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Dear Cannabis Commission,

As industry leaders in cannabis genetics and pathogen safety, our scientists strongly believe that the current microbial testing specifications are leading to patient and employee harm. Due to this public safety concern, we feel the current regulations should be amended to reflect ongoing efforts at the USP, CDC and the FDA, which are consistent with our findings at Medicinal Genomics.

The current microbial regulations recommend an obsolete metric known as CFU/g. This stands for Colony Forming Units and it directs labs to use obsolete microbial detection technologies, which are limited, as they can only detect pathogenic microbes **that can** form a colony, rather than the vast majority (**98%**) of microbes that do not form colonies. These regulations were likely based off of the American Herbal Pharmacopoeia (AHP) Cannabis monograph, which expressly states the CFU/g measurements are **not to be interpreted** as a pass-fail criteria. Through our scientific research at Medicinal Genomics, we have obtained additional safety data, which we feel could be used to improve and strengthen the current regulations. This would also improve public safety and data transparency.

To date, there are two major Cannabis pathogens identified by OSHA and the CDC as elements of concern: Powdery mildew and Botrytis¹. Scientific publications have proven that neither of these cannabis microbes are able to be cultured in 48 hour Total Yeast and Mold culture-based plating tests. As a result, major testing labs are not properly detecting these common pathogens, exposing patients and employees to undue health concerns. Luckily, this issue is preventable through the use of more current genomic based technologies. In 2018, Massachusetts witnessed its first employee lawsuit, which was directed at a growing facility with an alleged Powdery mildew infestation. The employee reported severe allergies due to work environment exposure. Two labs in the state currently use culture based plating methods. These pathogens could not be detected at these labs due to their strict adherence to CFU/g regulations. Given the labs passed samples from this grow, the employer mistakenly denied the employee's claims. As the Massachusetts cannabis industry continues to develop, we believe these types of exposures may increase, which is why modification of current regulations to include technologies to detect these pathogens effectively and quickly is a critical component to industry development.

The current regulations speak to fungal and bacterial concerns. The vast majority of the pathogenic risks published on cannabis are not being detected by some of the labs in the state. We understand a prominent testing lab, Proverde, may not be aware of the

scientific microbiology described above, or that Powdery mildew and Botrytis microbes do not culture. Their current website does not properly name which micro-organisms their testing is able to identify, which could be viewed as misleading. Unfortunately, under current Massachusetts regulations, there is no public validation data on Proverde's microbial methods applied to Cannabis. To test the accuracy of their pathogen testing methods, Medicinal Genomics sent Proverde multiple saturated bacterial cultures of antibiotic resistant *Pseudomonas aeruginosa* for BTGN testing. Using their culture-based plating methods for the BTGN test, they failed to detect any bacteria. It is important to note, *Pseudomonas aeruginosa* is a Bile Tolerant Gram Negative bacteria and therefore should have been detected by this assay. We believe that not only is Proverde running unvalidated methods, they are operating with antiquated methods unable to detect the pathogenic microbes found on the cannabis plant. We strongly feel this lack of transparency is dangerous to consumers and the industry at large.

Medicinal Genomics recommends the regulation language be modified to allow more accurate and more specific DNA based techniques that can detect any and all common microbes. This language is seen the [USP <1223>](#). Other agencies (FDA and the CDC) have supported this position as the best defense [against unculturable microbes](#). With **98% of microbes** identified as unculturable, improving current safety regulations with proper testing methods is an important next step to the cannabis industry.

Regulatory agencies like the USP have added language (USP <1223>) to allow validation of more rapid detection techniques capable of detecting unculturable pathogens. These methods are also supported by the FDA's [GenomeTrakr](#) network and the [CDCs Pulsenet](#).

The current regulation language regarding CFU/g presents the largest liability facing the cannabis industry. To date, the only clinical cannabis deaths are from those pathogens that have been proven to be difficult to culture. We believe that widening the scope of the current regulation language to include DNA based assays, will bring more comprehensive safety to the field, and minimize the potential of future cannabis-related fatalities.

To expand on our stated position, we have written a substantial review on this topic in the link below.

https://www.medicinalgenomics.com/wp-content/uploads/2018/09/microbiological-examination-of-nonsterile-cannabis-products_8_17_2018.docx

Thank you for your attention to this matter.
Medicinal Genomics

The authors of this letter were contributing authors on the Human Genome Project paper² and publishers of the first two genomics-based manuscripts scientifically identifying pathogenic risk on cannabis flowers^{3, 4}.

1. Victory KR, Couch J, Lowe B, Green BJ. Notes from the Field: Occupational Hazards Associated with Harvesting and Processing Cannabis - Washington, 2015-2016. MMWR Morbidity and mortality weekly report. 2018 Mar 2;67(8):259-60. PubMed PMID: 29494573. Pubmed Central PMCID: 5861698.
2. Lander ES, Linton LM, Birren B, Nusbaum C, Zody MC, Baldwin J, et al. Initial sequencing and analysis of the human genome. Nature. 2001 Feb 15;409(6822):860-921. PubMed PMID: 11237011.
3. McKernan K, Spangler J, Helbert Y, Lynch RC, Devitt-Lee A, Zhang L, et al. Metagenomic analysis of medicinal Cannabis samples; pathogenic bacteria, toxigenic fungi, and beneficial microbes grow in culture-based yeast and mold tests. F1000Research. 2016;5:2471. PubMed PMID: 27853518. Pubmed Central PMCID: 5089129.
4. McKernan K, Spangler J, Zhang L, Tadigotla V, Helbert Y, Foss T, et al. Cannabis microbiome sequencing reveals several mycotoxic fungi native to dispensary grade Cannabis flowers. F1000Research. 2015;4:1422. PubMed PMID: 27303623. Pubmed Central PMCID: 4897766.