

Dear Chairperson and Members of the Committee,

I am submitting this testimony in regard to House Bill 1566, to seek amendments to improve the legislation based on the best scientific data to prevent any unintended consequences. I applaud the work the North Dakota legislature has done thus far to consider the abundance of scientific literature related to mitragynine and kratom and the legislatures' efforts to regulate the botanical. In the last year the U.S. Food and Drug Administration published the first leg of their human clinical trial on kratom that showed it is both effective and well tolerated in human populations. Further, in the past two years, eight states (Virginia, West Virginia, Florida, Louisiana, Georgia, Texas, Kentucky and Maryland) have enacted legislation in favor of the safe sale of kratom to consumers in the form of a Kratom Consumer Protection Acts (KCPA). We, as an organization, believe that effective state regulations help ensure that this botanical can safely be in the hands of consumers and effective legislation will keep bad market actors out.

In regard to House Bill 1566, we feel that there are distinct differences from KCPAs that other states have enacted that raise some concern. While we do not recommend a wholesale replacement of House Bill 1566, we would like to recommend certain changes to make the proposed Bill more effective. I respectfully submit the following recommendations:

- (1) The definition of "synthesized material" in "*Definitions*" *Section 6* should be expanded to include semi-synthetic variations of alkaloids and metabolites in addition to just synthetic material. Depending on how a chemist might choose to manipulate alkaloids, both synthetic and semi-synthetic variants should be prohibited due to their lack of safety data.
- (2) In regard to "*Administration*" *Section 1.f*, pursuant to federal law, all ingredients in traditional foods must be Generally Recognized as Safe (GRAS) and those in dietary supplements must be GRAS or a compliant dietary ingredient. There is no reason to preclude items like psychoactive compounds and cytochrome P450 enzyme inhibitors. Some of these ingredients are either GRAS or compliant dietary ingredients and include some citrus products like grapefruit and certain oranges. It is unclear why these specific carveouts are necessary and seem rather arbitrary. No other KCPAs have included such carveouts. Each product manufacturer should have relevant safety data for their formulations and individual exclusions are unnecessary within the Bill if they can be safely marketed under federal law.
- (3) In "*Administration*" *Section 3.e*, the primary alkaloids should be disclosed on the container, specifically mitragynine and 7-hydroxymitragynine. The scientific literature clearly identifies mitragynine as the primary alkaloid that accounts for over half the alkaloid content on a percentage basis. Further, due to the restricted nature of 7-hydroxymitragynine ("*Administration*" *Section 1.a*), this alkaloid amount should also be specifically identified. Otherwise, there are over 40 kratom alkaloids and it is impractical to disclose amounts of all these minor alkaloids, plus no additional consumer safety comes from such disclosure. Further, disclosure of these two alkaloids is consistent with other KCPAs.

Thank you for your time and consideration. I welcome the opportunity to discuss this matter further.

Kind Regards,

Andrew Kulpa