September 8, 2014

Robin Schneider
NPRA Legislative Liaison
(517) 974-2265
www.nprausa.com

Re: Updated HB-4271 Language

Dear Robin,

Thank you for sending the updated HB-4271 language, and allowing us this opportunity to respond. Please find below our general commentary, attachments and suggested edits to House Bill 4271 (See attachment 1).

1. Accreditation

Accreditation is an important, necessary part of this bill. Third-party validation will ensure a certain level of professionalism and scientific accuracy in the industry. Our one concern is that the accreditation process itself can take anywhere from 6 – 12 months.[1] This could create a shortage of testing laboratories (and available medical marijuana) at a time when they are most needed, similar to the situation in Washington State, where they face a bottleneck in licenses for growing[2]. To address this issue, we suggest that the bill allow provisional licensure during the interim, while a laboratory is in the midst of accreditation review and assessment.

2. US Pharmacopeia is an Inappropriate Authority for Medical Cannabis

---

[1] See http://www.pjlabs.com/downloads/Steps_17025_Rev%207-09.pdf
[2] See http://bigstory.ap.org/article/pot-shortages-could-be-dire-washingtons-stores

Chapter 1111, Microbiological Examination of Nonsterile Products: Acceptance Criteria for Pharmaceutical Preparations and Substances for Pharmaceutical Use sets acceptable standards of certain microbiological organisms in nonsterile preparations. The need to test medical cannabis for microbiological organisms is certain, and laboratories thusly should be aware of acceptance criteria. However, by all indications Chapter 1111 of the USP is intended for true *pharmaceutical* drugs and is therefore an inappropriate criterion for cannabis.

Chapter 1121 provides the "nomenclature", designating each drug by a single, non-proprietary name. The examples listed in the chapter include: Acetaminophen Capsules, Aminophylline Delayed-Release Tablets, Aspirin Extended-Release Tablets, Hexylresorcinol Lozenges, Meperidine Hydrochloride Tablets, Calcium Carbonate Oral Suspension, Cetylpyridinium Chloride Topical Solution, Dexamethasone Ophthalmic Suspension, Epinephrine Bitartrate, Ophthalmic Solution, Isosorbide Dinitrate Sublingual Tablets, Miconazole Nitrate Topical Powder, and Triple Sulfa Vaginal Cream. The examples in Chapter 1121 help provide an illustration at just how vastly different medical cannabis is from those drugs Chapter 1111 seeks to regulate.

USP Chapter 561, Articles of Botanical Origin, contains "The General Method for Pesticide Residues Analysis." It is imperative that medical cannabis, especially when in flower form, is tested for pesticide residue. However, the list of pesticides contained in Chapter 561 is overly specific, causing concern. Not all target compounds are likely to be relevant to cannabis cultivation. There has not been sufficient research conducted to determine the acceptable levels of pesticide residue in cannabis. Thusly, it could be extremely inefficient both in terms of time and cost to measure all listed pesticides. Further, it may be extremely expensive for any lab to meet all the listed tolerances, as it would require significant expenses in extra testing equipment,

not to mention the additional time expenditures required to conduct additional tests.

Finally, the methods listed are inappropriate for cannabis. The listed sample sizes for "cut vegetable drugs", for example, are 50 grams. That would place a significant financial strain on growers/caregivers or provisioning centers, which would have to submit a 50-gram sample for each "flower" sample. By comparison, most current cannabis testing labs require a 1-3 gram sample size.

Both referenced chapters of the USP are inappropriate for the testing of medical cannabis. Cannabis was removed from the US Pharmacopeia removed in 1941 and there is no indication a new chapter will be reissued. No other medical or recreational marijuana states reference the USP in their legislation. It is simply the wrong authority to cite for House Bill 4271. To address this problem, we propose the substitute of US Pharmacopeia with the American Herbal Pharmacopoeia Monograph.

3. The "Cannabis Inflorescence" (American Herbal Pharmacopoeia Monograph) is an Appropriate Alternative to the USP

The American Herbal Pharmacopeia Monograph produced the first cannabis monograph in 1851, where it remained until 1942 – removed due to the Marijuana Tax Act. In December of 2013, the AHP released a new edition of the cannabis monograph, again defining the plant as a botanical medicine (See attachment 4). "Cannabis Inflorescence" was developed in collaboration with researchers at the University of Mississippi under the guidance of Dr. Mahmoud ElSohly, who oversees the only federally legal source of medical marijuana in the United States.

The cannabis monograph is currently used as the testing standard in Oregon and Washington State's medical marijuana program laws (See attachments 2 and 3). The

monograph, designed for the study and analysis of cannabis provides a clear alternative to the USP which, when used for cannabis is overbroad in its application.

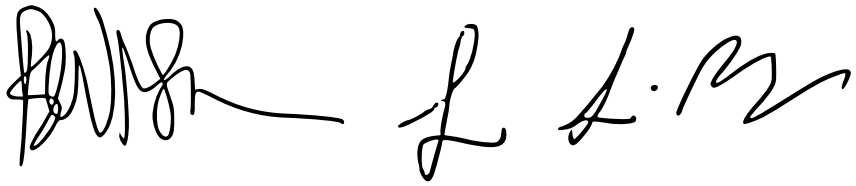
Conclusion

The use of our revisions will make for a more cost-effective Medical Marijuana Program. The accreditation process is costly, but necessary. However, the 6-12 month timeline for accreditation may create a prohibitive restriction for a new, albeit qualified, laboratory. Further, it may needlessly create a laboratory shortage, leading to the possibility of a medical marijuana shortage, not unlike that in Washington State.

The USP Chapter 1111 seeks to regulate pharmaceutical grade medicines. The USP Chapter 561 lists a number of pesticides, not relevant to medical cannabis and a cost-prohibitive sample size. "Medical" cannabis is, by its nature, a botanical medicine, better regulated by the American Herbal Pharmacopeia Monograph – the authority referenced in both Washington and Oregon State's medical marijuana laws. It directly deals with medical cannabis, rather than a broad range of pharmaceutical medicines.

Again, thank you for inviting our commentary on this matter. Should you have any follow-up questions or concerns, please do not hesitate to write or call to discuss this matter further.

Respectfully submitted,



Benjamin J. Rosman, J.D.
Lev Spivak-Birndorf, PhD

Encl:

ATTACHMENTS

1. **Suggested Changes - HB 4271 S-1**
2. **Washington 314-55-102**
3. **Oregon 333-008-1190**
4. ***American Herbal Pharmacopeia Monograph*, "Cannabis Inflorescence," December 2013**

Suggested Changes

HB 4271 S-1

TESTING (Blue = bjr/lsb Addition)

Pg 19 line 22

22 Sec. 12. (1) Beginning April 1, 2015, a provisioning center

23 shall not distribute or sell any product containing marihuana

24 unless the product has been tested by A licensed safety compliance facility, and meets the following acceptance criteria:

(A) FLOWERS OR OTHER USABLE MARIHUANA PLANT MATERIAL. USABLE MARIHUANA IN THE FORM OF FLOWERS OR OTHER PLANT MATERIAL MUST BE:

(1) TESTED FOR PESTICIDES, MOLD, MILDEW AND FUNGUS USING THE FOLLOWING CRITERIA, OR AN APPROVED ALTERNATIVE SCIENTIFICALLY VALID METHODOLOGY.

(a) "*PESTICIDE LIMITS*" (AMERICAN HERBAL PHARMACOPOEIA MONOGRAPH, CANNABIS INFLORESCENCE, 2013).

(b) "*MICROBIOLOGICAL AND FUNGAL LIMITS*" (AMERICAN HERBAL PHARMACOPOEIA MONOGRAPH, CANNABIS INFLORESCENCE, 2013)

(B) EDIBLES, LIQUIDS AND SOLID EXTRACTS. IF THE USABLE MARIHUANA USED IN THE EDIBLE, LIQUID OR SOLID EXTRACT HAS BEEN TESTED IN ACCORDANCE WITH THIS RULE AND TESTED NEGATIVE FOR PESTICIDES, MOLD, MILDEW OR FUNGUS, THE EDIBLE, LIQUID OR SOLID EXTRACT DOES NOT NEED TO BE TESTED FOR PESTICIDES, MOLD, MILDEW OR FUNGUS, BUT DOES NEED TO BE TESTED FOR AN ANALYSIS OF THE LEVELS OF THC AND CBD. IF THE USABLE MARIHUANA USED IN THE EDIBLE, LIQUID, OR SOLID EXTRACT WAS NOT TESTED IN ACCORDANCE WITH THIS RULE, THE EDIBLE, LIQUID OR SOLID EXTRACT MUST BE TESTED FOR PESTICIDES, MOLD, MILDEW OR FUNGUS IN ACCORDANCE WITH THE ACCEPTANCE CRITERIA IN SEC. 12.

(C) CONCENTRATES AND EXTRACTS. USABLE MARIHUANA IN THE FORM OF CONCENTRATES OR EXTRACTS MUST BE:

(1) TESTED FOR RESIDUAL SOLVENTS USING THE FOLLOWING CRITERIA, OR AN APPROVED ALTERNATIVE SCIENTIFICALLY VALID METHODOLOGY.

(a) "*SOLVENT RESIDUES*" (AMERICAN HERBAL PHARMACOPOEIA MONOGRAPH, CANNABIS INFLORESCENCE, 2013).

(D) THE LICENSING MUNICIPALITY MAY REQUIRE THIRD-PARTY VALIDATION OF ANY MONOGRAPH OR ANALYTICAL METHOD FOLLOWED BY THE LAB TO ENSURE THE METHODOLOGY PRODUCES SCIENTIFICALLY ACCURATE RESULTS PRIOR TO THEM USING THOSE STANDARDS WHEN CONDUCTING REQUIRED QUALITY ASSURANCE TESTS.

Washington 314-55-102

(4) As a condition of certification, labs must follow the most current version of the Cannabis Inflorescence and Leaf monograph published by the American Herbal Pharmacopoeia or notify the board what alternative scientifically valid testing methodology the lab is following for each quality assurance test. The board may require third-party validation of any monograph or analytical method followed by the lab to ensure the methodology produces scientifically accurate results prior to them using those standards when conducting required quality assurance tests.

(4) Testing. A PRF must ensure that each sample is tested for pesticides, mold, and mildew and for an analysis of the levels of tetrahydrocannabinol (THC) and Cannabidiol (CBD).

(a) Immature Plants. An immature plant may be tested for pesticides, mold or mildew by conducting a macroscopic or microscopic screening to determine if the plant has visible pesticide residue, mold or mildew.

(b) Flowers or other usable marijuana plant material. Usable marijuana in the form of flowers or other plant material must be:

(A) Tested for pesticides, mold and mildew using valid testing methodologies and macroscopic or microscopic screening may not be used;

(B) Tested for pesticides by testing for the following analytes:

(i) Chlorinated Hydrocarbons;

(ii) Organophosphates;

(iii) Carbamates; and

(iv) Pyrethroids; and

(C) Analyzed, using valid testing methodologies, to determine the levels of THC and CBD.

(c) Edibles, Liquids and Solid Extracts. If the usable marijuana used in the edible, liquid or solid extract has been tested in accordance with this rule and tested negative for pesticides, mold or mildew, the edible, liquid or solid extract does not need to be tested for pesticides, mold and mildew but does need to be tested for an analysis of the levels of THC and CBD. If the usable marijuana used in the edible, liquid, or solid extract was

not tested in accordance with this rule, the edible, liquid or solid extract must be tested for pesticides, mold or mildew in accordance with subsection (4)(b) of this rule.

Oregon Appendix A - 333-008-1190

Mold and Mildew limits for cannabis products (CFU/g)	Total yeast and mold (mold and mildew)
Processed materials*	10^4
Unprocessed materials*	10^4
CO_2 and solvent based extracts	10^3

*Unprocessed materials include minimally processed crude cannabis preparations such as inflorescences, accumulated resin glands (kief), and compressed resin glands (hashish). Processed materials include various solid or liquid infused edible preparations, oils, topical preparations, and water-processed resin glands ("bubble hash").

Source: American Herbal Pharmacopoeia Monograph, December 18th, 2013