

Friday, July 29, 2022

Nicole Elliott, Director California Department of Cannabis Control 2920 Kilgore Road Rancho Cordova, CA 95670

Director Elliott,

We write to you today with grave concerns for the state of the cannabis testing market in California. As more and more of the professional, good-faith actors in this market close or teeter on the brink of closure because of rampant potency inflation, downward pricing that could not possibly cover the costs of proper testing and a general lack of enforcement on testing practices, we are calling on the Department of Cannabis Control (DCC) to take swift and decisive action to put a halt to these practices.

When potency inflation is permitted and labs that are unable or unwilling to report contaminant findings are left unchecked, the race to the bottom is swift. More and more reputable laboratories will leave the market. As you have heard from us before and we continue to stress, the current lab testing environment in the state makes continued operations a near impossibility for those attempting to maintain scientific integrity and comply with regulatory requirements. The proposed rule-making regarding a single standard testing method is not only scientifically ill-conceived but will have no impact on the problems at hand. We will be submitting comments through the formal rule-making process to this end, but if the Department had presented this proposed solution at any point during the last year when we have worked diligently to engage and cooperate with you and your officers, we would have been unequivocal in our response.

Practices must change in the state in order to ensure the reliability, quality and safety of products on the market. We know that your Department is committed to those same goals, but we are calling on you again today to take swift action to maintain the integrity of the cannabis testing market. We have provided the attached suggestions to the Department previously, but ask that you take decisive action now, as so many reputable actors in the industry hang on the precipice of exiting. The departure of these laboratories will undoubtedly leave DCC with a weakened ability to ensure safe, quality assured cannabis products in the legal marketplace.

To that end, we request an urgent meeting with you and your laboratory leaders to discuss the concrete steps that the DCC is in the best position to take to rein in this pervasive threat to the industry. We remain open and available to provide industry expertise and scientific input on these important matters and look forward to your response.

All the best

C. Bruce Godfrey, Ph.D.

ACIL Chair



POLICY SUGGESTIONS FOR COMBATTING POTENCY INFLATION IN THE CALIFORNIA CANNABIS INDUSTRY

- Develop a Department of Cannabis Control round robin program and require all labs participate. Significant outliers would have to submit a plan to remediate their issue and/or be subject to audit by the DCC.
- Routinely perform random surveillance sampling/testing of items off store shelves. When internal results disagree with the labeled results by a significant margin (over 10% label claim from testing result), an investigation should be initiated to determine the cause, looking at the manufacturer, distribution center and testing laboratory. The retained sample should be pulled from the laboratory and analyzed. If the product is not homogeneous or has shelf life/stability issues, the testing lab should not be held liable. However, if the lab is found to be inflating numbers, they would be required to submit a plan to remediate the issue and/or be subject to license suspension in the most egregious cases.
- Quarterly or biannual virtual "training session" that all labs are mandated to participate in. Topics could be submitted from labs and DCC sets the agenda. This would allow the DCC to ensure that labs to get on the same page and ensure a fair playing field while also discussing problems and possible improvements to the broken system.
- The study of products on the shelf that we conducted shows a need for an audit. The DCC should conduct an audit on all laboratories' potency validation as well as the last 100 compliance samples run at each lab and review the data.
- The DCC should utilize existing licensed laboratories to assist with routine surveillance testing, similar to what is done in Michigan. In that state, whenever the agency wants to audit the results of a lab (either because the lab issued a questionable result or as a routine check), the retained sample for that batch is picked up from the lab and distributed to two to three other licensed laboratories for analysis. The results for those checks are then reported directly to the agency. If a significant variance exists between the initially reported result and the subsequent checks, then the agency can escalate the matter and/or perform testing at its internal laboratory. This system significantly increases the capacity to perform necessary checks and provides additional data points on the variance that exists between licensed laboratories.
- The ICV/CCV pass/fail acceptance limit in the regulations is set to 30%. This wide range is illogical given that the label claims are held to be within 10% accuracy. Setting both these limits to 10% would reduce the amount of mislabeling AND hold labs more accountable. We could take it even further and suggest the lab report the CCV data in a separate report (something commonly done in the environmental industry).