

### **KRATOM AT-A-GLANCE**

## 6/19/18

**KRATOM OVERVIEW:** Kratom leaves come from a tree native to Southeast Asian, *Mitragyna speciosa*. Also referred to as thang, kakuam, thom, ketum, biak.

Kratom can be chewed, smoked, steeped in tea or ingested in pill form. Proponents say It can cause pain relief, and can act as a stimulant depending on amount consumed. However many other symptoms can emerge depending on dosage, including euphoria, nausea, dizziness, drowsiness or even depression of the Central Nervous System. Kratom has also been found to be addictive, causing withdrawal.

#### WHO IS INVOLVED WITH KRATOM?

Since 2012, the recreational use, especially in Thailand, has increased and includes a tea and cocktail including the kratom tea mixed with other substances. This ready-to-drink form of kratom is convenient and is popular with youth, who are becoming addicted to its use. Kratom is illegal in several nations in that region including Australia, Malaysia and Thailand where it is classified as a narcotic.

In the United States, kratom is gaining popularity for its recreational use and alleged medical benefits. Some allege kratom can be used to withdraw from opioid addiction as its effects mimic opioids, however, few studies have been done on any therapeutic uses of kratom and those done are small. As a result, to date the medical clinical data is limited. Therefore results regarding safety and effectiveness are inconclusive.

#### **IS KRATOM ILLEGAL?**

Kratom is technically legal on the federal level. Its legal status remains a gray area state by state. Illinois allows kratom to be sold to those age 18 and up, but neighboring states Indiana and Wisconsin are among six states and the District of Columbia that have banned kratom. Several individual counties and municipalities have followed suit across the country. Much of this legislation came about because kratom contains psychoactive alkaloid opioid-like compounds that mimic the effects of opioid painkillers.

Federal agencies including the FDA and DEA have issued warnings to the public about kratom health risks since 2016, and have contemplated a federal ban of the substance. Several kratom distributors have recently drawn the ire of federal partners for unverified claims regarding their product's impact on cancer and the treatment of opioid addiction.

"Despite our warnings that no kratom product is safe, we continue to find companies selling kratom and doing so with deceptive medical claims for which there is not reliable scientific proof to support their use." Scott Gottlieb, FDA Commissioner.

Congress is currently reviewing legislation that could ban kratom and other controlled substance analogues.

# HOW IS KRATOM CLASSIFIED BY THE FDA AND U.S. DRUG ENFORCEMENT AGENCIES, AND THE STATE OF ILLINOIS?

The Food and Drug Administration Commissioner in February 2018 issued a written warning that kratom's serious side effects include seizures and respiratory depression. The FDA has not approved kratom for any medical use. Kratom has been classified as an opioid analogue, which makes it unsuitable for treating opioid addiction or withdrawal. The agency has not banned it or made it a schedule 1 drug, possibly partly due to the lack of study. To date, only case studies with few subjects and literature reviews are published in medical journals.

A 2017 review (Fluyau D and Revadigar N. Biochemical Benefits, Diagnosis, and Clinical Risks Evaluation of Kratom. Front Psychiatry 2017;5:62. <u>https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5402527/</u>) reached the following conclusion:

Our data analysis has not determined if biochemical benefits of kratom may prove to outweigh its toxicity and risks. On the contrary, it seems that its potential side effects outweigh the benefits, and severe and real health hazards can, insidiously, lead to death. Kratom clinical, psychological, and medical manifestations can be disturbing.

A 2018 review (White CM. Pharmacologic and clinical assessment of kratom. *Am J Health Syst Pharm.* 2018 Mar 1;75(5):261-267. <u>https://www.ncbi.nlm.nih.gov/pubmed/29255059</u>)

Kratom has been used to ameliorate opioid withdrawal symptoms but also induces withdrawal. Human pharmacologic, pharmacokinetic, and clinical data are of low quality, precluding any firm conclusions regarding safety and efficacy. Respiratory depression has not been commonly reported, but kratom does cause a host of adverse effects without clear guidance for how they should be treated. There are numerous assessments where people have been unable to stop using kratom therapy, and withdrawal signs and symptoms are problematic. Kratom does not appear in normal drug screens and, when taken with other substances of abuse, may not be recognized. Thirty-six deaths have been attributed to kratom, and the Food and Drug Administration issued a public health warning about the substance in November 2017.

Both studies found kratom's medical clinical use were inconclusive because the authors noted that not enough human drug studies on kratom have been published to produce data on therapeutic potential, risks, benefits, harms.

The U.S. Drug Enforcement Agency does not control kratom under the Federal Controlled Substances Act, and lists kratom as a Drug and Chemical of Concern due to the concerns about safety, effectiveness, abuse, and withdrawal risks (U.S. Department of Justice, Drug Enforcement Administration. *Drugs of Abuse: A DEA Resource Guide 2017 Edition*. <u>https://www.dea.gov/pr/multimedia-</u> <u>library/publications/drug\_of\_abuse.pdf#page=84</u>).</u>

#### WHAT IS HAPPENING AROUND KRATOM?

In 2016, just outside of Rockford, IL, U.S. marshals seized 90,000 bottles of kratom supplement worth \$400,000. In 2018, however, kratom remains a relatively newer supplement, especially in suburban Chicagoland area. Little is commonly known about kratom's safety and effectiveness by the general public, who may see kratom as a benign herbal offering on the menu of a smoke shop or tea shop.

The Centers for Disease Control and Prevention reported a kratom-linked salmonella outbreak nationwide in 2018; as of May 199 people with salmonella –50 hospitalized—prompted the FDA to issue recall of the unregulated supplement (<u>https://www.cdc.gov/salmonella/kratom-02-18/map.html</u>).

#### WHERE IS KRATOM SOLD?

Kratom is widely available online for purchase and is sold in shops In Illinois, Michigan and elsewhere.

#### HOW IS KRATOM USED/FORMS?

Kratom is used as a psychoactive substance for a euphoric dissociative effect. The dried leaves can be smoked, snorted or steeped as tea. Kratom tablets and capsules are available. Kratom extract is stronger, and can have intense effects, leading to a tolerance, requiring additional substance use.

A foil pouch of powdered kratom purchased in Chicago came with no directions for use, beyond the clerk's comment of "stirring a teaspoon into orange juice" for a 4-hour effect (Main F. Kratom, health supplement targeted by FDA, linked to 9 deaths in Cook County. *Chicago Sun-Times.* March 5, 2018. <u>https://chicago.suntimes.com/business/kratom-health-supplement-targeted-by-fda-linked-to-8-deaths-in-cook-county/</u>)

Tolerance can lead to compulsive drug seeking behavior, addiction, and overdose. According the FDA, at least 44 deaths have been tied to kratom in the USA between 2011-2017, nine of which were in Cook County in 2016 and 2017.

#### WHAT DO PARENTS NEED TO KNOW ABOUT KRATOM?

Online, kratom can be ordered by youth without restriction. If in states such as Illinois, the words "for 18 and older" may appear, however, often the customer is not required to prove age.

Calls increased tenfold nationwide to poison control centers monitored by the US Department of Health and Human Services/CDC (26 in 2010 and 263 in 2015). Symptoms of use may include psychosis, agitation, aggression, delusions, hallucination, insomnia, nervousness, nausea/vomiting and anorexia, itching, sweating, dry mouth, increased urination, constipation, tremors, respiration depression, and liver toxicity.

Long term use of kratom can be psychologically and physical addictive, with half developing dependence on kratom with 6 months of regular use. (Singh D, Muller CP, Vicknasingam BK. Kratom [*Mitragyna speciosa*] dependence, withdrawal symptoms and craving in regular users. *Drug Alcohol Depend.* 2014; June 1; 139:132-137. <u>https://www.ncbi.nlm.nih.gov/pubmed/24698080</u>).

A study analyzing samples of kratom from ER patients by a researcher at University of Florida—a region experiencing increased addiction to kratom—found that frequently, kratom isn't just kratom, as it was sometimes laced with morphine and other drugs. (Kounang N. Compounds in herbal supplement kratom are opioids, FDA says. CNN Feb 7, 2018. <u>https://www.cnn.com/2018/02/06/health/fda-kratom-opioid-bn/index.html</u>).

Withdrawal from kratom can produce sadness, tension, body aches and muscle spasms, difficulty sleeping, leading to cravings for kratom, putting user at further risk of abuse.

Opioid testing will not detect kratom because kratom has a similar but different chemical structure. Kratom use can be detected in urine if use was within the last five days.

#### WHEN CAN THE PUBLIC EXPECT MORE RESEARCH DATA ON SAFETY AND EFFECTIVENESS?

Clinical studies testing kratom in animals and humans have not been performed.

The FDA in February 2018 said it is "ready to evaluate evidence that could demonstrate a medicinal purpose for kratom. However, to date, we have received no such submissions and are not aware of any evidence that would meet the agency's standard for approval" (https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm595622.htm ).

FDA Commissioner Scott Gottlieb stated, "The extensive scientific data we've evaluated about kratom provides conclusive evidence that compounds contained in kratom are opioids and are expected to have similar addictive effects as well as risks of abuse, overdose and, in some cases, death. At the same time, there's no evidence to indicate that kratom is safe or effective for any medical use."