



September 3, 2019

TO: Honorable Mayor Waid and Town Councilmembers
Town of Parker, Colorado
20120 E. Mainstreet
Parker, CO 80138

FROM: Bernadette Albanese, M.D., M.P.H.
Medical Epidemiologist

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Re: Proposed ordinance for the Town of Parker to ban kratom sales

Tri-County Health Department (TCHD) is the district health department for Adams, Arapahoe, and Douglas Counties and the Town of Parker, Colorado. As physicians at TCHD, we are concerned about the potential consequences of increasing sales of kratom in our jurisdiction. Our stance on kratom use aligns with the U.S. Food and Drug Administration (FDA). **As a precautionary measure, TCHD strongly recommends that the Town of Parker proactively ban any sale of kratom in its jurisdiction.**

For several years, the FDA has issued clear warnings about the use of kratom^{1,2,3,4} and has banned importation of kratom for human consumption as a drug or dietary ingredient. FDA does not consider kratom safe to consume because of the lack of oversight of kratom's production overseas and adverse health effects. Kratom contains psychoactive chemicals that interact in the brain like opioids. The FDA ban and warnings are based on a growing number of

¹ www.fda.gov/news-events/public-health-focus/fda-and-kratom

² www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-new-warning-letters-fda-issuing-companies-marketing

³ www.fda.gov/news-events/press-announcements/fda-warns-companies-selling-illegal-unapproved-kratom-products-marketed-opioid-cessation-pain

⁴ www.fda.gov/food/outbreaks-foodborne-illness/fda-investigated-multistate-outbreak-salmonella-infections-linked-products-reported-contain-kratom

reports about significant adverse health effects in people, such as high heart rate, agitation, irritability, drowsiness, hallucinations, nausea, and high blood pressure. There are reports of liver damage, seizures, and death⁵ (including deaths attributed to kratom in Colorado⁶). Additionally, kratom is produced outside the U.S. from the leaves of a tropical tree native to Southeast Asia. That means there are no U.S. standards for kratom production, no quality control, and no system-wide safeguards to ensure the product being sold in the U.S. is kratom and free from impurities or contamination.

FDA has federal authority over drugs or other products marketed as having a medical claim to treat a health condition. However, kratom has not been FDA-approved as a drug, dietary supplement, or food ingredient. Despite these federal restrictions and concerns about production quality, the U.S. kratom industry still imports this product even if labeled not for human consumption, then repackages the substance and sells via online or other retail outlets purposely for people to ingest.

When consumed, kratom exerts opioid-like effects in the body and is being actively marketed by the kratom industry to treat medical ailments — like body aches, muscle fatigue, or to regulate mood, reduce tension, or support healthy metabolism, and as a way to wean off prescription opioids — despite absent or inadequate scientific evidence to support these unproven medical claims. Repeatedly, the kratom industry has been unable to provide scientific evidence to meet FDA criteria for kratom to be approved for therapeutic use or as a dietary supplement.

In public settings, kratom industry representatives have acknowledged these issues:

- That imported kratom can be adulterated or contaminated.
- That kratom can be addicting.
- That there are risks and unknown health effects of using kratom and other drugs, including opioids, despite the medical claim of using kratom to wean off opioids.
- That it is unknown whether kratom is contraindicated when using other prescription drugs.
- That the effects of using kratom while driving are unknown.
- That the effects of kratom on a pregnant woman or a fetus are unknown.

People are using kratom without being fully informed about risks, proper dosing, contraindications, or drug interactions. There is a lack of accurate information on whether kratom actually works to treat their medical condition. It is the responsibility of federal

⁵ Unintentional drug overdose deaths with kratom detected. *Morb Mortal Wkly Rep* 2019;68:326-7

⁶ Deaths in Colorado attributed to kratom. *N Engl J Med* 2019;380:97–8. <https://doi.org/10.1056/NEJMc1811055>.

authorities, not local municipalities, to ensure a product being sold for human consumption — as either a drug or dietary supplement (to treat a medical condition) or as a food ingredient — is legal, approved, and safe to use. However, given the current ambiguity under which kratom is being marketed, it is reasonable and appropriate for a local municipality to ban its sale.

Therefore, in summary, TCHD strongly recommends the Town of Parker ban sales of kratom in its jurisdiction. FDA does not consider kratom safe to consume and there are significant warnings from the medical community about adverse outcomes, including death. There simply is not enough scientific data in the U.S. on how to use kratom safely and properly to justify sales to anyone of any age. Possibly over time, the kratom industry will compile the necessary scientific evidence about safety, dosing, and proven medical effects needed to complete the FDA approval process.

For questions, concerns, or any additional information, please contact Dr. Bernadette Albanese at balbanese@tchd.org or 303-220-9200.

Supplemental materials:

- Sample warning letter from the FDA to kratom wholesalers violating the Federal Food, Drug, and Cosmetic Act by introducing kratom into interstate commerce.
 - www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/chillin-mix-kratom-559280-09042018
 - www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/mitra-distributing-inc-562402-09042018

This information is provided on behalf of the Tri-County Health Department as the district public health agency and not on behalf of the Commissioners of Adams, Arapahoe or Douglas Counties.