Kratom

Background

Kratom is a dietary supplement prepared from the leaves of the Mitragyna speciosa plant. While it has been used in Southeast Asia for centuries, it has only recently become popular in the United States. It is used to manage pain or withdrawal from opioids but is not FDA approved for any therapeutic use.[i] It is typically ingested in the form of capsules, brewed teas, or chewed leaves. Jurisdictions are grappling with how to balance potential risks and limited psychopharmacological understanding with reported benefits espoused by users.

Kratom is reported to produce mild stimulant effects in low doses (1-5 g) and opioid-like effects at moderate to high doses (5-15 g).[ii] The primary active compounds in kratom, mitragynine and 7-hydroxymitragynine, have some activity at opioid receptors. Research suggests that kratom acts on opioid receptors differently than typical opioids, which makes it less likely to slow or stop breathing.[i,iii] Rigorous research on psychoactive effects is limited, but reviews of user experiences indicate that associated euphoria is less intense than that experienced when using typical opioids.[iii] Physical dependence can develop but is less common than that associated with typical opioids, and withdrawal from kratom has been described as less severe and of shorter duration.[iv,v]

Public Health Concerns

Across the country, reports of adverse effects associated with kratom use have increased. Side effects may include increased heart rate, nausea, itching, constipation, and dry mouth. Serious adverse events, including seizures and death, have been reported. In most cases, deaths involving kratom have also included other drugs. The FDA reported that there had been 44 kratom-associated deaths worldwide as of 2018.[vi]

Federal Regulatory Landscape

Kratom is on the DEA's drugs of concern list. The DEA signaled its intention to temporarily classify it as a Schedule I substance in August of 2016 but withdrew the decision due to public opposition and the absence of a full FDA analysis.[vii] As of December 2019, it remains unscheduled. It is not FDA approved to treat any illness or condition and cannot be marketed as a product to treat, cure, or prevent any disease.

FDA considers kratom a new dietary ingredient for which reasonable assurance of safety has not been proven.[viii] Per section 413(d) of the Food, Drug, and Cosmetic Act, manufacturers and distributors are required to notify the FDA if they plan to market any new dietary ingredient. The notification must include information used to determine that the substance can reasonably be expected to be safe under the conditions of use recommended in the labeling.[ix] This requirement is not being actively enforced. Tens of thousands of brick and mortar retailers as well as online sales operate largely without federal oversight.

State and Local Regulatory Considerations

In response to both the risks of users developing physical dependence or experiencing adverse effects as well as the lack of federal oversight, jurisdictions may wish to establish some regulatory oversight at the state or local level. Potential strategies include:

- requiring registration and licensure of kratom retailers so governing authorities can maintain an up-to-date list of who is selling the product
- prohibiting the sale of kratom to minors due to the risk of physical dependence and unknown effects on the developing brain
- requiring signage and/or product labeling to inform the public of potential risks and the lack of regulatory oversight

Note that there are no federally recognized standards for acceptable ingredient composition or lab testing for contaminants. This makes regulating the content of kratom products extremely difficult.

Given the incomplete scientific understanding of kratom's mechanisms of action as well as the lack of a comprehensive federal regulatory stance, full bans or restrictions on specific chemical constituents may not be warranted at this time.

There are inherent limitations to any solely local response. Kratom products are often bought and sold online, which is not amenable to local regulation. Regulating the composition of kratom products and instituting quality control requirements is not feasible until kratom is either federally scheduled or determined to be safe as a dietary ingredient/supplement in particular formulations. Actions to limit access must also consider the effects on people who currently use kratom to manage chronic pain, opioid withdrawal, or opioid addiction.

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