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LEGAL DIVISION
CONSUMER PROTECTION



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April 22, 2013

William M. Rubenstein
Commissioner
Department of Consumer Protection, Room 103
165 Capitol Avenue
Hartford, CT 06106

Dear Mr. Rubenstein:

Pure Analytics, Inc. is writing this letter in respond to the Proposed Regulations Concerning Palliative Use of Marijuana.

Allow me to first thank you for putting such thorough medical marijuana guideline. It is about time that a governing body takes such seriousness in protecting medical marijuana patients by requiring thorough testing of the medical marijuana that patients consume. I am pleased to see that the great state of Connecticut is serious about submitting medical marijuana to rigorous scrutiny that matches other medical drugs in the pharmaceutical industry. It is very important that the safety of medical marijuana patients is not jeopardized. The guidelines put forth by the DCP are very appropriate. One example of a lack of safety enforcement, as you might be aware, happened in the state of Main where a medical marijuana producer was caught using harmful pesticides. The use of agriculture grade pesticides on Medical Marijuana is a serious issue which i believe this legislation successfully addresses. Additionally, as we look to states like California, where there is absolutely no control over the chemicals that are used on the production of medical marijuana, we can certainly identify places where Connecticut is excelling, for example, requiring that growers test ALL of the medical marijuana they produce and that those labs conducting the testing are also required to meet rigorous standards. This requirement makes sure that the consumers' safety is everyone's' number one priority.

There are a few aspects regarding the regulation that we would like to bring your attention:

The first issue that we would like to raise is in regards to the heavy metal (Arsenic <0.14, Cadmium <0.09, Lead <0.29, Mercury 0.29) content test (**Sec. 21a-408-58**). Since the water limits for two of the four heavy metals (Cadmium: 10,769 ppb and Lead: no limit published) that the medical marijuana batches will be tested for are higher than the limits allowed for drinking water here in Connecticut according to the Water Quality Standards published in 2011, by these regulations, we would like to suggest that the limits be revisited. Because the number of licensed growers will be limited at the beginning, if they fail the heavy metal portion of the quality control testing due to using untreated local water, patients might not be able to obtain their medicine on a timely manner.

The second issue that we would like to raise is in regards to the strain profile identification requirement for each individual strain that producers submit for testing (**Sec. 21a-408-59**). Although the regulations properly attempt to scientifically identified each strain in order to ensure that patients get the same product every time, it is, however, unreasonable to use terpenes and active ingredient content to achieve this goal even with a tolerance of $\pm 3.0\%$. This is due to the fact that the amount of terpenes and active ingredients that the marijuana plant generates (and any other plant for that matter) varies from crop to crop due to varying growing conditions like air humidity due weather conditions, soil quality, nutrients, and water quality, therefore, variables like these end up outside the control of the producers. Thus, a laboratory would not be able to earnestly produce and archive a permanent strain profile with the DCP. With this in mind, we propose that a ratio between terpenes and/or active ingredients be used instead as an alternative to producing a strain profile. Using a ratio with a $\pm 5.0\%$ tolerance would produce a more reliable result. This method is used by pharmaceutical companies when identifying and confirming molecules with potential therapeutic activity. Using this method stays within reasonable costs for producers. A more reliable but extremely more expensive method would be to construct a genome library of all the strains produced by growers. As producers submit subsequent

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samples, laboratories would sequence the genome and compare it to the library. Each sequencing experiment would cost producers in the average of \$250.

The third issue that we would like to address is in regards to the controlled substance requirement for laboratories (**Sec.21a-408-57**). Some concerned will argue that this puts an extraordinary burden on laboratories. However, we believe that laboratories must strive to obtain a Connecticut controlled substance registration. This will ensure that laboratories don't cut corners while following strict rules and guidelines.

Finally, we would like to address **Sec. 21a-408-58**. The regulations do not specify the size of the "batch". We recommend that medical marijuana be segregated into 1.0 ± 0.05 lbs. This will ensure optimal homogenization of the product and thus a laboratory will be able to produce more accurate results for all the required tests.

I greatly urge you to not succumb to any outside pressures to drop or water down the testing regulations. If the medical marijuana industry looks to obtain a serious and credible standing with the public, then it should be held to the same standards as any other pharmaceutical company in the business of making medical drugs.

Sincerely,



Jose A. Zavaleta
Director of Research and Development
Pure Analytics, Inc.