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APR 26 2013

DEPT OF CONSUMER PROTECTION
OFFICE OF THE COMMISSIONER

theraplant

April 25, 2013

William Rubinstein
Commissioner
Connecticut Department of Consumer Protection
165 Capitol Avenue
Hartford, CT 06106

Dear Commissioner Rubinstein:

Theraplant, LLC respectfully requests several clarifications with respect to the Regulations relating to Connecticut Law 12-55 Concerning the Palliative Use of Medical Marijuana.

Theraplant respectfully requests that the Commissioner clarify certain questions with respect to the current regulations.

1. In the event that a property allows for addition or expansion of a producer's structural space how will said expansion be addressed under the license?
2. Is expansion on the same property automatic?
3. Will expansion on the same property require modification of the producer's license?
4. Will the producer be asked to submit near term plans for expansion in the application?
5. Will any review by the DCP be required?

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Ethan Ruby".

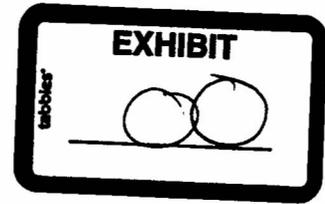
Ethan Ruby
Theraplant

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William Rubinstein
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Connecticut Department of Consumer Protection
165 Capitol Avenue
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Dear Commissioner Rubinstein:

Theraplant, LLC respectfully submits the following letter to you in hopes of assisting the DCP in making small but intelligent amendments to the Regulations concerning the Palliative Use of Medical Marijuana, codified as Connecticut Law 12-55("Regulations"). We would first like to begin by commending you on your thoughtful and inclusive approach to drafting the Regulations. We also hope that in reviewing our several specific suggestions, you take our limited commentary as a compliment to the level of skill exhibiting in creating the Regulations. We feel strongly that the State of Connecticut, and by proxy, the DCP have put into motion what will be the most complete and comprehensive set of rules and regulations surrounding Medical Marijuana("MMJ") in the United States. It is in the context of making sure that Connecticut's laws are a model to other states that we offer the following points and suggested changes to the Regulations.

As a general point, we believe that you have set up appropriately high barriers to entry in the licensure of potential producers and dispensaries. Given the controversial nature of the Federal/State MMJ legal dichotomy, it is important to ensure that the ultimate goal, to deliver medicine to people who are desperately seeking relief from serious ailments, is also a foremost consideration in both the drafting of the final Regulations and also in the license review process. The DCP has rightly recognized the difficulty of growing MMJ on an industrial scale and it is with that in mind, that we strongly urge you to keep in mind that this is a unique perishable product that cannot be treated like other lab based medicines. The voters have spoken and

hopefully it will be our shared duty to provide this medicine in a form they know and are used to taking.

While our focus is on production, and our comments tailored to address Regulations dealing with production, we understand the balance that must be struck in the regulation of the producer/dispenser relationship. Theraplant is eager for the opportunity to deliver the highest class medicine to the patients of Connecticut. Our specific comments and recommendations are as follows:

1. Sec. 21a-408-56. Packaging and labeling by producer

Theraplant recommends that the DCP consider making certain changes to the regulation above that requires producers to individually package marijuana prior to delivery to a dispensary. This rule ultimately hurts the patient. Patients and end sales people need to be able to inspect this medicine before purchase, for safety and preference reasons. The consumer asked for this, this is what they know. Producers need to produce, dispensaries should dispense. Specifically, we offer the following points in support of changes to this rule that would allow producers to ship batches in a wholesale manner for individual packaging by dispensaries, who will have a pharmacist on staff to oversee such individual packaging in a manner consistent with current pharmaceutical handling-i.e. the counting and packaging of pills at a local CVS as opposed to at a Merck or Eli Lilly production facility.

- a. **Licensed Pharmacist** The most compelling reason for shifting the individual packaging burden to dispensaries might be the presence of a licensed pharmacist on the premises. Dispensaries will be both well-equipped and staffed to take wholesale packaged MMJ and individually package it for resale. A licensed pharmacist is experienced in handling medicines both benign and dangerous. There is no one better to handle the marijuana last before it goes to patients than a pharmacist. The DCP must consider rewriting the Section in a way that empowers the only licensed professional with pharmaceutical experience in the supply chain to handle the medicine before it goes out to consumers. This will increase efficiency in the packaging process as package sizes and requirements can only be determined at the dispensary level by the licensed pharmacist. Dispensaries must store the marijuana product in a manner that would achieve proper preservation in an access-restricted location with pharmacists privately displaying the product to consumers prior to their purchase.
- b. **Shelf Life-Risk of Loss** If this regulation is adopted as written, producers would individually package the marijuana and hold on to it for a period of approximately one month as the strain and batch are tested. By the time a dispensary has sold it, the marijuana might be packaged unopened for 60 days or more. Marijuana is fragile

and even after it is packaged, needs constant attention and storage in very particular environments which a dispensary is best equipped to provide prior to final packaging and sale. There is a risk that incorrect storage could lead to spoilage at some level in the supply chain. This could lead to damaging economic effects since dispensaries and producers would likely fight over the cases of spoilage and who would bear the economic responsibility for the loss of product. The DCP should mirror other states that allow producers to deliver wholesale MMJ to dispensaries for individual repackaging and resale. There is a reason this has never been done before and Theraplant is concerned that Connecticut patients and the MMJ industry would suffer from this new precedent.

- c. **Naturally Occurring Substance** Marijuana is a naturally occurring substance. Unlike a pharmaceutically created substance, it must be cared for and inspected often and certainly before dispensed to a patient. Aside from the shelf life issue raised above, we merely point out that dispensaries must be able to touch a product they are ultimately responsible for selling. As now written, Section 21a-408-56 ends quality control well short of where it should and takes it out of the hands of actual person dealing with the buyers.

- d. **Consumer Choice** The MMJ industry in other states has empowered patients with education and knowledge about strains, dosage and patients can only apply that knowledge if they are able to interact with their medicine before purchase. That can only be achieved if individual packaging is done after an end user decision is made which would be prevented if producers are the final word in packaging before sale.

- e. **Specificity of Skill** Regardless of who is awarded a production license, the DCP and people of Connecticut have a vested interest in keeping that facility open and producing effective medicine. Growing marijuana at industrial scale is arduous, time-consuming, labor intensive and requires a specificity of skill and singular focus. Any activity that detracts or distracts from that facility conducting the production in the most efficient manner ultimately jeopardizes the supply chain that patients will rely on for their medicine. Dispensaries are well-equipped to handle individual packaging and shifting the responsibility for individual packaging to the dispensary level best protects the consumer and this industry as a whole.

- f. **Inherent Disadvantage to Producers without Dispensaries** Finally, consider the different roles and responsibilities that producers and dispensaries will bear. Producers will never interact with end-users and while some applicants may apply for both a producer and dispensary license, applicants like Theraplant, whose singular focus is on producing the highest quality MMJ, individual packaging would represent

a responsibility far afield from what they excel at. Theraplant does not, at this time, intend to be part of the retail process. The singular focus is to create medical grade marijuana at industrial scale so that Connecticut patients can have natural, palliative medicine. Dispensaries know their customers and know the type of packaging that works best, and because of their daily interactions with consumers, will best know the packaging needs and requirements. This rule highly disadvantages producers without dispensaries in that they would be taking on a role much more appropriate at the retail level. For those owning both dispensaries and production facilities, the packaging will simply be allocated amongst the collective workforce. That efficiency does not exist for sole producers.

Producers should be able to operate an industrial agriculture business. It would seem illogical to allocate a retail oriented component of the supply chain to those farthest removed from retailing and consumers. It would behoove the DCP to keep producers focused on the upstream production and supplying the dispensaries rather than individual packaging. At worst, there should be discretion between the producer/dispensary partners as to who will handle the responsibilities.

Recommendation:

Theraplant respectfully recommends that Section 21a-408-56: i) be amended to allocate the role of individual packaging to retail dispensaries, ii) producers be able to deliver dispensaries marijuana which has been sealed in a wholesale manner for individual repackaging at the dispensary level, and iii) maintain the labeling requirements at the producer level as currently prescribed in the Section.

Alternatively, if the DCP sees fit to reject Theraplant's recommendations above, we respectfully request that the Section be amended to allow discretion with respect to the individual packaging so that producers and dispensaries may negotiate and decide amongst themselves who will fulfill the role of individual packaging. In that case, the labeling onus would still be at the producer level. Section 56 could be rewritten to include language such as:

“Pharmacists employed by dispensaries are to be qualified and licensed to handle the marijuana product and display product to the patient under magnification equipment such as digital scope or other high powered illuminated magnification as dictated by widely established industry standards as well as allow the patient to smell but not handle the product.”

2. Section 21a-408-58. Laboratory Testing

Theraplant agrees that environmental testing is essential to the delivery of the highest quality medicine. Nevertheless, Theraplant respectfully requests that the DCP consider making changes to Section 58 in order to address concerns producers have with the laboratory testing requirements. There are several reasons why the DCP should consider our suggested changes:

- a. Lack of a Proven Testing Facility** Until the DCP identifies a testing facility that can be used by producers to conduct the required environmental testing, it should consider allowing producers to conduct their own marijuana testing. In other states, like Colorado, testing has been problematic due to the fact that there is no in-state facility and since marijuana cannot cross state lines, producers have been left conducting their own marijuana testing in a voluntary fashion.

- b. Lack of Effective Testing Methods** Theraplant is also concerned that even if the DCP identifies a laboratory to conduct the testing, the testing methods employed will prove flawed and lead to wildly inconsistent results. Until the DCP identifies not just a laboratory testing facility, but a laboratory facility that calibrates its instruments to accepted standards for creating baselines, we are concerned that producers will be relying on faulty testing results for running what is a very delicate growing operation. Producers must be in a position to rely unequivocally on the data that is presented since the goal is to deliver toxin/contaminant free medicine to the patients of Connecticut.

- c. Timing of Testing** Finally, Theraplant is concerned that a DCP-recommended facility could find itself overwhelmed with testing and could therefore greatly delay the delivery of medicine to patients. The DCP should strongly consider not just providing a sanctioned testing facility, but also stringent timeframes when the testing must be completed in so that batches being tested are released in a reasonable time.

Recommendation:

Theraplant respectfully requests that the DCP consider suspending any laboratory testing until the DCP identifies a laboratory which can competently, and consistently complete the testing requirements the DP has set in Section 58. Alternatively, the DCP could allow producers to conduct such testing themselves with independent verification. The DCP could require a certification that all environmental testing was done under proscribed conditions and that the results are legitimate. Any producer who falsely certifies any testing results would face strict punishment, including the potential loss of their license.

3. Section 21a-408-59. Brand Name

Theraplant is concerned that the DCP's requirement that strains do not deviate 3% from an established baseline is an unrealistic requirement that would require producers to grind their marijuana such that the strains were homogenized. Homogenization by grinding up the medicine is bad for several reasons and could have significantly negative effects on the quality of medicine delivered to patients in Connecticut. Homogenization is a term never used in the medical marijuana industry and we strongly caution against complicating an already complex endeavor.

- a. **Ratio** Rather arbitrarily select a variance number of 3%, the DCP would do better to rely on consistent ratios throughout a strain. The DCP should require ratios to be consistent without picking a target variance which can greatly vary based on time of year, weather, or even which part of the marijuana plant is being harvested. At a minimum, the variance range should be expanded to 20% to account for all of the natural variance that marijuana inherently has in its chemical profile.
- b. **Problems with Homogenization** The DCP's suggestion that producers grind up and homogenize the medicine is troubling. Grinding of the medicine will grind the trichomes and other parts of the plant that hold active chemical medical ingredients such as THC, CBDs and CBNs, thus altering the efficacy of the medicine from its original form. It would also affect the Terpene profile which affects the aroma and taste of the medicine, which makes a significant difference to a cancer patient. The unique combination about each plant is what makes that specific plant medicine effective to a patient. The DCP's homogenization requirement is quite simply counterproductive to delivering the most effective medicine to patients that are seeking specific relief.
- c. **Labeling** Each strain produced could be labeled to include its potency, and when packaged for dispensary delivery, further labeled to include the specific potency of the contents of a package so that a strain might have several potencies depending on the part of the flower or time of year, but identical ratios to other batches of the strain making it appropriate for sale. For instance, a strain called "Pineapple" might be delivered in containers labeled as "Pineapple 21" and "Pineapple 27" to convey its THC content for consumers who want more or less powerful medicine.

Recommendation:

Theraplant respectfully recommends that the DCP rely on the ratios of the individual strain components rather than relying on a baseline deviation of 3%. Alternatively, if the DCP rejects our recommended change, the DCP should raise the variance level for each strain to 20%.

See below for a sample of the type of label used by us in another state that might be attached to a batch of MMJ at the dispensary level that addresses the concerns the DCP has about full transparency and safety, and Theraplant has with respect to packaging and testing.



Marijuana Strain Name	MMR: 12345678
05/17/19	CBD: 100.2%
STRAIN: Four Diesel	THC: 17.94%
05/17/19	CBN: 00.37%
WEIGHT: 3.2 grams	ACTIVE TOTAL
ORGANIC LEVEL: 87%	CAC: 18.63%

FOR MEDICAL USE ONLY. TRANSFER OF SALE OF THIS MEDICATION IS PROHIBITED BY LAW.

Thank you for your time and consideration and the inclusive nature of your regulatory review.

Sincerely,

A handwritten signature in black ink that reads "Ethan Ruby". The signature is stylized and cursive.

Ethan Ruby
Theraplant