

STATE OF NEW MEXICO  
FIRST JUDICIAL DISTRICT COURT  
COUNTY OF SANTA FE

CPNM, INC.  
Petitioner

v.

No. D-101-CV-2015-00658

N.M. DEPARTMENT OF HEALTH and  
RETTA WARD, in her Official Capacity as  
Secretary of the N.M. Department of Health,  
Respondents.

**MOTION FOR TEMPORARY INJUNCTIVE RELIEF**

COMES NOW Petitioner CPNM, Inc., by and through its attorney, Jason Marks Law, LLC, Jason Marks, Esq., with a Motion for Temporary Injunctive Relief in order to prevent the Department of Health (hereinafter “the Department” or “DOH”) from enforcing regulations preventing medical cannabis failing microbiological screening for yeasts and molds at the levels specified by USP 2023 from being supplied to patients.

For its Motion, Petitioner states as follows:

1. The Department administers the Lynn and Erin Compassionate Use Act, NMSA § 26-2B-1, *et seq.*, which provides for patients with certain debilitating medical conditions to legally obtain, possess, and use medical cannabis through a regulated system.

2. The Department has licensed non-profit producers (LNPPs) of medical cannabis to grow and distribute cannabis to registered patients, beginning in 2009. The Department has also licensed testing laboratories for medical cannabis.

3. On February 16, 2015, after public hearing, the Department repealed and replaced its Medical Cannabis Program (MCP) administrative rules in 7.34.7.2, .3 and, .4 NMAC on February 16, 2015. New Rule 7.34.7.4.9(C)(1) NMAC states

**“Microbiological test:** A non-profit producer shall sample and test dried, usable cannabis and concentrated cannabis derived products for microbiological contaminants, using an approved laboratory. A dried cannabis sample may be deemed to have passed the microbiological test if it satisfies the standards set forth in Section 2023 of the United States Pharmacopeia.

The Standard set forth in USP Section 2023 includes a limit of 1,000 yeast or mold colony forming units (cfu) per gram of material. Cannabis which does not pass this testing standard may not be sold or distributed to patients, and must be destroyed.

7.34.7.4.9(C) NMAC.<sup>1</sup>

4. Although the effective date of the microbiological testing rule was February 27, 2015 (see 7.34.7.4.5 NMAC), the Department informed non-profit producers of medical cannabis in or around February 2015 that it would not enforce certain parts of its testing rules until further notice.

5. On December 1, 2015, the Department informed non-profit producers of medical cannabis that compliance with the microbiological testing rule would be mandatory, beginning January 25, 2016. Exhibit 1.

6. Prior to the fall of 2015, there had been no routine testing of medical cannabis for microbiological contamination in New Mexico.

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<sup>1</sup> Several of the rules promulgated DOH in February 2015 are the subject of the Petition for Declaratory Judgment that initiated the present case and docket. The parties have completed discovery on the Petition, and Petitioner intends to file a Motion for Summary Judgment with the Court shortly. The matter at issue in the present Motion for Temporary Injunctive Relief are closely connected with the Petition.

7. Kathleen O’Dea, Laboratory Director Scepter Labs, a DOH licensed testing laboratory, stated at a public hearing conducted by DOH on January 6, 2016, that she had over the past few months tested over 1,000 samples of medical cannabis from New Mexico producers, and found that approximately 20% of medical cannabis grown indoors failed the 1,000 cfu/gram standard for yeast and molds, and 85% of cannabis grown outdoors failed it. She stated that the failed samples almost always passed the other screens in USP 2023.

8. Ms. O’Dea stated that screening for yeasts and mold microbiological contaminants at the level of 1,000 cfu/gram provides no benefit to patient safety; and that contamination levels of up to 100,000 have been determined to be safe for consumption by medical cannabis patients. Ms. O’Dea informed the Department of a May 2015 white paper by the May 2015 Cannabis Safety Institute, “Microbiological Safety Testing of Cannabis,” by four authors including a Ph.D. researcher from Harvard Medical School, and medical doctors from Duke University and the Univ. of Vermont. She produced a copy of the CSI white paper to Petitioner, who produced it to Respondent as a supplemental response to discovery.

9. The authors of the CSI white paper, based on review of 249 published sources, and the application of microbiological and public health principles, determined that microbiological screening of medical cannabis for molds and yeasts was unnecessary, as it was impossible for patients to come to harm through exposure, *with one exception*. The white paper authors and Ms. O’Dea identify one specific family of mold fungus which present a risk to patient health, *Aspergillus* (*A. fumigatus*, *A. flavus*, *A. terreus*, and *A. niger*), the spores of which present a risk they are introduced into the

lungs of immuno-compromised patients via smoking of Aspergillus-contaminated cannabis.

10. Colorado and Washington screen for yeast and mold microbiological contaminants in medical cannabis using a standard of 10,000 cfu/gram, Oregon uses 100,000 cfu/gram; these are the only states besides New Mexico that have established regulatory standards for microbiological screening of medical cannabis. The World Health Organization, the American Herbal Products Association, and the ANSI set standards for yeast and mold in botanical materials at the level of 10,000 cfu/gram.

11. If DOH is allowed to enforce the USP 2023 screening requirement of 1,000 cfu/gram, which is 1,000 times stricter than the next most stringent state standards, it will result in more than one-quarter of all medical cannabis being produced in N.M. being prevented from reaching the market (i.e., patients). Exhibit 2 Affidavit of Zeke Shortes at ¶¶ 5-7, *see also* Exhibits 3 – 6, Affidavits of Eric Speegle, Erik Briones, Mandy Denson, and Vivian Moore.

12. Exclusion of this large proportion of the cannabis produced by New Mexico producers, because of an unnecessarily stringent testing standard, will result in acute supply shortages. Large numbers of patients will not be able to obtain the medicine they need to treat their debilitating conditions. *Id.*

13. Enforcement of the 1,000 cfu/gram standard for molds and yeast will lead to dramatically higher prices to patients for their medicine. *Id.*

14. Patients' lack of access to needed medicine and higher prices are irreparable harms.

15. Petitioner's members, who are LNNPs, will be economically harmed by the enforcement of the 1,000 cfu/gram standard through lost sales, and such losses will also be irreparable.

16. DOH has no scientific evidence to support its testing standard for yeasts and mold in medical cannabis. There are no reported cases of cannabis users being harmed by yeasts and molds (other than *Aspergillus*) in commercially produced medical cannabis in New Mexico or elsewhere.

17. Because the impact of enforcement of the 1,000 cfu/gram standard will be to deny patients access to needed medicine, DOH bears the burden of proving that its regulation is substantially related to a legitimate government interest (e.g., protecting patient well-being). Under the facts Petitioner can prove, the regulation is not only not substantially related to a legitimate governmental interest, it is detrimental to patient well-being.

18. Petitioner, through counsel, made a written request to DOH on January 11, 2016 for a non-litigated resolution to the matters herein. Exhibit 7. On January 26, 2016, DOH responded through counsel that it had decided not to delay or modify enforcement of the microbiological testing rule at the present time. Exhibit 8.

WHEREFORE, Petitioner requests that the Court enjoin the enforcement of 7.34.7.4.9(C)(1) NMAC on a temporary basis pending a full evidentiary hearing on whether the rule should be permanently enjoined.

Respectfully submitted,



Jason Marks, *Attorney for Petitioner*  
Jason Marks Law, LLC  
1011 Third Street NW  
Albuquerque, NM 87102  
(505) 385-4435  
lawoffice@jasonmarks.com

**CERTIFICATE OF SERVICE**

On this day, January 29, 2016, I caused the foregoing Motion to be filed in the Court's Odyssey system and causing a copy to be served electronically upon counsel for Respondent.

A handwritten signature in blue ink, appearing to read "Jason Marks", is written over a series of horizontal dashed lines.

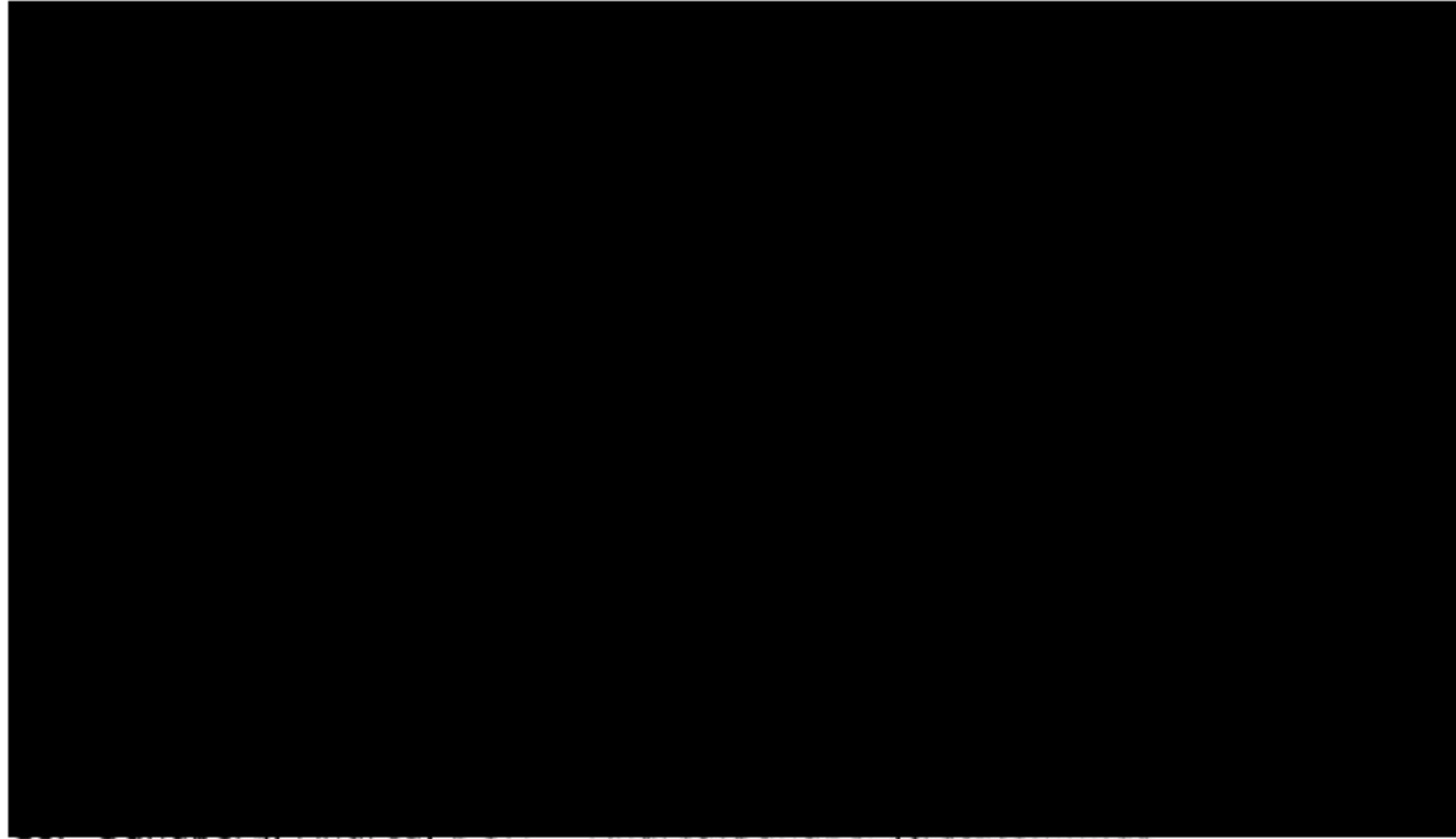
Jason Marks, *Attorney for Petitioner*

----- Original Message -----

Subject: MCP cannabis testing update

From: "Groggel, Ken, DOH" <[Ken.Groggel@state.nm.us](mailto:Ken.Groggel@state.nm.us)>

Date: Tue, December 01, 2015 4:31 pm



Good afternoon everyone,

We are pleased to announce that the MCP is moving forward with the staggered implementation for testing medical cannabis products (7.34.4.9.A. NMAC). Beginning on Monday, January 25, 2016 all dried usable cannabis and all CDPs produced, sold, or distributed by a licensed nonprofit producer shall be sampled for testing purposes, and tested for microbiological contaminants and quantity of THC & CBD by an approved laboratory prior to sale or distribution. Federal border checkpoints exempt Mother Earth Herbs from this requirement at present. Let me know if you have questions.

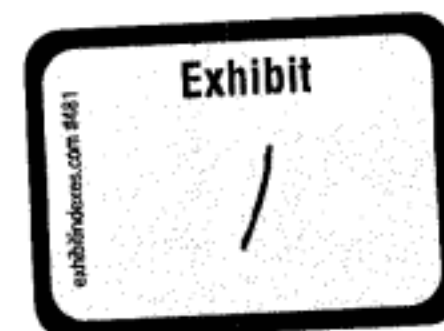
As always, thank you for your cooperation & support of the Medical Cannabis Program.

Ken Groggel

Program Manager

New Mexico Dept. of Health

(505) 841-559



STATE OF NEW MEXICO  
FIRST JUDICIAL DISTRICT COURT  
COUNTY OF SANTA FE

CPNM, INC.  
Petitioner

v.

No. D-101-CV-2015-00659

N.M. DEPARTMENT OF HEALTH and  
RETTA WARD, in her Official Capacity as  
Secretary of the N.M. Department of Health,  
Respondents.

**AFFIDAVIT OF ZEKE SHORTES**

I, Zeke Shortes, swear and affirm as follows:

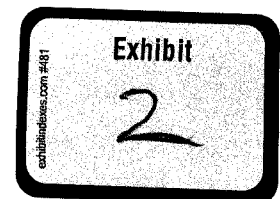
1. My name is Zeke Shortes. I am President of Sacred Garden, a licensed non-profit producer (LNPP) of medical cannabis in Santa Fe, N.M.

2. I am a currently president of CPNM, Inc., a trade association of licensed non-profit producers of medical cannabis.

3. I have been the President of Sacred Garden we were first licensed in 20\_\_.

I am personally knowledgeable and involved on a day-to-day basis in all aspects of producing and dispensing medical cannabis. I am personally knowledgeable about the general details of how most of the other medical cannabis producers in New Mexico operate, including type of growing locations (indoor/greenhouse/outdoor), distribution locations, types of products, pricing, and patient populations.

4. I believe that Kathleen O'Dea's report that 20% of indoor grown cannabis and 85% of outdoor grown cannabis will not pass 1,000 cfu/gram screening for molds and yeast is accurate based on Sacred Garden's experience and my knowledge of other medical cannabis production operations in the state.





5. I am confident that imposing the 1,000 cfu/gram screening requirement will result in *more than one-quarter* of all medical cannabis being produced in N.M. being prevented from reaching the market (i.e., patients).

6. Supply and demand for medical cannabis are currently in close balance. While plant count limits for producers have increased, the number of patients has also increased by more than 50% in a little more than a year. Given current and anticipated patient demand and producer supplies, withdrawal of cannabis that cannot pass USP 2023 screening will result in acute supply shortages. Large numbers of patients will not be able to obtain the medicine they need to treat their debilitating conditions.

7. Affordability is also a factor in access to medicine. Greenhouse and outdoor growing is less costly than indoor growing. Producers in New Mexico have only recently begun expanding into outdoor operations, and it was generally expected that outdoor grown cannabis will reach the market at lower prices. Enforcement of USP 2023 screening will make outdoor growing impossible and contribute in that way to increased pricing and diminished access to medicine. More critically, withdrawal of 25% or more of producers' production from the statewide market will drive prices dramatically higher, because of the resulting supply/demand imbalance, combined with producers need to recover the costs of growing failed batches in the prices charged for the product that can be sold.

8. Sacred Garden will *never* sell any medicine that poses a health risk to any patient. However, based on the research of the Cannabis Safety Institute, and the policies put in place by medical cannabis programs in Oregon, Washington, and Colorado (the only states other than NM to attempt to regulate microbiological contamination), it is

clear that medical cannabis with greater than 1,000 cfu/gram of microbiological contaminants (other than Aspergillus) is safe for use. Withholding safe medicine from patients because of an unsuitable testing standard will cause real harm to patients, and yield no benefits.

9. No patients have ever become ill as a result of microbiological contamination of medicine sold by Sacred Garden. To my knowledge, no patients have ever become ill as a result of microbiological contamination of medicine sold by other producers in the state.

10. New Mexico LNPPs are not eligible for any of the federal or state tax preferences generally available for non-profit entities. Medical cannabis LNPPs are taxed by federal and State of New Mexico authorities as if they were for-profit businesses, the only difference is that many business expenses cannot be deducted and as a result, cannabis producers pay a much higher effective tax rate than other businesses.

11. Becoming a producer, or expanding production as an existing producer, are capital-intensive. To expand production from 150 to 450 can require an upfront investment of between \$250,000 and \$750,000.

12. The non-profit restriction is a barrier to Sacred Garden and other LNPPs raising the capital needed to become a producer or to expand production. Sacred Garden has been unable to obtain debt financing from commercial lenders. Because Sacred Garden is required to be structured as non-profit, it cannot raise itself raise equity financing.

13. Because of these barriers, LNPPs raise capital by forming for-profit affiliates to acquire and build-out buildings and facilities and/or to provide management

services to the LNPP. The for-profit affiliates can attract and accept equity financing. However, the need to raise capital through these indirect mechanisms increases overhead and transaction costs. The indirect nature of the investments also increases the risk for investors, leading them to demand higher returns than might be needed in a direct financing situation. These higher costs of obtaining financing that are due to the non-profit restriction are ultimately borne by patients in the priced charged for medicine.

14. Indirect financing through affiliates will not be available in all circumstances.

15. N.M. medical cannabis producers are all small businesses with 50 or fewer employees.

16. Affiant further sayeth not.

I affirm that the foregoing statements are true and accurate, to the best of my knowledge, under the penalties of perjury.

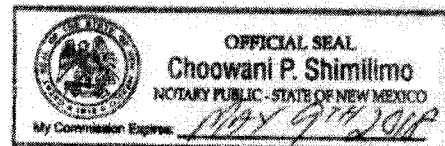


Zeke Shortes

Subscribed and sworn to before me, this 21 day of January, 2016.



NOTARY PUBLIC



My commission expires: MAY 9TH 2018

STATE OF NEW MEXICO  
FIRST JUDICIAL DISTRICT COURT  
COUNTY OF SANTA FE

CPNM, INC.  
Petitioner

v.

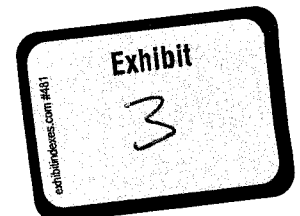
No. D-101-CV-2015-00659

N.M. DEPARTMENT OF HEALTH and  
RETTA WARD, in her Official Capacity as  
Secretary of the N.M. Department of Health,  
Respondents.

**AFFIDAVIT OF ERIC SPEEGLE**

I, Eric Speegle, swear and affirm as follows:

1. My name is Eric Speegle. I am the President of the Verdes Foundation, a licensed non-profit producer of medical cannabis in Albuquerque, N.M.
2. I am personally knowledgeable and involved on a day-to-day basis dispensing medical cannabis and also have management oversight of our testing program. I am also personally knowledgeable about the general details of how most of the other medical cannabis producers in New Mexico operate, including type of growing locations (indoor/greenhouse/outdoor), distribution locations, types of products, pricing, and patient populations.
3. I believe that Kathleen O'Dea's report that 20% of indoor grown cannabis and 85% of outdoor grown cannabis will not pass 1,000 cfu/gram screening for molds and yeast is accurate based on her knowledge and experience.
4. I am confident that imposing the 1,000 cfu/gram screening requirement will result in a large proportion of all medical cannabis being produced in N.M. being prevented from reaching the market (i.e., patients).



5. Supply and demand for medical cannabis are currently in close balance. While plant count limits for producers have increased, the number of patients has also increased by more than 50% in a little more than a year. Given current and anticipated patient demand and producer supplies, withdrawal of cannabis that cannot pass USP 2023 screening will result in acute supply shortages. Large numbers of patients will not be able to obtain the medicine they need to treat their debilitating conditions.

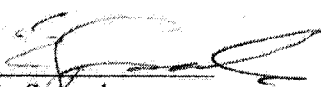
6. Affordability is also a factor in access to medicine. Greenhouse and outdoor growing is less costly than indoor growing. Enforcement of USP 2023 screening will make outdoor growing difficult and contribute in that way to increased pricing and diminished access to medicine. Withdrawal of a large fraction of producers' production from the statewide market will also drive prices dramatically higher because of the resulting supply/demand imbalance, combined with producers need to recover the costs of growing failed batches in the prices charged for the product that can be sold.

7. Verdes Foundation will *never* knowingly sell any medicine that poses a health risk to any patient. However, based on the research by the Cannabis Safety Institute, and the policies put in place by medical cannabis programs in Oregon, Washington, and Colorado (the only states other than NM to attempt to regulate microbiological contamination), it is reasonable that medical cannabis with greater than 1,000 cfu/gram and less than 10,000 cfu/gram of microbiological contaminants (other than *Aspergillus* and *E. Coli*) is safe for use. Withholding safe medicine from patients because of an unsuitable testing standard will cause real harm to patients, and yield no benefits.

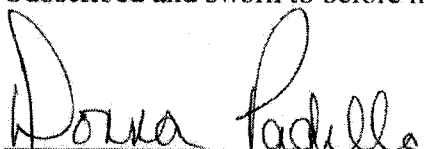
8. It is my professional opinion, and the position of The Verdes Foundation, that the Department of Health should be required to use a standard of 10,000 cfu per gram of yeast or mold as the threshold for identifying medical cannabis not safe for consumption, except for Aspergillus and E. Coli.

9. Affiant further sayeth not.

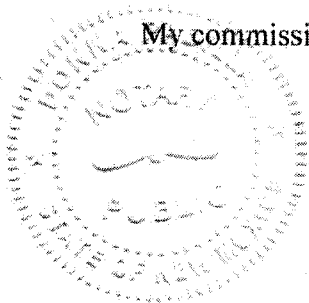
I affirm that the foregoing statements are true and accurate, to the best of my knowledge, under the penalties of perjury.

  
Eric Speegle

Subscribed and sworn to before me, this 28<sup>th</sup> day of January, 2016.

  
NOTARY PUBLIC

My commission expires: 3/31/2019



STATE OF NEW MEXICO  
FIRST JUDICIAL DISTRICT COURT  
COUNTY OF SANTA FE

CPNM, INC.  
Petitioner

v.

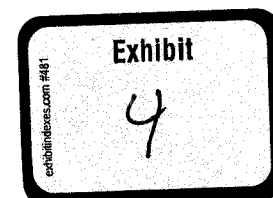
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N.M. DEPARTMENT OF HEALTH and  
RETTA WARD, in her Official Capacity as  
Secretary of the N.M. Department of Health,  
Respondents.

**AFFIDAVIT OF ERIK M. BRIONES**

I, Erik Briones, swear and affirm as follows:

1. My name is Erik Briones. I am President of Minerva Canna Group, Inc., a licensed non-profit producer (LNPP) of medical cannabis in Albuquerque, N.M.
2. I have been the President of Minerva Canna Group, Inc. we were first licensed in 2010. I am personally knowledgeable and involved on a day-to-day basis in all aspects of producing and dispensing medical cannabis. I am personally knowledgeable about the general details of how most of the other medical cannabis producers in New Mexico operate, including type of growing locations (indoor/greenhouse/outdoor), distribution locations, types of products, pricing, and patient populations.
3. I believe that Kathleen O'Dea's report that 20% of indoor grown cannabis and 85% of outdoor grown cannabis will not pass 1,000 cfu/gram screening for molds and yeast is accurate based on Minerva Canna Group's experience and my knowledge of other medical cannabis production operations in the state.



4. I am confident that imposing the 1,000 cfu/gram screening requirement will result in *more than one-quarter* of all medical cannabis being produced in N.M. being prevented from reaching the market (i.e., patients).

5. Supply and demand for medical cannabis are currently in close balance. While plant count limits for producers have increased, the number of patients has also increased by more than 50% in a little more than a year. Given current and anticipated patient demand and producer supplies, withdrawal of cannabis that cannot pass USP 2023 screening will result in acute supply shortages. Large numbers of patients will not be able to obtain the medicine they need to treat their debilitating conditions.

6. Affordability is also a factor in access to medicine. Greenhouse and outdoor growing is less costly than indoor growing. Producers in New Mexico have only recently begun expanding into outdoor operations, and it was generally expected that outdoor grown cannabis will reach the market at lower prices. Enforcement of USP 2023 screening will make outdoor growing impossible and contribute in that way to increased pricing and diminished access to medicine. More critically, withdrawal of 25% or more of producers' production from the statewide market will drive prices dramatically higher, because of the resulting supply/demand imbalance, combined with producers need to recover the costs of growing failed batches in the prices charged for the product that can be sold.

7. Minerva Canna Group, Inc. will *never* sell any medicine that poses a health risk to any patient. However, based on the research of the Cannabis Safety Institute, and the policies put in place by medical cannabis programs in Oregon, Washington, and Colorado (the only states other than NM to attempt to regulate



microbiological contamination), it is clear that medical cannabis with greater than 1,000 cfu/gram of microbiological contaminants (other than Aspergillus) is safe for use.

Withholding safe medicine from patients because of an unsuitable testing standard will cause real harm to patients, and yield no benefits.

8. No patients have ever become ill as a result of microbiological contamination of medicine sold by Minerva Canna Group. To my knowledge, no patients have ever become ill as a result of microbiological contamination of medicine sold by other producers in the state.

9. Affiant further sayeth not.

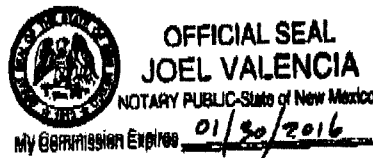
I affirm that the foregoing statements are true and accurate, to the best of my knowledge, under the penalties of perjury.

  
Erik M. Briones

Subscribed and sworn to before me, this 27<sup>TH</sup> day of January, 2016.

  
NOTARY PUBLIC

My commission expires: 01/30/2016



STATE OF NEW MEXICO  
FIRST JUDICIAL DISTRICT COURT  
COUNTY OF SANTA FE

CPNM, INC.  
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v.

No. D-101-CV-2015-00659

N.M. DEPARTMENT OF HEALTH and  
RETTA WARD, in her Official Capacity as  
Secretary of the N.M. Department of Health,  
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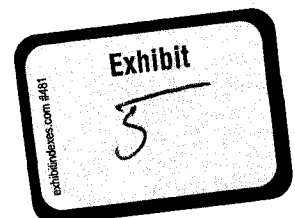
**AFFIDAVIT OF MANDY DENSON**

I, Mandy Denson , swear and affirm as follows:

1. My name is Mandy Denson. I am President of Compassionate Distributors, Inc. a licensed non-profit producer (LNPP) of medical cannabis in Ruidoso, N.M.

2. I have been a Director of Compassionate Distributors since we were first licensed in 2010, and I am the current President. I am personally knowledgeable and involved on a day-to-day basis in all aspects of producing and dispensing medical cannabis. I am personally knowledgeable about the general details of how most of the other medical cannabis producers in New Mexico operate, including type of growing locations (indoor/greenhouse/outdoor), distribution locations, types of products, pricing, and patient populations.

3. I believe that Kathleen O'Dea's report that 20% of indoor grown cannabis and 85% of outdoor grown cannabis will not pass 1,000 cfu/gram screening for molds and yeast is accurate based on my knowledge experience.



4. I am confident that imposing the 1,000 cfu/gram screening requirement will result in a large proportion of all medical cannabis being produced in N.M. being prevented from reaching the market (i.e., patients).

5. Supply and demand for medical cannabis are currently in close balance. While plant count limits for producers have increased, the number of patients has also increased by more than 50% in a little more than a year. Given current and anticipated patient demand and producer supplies, withdrawal of cannabis that cannot pass USP 2023 screening will result in acute supply shortages. Large numbers of patients will not be able to obtain the medicine they need to treat their debilitating conditions.

6. Affordability is also a factor in access to medicine. Greenhouse and outdoor growing is less costly than indoor growing. Enforcement of USP 2023 screening will make outdoor growing difficult and contribute in that way to increased pricing and diminished access to medicine. More critically, withdrawal of a large fraction of producers' production from the statewide market will drive prices dramatically higher, because of the resulting supply/demand imbalance, combined with producers need to recover the costs of growing failed batches in the prices charged for the product that can be sold.

7. Compassionate Distributors will *never* sell any medicine that poses a health risk to any patient. However, based on the research of the Cannabis Safety Institute, and the policies put in place by medical cannabis programs in Oregon, Washington, and Colorado (the only states other than NM to attempt to regulate microbiological contamination), it is clear that medical cannabis with greater than 1,000 cfu/gram of microbiological contaminants (other than *Aspergillus*) is safe for use.

Withholding safe medicine from patients because of an unsuitable testing standard will cause real harm to patients, and yield no benefits.

8. No patients have ever become ill as a result of microbiological contamination of medicine sold by Compassionate Distributors. To my knowledge, no patients have ever become ill as a result of microbiological contamination of medicine sold by other producers in the state.

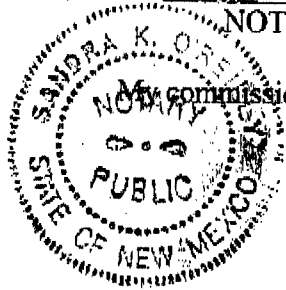
9. Affiant further sayeth not.

I affirm that the foregoing statements are true and accurate, to the best of my knowledge, under the penalties of perjury.

Mandy Denson  
Mandy Denson

Subscribed and sworn to before me, this 21<sup>st</sup> day of January, 2016.

Sandra K. Orsico  
NOTARY PUBLIC  
My commission expires: 10-27-2018



STATE OF NEW MEXICO  
FIRST JUDICIAL DISTRICT COURT  
COUNTY OF SANTA FE

CPNM, INC.  
Petitioner

v.

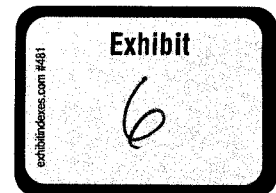
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N.M. DEPARTMENT OF HEALTH and  
RETTA WARD, in her Official Capacity as  
Secretary of the N.M. Department of Health,  
Respondents.

**AFFIDAVIT OF VIVIAN MOORE, CPA**

I, Vivian Moore, swear and affirm as follows:

1. My name is Vivian Moore. I am the Executive Director for Mother Earth Herbs, Inc., a licensed non-profit producer of medical cannabis in Las Cruces, N.M which is currently exempt from mandatory testing due to the federal checkpoints.
2. I am a Certified Public Accountant.
3. I am personally knowledgeable and involved on a day-to-day basis in all phases of producing and dispensing medical cannabis. I am also personally knowledgeable about the general details of how most of the other medical cannabis producers in New Mexico operate, including type of growing locations (indoor/greenhouse/outdoor), distribution locations, types of products, pricing, and patient populations.
4. I believe that Kathleen O'Dea's report, that 20% of indoor grown cannabis and 85% of outdoor grown cannabis will not pass 1,000 cfu/gram screening for molds and yeast, is accurate based on my knowledge and experience.



5. I am confident that imposing the 1,000 cfu/gram screening requirement will result in a large proportion of all medical cannabis being produced in N.M. being prevented from reaching the market (i.e., patients).

6. Supply and demand for medical cannabis are currently in close balance. While plant count limits for producers have increased, the number of patients has also increased by more than 50% in a little more than a year. Given current and anticipated patient demand and producer supplies, withdrawal of cannabis that cannot pass USP 2023 screening will result in acute supply shortages. Large numbers of patients will not be able to obtain the medicine they need to treat their debilitating conditions.

7. Affordability is also a factor in access to medicine. Greenhouse and outdoor growing is less costly than indoor growing. Enforcement of USP 2023 screening will make outdoor growing difficult and contribute to increased pricing and diminished access to medicine. Withdrawal of a large fraction of producers' production from the statewide market will also drive prices dramatically higher as a result of the supply/demand imbalance, combined with the producers' need to recover the costs of growing failed batches in the prices charged for the product that can be sold.

8. Mother Earth Herbs will *never* knowingly sell any medicine that poses a health risk to any patient. Mother Earth Herbs will never sell anything that the patient board members have not consumed themselves. Based on the research by the Cannabis Safety Institute, and the policies put in place by medical cannabis programs in Oregon, Washington, and Colorado (the only states other than NM to attempt to regulate microbiological contamination), it is clear that medical cannabis with greater than 1,000 cfu/gram of microbiological contaminants (other than *Aspergillus*) is safe for use.

Withholding safe medicine from patients because of an unsuitable testing standard will cause real harm to patients, and yield no benefits.

9. No patients have ever become ill as a result of microbiological contamination of medicine sold by Mother Earth Herbs. To my knowledge, no patients have ever become ill as a result of microbiological contamination of medicine sold by other producers in the state.

10. It is my professional opinion, and the position of Mother Earth Herbs, that the Department of Health should be required to use a standard of 10,000 cfu per gram of yeast or mold as the threshold for identifying medical cannabis as "not safe for consumption", except for Aspergillus, for which any quantity of living organisms or spores should be grounds to keep a batch of cannabis from being dispensed to patients.

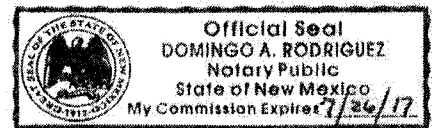
11. Affiant further sayeth not.

I affirm that the foregoing statements are true and accurate, to the best of my knowledge, under the penalties of perjury.

  
Vivian M. Moore

Subscribed and sworn to before me, this 19<sup>th</sup> day of January, 2016.

  
NOTARY PUBLIC



My commission expires: July 26, 2017.

**Subject:** MCP Microbiological Testing  
**From:** "Jason Marks, Esq." <lawoffice@jasonmarks.com>  
**Date:** 1/11/2016 4:54 PM  
**To:** "Woodward, Chris, DOH" <Chris.Woodward@state.nm.us>

Dear Chris:

As I think you're aware, and I know Ken is aware, many producers are extremely concerned about the effects of enforcement of 7.34.7.4.9(C)(1) NMAC, Microbiological Testing, and the USP 2023 standard, which is scheduled to begin 1/25/16.

To summarize, it appears that 20% of indoor grown cannabis, and 85% of outdoor grown cannabis, will likely fail the USP 2023 standard. At the same time, based on what we now know from the CSI white paper, Kathleen O'Dea's analysis and comments, and in looking at the assessments made by DOH's counterparts in Oregon, Colorado, and Washington, testing to the <USP 2023> 1,000 cfu/gram standard provides no safety benefits to patients.

Producers reasonable expect that there will be a "train wreck" if the USP 2023 standard is enforced on 1/25. Exclusion of even 20% of of the cannabis produced by New Mexico producers from the market is certain to result in acute supply shortages affecting patients. And while it's hard to predict all the economic effects of producers having to destroy that much usable cannabis, a minimum, I'd expect to see producers repricing up in order to recover the costs of growing the non-marketable batches from their remaining sales.

CPNM is so concerned that they have asked me to draft a Motion for an Injunction in the existing Dec Action docket (you may not believe this, but they are not litigation-happy). But they also believe that MCP staff have heard their concerns and that there is a very good likelihood that we'll have a resolution without litigation. The problem is timing - if we need to request a TRO, we can't put the judge's back up against the wall in terms of setting a hearing. So I am hoping that DOH can give both sides some "breathing room" by indicating that the enforcement date can be pushed off for 2 or 3 weeks while MCP staff evaluates the issue. (Or even better, if you are able to offer that MCP staff will come up with a new policy/approach to 7.34.7.4.9(C)(1) microbiological testing this week that avoids the "train-wreck.")

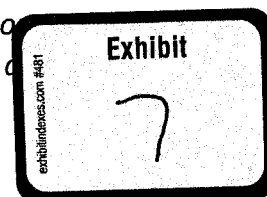
Looking forward to hearing from you. Thanks,

Jason

--

Jason Marks Law, LLC | 1011 Third St NW | Albuquerque, NM 87102 | (505) 385-4435

*This message is sent by an attorney and may contain information that is privileged or confidential. If you received this transmission in error, please notify the sender by reply e-mail and delete this message and any attachments.*





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January 26, 2016

## Via E-Mail

Mr. Jason Marks  
Jason Marks Law, LLC  
[lawoffice@jasonmarks.com](mailto:lawoffice@jasonmarks.com)

**Re: CPNM, Inc. v. N.M. Department of Health and Retta Ward, in her Official Capacity as Secty. of the N.M. Department of Health;  
First Judicial District Court No. D-101-CV-2015-00658  
and  
CPNM, Inc. v. N.M. Department of Health and Retta Ward, in her Official Capacity as Secty. of the N.M. Department of Health;  
First Judicial District Court No. D-101-CV-2015-00659**

Dear Mr. Marks:

I am in receipt of your letter of January 22, 2016 formally rejecting the DOH's proposal of December 1, 2015. Please let us know if your clients have a counter-proposal.

The Department of Health does not intend to delay implementation and enforcement of the microbiological testing requirement because of patient safety concerns. While we appreciate receiving the material from Ms. O'Dea, there are concerns about the validity of what she has stated.

Once microbiological testing is implemented, if a significant number of batches fail, CPNM should feel free to communicate concerning about the testing process to the MCP and the MCP will consider proposing revisions to the testing standard at that time, through a rule-making process.

The Department of Health has no immediate plans to enforce the mycotoxin testing requirement.

A PROFESSIONAL ASSOCIATION

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(505) 842-1950

FARMINGTON  
(505) 326-4521

LAS CRUCES  
(575) 523-2481

Exhibit

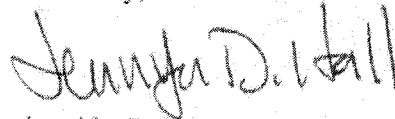


exhibitindex.com #461

Mr. Jason Marks  
January 26, 2016  
Page 2

Please feel free to call me with any questions or concerns.

Sincerely,



Jennifer D. Hall

JDH:bad

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