



Common Sense Initiative

Mike DeWine, Governor
Jon Husted, Lt. Governor

Carrie Kuruc, Director

MEMORANDUM

TO: Ali Simon, State of Ohio Board of Pharmacy

FROM: Ethan Wittkorn, Regulatory Policy Advocate

DATE: May 31, 2019

RE: CSI Review – Controlled Substance Scheduling – Kratom (4729:9-1-01.1)

On behalf of Lt. Governor Jon Husted, and pursuant to the authority granted to the Common Sense Initiative (CSI) Office under Ohio Revised Code (ORC) section 107.54, the CSI Office has reviewed the abovementioned administrative rule package and associated Business Impact Analysis (BIA). This memo represents the CSI Office's comments to the Board as provided for in ORC section 107.54.

Analysis

This State of Ohio Board of Pharmacy (Board) rule package consists of one new rule. It was submitted to the CSI Office on April 12, 2019, and the public comment period was open through April 30, 2019.

The proposed rule adds kratom as a schedule I controlled substance in Ohio. The business community impacted by the proposed rule is any business currently selling kratom products. Violation of the proposed rule could result in criminal penalties. The Board's research shows that there are three kratom-specific businesses and a kratom vending machine in Ohio that will no longer be permitted to operate under the proposed rule. Additionally, businesses that advertise kratom may lose advertising revenue.

ORC section 3719.44 grants the Board authority to add a previously unscheduled substance to any drug schedule established by law and provides guidelines for the Board's review and analysis of such decisions. The Board decided to classify kratom as a schedule I controlled substance, citing a

77 SOUTH HIGH STREET | 30TH FLOOR | COLUMBUS, OHIO 43215-6117

CSIPublicComments@governor.ohio.gov

high potential for abuse, no accepted medical use for treatment, a lack of accepted safety for medical treatment under supervision, and a public health risk to the citizens of Ohio.

While drafting the rule, the Board considered data from state, federal, and international agencies and peer-reviewed articles. During the period of early stakeholder outreach, the Board posted its proposed rule for comment. Several stakeholders submitted comments of support and opposition. For example, both the Cleveland Clinic and Columbus Public Health commented in support of the proposed rule as a public health measure. Three comments objected to the proposed rule. One referenced a petition signed by Ohio residents who oppose the classification of kratom as a schedule I controlled substance. The Botanical Education Alliance and others argued that unadulterated kratom is safe. The Board did not make any changes as a result of these comments.

There was significant feedback during the CSI public comment period. The Ohio Chapter of The American Academy of Pediatrics submitted a letter of support. From opponents to the classification, there were anecdotal remarks about kratom's pain treatment benefits and suggestions that kratom should be regulated and allowed in an unadulterated form, rather than completely prohibited. Several commenters pointed out the possibility of using kratom to treat opioid addiction or abuse, or the concern that the proposed rule would prevent research into kratom's potential benefits. There were also comments citing a negative business impact on retailers that currently sell kratom.

The Board did not adopt any changes due to the comments received, citing the lack of documented medical evidence to support the use of kratom to treat opioid dependence, as well as several case studies in which kratom was shown to have a negative effect on health. The Board clarified that the proposed classification of kratom would not prohibit research on the substance and that any potential adverse business impact is superseded by the public health risk that kratom poses.

Recommendations

Based on the information above, the CSI Office has no recommendations on this rule package.

Conclusion

The CSI Office concludes that the Board should proceed in filing the proposed rules with the Joint Committee on Agency Rule Review.