Item # 7 (12)

ADDITIONAL MATERIAL

PUBLIC HEARING

OCTOBER 28, 2014

SUBMITTED AT THE REQUEST OF

COUNTY ADMINISTRATION

BERTHA HENRY, County Administrator
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MEMORANDUM

TO: Board of County Commissioners

FROM: Bertha Henry, County Administrator

RE: Proposed Ordinance Related to Kratom Distribution (PHI # 7)

DATE: October 24, 2014

The Board of County Commissioners directed staff to undertake an analysis examining Kratom, to include, but not be limited to: overview of the substance, research studies related to the substance(s), legitimate and illegitimate uses, hazards, benefits, as well as government treatment of the substance internationally, nationally, and by other governments within Florida.

The *Mitragyna speciosa* tree is in the coffee tree family, with yellow flowers, and is often used as an ornamental in warm climates. The seeds of the flower are of little use as they lose the ability to germinate very quickly. It is usually propagated using cuttings from the plant. Mytragyna speciosa originates in Southeast Asia, is quite intolerant to cold, and dies when temperatures reach freezing or below for any significant period of time. South Florida and parts of California are the primary regions in the United States where the tree can survive; it is readily available at nurseries throughout the region. The tree is similar to several other psychoactive plants that grow in South Florida including Passion Flower, Heliotrope, Belladona, Morning Glory, and Prairie Bundleflower.

The substance at issue, Kratom (*aka* krypton) derives its name from one of at least twenty (20) alkaloids present in the leaves of the Mitragyna speciosa tree. An alkaloid means it has a nitrogen atom along with other elements in the chemical compound. Other common alkaloids include caffeine, nicotine, and ephedrine. Many alkaloids have a pharmacological effects and are used as medications or recreationally without regulation. And while most opiates are alkaloids, not all alkaloids are opiates. While there is a common perception that the compounds derived from the tree are hallucinogenic, staff was unable to locate any scientific basis for that assertion.

Proponents of the continued unregulated sale, distribution and use of Kratom cite historical data indicating its safety. However, like many naturally-occurring, synthetic and/or pharmaceutically manufactured substances, disagreement exists within the scientific community as to its beneficial uses and harmful effects. National Institutes of Health studies on the effectiveness of the drug for combatting opioid dependence withdrawal symptoms showed remarkable promise[1]; however, the addictive nature of Kratom itself seems to be a topic of considerable debate. Researchers appear cautiously optimistic about Kratom's utility as tool for treating addictive disorders; asserting its benefits must be weighed against evidence that the substance does cause some level of dependency. Interestingly, physical reaction to cessation of Kratom use in three (3) studies reviewed by staff were primarily flu-like symptoms[2]. The effects of use, abuse[3] and symptoms related to abstinence after prolonged use of Kratom are significantly less severe than many well-known, widely used, pain medications.

Proponents of the drug point to its use as an analgesic for centuries; it is also purported to effectively manage diarrhea, anxiety and attention deficit. Advocates cite concerns that pharmaceutical companies (which have pursued developing and marketing synthetic versions of the drug over the last fifty years) may be engendering health concerns and encouraging regulatory actions of Kratom, in an effort to limit competition with pharmaceutically-manufactured products.

Opponents of the drug point to evidence of dependency and questions as to its safety, especially when combined with other drugs/substances (at least one scientifically-verified instance of a user suffering a seizure after ingesting Kratom[4], an instance where a death was associated with ingestion of Kratom in Denver[5], and other examples of adverse reactions in combination with other substances[6]). While the suicide reported in Palm Beach County was associated with the use of Kratom, other drugs were found in the person's bloodstream; of significance, Gabapentin and

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[1] See http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3670991/

[2] NIH study on of 293 individuals regarding Kratom dependence, craving and withdrawal symptoms, http://www.ncbi.nlm.nih.gov/pubmed/24698080; http://www.ncbi.nlm.nih.gov/pubmed/21528385 see also, Scientific American article, http://www.scientificamerican.com/article/should-kratom-be-legal/

[3] See http://www.ncbi.nlm.nih.gov/pubmed/21528385: concluding abuse of powdered mytragynine caused intrahepatic cholestasis, the symptoms of which are: clay-colored or white stools, dark urine, inability to digest certain foods, itching, nausea or vomiting, pain in the right upper part of the abdomen, yellow skin or eyes.

[4] http://www.ncbi.nlm.nih.gov/pubmed/20411370

[5] There is a single case in Denver of a death where only Kratom was found to be present in the bloodstream. The Broward County Medical Examiner contacted the Denver Medical Examiner and who stated that the Chief at the time of the death, Dr. Amy Martin, ruled the death as *associated* with Kratom and did not make a definitive call as to the cause of death. The case was further complicated by circumstances surrounding the death that are inconsistent with an opioid overdose, as well as organ donation (thus, they were not available for subsequent examination). See also, Baselt R.C., *Disposition of Toxic Drugs and Chemicals in Man*, 10th edition, 2014, Biomedical Publications, Seal Beach, CA, pp. 1382-83, 2021-2023.

[6] Mixing Kratom with other drugs and medications increases the likelihood of an adverse reaction. Contraindications appear when Kratom is combined with: carisoprodol (a muscle relaxant), Modafinil (a wakefulness drug) and propylhexedrine (a cold medication).

Citalopran (commonly known as Celexa), both of which warn of suicidality and clinical worsening of depression, as potential side effects.

FDLE records of drug-related deaths in 2013 show no incident of Kratom overdose in the State.

The University of Mississippi is undertaking trials related to the plant's extracts and compounds that may shed additional light on its potentially beneficial and deleterious properties.

International Legal Issues:

The tree was outlawed in Thailand over fifty years ago, but enforcement has proven challenging and the government is pursuing overturning the ban. Following the death of nine (9) youth in Sweden, countries reacted by banning the plant/alkaloids, including: Australia, Burma, Finland, Denmark, Poland, Lithuania, Malaysia, Romania, Sweden, Myanmar and Vietnam. The deaths were further investigated and it was found that the Kratom had been spiked with high concentrations of the synthetic opiate Tramadol (aka Ultracet and Ultram). Some countries make the plant illegal, others make the alkaloids in the plant illegal, leading to international enforcement confusion.

United States Regulations and Legislation:

The Drug Enforcement Administration (DEA) has listed Kratom as a "Drug and Chemical of Concern." The bulletin from the DEA about *Mitragyna Speciosis* cites animal studies and mostly anecdotal observations about the dangers of long term use (as there is little in the way of controlled scientific studies supporting or refuting these findings). The DEA has not ruled Kratom a schedule I drug (i.e., no legitimate human use) or as any other scheduled controlled substance. The FDA has been the most aggressive about Kratom, based on alleged labelling inconsistencies.

Indiana, Tennessee and **Vermont** presently ban alkaloids in Kratom.[7]

In **Oklahoma**, legislation was withdrawn after legitimate uses for the herb were cited, said the Oklahoma Bureau of Narcotics. Other states such as **Iowa** and **Louisiana** pursued legislation intended to restrict the use of Kratom leaves; neither bill passed and at present Kratom (and its alkaloids) is permitted in these states. Louisiana did enact legislation restricting the sale of Kratom to persons over the age of 18.

Wisconsin Statute 961.14 (7) lists the chemical compounds of Kratom as a controlled substance; specifically, mitragynine and hydroxymitragynine *(modification of 7-oh or Mit are outlawed.)*[8]

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[7] http://www.in.gov/legislative/bills/2012/HE/HE1196.1.html (Indiana);
http://state.tn.us/sos/acts/108/pub/pc0161.pdf (Tennessee)
http://healthvermont.gov/regs/documents/regulated_drugs_rule.pdf (Vermont)

[8] http://docs.legis.wisconsin.gov/2013/related/acts/351

Arizona, in early 2014, proposed to place two chemicals unique to Kratom to a list of banned designer drugs, but decided to remove the substances from the legislation prior to its passage, purportedly as a result of persuasive potentially beneficial uses of the products.

To date, the State of **Florida** has not made any attempt to regulate any aspect of the sale of the *Mitragyna speciosa* tree, Kratom, or its alkaloids.

Sarasota ordinance: Sec. 62-351 states in pertinent part:

"Regulation of Designer Drugs and Misbranded Consumer Commodities.
(1) Prohibitions – Designer Drugs . . .
(2) Prima Facie Evidence — Designer Drug.
A Designer Drug is any capsule, pill, powder, liquid, vegetative material, product, or other substance, however constituted, including but not limited to any Synthetic Cannabis, Substituted Cathinone, or Kratom, designed to be injected, ingested, inhaled or otherwise introduced into the human body."

Palm Beach County: In October 2014, the Board of County Commissioners discussed the potential regulation of Kratom, with specific interest in marketing and labeling changes; discussions with county staff indicated an unlikelihood that the Board would move to ban the sale or use of Kratom (the tree) or any of its alkaloids.

Pinellas County: attempted to institute a local ban of Kratom in 2012, at the same time the government implemented regulations of bath salts and synthetic cannabinoids. Advocates for the continued legality of Mytragina speciosa appear to have halted the county's efforts.

C: Joni Armstrong Coffey, County Attorney
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