MEMORANDUM

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TO	David Herman Chair, Board of Directors	**ORGANIZATION**	American Kratom Association
FROM	Lynn W. Mehler Delia A. Deschaine	**TELEPHONE**	202-637-6419
DATE	June 21, 2017		
SUBJECT	Analysis of the Stop the Importation and Trafficking of Synthetic Analogues Act of 2017 (SITSA)		

Per your request, please find below our analysis of SITSA and its implications on the regulated community. In sum, we believe that the scope of the law far exceeds its stated intent: the control of fentanyl analogs and other synthetic substances that pose a high potential for abuse.

- Under the current Controlled Substances Act (CSA), DEA has ample authority to immediately control substances with a high potential for abuse. DEA has appropriately exercised this authority to control fentanyl and other synthetic analogs in the past. For example, DEA has temporarily placed at least fifteen fentanyl analogs in Schedule I through the use of its emergency scheduling authority. When enacting the CSA, Congress wisely chose to authorize DEA to temporarily control only those substances that have a high potential for abuse, by requiring their placement in Schedule I.

- SITSA as drafted contains broad language that would allow DEA to control substances with low abuse potential based purely on these substances chemical similarity to lower schedule (Schedule V) controlled substances. Specifically, the law would allow DEA to temporarily and permanently control a drug or substance with a chemical structure that is substantially similar to that of a Schedule V controlled substance and an actual or predicted stimulant, depressant or hallucinogenic effect on the central nervous system that is substantially similar to that of Schedule V controlled substance. In determining the latter, DEA *may,* but is not required to consider a number of factors, one of which is "the chemical structure, structure activity relationships, binding receptor assays, or other relevant scientific information about the substance." As DEA's authority would remain unchecked (there is no requirement or process to allow for public comment or judicial review for a period of at least five years), DEA may succeed in using this authority to control substances with low or no abuse potential, such as Kratom, based purely on the substance's chemical properties.

- SITSA would allow DEA to sweep in substances that pose no actual abuse potential and precedent indicates DEA would take full advantage of the broad language in the legislation. For example, the current CSA controls in Schedule II any salt, compound, derivative or preparation which is chemically equivalent or identical with opium, an opiate, or any salt,

compound, derivative or preparation of opium or opiate. DEA's broad interpretation and application of these provisions has swept a number of substances into Schedule II based on their chemical relationship to opioids, regardless of whether the substance has any abuse potential. For example, naloxegol was controlled in Schedule II as a result of its chemical relationship to an opiate. In 2015, DEA removed the drug from control after FDA approval, as it lacked a potential for abuse sufficient to schedule the drug in any schedule. *See* 80 Fed. Reg. 3468 (Jan. 23, 2015). *See* 79 FR 64349, 64350 (Oct. 29, 2014) (Naloxegol, or PEG-naloxol, is a new molecular entity and is a polyethylene glycolyated (PEGylated) derivative of naloxone . . . Naloxegol is an antagonist predominantly of peripheral mu opioid receptors).

- SITSA as drafted would significantly expand the universe of drugs or substances that DEA could immediately control with little notice to legitimate stakeholders or input from experts and with few curbs on the authority of DEA. In so doing, the proposed law would give DEA the unfettered ability to eliminate access to such substances, despite what may be long-standing and legitimate non-medical uses (*e.g.*, industrial uses, uses in foods, uses in dietary supplements) and would substantially curtail and burden legitimate scientific research and product development. Furthermore, despite the reference to synthetic analogues in the title of the legislation, the legislative language is so broad as to sweep in a range of drugs or substances.

- SITSA as drafted would further allow DEA to control such substances for a period of five years, without providing interested members of the public any due process to challenge the DEA conclusions and removal of the substance from legitimate commerce. The length of time for such a "temporary" scheduling along with the absence of any opportunity for judicial review or public participation renders this provision of SITSA unconstitutional.

- Even if extending the period of temporary control without public participation were constitutional, Congress could do so simply by amending the existing temporary control provisions of the CSA, as it has in the past. *See* Food and Drug Administration Safety and Innovation Act, Pub. L. No. 112-144, § 1153 (2012). Congress does not need to also lower the standard for temporarily controlling substances to include substances with a low potential for abuse.

- The proposed law would schedule substances with a potential for abuse that are substantially similar to Schedule V controlled substances, however, would attach penalties comparable to those that apply to Schedule III controlled substances for the unlawful manufacture, distribution, or dispensing of those substances. It is not clear why the penalties that apply to the illicit use of such analogs should be more stringent than they are for their controlled counterparts.

- The attached proposed revisions may correct some but not all of the flaws of the proposed law described above. As a whole, the proposed law is unnecessary, unjustified and unconstitutional.