

Cannabis Lab Culture: Some Observations

The 2016 election has not only transformed the landscape of business on a national and international level, but also on the state level. Proposition 64 showed that the majority of Californians no longer wanted to incarcerate people for their recreational use of cannabis. Californians wanted to tap into cannabis legally with the promise of a tax windfall along with a plethora of new businesses.

What has evolved from the end of cannabis prohibition is not unlike what is happening with the Trump administration-big business swooping in, wielding big capital, like a big broom, sweeping all small business out of the marketplace. Home Depot starts all of its quarterly meetings with a list of small mom and pop hardware stores they put out of business. Walgreen's has decimated privately owned pharmacies. The same model is coming to the cannabis industry before Californians collect the first penny of promised tax revenue. Regulations protect these large capital investments from any competition from small businesses guaranteeing a monopoly industry.

New rules outlined under Title 16 of the California Code of Regulations, Section 5715 describe the state's expectations for testing facilities for cannabis product. The testing industry has been around since the legalization of cannabis for medical purposes. It is imperative that people using cannabis products for the treatment and reduction of symptoms related to diseases from epilepsy to various cancers is dependent upon knowing potency and content of the product. Small laboratories popped up. Scientific collaboration is imperative to assure lab results are accurate, repeatable and trustworthy and therefore the consumer is guaranteed a safe and reliable product. Unfortunately, the rules, as they are outlined under Title 16, Section 5715, almost assure the opposite by making the financial obligations too onerous for most small labs. The cannabis testing regulations will exclude many small labs from the market limiting scientific collaboration.

Title 16 regulations require all testing be performed in the same lab where samples have been sent. The regulation is meant to prevent tampering with test products, by reducing chain of custody. Demanding all labs perform all testing in house will reduce the businesses' ability to compete, because the new laws outlined include testing from microbial, fungal and pesticide contamination (see list below). Many labs, both clinical and pharmaceutical, outsource many types of tests because it is more cost effective and provides higher quality results. Subcontracting testing assures that a lab can focus on a specific scientific expertise, whether it be microbial or pesticide testing. The new regulations mandating tests be performed under one lab license will mean only very large labs with very deep pockets will be able to continue operations. Those labs, without competition, will

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likely go with the bully business model of any other large corporation-their prices will go up, the quality of testing will go down. Many small farmers will have no choice but to return to illegal cultivation.

I spoke with a small lab owner who, after working 30 years as an analytical chemist in the pharmaceutical industry, started her own lab supporting the medical cannabis community. She purchased state of the art equipment and developed and validated many assays to assure the results she provides her customers are accurate, creating a trusted source for cannabis medicine.

LAM: How will the new regulations affect your business?

LAB OWNER: In the last 3 years, I've heard complaints from clients that found discrepancies in testing results even within the same lab. Several of the larger labs have returned completely different results on the same sample, failing it the first time and passing it the next. This could be indicative of poorly trained staff. The instrumentation is highly complex and requires extensive experience to operate. For instance, without proper maintenance, samples can be contaminated on the instrument with carryover. Discrepant results can be indicative of less than robust or well-controlled testing methods. With the new regulations, a positive pesticide result will mandate destruction of the entire lot tested.

The amount of testing being required is obsessive and unnecessary. The limits are set too low, and very little can pass this level of purity. Nearly every vegetable now being sold at the local markets would fail this level of testing. It would be necessary if people were getting sick constantly from "bad" cannabis, but such is not the case. People die every minute from prescription drugs, but no one has died from tainted cannabis. It seems to be a way to limit testing to a few, very well funded, labs and a way to get rid of competition from smaller labs.

Prices will be determined by a few operators, and it will be not only prohibitively expensive to test, but will take a long time. The smaller labs were handling a good share of the testing, helping to keep prices down and turnaround times low. That is no longer the case.

LAM: What testing is being mandated under Title 16 Section 5715?

LAB OWNER: Cannabinoid testing, Moisture Content, Category I and II Residual Solvents and processing Chemicals, Category I and II Residual Pesticides, Microbial (A. fumigatus, A. flavus, A. niger, A. terreus), Microbial (E. coli, Salmonella sp), Homogeneity, Water Activity of Solid or Semi-solid Edibles of edibles, Foreign Material Terpenoids, Mycotoxins, Heavy Metals

LAM: Of those tests, which, do you see, as causing health risks to cannabis users?

LAB OWNER: Mostly pesticides, certain ones more than others. One pesticide that frequently is found on cannabis is myclobutanil, a compound used extensively on grapes. The grape growers wash it off and it goes into the ground water,

where it gets absorbed into the growing cannabis. Though toxic, it isn't nearly as bad for you until it gets heated (smoked) as it then turns into cyanide. This compound isn't even on the list of what is to be tested for during the first 6 months of testing. In fact, the 6-8 pesticides usually seen on cannabis are not on the Schedule I list.

Residual solvents are important to know, especially if butane and hexane were used for processing the cannabis into some other form-like an extract. The extraction process could concentrate the amounts of these solvents.

It's good to know if there are possible toxic microbes on the plant, but aflatoxins are mostly found in peanuts, not on cannabis. It's both a complicated and expensive test and very few people ever have had issues. If they did, there would be deaths from cannabis use, and we just don't see that. In 3 years, I have not seen one positive Salmonella or E. Coli on the thousands of buds I have tested.

One potential problem is mold, yet the regulations now say it can pass with 1/4 of the plant covered in mold. If you were to throw such a bud into your smoothie, you could have some health risks.

LAM: What agency is overseeing the lab testing and how are they regulating testing?

LAB OWNER: Bureau of Cannabis Control (BCC). Licenses, at a minimum, cost \$1000 to apply, and \$20,000/year for a lab. (That's if you're making over \$50 million, so obviously they did not expect any small lab to survive). The lab needs to be ISO certified (International Standardization Organization is an international oversight organization that provide certifications for quality assurance of testing facilities), which costs between \$10,000 and \$20,000, and needs to be done each year. Each type of testing is subject to "proficiency testing", where a blinded sample is sent to the lab from a certified proficiency testing lab twice a year. They have to be within a certain percentage of what the "true" value to pass and maintain the state lab license.

Instrumentation is prohibitively expensive for a small lab. If you had labs that specialized in each type of testing, then the cost of the instrumentation and personnel would be reduced. Each type of test requires a different piece of equipment. If I would purchase all the equipment to do all the testing, it would cost \$500,000. That doesn't include the lab space, the licensing fees, security, insurance and specialists in each field be it analytical chemistry, microbiology or molecular biology.

The lab owner interviewed was not identified because she cannot meet regulations. As we all have been hearing, many farms are being forced to continue outside the law because the regulations and licensing procedure are too onerous. The new regulations affect all small business associated with this budding industry and favor only those with deep pockets.

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