Kirsten Elin Smith, PhD
Assistant Professor
Johns Hopkins University
Department of Psychiatry and Behavioral Sciences

Department of Psychiatry and Behavioral Sciences
Behavioral Pharmacology Research Unit
5510 Nathan Shock Drive
Baltimore, Maryland 21224
Phone: 865-418-8177 (cell) 410-550-0035 (office)
Email: ksmit398@jh.edu

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Re: Ohio Senate Bill 103

Good day and thank you for the opportunity to provide written testimony on Senate Bill 103 (SB 103) for consideration by the 135th General Assembly of Ohio.

My name is Kirsten Smith, Ph.D., L.M.SW., and I have been clinically or scientifically involved in understanding kratom since 2015.

By way of disclosure, I am presently research faculty at Johns Hopkins University School of Medicine, specifically an Assistant Professor in the Department of Psychiatry and Behavioral Sciences. I came to Johns Hopkins University after completing a four-year postdoctoral fellowship at the National Institute on Drug Abuse Intramural Research Program within the Translational Addiction Medicine Branch. I also hold a license for a Masters of Social Work in the state of Maryland, but do not engage in any clinical practice or activities at this time. I devote 100% of my time to scientific research.

The views expressed in my testimony are my own and do not necessarily reflect the views or positions of Johns Hopkins Medicine. They also do not necessarily reflect the views of the National Institute on Drug Abuse, who funds my research on kratom, and other kratom research.

I am providing this testimony in support of the passage of SB 103 because we are presently in what I consider to be an incoherent and untenable situation with respect kratom policy in the United States. Across government agencies at both the federal and state level, our regulatory and legal frameworks are vast and byzantine. The extensive funding and sweeping regulatory powers of state and federal government makes it *feel* as though our institutions should be equipped and ready to address all manner of issues, however nuanced and complex. Although our local, state, and federal institutions are critical to maintaining public health and enforcing existing laws, they are not perfect. Nor could they be given the breadth of what these institutions are tasked with overseeing within an increasingly complex world.

Complexity is not easy to scientifically investigate, communicate, or regulate. The botanical, *Mitragyna speciosa*, commonly referred to as "kratom" in the United States, is complex.[1-6] The naturally growing botanical, and the commodification of kratom leaves into commercial products, are each complex in turn. Neither fit neatly into a box, which is why we are here today. Kratom's complexity has made it challenging for lay people or "non-experts" to understand. This seems to have resulted in gross oversimplifications, misunderstandings, or debates of what kratom is or is not.[7] The scientific community involved with kratom research is still learning how to characterize kratom's pharmacology; but even as the science unfolds---and will continue to unfold for many years--we presently have sufficient information to discount some of the more egregious oversimplifications of kratom. These include oversimplifications that kratom is a "miracle plant" as well as oversimplifications that kratom is a "dangerous opioid."

If kratom could be scientifically recommended for scheduling by the US Drug Enforcement Administration under the Controlled Substances Act (CSA), it likely would be. It has not been scheduled under the CSA, in part, because we presently do not have scientific evidence to support such a recommendation, nor do we have evidence to counter the legitimate concern that if kratom were placed into Schedule I that it would not be a detriment, rather than a benefit, to public health. It is my opinion that scheduling would do more public harm than good.

However, with kratom not placed into Schedule I, and with it considered an unregulated new dietary ingredient by the US Food and Drug Administration[8], kratom is relegated to the greyest of areas. Such regulatory limbo is unhelpful for clinicians, law enforcement, boards of health, and, most particularly, kratom consumers. Kratom's being relegated to a grey market, rather than regulated and clearly labeled, puts consumers and would-be consumers at risk[9]; it allows commercial bad actors to operate largely without consequences.

I do not know if there is a perfect solution to kratom at the federal or state level that can be adopted and implemented in the US given our current systems, given the complexity of kratom, and given the still-ongoing scientific efforts to better understand kratom's full effects. However, commonsense legislation to regulate the manufacture and sale of kratom in the absence of perfect scientific knowledge is a significant stride toward improving consumers' access to information and to products that are held to some minimum standards to promote greater transparency, safety, and reliability in the marketplace, including helping consumers differentiate the ingredients and potency of an increasing array of kratom products available for purchase.

The first appearance of kratom in the United States is unknown, but clinical case reports in the literature documenting use appeared in 2007 and 2008, with additional anecdotal accounts in 2014.[10-12] At this time, I had not heard of kratom and it was not until around 2015 that I became aware of it. I learned about kratom during my graduate clinical practicum in an addiction treatment center. There, some clients with a history of opioid use disorder began using kratom to address anxiety and opioid craving. I subsequently conducted my first survey on kratom among adults with a history of substance use disorders (SUDs) enrolled in such treatment centers and found that nearly 70% had tried kratom as a means of reducing or stopping prescription opioid or heroin use.[13,14] Although an interesting finding, I had no intention to pursue kratom as my focus of study in my Ph.D. program. In part, kratom seemed, of all things, quite *boring*. Nobody I encountered was injecting it or using it because they were trying to get "high"—indeed, had they wanted to get "high" they would have been able to do so far more readily with alcohol or increasingly available synthetic opioids.

Yet, through my nearly 9 years of volunteer work in Kentucky interacting with addicted men and women, I continued to meet people who had used kratom to attenuate withdrawal from opioids and alcohol and some who had turned to kratom to stay off of opioids and stimulants long-term. Among these included people who did manual labor and/or who had chronic pain and who also used kratom to help reduce fatigue, increase energy and focus, or to reduce pain. These folks had jobs they had to show up to each day and kratom, they believed, helped them function. These people did not have charmed lives. Instead, many were trying to maintain their recovery or remission from SUDs while rebuilding what had been destroyed during active addiction. To be clear: I am making **no** medical or therapeutic claim about kratom. Rather, I am stating for the record what I observed, which is simply people who had established long-term SUD recovery and remission from opioids and stimulants while also using kratom daily. I know, too, that many of these people developed some tolerance to kratom, which is unsurprising given that regular daily use of this or many other substances is known to product tolerance.[15]

The use of kratom among addicted or formerly addicted people as a harm-reduction tool has been evaluated and documented in the clinical literature.[16] What is also worth emphasizing is that there are dozens of motivations

for kratom use now documented beyond using as a substitute for alcohol, opioids, or stimulants. Many are using to address or nonmedically self-manage symptoms related to psychiatric, attentional, mood, fatigue, or pain disorders, while others are simply using for increasing energy, recreation, quality-of-life, or as a wellness "pre-workout" or fitness-enhancing product.[17-24]

Myself and others have documented kratom-related withdrawal as mild to moderate, and that tolerance symptoms can be managed.[15,18,24-28] There are, globally, only 55 cases of kratom-related dependence or addiction that I have reviewed with colleagues, and while there are undoubtedly more that have never been written up and published, this calls into question why they have not been documented in the medical literature.[29] If kratom is causing widespread addiction, where is the documentation for this? Of note, these cases pertaining to kratom dependence or addiction, similar to cases related to forensic toxicology and physical health morbidities, were poorly documented at best given the myriad factors involved (e.g., coingestants, adulteration), and at worst grossly mischaracterized in light of available evidence (e.g., amounts of kratom used).[5,29-37] I am not making a claim that kratom cannot ever become problematic for a person, but rather noting that if kratom-related problems are occurring among a plurality of consumers, we have very little and very poorly documented evidence of it at this time.

I and others have assessed DSM-5 diagnostic criteria for SUD for kratom; we found that many adults regularly consuming kratom did not meet diagnostic criteria and, among those who did, it was primarily mild or moderate symptomatology.[18,28] Most importantly, individual symptoms pertained primarily to those related to physical dependence (defined as the presence of tolerance and/or withdrawal symptoms), and, to a lesser extent, to symptoms of craving, using more than intended, and some unsuccessful attempts to reduce use.[26-28] What was not widely found were symptoms related to what I believe to be the most clinically concerning, and what are hallmarks of addiction, namely: risky use and impairments in psychosocial functioning. These include use despite physical or psychological problems related to use; excessive time using or recovering from use; use despite social or occupational problems; use that interferes with daily roles and obligations; giving up important activities; and hazardous use.[26-28]

Such data, while limited, are consonant with other survey and ambulatory data that kratom is being used during the first half of people's waking hours (presumably when they are working) and is being used to help with daily productivity.[15,21,27] The kratom consumers that I have studied using ecological momentary assessment methods, which measures use in real-time rather than retrospectively, report that kratom's stimulatory and analgesic effects are overwhelmingly a help, not a hindrance, to their meeting their daily roles and obligations.[27,38]

The acute effects of whole leaf kratom products among adults who use regularly have not been established as impairing or intoxicating when consumed at self-selected servings (typically less than 5 grams per serving on average) as was directly observed in a laboratory-based study that I received NIDA funding to conduct. Participants' typical serving of kratom did produce measurable acute effects, but we did not find clear indicators of abuse potential or psychomotor impairment using well-validated measures.[39,40]

The caveat is that we have significantly more work to do to understand the pharmacokinetics and pharmacodynamics of kratom as a whole and its individual alkaloid constituents.[41] The scientific understanding of kratom's clinical and behavioral pharmacology is in its early days.
That fact does not recommend that we leave kratom in regulatory limbo. As the much-needed research continues, a coherent public policy response to kratom should be established so that consumers and would-be consumers are better equipped to make decisions about using kratom in light of what data we do have. This includes clear labeling, age restrictions, and products free from adulterants and contaminants.

We will continue to live in a world with imperfect information on kratom for some time. This is why it is of considerable urgency to pass legislation that will regulate kratom products as scientific research continues and clinical documentation of kratom grows. Kratom is not, in my estimate, public health threat number one in this country. In order to ensure that it does not edge towards public harm, kratom products should be regulated and labeled appropriately so that they can be consumed responsibly by informed adults.

Thank you for permitting me the opportunity to provide written testimony. Please feel free to reach out should you have any questions.

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