State of Rhode Island and Providence Plantations

HOUSE OF REPRESENTATIVES

REPRESENTATIVE BRIAN PATRICK KENNEDY *District 38*
Speaker Pro Tempore
Committee on Corporations
Committee on Rules
Dean of the House

October 31, 2017

Nicole Alexander-Scott, MD, MPH
Director of Health
Rhode Island Department of Health
Three Capitol Hill
Providence, RI 02908-5097

Dear Director Alexander-Scott:

I have received inquiries from several people regarding the decision of the RI Department of Health, effective April 10, 2017, to add two chemicals, Mitragynine and Hydroxymitragynine, to the Rhode Island Uniform Controlled Substances list because DOH determined they may pose a danger to public health. As I understand it, these are two alkaloids of the botanical plant kratom.

The specific concerns that have been brought to my attention are as follows:

1. Mitragynine and Hydroxymitragynine were subject to a proposed scheduling by the DEA on August 31, 2017,[1] but that proposal was **subsequently withdrawn** by the DEA on October 13, 2016[2] when substantial public comments were received by the DEA calling into question whether these alkaloids met the standards set for scheduling under Title 21 U.S.C., Subchapter I, § 811(c); and
2. That stakeholders concerned with access to kratom were not aware of any rulemaking procedure that would have allowed for public input on this scheduling decision by the Rhode Island Department of Health.

As you know, Rhode Island Title 21, Food and Drugs, § 21-28-2.01, mirrors the federal Controlled Substances Act (CSA) requirements on the eight factors to be considered in scheduling any substance. To the extent that Rhode Island relies upon federal rulemaking to guide our own scheduling decisions, I believe it is relevant to consider that the federal CSA is a carefully constructed, multi-factorial administrative process that allows a substance to be added

[1] Federal Register/Vol. 81, No. 169/Wednesday, August 31, 2016/Proposed Rules, Department of Justice, Drug Enforcement Administration, 21 CFR Part 1308, Docket No. DEA – 442, Schedules of Controlled Substances: Temporary Placement of Mitragynine and 7-Hydroxymitragynine into Schedule 1, Notice of Intent, Pages 59929-59934.

[2] Federal Register/Vol. 81, No. 198/Thursday, October 13, 2016/Proposed Rules, Department of Justice, Drug Enforcement Administration, 21 CFR Part 1308, Docket No. DEA – 442W, Withdrawal of Notice of Intent to Temporarily Place Mitragynine and 7-Hydroxymitragynine into Schedule 1, Withdrawal of Notice of Intent, Pages 70652-70654.

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to a CSA schedule only after a detailed analysis of data and evidence relating to a substance's medical use, potential for abuse, and dependence liability.[3]

Reflecting the significance of the contemplated action, the process is measured and deliberate, with complementary analyses required from two federal departments and three federal agencies, followed by a public rulemaking in which all interested parties may participate. Moreover, the two lead participants in the process – DEA and the Department of Health and Human Services (HHS) – act together to provide a series of checks and balances, with the HHS analysis (typically conducted jointly by FDA and NIDA) binding on DEA as to scientific and medical matters. If HHS recommends against scheduling, the proposed action cannot occur. These multiple layers of process and safeguards are required because the U.S. Congress recognized the extraordinary consequences of scheduling a substance.

Given that the DEA has withdrawn its proposed scheduling of these alkaloids, I would request that you provide any documents that were used or relied upon for the RI Department of Health scheduling decision, and any "findings," as provided in § 21-28-2.01(2),[4] made in justifying the issuance of the Designation of Controlled Substance for the kratom alkaloids on April 10, 2017. Rhode Island is outside the norm with the actions in April and I would like to understand why the Department of Health decided to address this matter without following the DEA actions.

Finally, it is my understanding that the American Kratom Association commissioned Jack Henningfield, one of the world's leading experts on addiction, and the behavioral, cognitive, and central nervous system effects of drugs, and who frequently works with the FDA on issues of drug scheduling and addiction, to produce an 8-Factor Analysis on kratom and its alkaloids. Dr. Henningfield concluded, after reviewing all available literature, that "Placement of kratom in the CSA is not warranted."[5] For reference, I have attached a copy of Dr. Henningfield's analysis.

To the extent you agree that this information merits a reconsideration of the scheduling decision, I would respectfully suggest that a meeting with Dr. Henningfield, and with representatives of the American Kratom Association, might be helpful to you in reviewing available scientific literature to determine if these alkaloids truly meet requirements for scheduling under the applicable statutes, and to determine if the information and research Dr. Henningfield has conducted better informs the question on whether these alkaloids pose any threat to public safety.

Based on the information I have reviewed on this issue, I believe a reconsideration of the scheduling decision is in order, and I urge you to review this new information on kratom and its alkaloids. I also have specific concerns about the transparency of the scheduling process, and

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[3] 21 USC 811(b), (c).

[4] § 21-28-2.01(2) After considering the factors in subdivision (1) of this section the director of health shall make findings with respect to these factors and shall issue an order controlling the substance if it is found that the substance has potential for abuse.

[5] Assessment of Kratom under the CSA Eight Factors and Scheduling Recommendation, Jack Henningfield, MD, November 28, 2016, page 16.

whether the existing statutory framework allows for adequate public input on any proposed scheduling decision. I would certainly welcome your recommendations on how we might strengthen this process to assure that a rulemaking process is as open and transparent as possible to allow for appropriate checks and balances on decisions of this magnitude.

Thank you for your consideration of the issues I have raised in this letter, and I will look forward to receiving your responses in a timely manner.

Sincerely,

Brian Patrick Kennedy
State Representative
Speaker Pro Tempore