



Informational Hearing on Unregulated Intoxicants

House Health Committee

April 26, 2023

Chair Frankel, Chair Rapp, members of the committee, thank you for including the Department of Health today. The Department is still reviewing information on the health impacts of kratom, delta 8 and CBD but will speak to the significant administrative impacts that regulating these substances could have in the Commonwealth.

Last year, the Department outlined concerns with the preparation, sale, distribution and enforcement required for regulated kratom use as described in HB 2357. Currently, kratom is a legal substance that is readily available and commonly sold as a powder, capsule or extract. At the present time, the Food and Drug Administration (FDA) has publicly stated that kratom is not a controlled substance according to the Controlled Substances Act. The FDA has yet to approve kratom for medical use. Studies of kratom have shown safety concerns and no clear benefit. The Drug Enforcement Agency (DEA) has listed kratom as a “drug or chemical of concern.” However, kratom is often marketed as a treatment for opioid cessation, pain, and other medical issues. These claims are unsubstantiated and are in violation of the federal Food, Drug and Cosmetic Act. Kratom can be addictive since its effects are similar to that of opioids and stimulants.

Of major concern to the Department are patients who utilize kratom as a “treatment” for Substance Use Disorder (SUD) and may not seek appropriate FDA-approved therapies, thereby continuing with unmanaged SUD, including withdrawal and/or overdose. Most herbal derived products are not regulated as drugs but rather as food or dietary supplements. Food and dietary supplement oversight falls under the federal Dietary Supplement Health Education Act (DSHEA). At the state level, DSHEA compliance is managed by the Department of Agriculture. The state’s Drug, Device and Cosmetic Act (DDC) is counterpart to the FDA’s section that deals with drugs and devices, not food or dietary supplements. The American Kratom Association wants kratom to be regulated as a vitamin or food supplement, not like a drug or medication. Therefore, this would likely place kratom under the oversight of DSHEA.

Similarly, the Department of Health has not been involved in overseeing the use of delta 8 or CBD in non-medical marijuana products. The Department of Agriculture (DOA) oversees hemp and those general hemp permits for growers and processors. Accurate regulation of these products would require chemical analysis. Hemp is typically grown outdoors and tested by DOA-approved labs to determine that the crop is legally defined as hemp, which is defined as less than 0.3% THC. Growing and testing of hemp does not fall within DOH's purview. Hemp obtained by permitted Grower/Processors in the Department's Medical Marijuana Program to be added to the permitted forms of medical marijuana must meet the testing standards in Section 704 of the Medical Marijuana Act (Act 16 of 2016). Edibles are not a permitted form of medical marijuana in Pennsylvania and therefore, are not the delta-8 and CBD products at issue. Further, kratom is not permitted in the medical marijuana program because substances that cause pharmacological effects are not permitted to be added to medical marijuana products and a grower/processor permit only allows a grower/processor to grow medical marijuana, not other plants like the evergreen tree kratom is extracted from.

Hemp-derived delta 8 and CBD are frequently sold in edible forms. Kratom is ingested by mouth and could be defined as an edible product. For any of these substances to be regulated by the Department, it would need to hire a new team as well as develop policies regarding delta 8, CBD, and kratom outside of the medical marijuana program. A new testing and sampling category would have to be created to analyze products including these substances accurately. Notably, the state DDC only oversees FDA approved products and defers to the FDA on product quality, chemical analysis and field staff.

From an enforcement perspective, laws that prevent adulteration of product for abuse or addictive properties are usually set up as criminal misdemeanors in Pennsylvania and involve enforcement by PA State Police or the Office of Attorney General's Bureau of Narcotics,

rather than administrative agencies. If the Department were to take on an enforcement provision the Department would have to contract with organizations to manage that enforcement similar to the Tobacco Enforcement Program (TEP). A program similar to TEP would necessitate identifying retailers who sell kratom, delta 8 and/or CBD. Currently there is no mechanism comparable to a license to sell tobacco products for kratom, delta 8 or CBD. A license for any of these substances would need to be legislated and retailers would apply to the Department of Revenue for a “kratom license,” “delta 8 license” or “CBD license.” Unless provided with funding and staff, the Department does not have the ability to set up this type of program. The estimated program costs for implementation of HB 2357 of the 21-22 Legislative Session alone would be on the scale of \$8.7 million for the creation of a new office and the promulgation of regulations dealing only with kratom. Since enforcement is not traditionally under the purview of the Department it is difficult to accurately estimate the costs involved.

The Department believes that the substances discussed today need to be addressed at the federal level for meaningful oversight to occur. If the Department were tasked with a role relating to kratom, delta 8 or CBD it would require the guidance of the FDA. Moreover, issuing these new types of licenses, inspections, new regulations, new forms, public notices, product analyses and staff require upfront funds. Neither kratom, delta 8, nor CBD fall neatly under the purview of any state agency.

For all of these reasons, the Department believes a multi-agency group must come together to provide input on the creation of kratom, delta 8 and/or CBD programs. The Department of Health believes there are other agencies better suited to manage large components of these administrative programs, particularly enforcement. Other than the cannabinoids regulated as part of the medical marijuana program, these substances are currently used for recreational rather than health uses. But the Department welcomes the opportunity to provide input

to the legislature and will continue to partner with its sister agencies to find solutions for the citizens of the Commonwealth.