Medical Marijuana Advisory Board Meeting

Thursday, July 28, 2022
10am - noon
MMAB Agenda

I. Call to order, roll call and introduction of new Board members
II. Approval of the previous meeting’s minutes – meeting March 22, 2022
III. Program Update
IV. Old Business
   a. Health Contact Form Feedback
V. New Business
   a. Subcommittee Changes & Expectations
   b. Subcommittee Updates:
      i. Regulatory Review – Christine Roussel, Pharm.D., R.Ph.
         Subcommittee Chair
      ii. Medical Review – Carolyn Byrnes, Subcommittee Chair
         • Propose policy and application to allow Serious Medical
           Conditions to be approved for research purposes only
      iii. Medical Research – Bhavini Patel, Subcommittee Chair
      iv. Patient and Caregiver – Shalawn James, Subcommittee Chair
VI. Research Initiative presentation with regard to the antimicrobial
    effects of applying a solvent-based extraction method
VII. Additional Discussion/Q&A
VIII. Adjournment
Medical Marijuana Program Update

• Medical Marijuana Regulations
• Program Metrics
• Patient Purchasing Activity
• Permittee Pricing Trends
Medical Marijuana Program Update

Program Metrics
Medical Marijuana Program Update

- Program to date:
  - 773,307 Patients and Caregivers Registered;
  - 414,446 Active Patient Certifications;
  - 1,830 Approved Practitioners;
  - 23.3 Million Patient Dispensing Events;
  - 66.3 Million Products Dispensed;
  - $5.7 Billion in Total Sales;
  - $2.3 Billion by G/Ps to Dispensaries; and
  - $3.4 Billion by Dispensaries.
Month on Month Dispensary Sales

Previous 12 Months (7/20-6/21) vs Most Recent 12 Months (7/21 - 6/22)
Medical Marijuana Program Update

Dispensary Sales by Month Since Jan 2020

[Bar chart showing monthly sales from January 2020 to December 2022, with data points for 2020, 2021, and 2022 indicated by different colors.]
Medical Marijuana Program Update

Year on Year Dispensary Sales for May and June

May 2020
May 2021
May 2022

Jun 2020
Jun 2021
Jun 2022

$0
$20,000,000
$40,000,000
$60,000,000
$80,000,000
$100,000,000
$120,000,000
$140,000,000

2020
2021
2022
Permittee Pricing Trends
Medical Marijuana Program Update

Patient Purchasing Trends by Product Category

- Dry Leaf
- Vape
- Concentrate
- Infused
- Topicals
- Other

Percentage of Total Sales

- 2020-Jan
- 2020-Feb
- 2020-Mar
- 2020-Apr
- 2020-May
- 2020-Jun
- 2020-Jul
- 2020-Aug
- 2020-Sep
- 2020-Oct
- 2020-Nov
- 2020-Dec
- 2021-Jan
- 2021-Feb
- 2021-Mar
- 2021-Apr
- 2021-May
- 2021-Jun
- 2021-Jul
- 2021-Aug
- 2021-Sep
- 2021-Oct
- 2021-Nov
- 2021-Dec
- 2022-Jan
- 2022-Feb
- 2022-Mar
- 2022-Apr
- 2022-May
- 2022-June
Medical Marijuana Program Update

Wholesale Price Decline Trend More Inline With Retail Price Declines

Dry Leaf Retail and Wholesale Pricing Trends
Medical Marijuana Program Update

Dry Leaf Retail and Wholesale Pricing Details

Retail Price/Gram

Wholesale Price/Gram

--- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | ---
$10.19 | $10.09 | $10.28 | $9.54 | $10.65 | $10.45 | $9.38 | $8.19 | $7.61 | $5.36 | $4.83
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    effects of applying a solvent-based extraction method

VII. Additional Discussion/Q&A

VIII. Adjournment
35 P.S. § 1201(j)(5)(i)-(v)

Subcommittee Assignments:

• Regulatory (i) Types of Medical Professionals
• Medical Review (ii) Modify Types of Conditions
• Medical Research (iii) Form of Medical Marijuana
• Patient and Caregiver (v) Affordable Access
Subcommittee Updates

• Regulatory Review – Christine Roussel, Pharm.D., R.Ph. Subcommittee Chair
• Medical Review – Carolyn Byrnes, Subcommittee Chair
  o Propose policy and application to allow Serious Medical Conditions to be approved for research purposes only
• Medical Research – Bhavini Patel, Subcommittee Chair
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An Analysis of the Efficacy of Organic Remedies Inc. Manufacturing Infrastructure for the Production of Sterile Extracts Derived from Contaminated Feed Stock

June-Wells MR, Fochtman FW, Balin B, Petroski WP, Niesen D, Hauser E
OVERVIEW

What Will This Talk Cover:

~ Current State Regulations – Marijuana and Extract Testing
~ Impact of Crop Destruction on Business
~ FDA Approved Remediation Technologies
~ Purpose and Goals of This Study
~ Overview of Organic Remedies Manufacturing Processes
~ Study Methodology
~ Study Findings
~ Conclusions
CURRENT PENNSYLVANIA CANNABIS MICROBIAL REGULATIONS

~ **Plant Material:**
  ~ *Escherichia coli* – non-detect
  ~ *Salmonella spp.* – non-detect
  ~ Total aerobic bacteria – <10,000cfu/g
  ~ Total yeast and mold – <10,000cfu/g
  ~ Total enterobacteriaceae – <1,000cfu/g

~ **Extracts:**
  ~ *Escherichia coli* – non-detect
  ~ *Salmonella spp.* – non-detect
  ~ Total aerobic bacteria – <10,000cfu/g
  ~ Total yeast and mold – <1,000cfu/g
  ~ Total enterobacteriaceae – <100cfu/g

**Notes:**
~ Material that does not pass compliance testing in plant material phase can not be utilized in extraction.
BUSINESS RAMIFICATION OF
BATCH DESTRUCTION

~ Cost of goods (Flower Production)
~ Lost revenue
~ Lost employment opportunities
~ Higher cost of therapeutic products to patients
USFDA APPROVED STERILIZATION TECHNIQUES

~ Steam Sterilization
~ Dry Heat Sterilization
~ Gas Sterilization
~ Ionizing Radiation
~ Sterilizing Filtration
~ Unidirectional Aseptic Processing
STERILIZATION STUDY PURPOSE AND GOALS

~ **Purpose:** To evaluate the potential of a well-designed solvent extraction process to deactivate and remove microbial contaminants from compromised feed material.

~ **Goals**

  ~ Evaluate the efficacy of Organic Remedies Inc.’s hydrocarbon and supercritical manufacturing lines for the removal of microbial contaminants during the extract manufacturing process.

  ~ To determine the critical steps in the manufacturing process that remove microbial contaminants that were present in feed material.

  ~ To determine whether Organic Remedies Inc.’s manufacturing process are capable of creating raw extracted materials that conform to current PADOH regulations when contaminated feed stock is utilized in the extract manufacturing process.
MANUFACTURING: CARBON DIOXIDE PIPELINE

*PLANT MATERIAL/*EXTRACTION → WINTERIZATION → FILTRATION

* SOLVENT RECOVERY ← STERILIZATION ← CLARIFICATION

*DECARBOXYLATION → *CANNABINOID DISTILLATION

* Indicates indicates sample collection during study
MANUFACTURING: HYDROCARBON PIPELINE

*PLANT MATERIAL/EXTRACTION → WINTERIZATION → FILTRATION

* SOLVENT RECOVERY ← STERILIZATION ← CLARIFICATION

*PURGING

* Indicates indicates sample collection during study
STUDY METHODOLOGY

~ PLANT MATERIAL AND BATCH SIZE
~ REPLICATES
~ HYDROCARBON PROCESSING AND REPLICATES
~ CARBON DIOXIDE PROCESSING AND REPLICATES
~ STATISTICAL DESIGN
~ SAMPLE TESTING
An Analysis of the Efficacy of Organic Remedies Inc. Manufacturing Infrastructure for the Production of Sterile Extracts Derived from Contaminated Feed Stock

June-Wells MR\(^1\), Fochtman FW\(^2\), Balin B\(^3\), Petroski WP\(^1\), Niesen D\(^4\), and Hauser E\(^1\)

**Total Yeast and Mold By Stage**

![Graph showing log CFU/g for Total Yeast and Mold by stage.](image)

*10\(^{6}\) CFU/g used to indicate TNTC

**Total Aerobic Bacteria By Stage**

![Graph showing CFU/g for Total Aerobic Bacteria by stage.](image)

**Total Enterobacteria By Stage**

![Graph showing CFU/g for Total Enterobacteria by stage.](image)
## Hydrocarbon Pathway Sterilization Data

<table>
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<tr>
<th>Stage</th>
<th>Strain</th>
<th>THC (%)*</th>
<th>CBD (%)*</th>
<th>TTI Can (%)</th>
<th>TTI Terp (%)</th>
<th>TYM cfu/g</th>
<th>TAB cfu/g</th>
<th>ENT cfu/g</th>
<th>E. coli cfu/g</th>
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*indicates percentages calculated from the conversion of the acid-form percentages plus the percentage of the neutral form.

Converted % = (0.87*Acid Form %) + Neutral Form %
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June-Wells MR¹*, Fochtman FW², Balin B³, Petroski WP¹, Niesen D⁴, and Hauser E¹

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Converted % = (0.87*Acid Form %)+ Neutral Form %
STUDY FINDINGS

Organic Remedies Inc. found through this research initiative that the infrastructure deployed at the manufacturing facility to comply with CFR21's definition of unidirectional aseptic processing was highly efficacious for the removal of biological contaminants and their metabolites.

- The critical phase for removal of biological contaminants and their metabolites was the extraction infrastructure.

- All other steps in the process maintained or enhanced the capture of biological contaminants and their metabolites.

We assert that Organic Remedies Inc.'s manufacturing laboratory's infrastructure and unidirectional aseptic processing design results in raw materials that exceed the regulatory limits set forth by The State of Pennsylvania.

Finally, we assert that there is little need for testing prior to extraction due to the finding herein and because of the regulatory requirement for final product testing prior to release to the medical marijuana patients of Pennsylvania.
CONCLUSIONS
THANK YOU

MARK JUNE-WELLS, PH.D.
CHIEF SCIENCE OFFICER – ORGANIC REMEDIES INC.
M.JUNEWELLS@ORGANICREMEDIESTPA.COM
MMAB Meeting

- Additional Discussion/Q&A
- Next Board Meeting
  - September 27, 2022 (10:00am to noon)