.
2. Open a *Federal Register* notice-and-comment proceeding on placing kratom into Schedule I and inform the public that the DEA's proposal is a "significant regulatory action" under Executive Order 12866 because it,
 - a) Has an annual effect on the economy of \$100 million or more or
 - b) Creates a serious inconsistency with an action taken by another agency, FDA, or
 - c) Raises novel legal and policy issues arising out of legal mandates.
3. Submit the proposed listing to OMB for review pursuant to Executive Order 12866.
4. Inform the US-Canada Regulatory Cooperation Council (RCC) via OMB of DEA's intent to place kratom on schedule I and seek its comments.
5. Conduct an interagency peer review of DEA's science which lead to a Schedule I listing of kratom as required by the HISA requirements of the Data (Information) Quality Act.

Respectfully,



[Jim Tozzi](#)
[Member, Board of Advisors](#)

cc: Honorable Loretta Lynch, Department of Justice
Elana Tyrangiel, Principal Deputy Assistant General, Office of Legal Policy, DOJ
Honorable Howard Shelanski, OMB
Andres Buonanno, NIH, National Institute of Child Health and Human Development (NICHD)
Editor in Chief—Brain Research Bulletin
Chavonda Jacobs-Young, Agricultural Research Service
D. Singh, Centre for Drug Research, Universiti Sains Malaysia