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TESTIMONY ON SENATE BILL 1353 SD3 HD1
RELATING TO INDUSTRIAL HEMP
By
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House Committee on Judiciary
Representative Chris Lee, Chair
Representative Joy A. San Buenaventura, Vice Chair

Monday, March 18, 2019; 2:05 PM
State Capitol, Conference Room 325

Thank you for the opportunity to provide testimony on this measure, which is an amended version of HB131 HD2. Please consider the following comments:

Comment #1 - This bill seems to be based upon the assumption that hemp farmers in Hawaii will only be growing hemp for fiber and seed. As a result, this bill is lacking any provisions for the state regulation of cannabinoids derived from hemp that are already FDA-approved drug products in the United States. This is something that the U.S. Department of Agriculture (USDA) will likely be looking at when it evaluates new state hemp program proposals.

The Agriculture Improvement Act of 2018 provides a new definition for hemp within the Agricultural Marketing Act of 1946:

"SEC. 297A. DEFINITIONS.
"In this subtitle:
"(1) HEMP.—The term 'hemp' means the plant Cannabis sativa L. and any part of that plant, including the seeds thereof and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis."

This Act also removes hemp from the federal Controlled Substances Act (CSA) by separating hemp from the definition of marihuana, and exempts tetrahydrocannabinols found in hemp from federal Schedule I:

SEC. 12619. CONFORMING CHANGES TO CONTROLLED SUBSTANCES ACT.
(a) IN GENERAL.—Section 102(16) of the Controlled Substances Act (21 U.S.C. 802(16)) is amended—
(1) by striking "(16) The" and inserting "(16)(A) Subject to subparagraph (B), the"; and
(2) by striking "Such term does not include the" and inserting the following:
"(B) The term 'marihuana' does not include—
"(i) hemp, as defined in section 297A of the Agricultural Marketing Act of 1946; or
"(ii) the".
(b) TETRAHYDROCANNABINOL.—Schedule I, as set forth in section 202(c) of the Controlled Substances Act (21 U.S.C. 812(c)), is amended in subsection (c)(17) by inserting after "Tetrahydrocannabinols" the following: ", except for tetrahydrocannabinols in hemp (as defined under section 297A of the Agricultural Marketing Act of 1946)".

However, the Agriculture Improvement Act of 2018 does not lessen the authority of the Food and Drug Administration (FDA) to regulate cannabinoids found in hemp that have been approved for or are being investigated for inter-state marketing as approved drug products:

"(c) EFFECT ON OTHER LAW.—Nothing in this subtitle shall affect or modify—
"(1) the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.);
"(2) section 351 of the Public Health Service Act (42 U.S.C. 262); or
"(3) the authority of the Commissioner of Food and Drugs and the Secretary of Health and Human Services—
"(A) under—
"(i) the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.); …"

This provision is necessary in order to prevent state hemp producers from extracting and marketing delta-9-tetrahydrocannabinol (THC) found in hemp.

This provision is also necessary to prevent state hemp producers from extracting and marketing other cannabinoids found in hemp, such as Cannabidiol (CBD), that are already FDA-approved drug products.

The FDA is very clear about the situation with CBD: now that it is an approved drug product it cannot be marketed for inter-state commerce as a food additive or a dietary supplement:

"Under the FD&C Act, it's illegal to introduce drug ingredients like these into the food supply, or to market them as dietary supplements. This is a requirement that we apply across the board to food products that contain substances that are active ingredients in any drug."

Perhaps the regulation of hemp-derived CBD would be less of a concern if CBD had zero risk to public health. However, the FDA has already shown that many of these unregulated hemp CBD products entering inter-state commerce do not contain what is being advertised, and several of these products have been marketed with false claims for medical use.

CBD has also been shown to affect human Cytochrome P450 liver enzymes, which are responsible for the metabolism of a broad range of pharmaceutical prescription medications. This could be especially dangerous for patients on Coumadin, since taking CBD at the same time could potentially cause excessive anti-coagulation and result in life-threatening internal bleeding. One study found that as little as 25 mg of CBD can impact human P450 function.

Unfortunately, all the unregulated Hemp CBD products that we have seen being sold in Hawaii have been devoid of any warnings about these potential drug interactions, and most do not provide third party laboratory testing for heavy metals and pesticides. This is a serious consideration given hemp's know phytoremediation properties.

CBD can also be readily converted to THC, as demonstrated by the United States patent held by the discoverer of THC himself, which could provide a source for illicit THC production if hemp-derived CBD is not properly regulated at the state level.

In addition, the clinical studies conducted for FDA approval of Epidiolex demonstrated that CBD is not without adverse reactions:

"The most common adverse reactions (10% or more for EPIDIOLEX and greater than placebo) are: somnolence; decreased appetite; diarrhea; transaminase elevations; fatigue, malaise, and asthenia; rash; insomnia, sleep disorder, and poor quality sleep; and infections."

Clearly, our state Legislature needs to address the issue of hemp-derived CBD in order to craft a state hemp program proposal that will meet with the approval of the USDA. Addressing this issue is not only required to comply with the federal regulation of approved drug products, but also to control the unapproved and unregulated CBD snake oils that are flooding our state commercial market and threatening the safety of our consumers and patients.

Other states have already started to address this situation:
In July of 2018, the California Department of Public Health issued a FAQ on Industrial Hemp and CBD in food products based on federal law, which clearly prohibits the use of hemp-derived CBD as a food additive or dietary supplement in that state.

New York's Department of Health and Mental Hygiene has also started prohibiting the addition of CBD to food products, a clear signal that other states are starting to recognize that regulation in this area is necessary in order to protect consumers and comply with federal law.

Please do not allow this bill to pass out of your committee without addressing the intra-state and inter-state regulation of hemp-derived CBD products being manufactured inside and outside of Hawaii.

Comment #2 - The outdoor cultivation of hemp in Hawaii will inevitably mean that the dispersion of male hemp pollen will be widespread wherever hemp is being cultivated. Potential cross pollination could severely restrict the ability of patients and dispensaries to produce high quality outdoor cannabis, which will only increase the costs of medical use production, reduce patient access, and increase dependence upon the black market.

This is something the Legislature needs to address in order to protect our patients and Hawaii's Medical Use of Cannabis Program.

One solution would be to restrict hemp cultivation to at least 10 miles away from any dispensary cultivation facility or registered patient grow site. Requiring all hemp licensees to use feminized hemp seeds would be another solution. Whatever the solution may be, please do not ignore the impact that outdoor hemp cultivation will have upon the already established legal cultivation of cannabis for medical use in Hawaii.