



Kratom

MN Public Health Collaborative Presentation

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What are we talking about today?

1. What is Kratom
2. Reported uses and effects of kratom
3. Example of new product research
4. Regulatory status in Minnesota
5. Current and future and oversight approach



What is Kratom and why do we care?

- Kratom is a tropical tree that is native to Southeast Asia.
- Historically used for both medicinal and recreational purposes in the region – consumed by chewing leaves, making tea from leaves
- Kratom leaves contain many pharmacologically active compounds (40+ alkaloids)
- Big 2: mitragynine and 7-hydroxymitragynine (7-OH)
- 7-OH has greater potency than many classical opioids; For example – 3 to 13x greater than morphine



Reported Kratom uses

- Self Treatment of:
 - pain
 - coughing
 - diarrhea
 - anxiety and depression
 - opioid use disorder and opioid withdrawal
- Recreational Use



Methods of Consumption

- Consumed orally – tablet, capsule, beverage, extract/tincture form
- Additionally leaves can be chewed raw or dried & powdered and used to make tea.



Effects and Impacts of Kratom

- Adverse outcomes from kratom use may include but are not limited to:
 - Psychosis (hallucinations, delusion, confusion, etc.)
 - Seizures
 - Liver toxicity
 - Substance use disorder (SUD)
 - Nausea/Vomiting
 - Reported cases of neonatal abstinence syndrome



MDA – Food and Feed Safety Division Overview

- Responsible for oversight and regulation of 4 areas of food in Minnesota
 - Retail Food – grocery stores, convenience stores, etc.
 - Manufacturing of Food – manufacturing plants, but also includes storage and transportation of food
 - Produce – fresh produce growing, processing, storage, packing
 - Commercial Feed – manufacture and sale of food for both livestock and pets; includes medicated feed
- Staff of around 50 field staff responsible for inspecting a constantly fluctuating population of businesses numbering somewhere in the 15,000 range.

DEFINITIONS: Food – Dietary Supplements – Drugs

- **FOOD:** “every ingredient used for...food, drink, confectionery, or condiment for humans or other animals, whether simple, mixed, or compound; and articles used as components of these ingredients” - Minnesota Statute 34A
- **Dietary Supplements:** In Minnesota considered a subset of “Food”; Limited to structure and function claims.

- **DRUG:** “includes all medicines and preparations recognized in the United States Pharmacopoeia or National Formulary and any substance or mixture of substances intended to be used for the cure, mitigation, or prevention of disease of either humans or other animals.” – Minnesota Statute 152

Can you sell Kratom in Minnesota...? NOPE!!!

Why?

- **Kratom is currently not approved by FDA as:**
 - Over the counter or prescription drug
 - For use as a food additive in conventional food
 - For use as a nutritional supplement
- **Kratom unapproved in Minnesota as a food or drug because:**
 - Kratom is considered a new ingredient
 - There is not enough information to provide reasonable assurance that it does not present an unreasonable risk to the consuming public AND
 - There is evidence that suggest consuming Kratom poses a risk to the consumer
 - Does not meet the criteria of “Generalized Recognized As Safe”
- **Per Minnesota Statute** – any drug, conventional food or dietary supplement containing kratom is therefore adulterated, and distribution of any adulterated product is a prohibited act.

The MS 152.027 confusion

- Minnesota Statute 152.027 - Controlled Substance Crimes
- Criminalizes sale to or possession by minor
- DOES NOT approve as a product or allow a sale to an adult



What is Minnesota doing?

- **MDA**
 - Responding to complaints when received
 - Have communicated guidance to our industry partners and our licensed entities regarding kratom and its status
 - Ongoing follow up and education by our field staff via routine inspection process
- **Multiple State of Minnesota agencies continue to collaborate including:**
 - Department of Agriculture
 - Department of Health
 - Department of Public Safety
 - Board of Pharmacy



Emerging Products – Information Challenges

- “A pilot, placebo controlled, dose-finding, pharmacodynamic and pharmacokinetic study of orally administered botanical kratom in non-dependent, recreational polydrug users with opioid experience under fed conditions” – Reissig, C., et al.
 - Study provided to MDA as evidence of safety of Kratom as a product – found to be “well tolerated”



“A pilot, placebo controlled, dose-finding, pharmacodynamic and pharmacokinetic study of orally administered botanical kratom in non-dependent, recreational polydrug users with opioid experience under fed conditions” – Reissig, C., et al.

- Subjects:
 - 40 healthy “recreational polydrug users”;
 - Required to “have experience with opioids”; i.e. recreational use 10+ times in life and at least 1 time in the last 12 weeks AND 2+ “perception altering” drugs 5+ times in life
 - “Otherwise healthy”



“A pilot, placebo controlled, dose-finding, pharmacodynamic and pharmacokinetic study of orally administered botanical kratom in non-dependent, recreational polydrug users with opioid experience under fed conditions” – Reissig, C., et al.

- Single kratom product used for doses (a “pure leaf” product)
 - Laboratory tested for Alkaloid content; verified no 7-OH;
 - Subjects were administered a single dose and then monitored for a period of 48 hours with blood samples and visual assessment
- Exposure Groups: randomly assigned individuals 1g, 3g, 8g, 10g, 12g, or placebo



“A pilot, placebo controlled, dose-finding, pharmacodynamic and pharmacokinetic study of orally administered botanical kratom in non-dependent, recreational polydrug users with opioid experience under fed conditions”
– Reissig, C., et al.

- “...at the doses tested, using the specific botanical kratom sourced for the study, and under carefully controlled clinical conditions (i.e., an inpatient study), kratom was well-tolerated.”
 - Per the study – those given Kratom experienced a variety of GI disorders, Nervous system Disorders, Psychiatric Disorders, etc. with increased frequency at higher doses
- “These data help inform the safety profile of botanical kratom for use in **future investigations to more thoroughly characterize its pharmacological effects and abuse potential**.”
- “...**did produce a constellation of effects commonly associated with drugs of abuse** such as increases in subject-rated measures of good effects, high, and feeling drunk. These data **warrant additional studies to more thoroughly assess the abuse potential of kratom**.”

Future Status of Kratom in Minnesota???

- Not attempting to “ban” Kratom products
 - Don’t need to ban anything – already not allowed
- AND would prefer to support the development of a safe, well regulated, well researched product and industry with clear standards and analytics.
- However – current state of industry/products are not mature, and the average consumer should not serve as a de facto human trial.

Summary:

- All Kratom Products are currently not approved to be sold as a food (including as a dietary supplement), or drug to anyone in Minnesota
- It is a criminal act to sell kratom products to individuals under 21 per Board of Pharmacy Statute 152.
- The MDA and other partner agencies are not working to ban kratom – but rather are prioritizing protecting public health and hope to support the development of a safe, scientifically, and technically sound industry.

Thank you for your attention!

Questions?

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