Risk of Death Associated with Kratom Use Compared to Opioids Key Points by the Authors Prepared November 4, 2019

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Background

- Kratom use appears to be increasing across the United States (US), increasing attention to deaths
 in which kratom use was detected.
- Although headlines suggest kratom use is the cause of some deaths, in most cases the deaths
 have been due to use of another drug in combination, such as fentanyl, heroin, benzodiazepines,
 prescription opioids, or cocaine, or to other causes (e.g., homicide, suicide and various preexisting
 diseases).
- There has yet to be a verified overdose death from kratom use alone in the US or in South East
 Asia where kratom has been widely used for more than a century. This does not mean that
 overdose death on kratom has not happened or is not possible but it does support the conclusion
 that the risk of death for people who use kratom is very low compared to opioids.
- This study evaluated the relative risk of kratom-associated death based on US federal government data on deaths involving opioids and estimates of kratom-associated deaths by the US Food and Drug Administration (FDA).

What This Study Adds to What is Known About the Risks of Kratom

Because there is no nationally projectable survey estimating the number of US kratom users, we used two plausible estimates (approximately 11 and 16 million people) to provide a range for calculations. We also compared "any opioid" to "heroin" based on estimates by the US Centers for Disease Control and Prevention (CDC).

Our main conclusion is that the risk of overdose death is more than 1,000 times greater for opioids in general than for kratom, and may be many thousand times greater for heroin or "any opioid" as shown in the tables summarizing the basis for comparisons.

Just like users of prescription medicines and other dietary supplements, some kratom users may have medical conditions that increase their risk of death and/or may assume risks that could greatly increase the possibility of kratom-associated mortality, e.g., use with opioids, sedatives, alcohol or other drugs.

More studies of kratom safety are needed. If kratom use increases, it is likely that among the 2,744,248 total US deaths per year (CDC, 2017), an increasing number will be kratom users. Without understanding the involvement of other licit and/or illicit drug(s), kratom may be falsely blamed for overdose deaths that were more likely caused primarily by other substances, and we miss the opportunity both to prevent those deaths and to learn more about the potential benefits and actual effects of kratom.

Because many deaths possibly involving kratom also involved opioids and other drugs that are known to carry a high risk of overdose death, regulation establishing standards for kratom purity, packaging, labeling, and alkaloid content is urgently needed to reduce risks for persons who purchase lawfully marketed products. In this context, it is promising that four states (Arizona, Georgia, Nevada and Utah) have passed kratom consumer protection laws that include standards for kratom product purity and

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labeling and requiring registration and oversight. It would be in the public health interest for FDA to set standards as it does for most foods and manufactured dietary products.

Author disclosures:

Jack E. Henningfield, Reginald V. Fant, Daniel Wang and Edward J. Cone consult through PinneyAssociates on the development of medicines for a broad range of disorders including pain and addiction, as well as cannabinoids, potential medicines based on psychedelic substances, dietary supplements, and tobacco harm reduction (see more at www.PinneyAssociates.com). They advise the American Kratom Association on kratom science and regulation. No clients of PinneyAssociates provided funding or had any input into the writing of this paper.

Views expressed by Oliver Grundmann in this commentary represent his personal and professional views and not the views of his employer, the University of Florida.

Jane K. Babin is a California attorney, registered to practice before the U.S. Patent Office, who represents clients in the biotechnology, pharmaceutical, chemical and other industries in patent, trademark and licensing matters. She has counseled the American Kratom Association on a variety of legal and scientific issues, with and without compensation. The views expressed in this commentary are her own and she has received no compensation for her contributions to this letter.