House Health Committee
4/26/23, 9:00 a.m., Room G-50, Irvis Office Building
By Ashlee Reick, Pennsylvania Legislative Services

The committee held a hearing on unregulated intoxicants and psychoactive substances.

Chairman Frankel stated that it is a "busy session day," so members of the committee may leave to attend other committee meetings, then return. He indicated that he will step out for 15 minutes and Rep. Sanchez will lead the meeting in his absence. "The purpose of this meeting is to receive testimony regarding unregulated substances such as Delta-8-Tetrahydocannabinol (Delta-8 THC), Kratom and cannabidiol (CBD)," Chairman Frankel stated. He stressed the presence of advertisements for Delta-8 THC, Kratom and CBD, noting the hearing packet includes a picture of a store and its advertising near his district office. "The market is flooded with products making unproven health claims," he remarked. Chairman Frankel argued the legalization of hemp products on the federal level and "ever advancing technology" created a gray area as some new products are questionable. He raised concerns regarding the lack of information on the concentrations of active ingredients in the aforementioned drugs. "In this case, what you do not know may not kill you, but it can cause some serious health problems," Chairman Frankel asserted.

Chairman Rapp stressed her concerns about drugs and minors' access. She indicated that she, like Chairman Frankel, sees the products in her community.

Dr. Michael Lynch, health plan and substance use disorder services medical director, University of Pittsburgh Medical Center (UPMC), said that he "first became aware of Delta-8 THC and the prevalence when I was taking care of two kids in the UPMC's Children Hospital of Pittsburgh." He explained that the two children were admitted to the pediatric intensive care unit "where they stayed for two days essentially in a coma" due to Delta-8 THC. Per Dr. Lynch, the father was treating chronic back pain with Delta-8 THC gummies, but his children consumed the gummies. Dr. Lynch reported the children recovered without any "long-lasting effects." He spoke of "at least a dozen cases" managed at hospitals with patients ranging from ages 14 to 19. Three of the patients experienced low-blood pressure, which required medication to address. Dr. Lynch raised concerns about the labeling of Delta-8 THC and Delta-9 THC. He continued, stressing the health risks of electric cigarettes. Per Dr. Lynch, Tianeptine is also of concern, citing "several deaths associated" with the drug. He raised concerns about the addictive nature of Tianeptine. Regarding Kratom, Dr. Lynch reiterated that it is not a regulated drug. "I think there is a lot of interest and potential benefit for managing pain potentially more safely than traditional opioids, as well as opioid use disorder," Dr. Lynch remarked. He spoke of CBD, which he described as "not psychoactive," though he raised concerns about the lack of labeling regarding the percentage of CBD present in products. While people may experience benefits, Dr. Lynch emphasized the importance of people understanding "what it is that they are buying."

Rep. Borowski stated that she had a store like Chairman Frankel described open "about 500 yards from an elementary school," prompting concern in the community. She raised concerns about the products "being marketed in soda and gummies," which attract children. Per Rep. Borowski, the store enacted "certain protections" to prevent selling the products to students. "It still was a huge concern," she added. Per Rep. Borowski, the community enacted an ordinance that restricted "where the stores could go." Rep. Borowski asked if there are "better ways to market" the drugs. Dr. Lynch emphasized the importance of packaging that does not attract children. He also raised concerns about drugs promoted as candy. He advocated for minimizing "the risk" by educating adults and enhancing labeling.

Rep. Brown mentioned that 13 states prohibited Delta-8 THC and Delta-9 THC and nine states established regulations "to promote public safety." She asked, "Are you aware of any positive results coming out of those states?" Dr. Lynch suggested that it requires further research, expressing doubt that there has been "enough time" to determine the results.

Rep. Krajewski raised concerns about issues that Dr. Lynch described regarding packaging, which may attract children. He asked Dr. Lynch to provide guidance on the regulations that the General Assembly should consider. Dr. Lynch urged the committee to enact regulations with caution. He advocated for regulations to address issues with packaging and labeling.

"Are you promoting either banning these or regulating these?" Rep. Keefer asked. Dr. Lynch replied, "I do not necessarily have a strong agenda to ban lots of things." He called for classifying Delta-8 THC similar to Delta-9 THC. Dr. Lynch advocated for selling products "in a way that accurately reflects what it is."

Rep. Shusterman emphasized the availability of CBD, noting it is sold in Target. She advocated for "creating the product here," suggesting that production in Pennsylvania would lead to "better control" of the products' contents. Dr. Lynch reiterated that he is focused on "quality control" to help people make decisions.

Rep. Rossi asked if Delta-8 THC is addictive. Dr. Lynch explained that people may develop cannabis use disorder, but argued THC products are not addictive. Rep. Rossi asked if the patient that took Tianeptine was aware of the addictive nature of the drug. Dr. Lynch said that was not a notification of the addictive nature of the drug. Rep. Rossi asked if Dr. Lynch believed such a label would help. Dr. Lynch suggested it would help but raised doubts about such labeling fully solving the situation. He advocated for a "multi-pronged approach of labeling, public education and so forth." Rep. Rossi asked if the patient wishes he knew the drug "was addictive." Per Dr. Lynch, the patient informed him that he wished that he knew he would "feel so much sicker" after stopping the drug.

Chairman Frankel noted that he will now leave the meeting and Rep. Sanchez will lead the meeting in his absence.

Rep. Zimmerman indicated the General Assembly is working on a new Pennsylvania Farm Bill. He asked if the bill should include any language related to the topic being discussed in the meeting. Dr. Lynch advocated for further regulations to provide for clarifications. He stated that he is not aware of specific language being discussed in the new Pennsylvania Farm Bill.

Chairman Rapp asked about Dr. Lynch's opinion on increased Delta-8 THC exposure. Dr. Lynch explained that Delta-8 THC reached the marketplace in late 2020, which contributed to increased exposure. "Is there research being done to determine why hospitals do not have a test to determine or differentiate between Delta-8 THC and Delta-9 THC?" Chairman Rapp inquired. Dr. Lynch stressed the difficulties with differentiating due to similar chemical structures. He noted that Delta-8 THC and Delta-9 THC can cause similar side effects.

Bob Miller, chief operating officer, ACT Laboratories, reported that ACT Laboratories conducted a study to test 21 products from the marketplace. Per Miller, eight of the 21 products "actually met the specification" from claims on the labels. He raised concerns about nine of the products containing Delta-8 THC. Other products contained heavy metals, according to Miller. He advocated for regulations, such as requirements for manufacturing the product in state to establish "some quality control standards for the product." Miller said, "I think there is a call to action to be able to ensure we can really ensure the health and safety of our customers, patients and children in this marketplace." He emphasized that ACT Laboratories is committed to supporting the work of the committee. "We recommend tests with specific specifications to ensure the overall reliability of the product," he remarked.

Dr. Chris Hudalla, founder and chief scientific officer, Pro Verde Labs, detailed the testing process for cannabis products. Per Dr. Hudalla, the Pennsylvania Farm Bill provided for an "unintended loophole for the creation of these synthetic conversions to psychoactive compounds." He reported that the Delta-8 THC products on the market are not the same as Delta-8 THC in cannabis. Dr. Hudulla raised concerns about the lack of regulations and oversight. Per Dr. Hudulla, there is disinformation which misleads

consumers. He indicated that he is not against synthetics, but raised the question as to if synthetics can be manufactured without contaminants.

Rep. Borowski questioned the tests' efficacy. Miller explained that tests provide for the level of certainty of the quality of materials in the drugs. Rep. Borowski stated that the study Miller described demonstrated that people do not know the contents of the drugs they are consuming, which Miller affirmed. She wondered if regulations, such as adherence to standards, would solve the problem. "It will not solve all our issues, but it should get us to a very different pace than we are today," Miller said.

Rep. Twardzik stated, "It is so unfortunate that people today will just buy anything and there is no consumer safety." He thanked the testifiers for their testimony. Rep. Twardzik said that he looks forward to working with the testifiers to address safety concerns.

Rep. Zimmerman asked about who issues requests for testing, in addition to the contents requested in the test. Per Miller, requests for testing are rare. He indicated that ACT Laboratories occasionally receives requests from the Pennsylvania State Police (PSP) or companies "wanting to see what is in their product." ACT Laboratories charges $7 per potency test, Miller reported. He added that full testing can cost $300 to $350 per test. Dr. Hudalla reported that some consumers test the product, especially if their children "got sick from it" and experience "serious adverse effects." Per Dr. Hudalla, the CBD profile is $65 per test. "Very few producers will go to the extent to test for heavy metals and residual solvents," he said. He raised concerns about "other processing reagents," such as acids. He asserted that Pro Verde Labs does not have the testing abilities for acids.

Rep. Khan raised concerns about regulations impacting people of color and low-income people. He asked about Dr. Hudulla's perspective on the "issue of regulation versus access." Miller highlighted the importance of "having access to medicine," though he stressed the importance of labeling to inform consumers of the products they purchase. Dr. Hudalla asserted that it is possible to create Delta-8 THC products without contaminants. He suggested that creating Delta-8 THC products that meet regulatory requirements are "not financially profitable."

Chairman Rapp asked if Dr. Hudalla resides in Massachusetts or Pennsylvania. Dr. Hudalla indicated that he resides in Massachusetts, which is where the lab is located. Chairman Rapp asked if Dr. Hudalla sees other states taking action to enact regulations that remove contaminants and therefore regulate distributors. Dr. Hudalla emphasized that there are discussions about the "fate of Delta-8 THC" and reiterated his focus on ensuring access to products without contaminants. He raised concerns about the "regulatory ambiguity," citing regulations in Colorado that allow production and sale of synthetics. Miller added that Michigan discussed the topic recently, specifically regarding "additional controls." Dr. Hudalla added that there are issues about contaminants, calling for guidelines for the "main composition."

Chairman Frankel inquired about comments on Delta-8 THC, specifically regarding the lack of regulations and contaminations. Miller emphasized that testing only provides information on the contents in the drug, not what is not in the drugs. Dr. Hudalla added that Kratom is "not a natural product." He raised concerns about the "unknown in toxicity and unknown in behavior." Dr. Hudalla indicated that he is not concerned with Kratom, so long as it is "somewhat regulated."

Grant Martin, president, MAG Industries, indicated that MAG Industries is a "Pennsylvania-based processor and distributor of Kratom and Hemp derived CBD products such as Delta-8 THC." He indicated that MAG Industries supports efforts to regulate the products to protect consumers. According to Grant Martin, MAG Industries primarily supplies to retailers, though it buys and resells some products. He noted that MAG Industries owns and produces its own brand of Delta-8 THC products. MAG Industries contributes to job creation and technological innovations, as indicated by Grant Martin. He said, "We believe that the first step is to pass reasonable regulations that keep the products away from minors, empower consumers with facts about what they are consuming, and force irresponsible sellers out of the market."

Mairi Martin, president, MAG Industries, recommended "prohibiting sales to anyone under the age of 21," mandating "certain basic information" on products' labels, requiring and standardizing safety testing and registering products and sellers.

Mac Haddow, senior fellow on public policy, American Kratom Association, emphasized that the American Kratom Association is a consumer advocacy organization. He argued science "should dictate the public policy surrounding Kratom." He raised concerns about Kratom vendors buying from "Indonesian farmers who are not testing their products." Haddow stressed the importance of complying with good manufacturing practice (GMP) standards recognized by the U.S. Food and Drug Administration (FDA). Per Haddow, 10 states adopted the Kratom Consumer Protection Act. Haddow remarked that children do not like the "terrible" taste of Kratom. He said that due to the taste and self-limiting ingestion model, Kratom does not attract children. Haddow recommended banning Kratom sold as candy. Per Haddow, some states faced issues following their bans of Kratom.

Chairman Frankel asked about the manufacturing progress and protection of consumers at MAG Industries. Per Grant Martin, MAG Industries extracts CBD to convert it into Delta-8 THC. He stressed that MAG Industries would like to "buy directly from Pennsylvania farmers." MAG Industries conducts testing approved by the Department of Agriculture (PDA), citing the approval process for hemp products. Mairi Martin argued there are efforts to "source high quality distillates" and conduct testing for contaminants. She added that packaging includes labels that the productions are "not intended for consumption or sale to individuals under the age of 21." Grant Martin added that MAG Industries does not sell to retailers who sell to minors. Chairman Frankel asked if MAG Industries vets retailers, which Grant Martin confirmed.

Rep. Borowski inquired about an estimate of businesses that do not produce products meeting the standards. Haddow raised concerns about the lack of labeling standards. He suggested that a "vast majority" do not comply within the Kratom industry. He reiterated the importance of regulations to "clean up this industry." Rep. Borowski asked if Haddow opposes regulations, which Haddow denied. "We welcome regulations," Haddow remarked.

Rep. Zimmerman asked if PDA is equipped to conduct testing. Grant Martin clarified that he does not recommend PDA is responsible for administering regulations. He added that PDA currently has regulations in place. "We are just doing our best to be compliant to what little we have," Grant Martin said. Mairi Martin explained PDA currently holds regulatory jurisdiction. She expressed that MAG Industries does not oppose regulatory authority for the Department of Health (DOH).

Rep. Khan asked if MAG Industries witnesses growth in Pennsylvania, specifically regarding farms and other agricultural industries to produce the products. Grant Martin described cannabis as a "huge opportunity" across the country. Mairi Martin emphasized that regulations could help farming industries, citing a recent regulation in Kentucky on Delta-8 THC. "There is huge promise here for the agricultural community and business across... the industry," Mairi Martin remarked. Grant Martin recommended an incentive for farmers to grow hemp, so as to allow MAG Industries to purchase hemp from Pennsylvania farmers. Rep. Khan asked Haddow about the effects of Pennsylvania scheduling Kratom as "something... illegal." Per Haddow, science should dictate the policy decisions on the federal and state level. He argued Kratom could only be scheduled as a Schedule I drug. Haddow emphasized the importance of safely formulating and properly labeling Kratom.

Chairman Rapp raised concerns about minors "gaining rapidly available access to products that contain unsafe or addictive additives." She indicated that she looks forward to working with colleagues to protect Pennsylvania residents "while at the same time not burdening an industry with overly aggressive regulations that could harm businesses and the people that work for them."

Chairman Frankel thanked the testifiers for their testimony, noting the testimony will help to provide input on regulations that the General Assembly considers.

The committee also received written testimony from the following entities:

- Pennsylvania District Attorneys Association,
- Meredith Buettner, executive director, the Pennsylvania Cannabis Coalition (PCC),
- All Together Now Pennsylvania and
- Department of Health (DOH).