

March 25, 2015

To: Joint Committee on Implementing Measure 91

Re: Testimony on SB 464

My name is Todd Dalotto, I live in Rep. Andy Olson's district near Albany, Oregon and have been working professionally in the cannabis industries for over 21 years. I'm a horticultural scientist, industry consultant, and public policy advisor. I'm a current member and former Chair of the Oregon Health Authority's Advisory Committee on Medical Marijuana and Chair the ACMM's Dispensary Program Committee. I've served on numerous DHS and OHA Legislative and Administrative Rule Advisory Committees, including the three RACs that advised the OHA on rulemaking to implement HB 3460 and HB 1531, the bills, which created and amended Oregon's Medical Marijuana Dispensary Program.

Supercritical Fluid Extraction. In recent years, cannabis processors have been applying the technique of supercritical fluid extraction (SFE) to the extraction of cannabinoids and terpenes from cannabis. SFE is a process that uses solvents such as carbon dioxide, butane, and other alkanes, and adjusts heat and pressure to achieve a supercritical fluid state. Solvents in the supercritical state have the physical and chemical properties of both gas and liquid and thus can extract at much greater efficiency and accuracy than the solvents can in a distinct liquid or gas state.

Solvents. Carbon dioxide is the most common solvent used in SFE and has the advantages of being non-toxic and non-flammable, but has the disadvantages of being selective for organochloride pesticides, heavy metals, and other contaminants and less selective for cannabinoids and terpenes. **Alkane** is a chemical group of saturated hydrocarbons defined by the number of carbons in their chains, branches, and rings. The two most common linear alkanes used in SFE are **butane** (4-carbon) and **propane** (3-carbon), which have the advantages of being highly-selective for cannabinoids and terpenes, and less selective for contaminants, yet has the disadvantages of being toxic and flammable. Sources are available for each of these solvents that have been affirmed as Generally Recognized as Safe (GRAS) for use in food processing by the FDA.

SFE Applications. Supercritical fluid extraction is commonly used in many industries, including extraction of essential oils, removing contaminants from food & herbs, de-caffeinating coffee, many petrochemical & pharmaceutical manufacturing processes, and extraction of hop oil by breweries to improve the flavor of beer. Applications of SFE in cannabis processing has resulted in high-quality extracts that can be used alone for vaporizing & ingestion or used as an ingredient in numerous cannabinoid products such as lotions, food, beverages, tinctures, and capsules.

Safety. SFE is a reasonably safe manufacturing process when conducted in a proper facility, with proper equipment, by qualified technicians, with pure solvents. The few explosions and fires that have occurred in Oregon have been the result of inadequate facilities & equipment, and incompetent people. Substandard processors often use over-the-counter butane and propane in 12 to 16-oz canisters, which is laden with contaminants, which poses a health hazard. Licensed processors should be prohibited from using any solvent that is not Generally Recognized as Safe.

Regulatory Strategy. It is important to regulate cannabis processing facilities for the purpose of protecting the health and safety of the public, employees, and consumers, yet requiring the OHA & the OLCC to establish standards for safety, equipment design, training, emergencies, and more is redundant because adequate

standards are already established for these same manufacturing processes in other industries. The only difference in this context is the material being processed is marijuana, and marijuana contributes no additional risk to the manufacturing process, and thus there is no need for the OHA or OLCC to go to the trouble of creating a new set of regulations for the supercritical extraction of cannabis.

Instead, I propose that the OLCC and OHA require that licensed processors who engage in supercritical extraction maintain third-party certification for state-enforceable **Good Manufacturing Practices (GMPs)** that have been established for botanical extraction or the manufacture of herbal medicines. GMPs cover all the areas of concern listed in Sections 2(4) and 4 of SB 464.

Proposed Amendments to SB 464.

1) Amend the definition of “Cannabinoid extract” as follows:

SECTION 1. (1)(a)(A) “Cannabinoid extract” means a preparation made from the cannabis plant that is intended to be ingested, vaporized{+ , +} {- or -} smoked{+ , **or used as an ingredient in other cannabinoid products** +} and that contains cannabinoids extracted from the cannabis plant by using a solvent to dissolve the cannabinoids. For purposes of this subparagraph, “solvent” does not include {+ **non-volatile solvents such as** +}water{+ , +} {- or -} vegetable glycerin{+ , **fats and vegetable oils; or when high heat and high pressure is not applied, ethanol and carbon dioxide** +}.

Rationale:

- Extracts are commonly used as ingredients in cannabinoid products, as well as used alone.
- Water, glycerin, fats, and oils are very safe and non-volatile solvents that are very commonly used by medical marijuana patients at home to prepare their medicine into forms most suitable for the treatment of their condition(s). Ethanol and carbon dioxide are reasonably safe solvents to use at home and only becomes a hazard when high heat and pressure is applied.

2) Amend the definition of “Process” as follows:

Section 1. (1)(b) “Process” means the {+ **chemical extraction of target solutes from marijuana** +} {- *processing or conversion of marijuana into a cannabinoid extract* -}.

Rationale: Technical correctness

By properly and reasonably regulating the commercial extraction of cannabinoids using CO2 and alkanes in the areas discussed here, we have an opportunity to support the safe & responsible operation & innovation of the cannabinoid extraction industry and promote the availability of safe & effective marijuana products, while reducing the activity of unsafe & irresponsible unregulated extraction.

Feel free to contact me if you have any questions or would like my assistance in developing this legislation.

Best,



Todd Dalotto, President