



Why Poison Control Center Mortality Data Cannot Accurately Reflect Concentrated Synthetic 7-OH Risk

Claim: HART contends that the FDA safety review of concentrated synthetic 7-OH lacks substance because it does not focus on the lack of deaths in poison control databases.

Reality: The FDA is correct. There are serious confounders that preclude these databases from being used accurately for this purpose at this time.

On August 21st, 2025, [a press release](#) from the Holistic Alternative Recovery Trust (HART) stated that the FDA's concerning scientific findings of 7-hydroxymitragynine (concentrated synthetic 7-OH) products were unfounded. Instead of reflecting on the FDA's prudent findings of serious potential health risk, HART refuses to be honest about the data they are citing creating intentional disinformation.

We have already dispelled clear lies from HART on the results of their [beagle study](#) which shows serious health risks. Their initial dosing strategy caused such severe adverse neurological events that they abandoned it and used one that was 1/20th what was originally intended. Even the lower doses were associated with more adverse events including new onset drooling which can be a sign of neurological issues. Yet HART continue to clam their study shows concentrated synthetic 7-OH's safety.

We demonstrated that HART only selectively disseminated results of their consultant's report, leaving out the [Marwood Group's findings](#) that concentrated synthetic 7-OH's pharmacology suggests it is likely highly addictive, causes physical dependence, and is markedly riskier than mitragynine (the main alkaloid in natural leaf kratom). When we pointed out their demonstrable falsehoods, they responded by removing access to the aspects of the Marwood Group's report that were unflattering to concentrated synthetic 7-OH.

Confounders That Can Lead to Undercounting of concentrated synthetic 7-OH Risks

In this latest press release, HART focuses the reader on a poison control center database report which did not report any concentrated synthetic 7-OH deaths. Poison control centers reported on August 12, 2025, concentrated synthetic 7-OH adverse events reported to them from January 1, 2025 to June 30, 2025. It is important to clarify that a code specific to concentrated synthetic 7-OH was not even input into the system until February of 2025. Of the 165 reported exposures to concentrated synthetic 7-OH alone, 35% had serious health problems and 67% were treated at a healthcare facility. The main adverse events included trouble breathing, seizures, agitation, confusion, rapid heartbeat, high blood pressure, nausea and vomiting, sweating and loss of consciousness. HART doesn't focus on these newly reported adverse events, but rather contends that the lack of concentrated synthetic 7-OH induced deaths in the report shows their products are safe.



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The [FDA is clear](#) that since concentrated synthetic 7-OH is so new to market that regardless of short-term sales figures, reports of death would be anticipated to be grossly undercounted and those data sources unreliable to assess deaths. They did not expound on the reasons they state this, but based on the KCAC's review of the literature, we found three very plausible scenarios where concentrated synthetic 7-OH products could induce death and not have it attributed to them.

If a person dies at home or on the street and the cause of death is unknown, what do coroners use to determine the cause of death? One major step is to collect [blood, urine, or other body fluids](#) and send them to the laboratory for testing. The standard tests include common drugs like fentanyl, heroin, cocaine, benzodiazepines, alcohol, and cannabis. If the tests come back with no or low concentrations of the common drug, drug induced death is ruled out. If one or more of these drugs come back with appreciable concentrations, the death is attributed to those drugs. It is critical for readers to understand that standard post-mortem drug testing does not include determining concentrated synthetic 7-OH concentrations. So, if concentrated synthetic 7-OH was the real cause of death and no one specifically told a first responder or clinician about the use of a concentrated synthetic 7-OH product, they would never determine it.

Until very recently, a consumer, first responder, poison control center employee, or emergency department clinician didn't know that concentrated synthetic 7-OH products were distinct from kratom products. The makers of concentrated synthetic 7-OH products and the sellers of the products told people in their marketing that their products were kratom. This means that a consumer dying after taking a concentrated synthetic 7-OH product would likely have a family member or roommate tell first responders or clinicians the consumer was taking kratom. In this case, in addition to a standard test of body fluids, they could specifically test for mitragynine, the most abundant alkaloid in natural leaf kratom or mitragynine extract products. If the concentrated synthetic 7-OH product had little to no mitragynine in it, the test for mitragynine would come back negative and the death would not be attributed to the concentrated synthetic 7-OH product. If the concentrated synthetic 7-OH product also had appreciably mitragynine in it (as some products do), the test for mitragynine would come back positive and the death attributed to kratom products and not concentrated synthetic 7-OH products.

Concentrated synthetic 7-OH is very unstable in biological fluids and quickly degrades, especially in the presence of [warmer temperatures and changes in pH](#). Since acidosis is common in death, and deceased people remain at room temperature until discovery, samples that are not quickly taken and refrigerated will show much lower concentrated synthetic 7-OH concentrations than existed at the time of death. Additionally, even if the sample sits under refrigeration, the ability to detect concentrated synthetic 7-OH goes down precipitously over time. In an assessment of [51 post-mortem cases](#), investigators found that when refrigerated (4°C or 39°F), mitragynine was stable for up to 30 days but 7-hydroxymitragynine was only stable for up to 7 days. By 60 days, nearly half of the concentrated synthetic 7-OH that was originally refrigerated will be degraded and not detected. Post-mortem toxicology samples frequently have [long delays](#) before testing. It is estimated that from the time laboratory samples are taken, it takes an average of 55 days with a maximum of 250 days to run the samples at public labs. In an assessment from [Kenosha County](#), post-mortem analysis may take 4-6 weeks if no drugs are present but 8-12 weeks to perform the necessary confirmations and report the actual concentrations. Thus, there are



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two distinct periods, the time from death to harvesting samples and the time from refrigeration until the samples are actually run, that the concentrations of concentrated synthetic 7-OH can be substantially reduced from what was seen at the time of death.

Taken together, the KCAC believes that the FDA is exactly right. Concentrated synthetic 7-OH measurements are rarely done unless a high suspicion of concentrated synthetic 7-OH product poisoning occurs and deaths caused by concentrated synthetic 7-OH or a combination of drugs including concentrated synthetic 7-OH will not be accurately attributed. Additionally, the longer the delay from death until testing for concentrated synthetic 7-OH, the less reliable the tests are and the chances are greater that concentrated synthetic 7-OH deaths can be under attributed.

Are concentrated synthetic 7-OH Products Risky Even Without Mortality Data in Humans?

Yes, potent opioid receptor products that cause rapid tolerance, are highly addictive, and have severe withdrawal are a public health threat. There are many anecdotal experiences of people who have become addicted to concentrated synthetic 7-OH, cannot stop using the product due to severe withdrawal, and who life savings and ability to function normally have been ruined. These are terrible detractors to public health in their own right. Like all potent opioid receptor stimulators, concentrated synthetic 7-OH needs sufficient pre-clinical investigation which has not yet been done and then undergo Phase I clinical trials in normal volunteers and Phase II and III clinical trials in patients before it seeks FDA approval for use in humans. Only then will we truly know the risk profile of the products and whether there are any proven benefits of therapy.