
QUALITY CONFESSIONS INSIDE THE LICENSED CANNABIS INDUSTRY

2026 09 24

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SE VUOI TORTELLI CON FIORI DI CANAPACCIA...



Take cannabis flowers without leaves and cook with pancetta (pork belly), add water and boil until meat is [the pork] is cooked. [Deglaze and pound] both together until fine. Add cascio [cheese] equal to the amount of meat, spice, and make the tortelli [with this as filling]

-Fragment of a 14th century Italian Cookbook, ca. 1350-1405, recipe xxvi

SCIENCE AND SOCIETY OF CANNABIS TORTELLINI

A strategic material – Cannabis (hemp) is required for rope and cordage for naval strength

State regulated – Monopoly controls processing and pricing

The recipe is for the upper classes

Cannabinoids

- Use only flowers – Flowers contain trichomes that express cannabinoids, leaves do not.

Extraction

- Cook in pork fat– Cannabinoids are lipophilic, fat extracts them.

Decarboxylation

- Boil again – Heating causes decarboxylation, or changing acid forms (THCA, CBDA) to active forms (THC, CBD)

SOCIETY AND SCIENCE IN CANNABIS TODAY

Society

- Federally illegal
 - NO use in foods for either CBD or THC
- Regulatory in the NE states
 - Maine
 - Massachusetts
 - Vermont
 - New Hampshire – medical monopoly, highly controlled
- Societal uptake and use

Science

- Cannabinoids
- Pharmacology
- Current processes
- Quality journeys

THE REGULATORY ENVIRONMENT



Massachusetts

- Medical 2012
- Adult use 2018
- Home grow permitted
- Mandatory testing for all dispensed products
- METRC TNT (Track and Trace)



Maine

- Medical 1999
- Adult Use 2020
- Home grow permitted
- Mandatory testing for adult use, none for medical
- METRC TNT (Track and Trace)

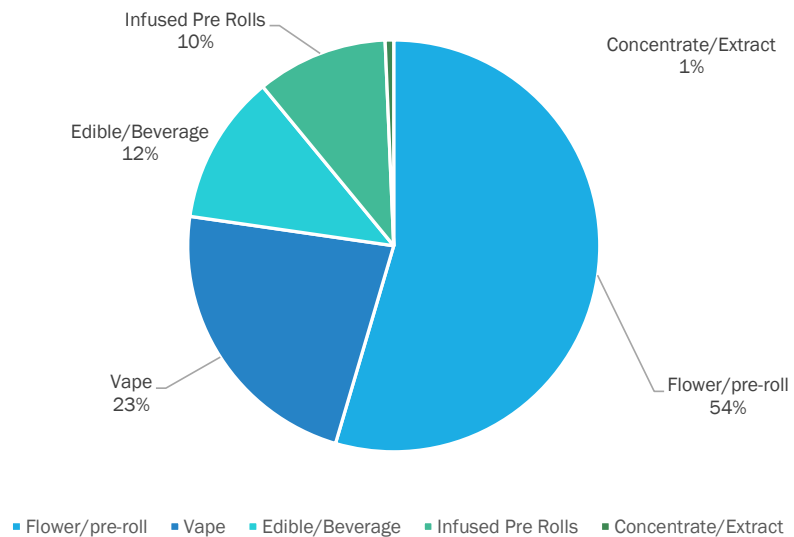


Vermont

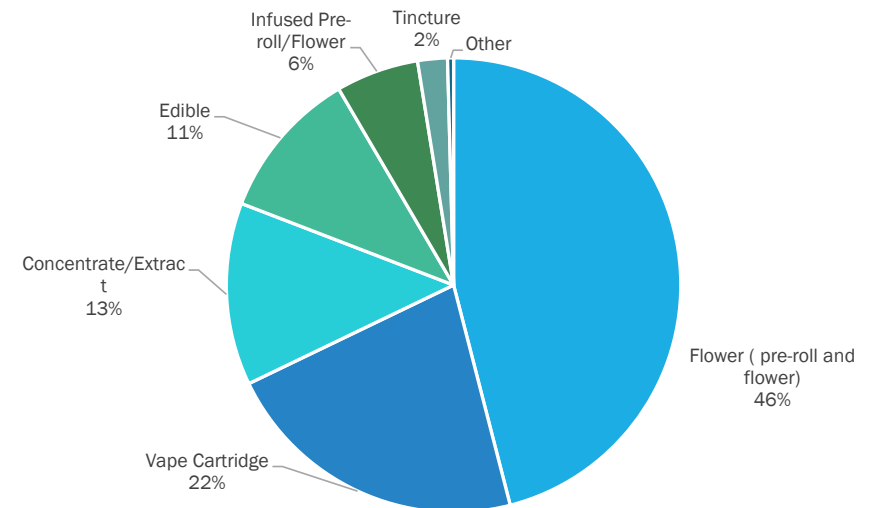
- Medical 2004
- Adult Use 2022
- Home grow permitted
- Mandatory risk-based testing by product category
- State TNT (Track and Trace)

PRODUCTS ARE DIVERSE BUT SIMILAR ACROSS STATES

Massachusetts adult use cannabis sales



Vermont Adult Use Product Registrations



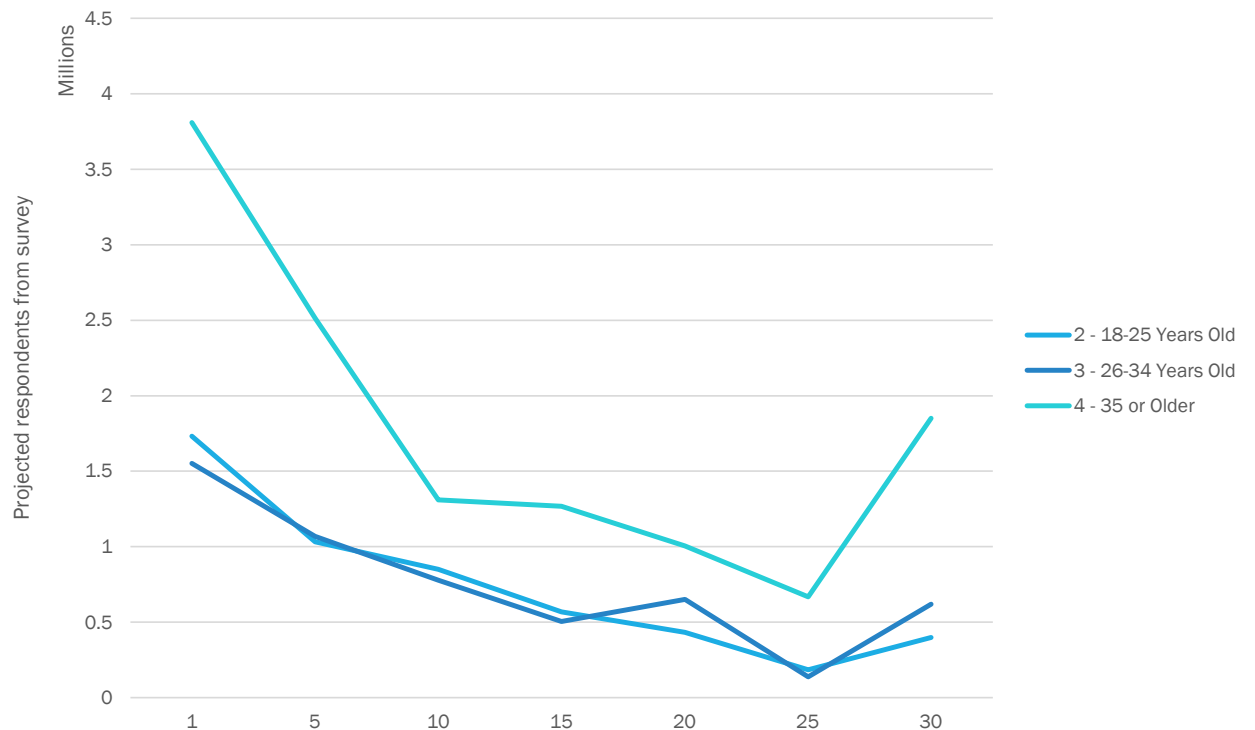
CONSUMERS ARE ABOVE US MEDIAN AGE

Motivations for use fall into fixed categories

1. Social enjoyment
2. Pain relief
3. Anxiety relief
4. Better sleep

Frequent users drive the industry

Cannabis use Frequency US 2024 SAMHSA Data



REACHING A STABLE MARKET

Approximately \$2.4bn sales rate/year

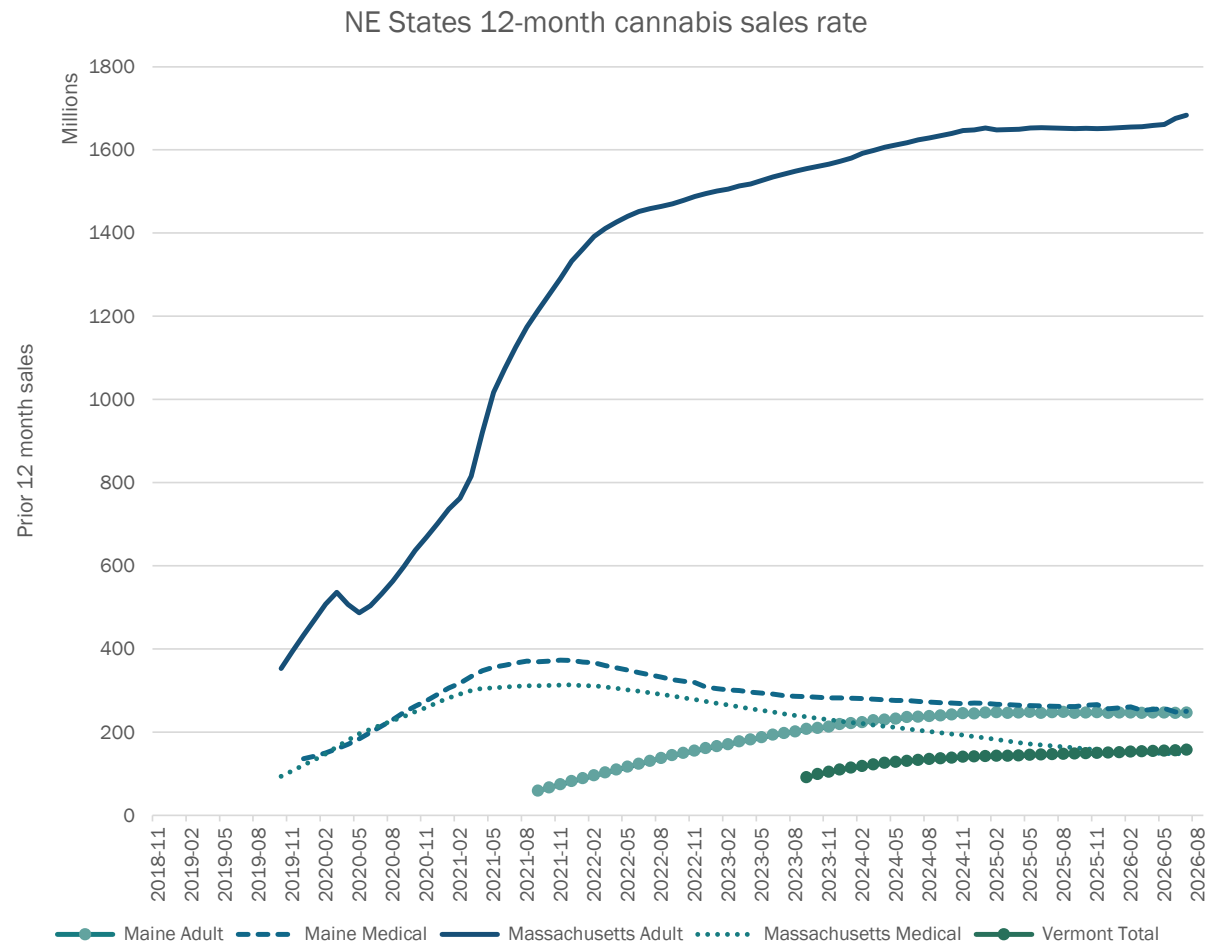
Medical influenced by tax and local regulation

Average adult-use expense is \$274/capita/year

Maine: \$222

Massachusetts: \$291

Vermont: \$310

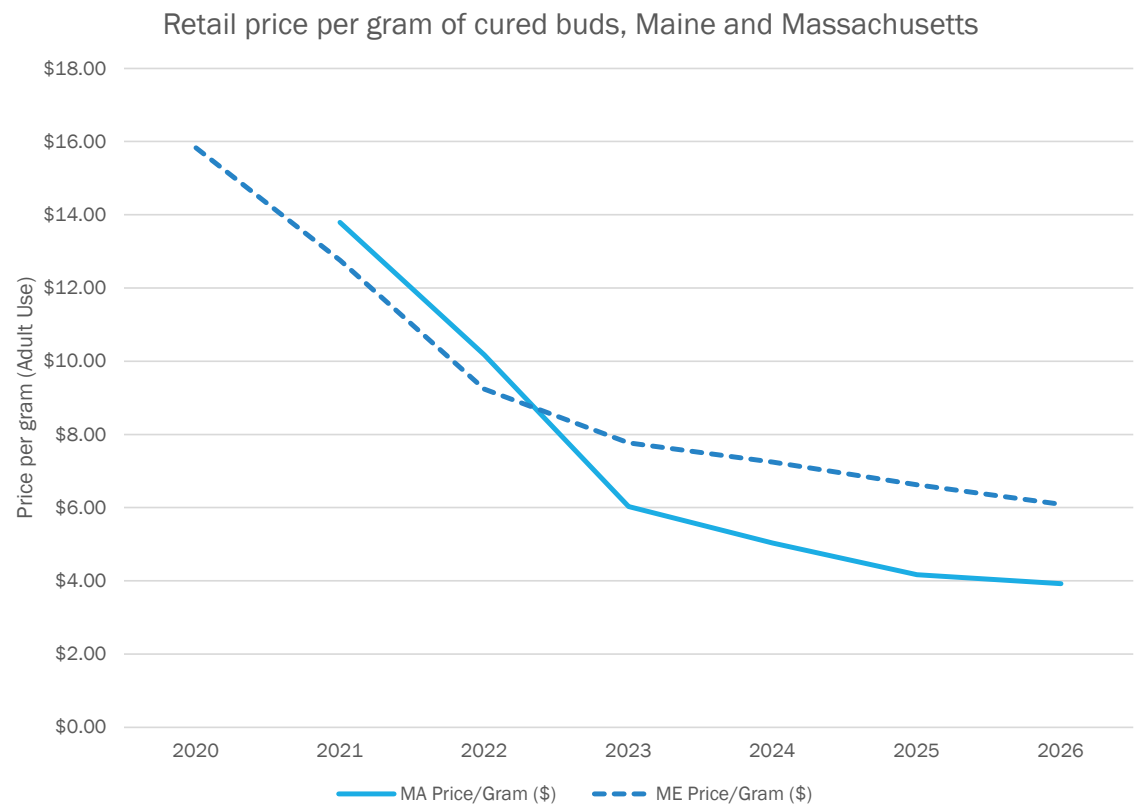


THE MARKET WORKS TO REDUCE COSTS

Cost reduction averages 20% per year

Reduces illicit market

Drives cross border purchasing

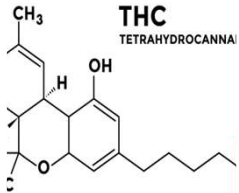




PHARMACOLOGY (VERY BRIEF)

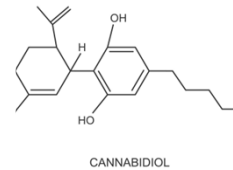


THE PRIMARY CANNABINOIDS: THC AND CBD



THC

- Discovered 1964
- Psychotropic, anti-inflammatory, neuro-protective, anti-nausea, and analgesic effects
- 11-OH-THC, a metabolite from digestion is 4 x more psychoactive than THC



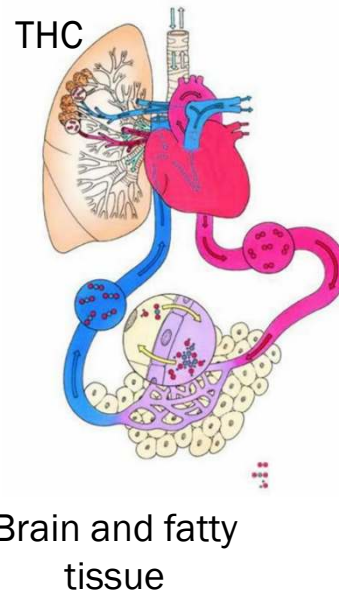
CBD

- Discovered 1940
- Non-psychoactive (87%), with a wide range of molecular targets
- Mitigates side effects of THC
- Used in seizures (childhood epilepsy-Epidiolex®), anxiety, some evidence for analgesia, some evidence for opioid withdrawal
- 7-OH-CBD is main metabolite, equally anticonvulsive as CBD

SMOKED VERSUS INGESTED CANNABINOIDS

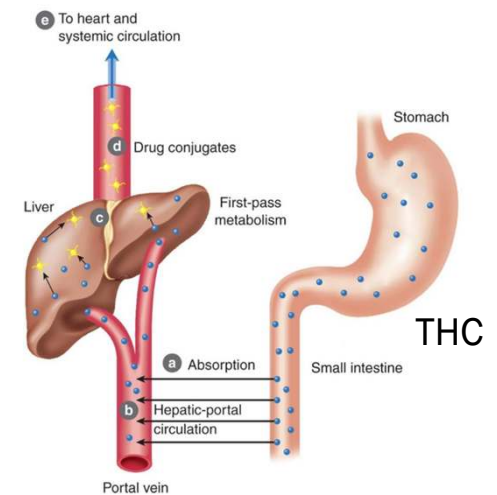
Inhaled THC. (CBD) other cannabinoids

- Inhaled THC enters bloodstream directly
- Distributes rapidly to the brain and fatty tissue
- Liver finally converts remaining THC to 11-OH-THC, 4x as psychoactive as THC
- Faster uptake
- Shorter effect
- ~25% bioavailability



Ingested THC, (CBD), other cannabinoids

- Ingested THC is digested and passes primarily to the liver
- Liver oxidizes THC to a 11-OH-THC, 4x as psychoactive as THC
- Slower uptake
- Longer effect
- ~15% bioavailability



DOSING GUIDELINES (NOT MEDICAL ADVICE)

Body Weight		THC Edibles/Beverages/Tinctures			CBD ingestibles
Pounds	Kg	Low Tolerance	Medium Tol	High Tolerance	Acute therapeutic dose
100	45.5	3	7	16	11
120	54.5	4	8	19	14
140	63.6	4	10	22	16
160	72.7	5	11	25	18
180	81.8	6	12	29	20
200	90.9	6	14	32	23
220	100	7	15	35	25
240	109.1	8	16	38	27
260	118.2	8	18	41	30
280	127.3	9	19	45	32
300	136.4	10	20	48	34
mg/kg		0.07	0.15	0.35	0.25
Doses are from JOURNAL OF PSYCHOACTIVE DRUGS https://doi.org/10.1080/02791072.2025.2449932					
THC Based on 0.07 mg/kg from CESAMET, NABILONE, Marinol and others					
CBD from anxiety and sleep studies https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6326553/					

- Ingestibles must be dosed by body weight
- Table compiled from FDA IFUs for THC approved drugs; limited CBD studies
- Effects will vary with food and mood
- Ask your doctor about prescription drug interactions! (CYP 450 competition)

SETTING THE STAGE FOR QUALITY JOURNEYS

Situation	Implication
A flattening market	Operators are seeking new products and new consumers
High tolerance users drive the market; frequent purchases with desire for lower prices	Operators seek effective and efficient ways to address this subgroup
Price erosion of flower and flower based inhalables	Operators want efficiency and alternate products
Client purchase decisions based on consistency and safety	Operators want assistance in assuring consistency and safety



QUALITY JOURNEYS

COVID KAIZEN

LEAN FOR GUMMY PRODUCTION

GEMBA WALKS

CONTROL CHARTS AND PROCESS CAPABILITY

POWER OF INFORMATION IN VAPE PENS



THE COVID KAIZEN



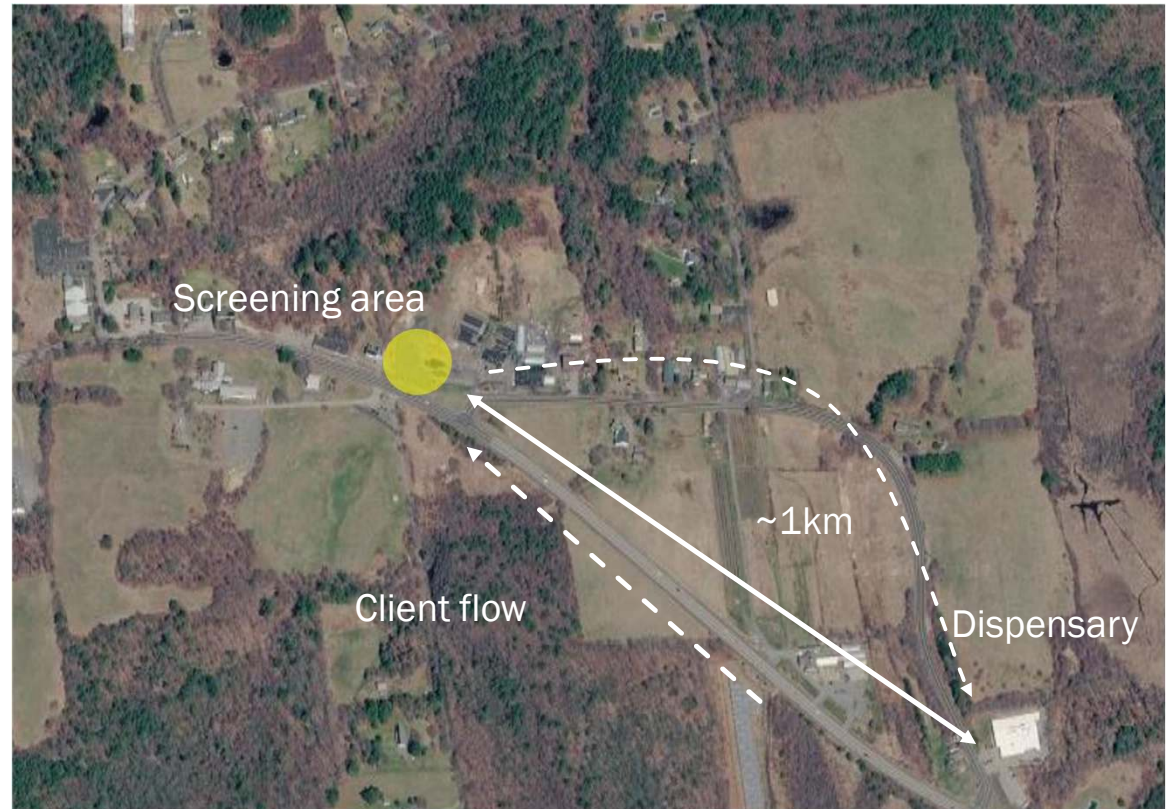
CANNABIS IS AN ESSENTIAL BUSINESS

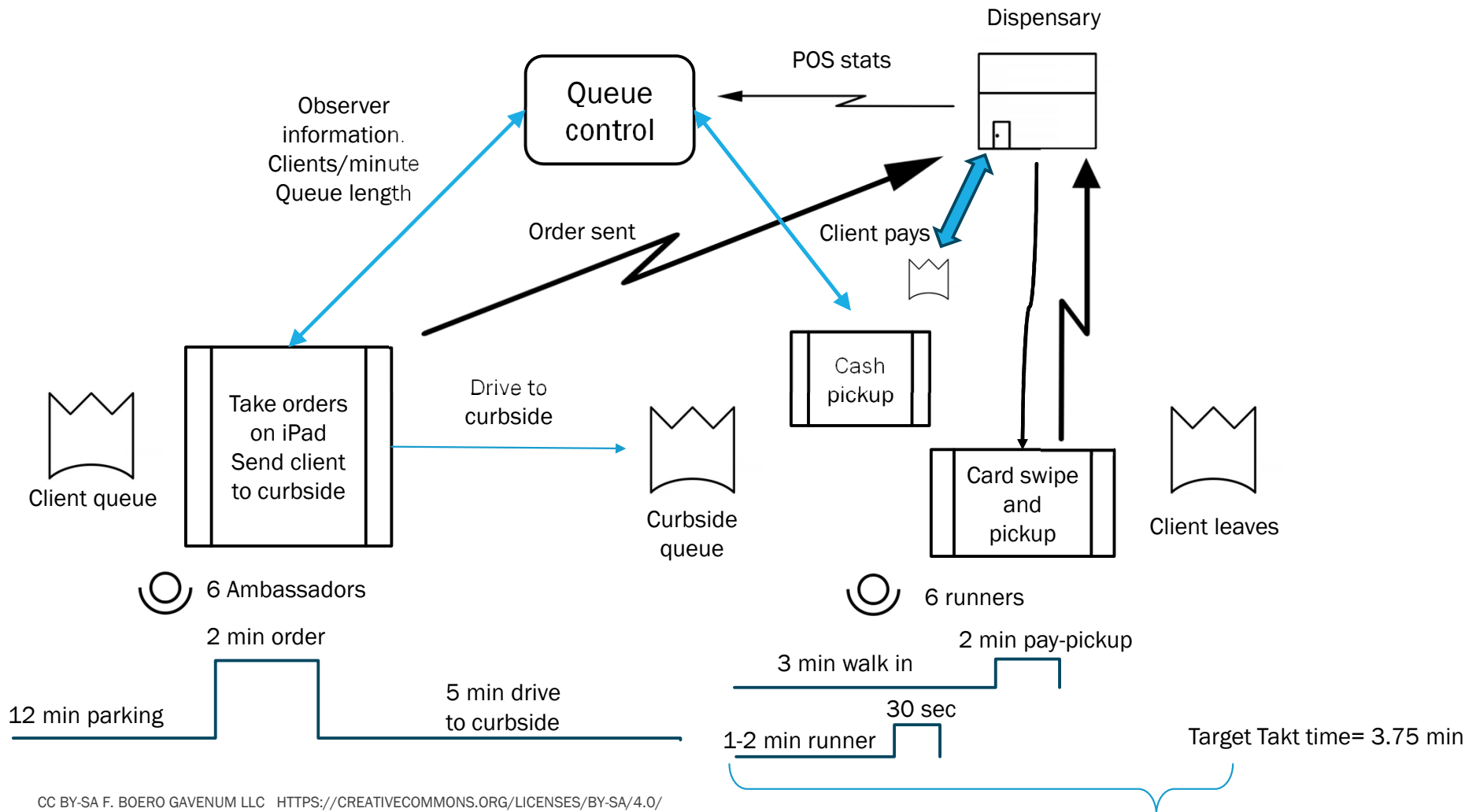
First permitted opening during
COVID

CCC required client screening
off-site,

Curbside pickup with minimal
contact.

Create a live-time VSM to
maximize service





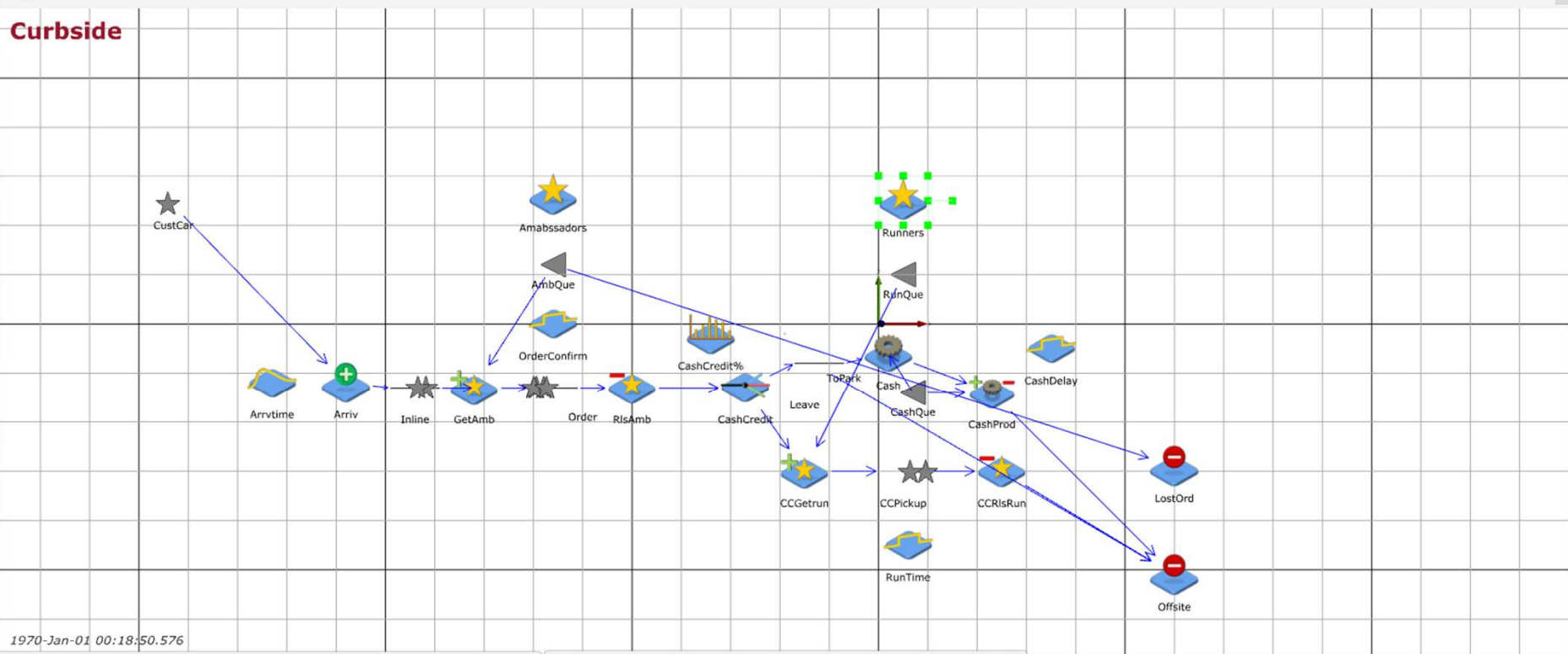
PROBLEM SOLVING FOR CURBSIDE PICKUP

Definition	Measure	Analyze	Innovate Implement	Control
• Predicted customer volume to be 3-4x normal • All in-store transactions limited • Serve the maximum number of clients possible	• Establish observers at key process points to measure service times • Read POS system to provide breakdown for cash/credit; medical/rec	• Set up model in Jaam Sim • Set parameters from observers and POS to simulate queues and service times • [Cash patients were the bottleneck]	• Shift runners from curbside to cash transactions inside • Shift ambassadors in response to abandonment to curbside	• Confirm changes via observers and POS in real time • Adjust as needed for arrivals • [*Handled 3.5x normal daily volume*]

- Graphics Objects
- Probability Distributions
- Basic Objects
- Resource Objects
- Process Flow
- Calculation Objects
- Fluid Objects
- SubModel Objects
- Pre-built SubModels

- CashDelay
- OrderConfirm
- RunTime
- ErlangDistribution
- Arrivtime
- DiscreteDistribution
- CashCredit%
- Resource
- Resource
- Amabassadors
- Runners
- Process Flow
- SimEntity
- Arriv_24
- Arriv_25
- Arriv_26
- Arriv_27
- Arriv_28
- Arriv_29
- Arriv_30
- Arriv_31
- Arriv_32
- Arriv_33
- CustCar
- EntityGenerator
- Arriv
- EntitySink
- CC BY-SA F. BOERO GAVENUM LLC
- LostOrd
- Offsite

Curbside



1970-Jan-01 00:18:50.576

Input Editor - Runners

Key Inputs Options Graphics

Keyword	Default	Value
Name	None	Runners
Description	None	'In store to car'
StrictOrder	FALSE	
Capacity	1	6

Property Viewer - Runners

Entity DisplayEntity AbstractResourceProvider Resource

Property	Type	Value
\$assertionsDisabled	boolean	true
active	BooleanInput	true
attributeDefinitionList	AttributeDefinit...	[]
cloneList	ArrayList	<null>
clonePool	ArrayList	<null>
desc	StringInput	In store to car
entityName	String	Runners
entityNumber	long	376
flags	int	1632
inList	ArrayList	[Runners, In store to car, false, true, [], [], 0...

Output Viewer - Runners

Output	Value
UserList	{[[CashProd], [CCGetrun]]}
Capacity	6
UnitsInUse	2
AvailableUnits	4
UnitsSeized	26
UnitsReleased	24
UnitsInUseAverage	2.61655
UnitsInUseStandardDev...	1.74130
UnitsInUseMinimum	0
UnitsInUseMaximum	6
UnitsInUseTimes	{0.0486257[h], 0.0514898[h], 0.0339082[h], 0.0...

LEAN FOR EDIBLES (GUMMIES)



10 GUMMIES

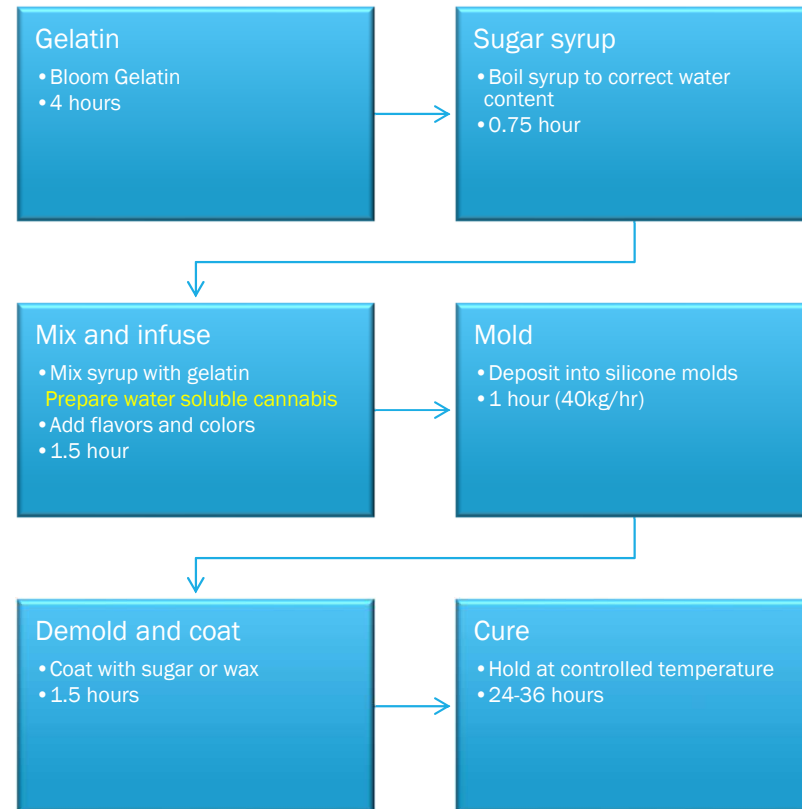


INFUSED, BATCH GELATIN GUMMY PROCESS

Typical for 10,000 units, 40kg
total weight, 500 retail
packages. Total value at retail:
\$10,000

Total time 8.75 hours in kitchen

24-36 hours in curing before
packaging



ISSUES WITH THE CONFECTIONERY APPROACH FOR INFUSED GUMMIES

Large setup times

- 4 hours to prepare gelatin
- 1.5 hours to create a cannabinoid emulsion

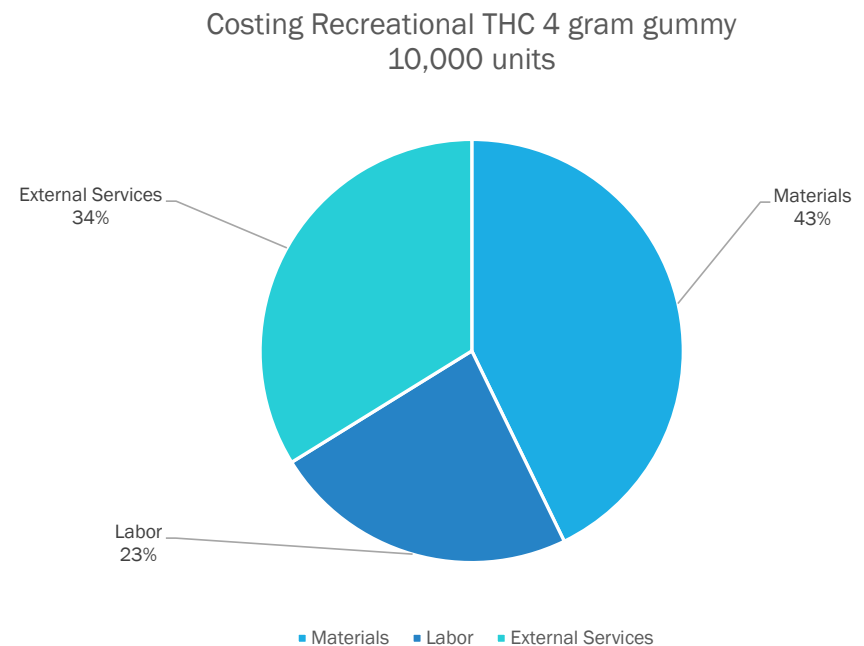
High variability

- Each batch adds variability: gelatin hydration, emulsion prep, water boil off
- Risk of not meeting state requirements of $\pm 10\%$ dose accuracy

Limits production to 1 batch per day

STRUCTURAL AND FINANCIAL PROBLEMS

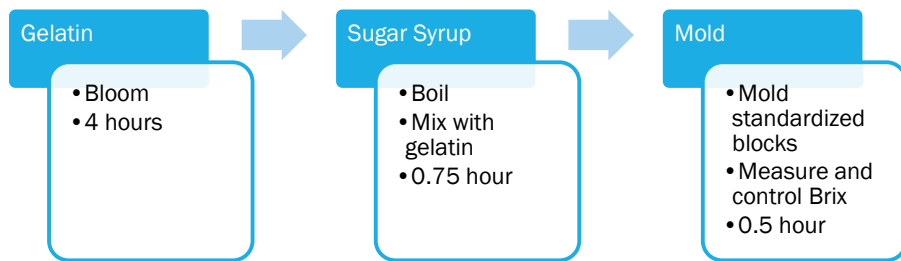
- External services (laboratory testing) makes up 1/3 the cost—paid by daily production, not volume.
- Manufacturers want to maximize daily production while maintaining consistency



SOLUTION—CREATE SUB PROCESSES

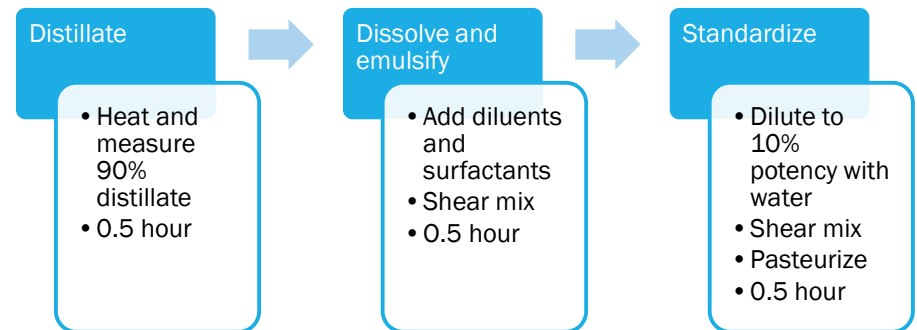
GELATIN AND CANNABINOID EMULSIONS

Gelatin block preparation



- Gelatin may be remelted – thermoreversible
- Can produce large quantities, off-line.
- No cannabinoids—no security controls
- Standardize and control Brix content

Cannabinoid emulsions



- Standardized potency simplifies operations; reduces errors
- Pasteurize to permit long-term storage
- Can produce large quantities off-line.

SUB PROCESSES

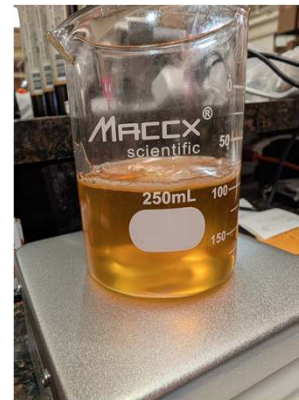
Gelatin

- Syrup gelatin mixing and molding



Emulsion

- Conversion of hydrophobic THC distillate (L) to water soluble emulsion (R), standardized at 10% THC



LEAN PROCESS

Typical for 20,000 units, 80kg total weight, 1000 retail packages.

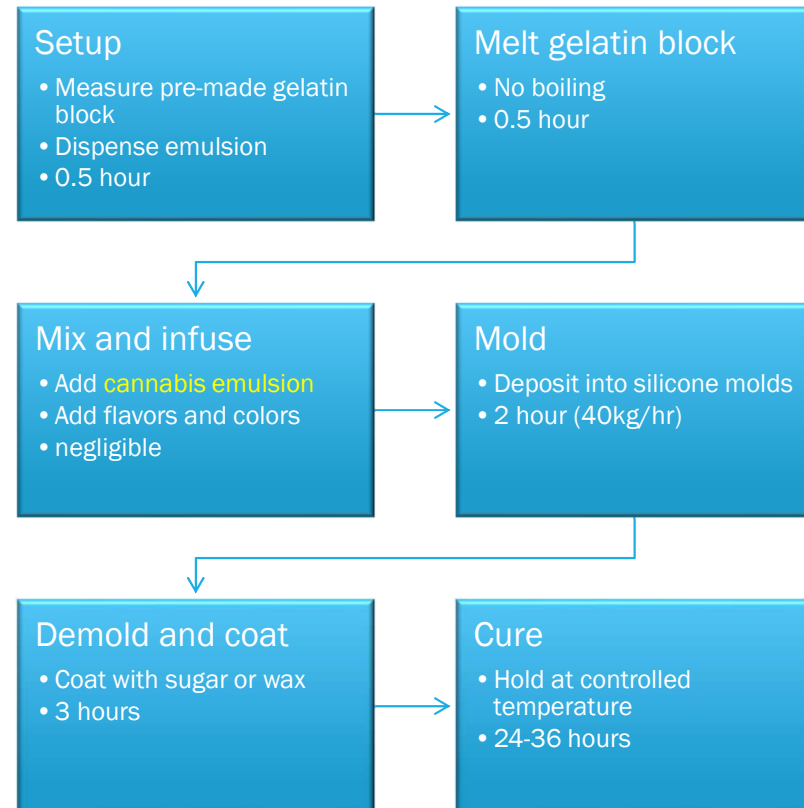
Total value at retail: \$20,000

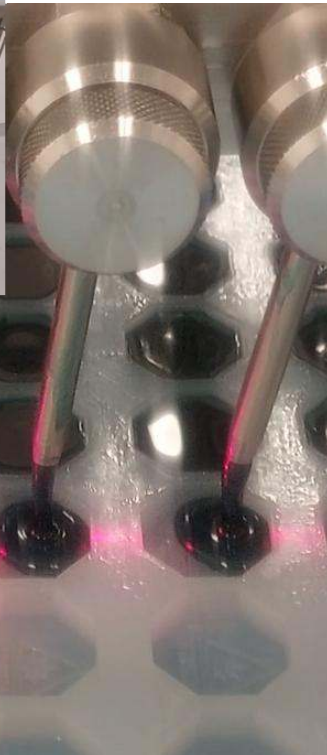
Total time 6 hours in kitchen

Allows two mixes per day

24-36 hours in curing before packaging

Standardization minimizes dose risk







GEMBA WALKS



CLIENT REQUESTS

Disorganized areas

“Can you give us more room?”

“Do a 5s for us”

Set the goal

Define the area

Be respectful

Reflect and share findings

Brainstorm
implement

PROBLEM: INVENTORY IN AISLES AND CORRIDORS

- Most inventory related to pre-rolls and packaging
- Ask questions after the Gemba walk
 - What's happening here? (product damage, lost inventory)
 - How do you use these? (obtain, load machine, etc.)
 - How many do you use?
(One lot is about 1200 units, use once a week)
~5000/month
 - How many do you purchase? (about 100,000)
 - Five whys in subsequent sessions



AFTER 5 WHYS? – ONE ISSUE

- Cash accounting basis; departments measured on what they spend in the month they spend
- Operations manager and kitchen manager incentivized to reduce cash spend per unit
- Purchases were at the maximum quantity to obtain discounts—lower price per unit.

THE FINAL QUESTION – WHEN DO YOU RECOGNIZE SAVINGS?

- Working with the managers and finance, agreed that *savings are only recognized when the inventory is used in a product to be sold*
- Created models to show actual costs
 - Cycle counts – Count boxes every month
 - Obsolescence risk – About 5%/year; state changes specs
 - Storage costs based on sq. ft. used
- Which is better: Buy 30000 units every 6 months at \$0.50 a unit or 100000 units at \$0.35 per unit?
- Buying at a discount costs the company \$8,200 in cash flow.

Base Case	Jan	Feb	Mar	Apr
Inventory	30000	25000	20000	15000
New Case				
Inventory	100000	95000	90000	85000
Use benefit	\$ 750.00	\$ 750.00	\$ 750.00	\$ 750.00
Incremental Spend	\$ (20,000.00)			
Incremental Costs	\$ (206.58)	\$ (206.58)	\$ (206.58)	\$ (206.58)
Net (benefit-costs)	\$ 543.42	\$ 543.42	\$ 543.42	\$ 543.42
Differential cash value	(\$8,231.88)			
	5% discount rate			



DEMONSTRATING THE DEMING FUNNEL EXPERIMENT

Edibles testing and control charts

CHALLENGES TO DOSING EDIBLES

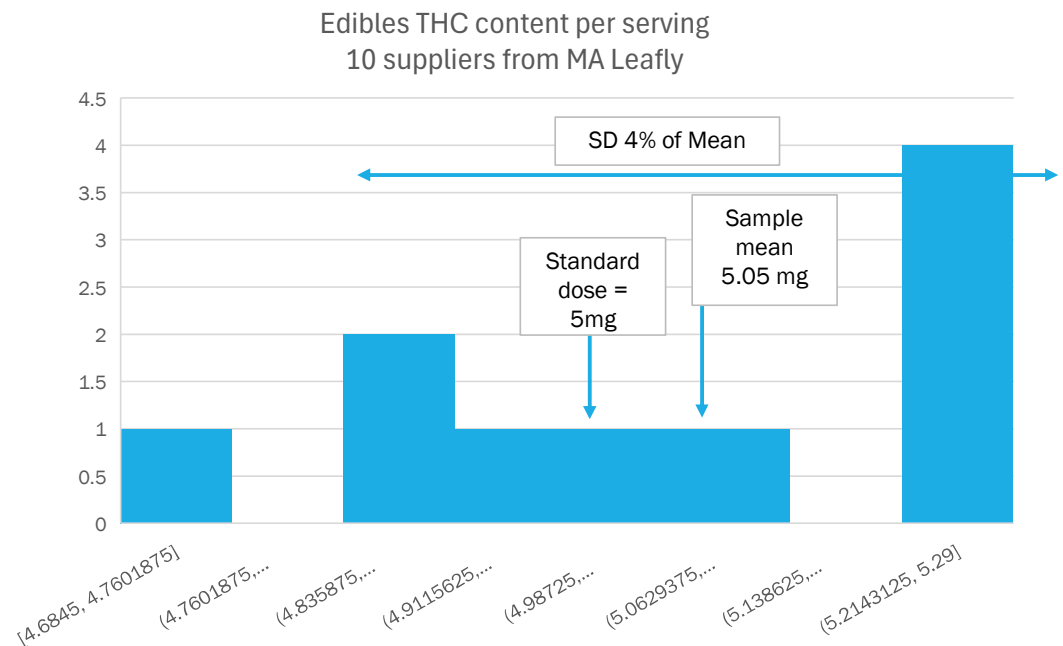
Challenge	Current state	Issues
Analytic methods have poor repeatability at low THC concentrations	Edible concentrations • Gummies 0.1-0.2% THC • Chocolates: 0.2% • Beverages: 0.004%	• AOAC SMPR (Standard Method Performance Requirement 2017) has >7% allowable repeatability variation (at 1 SD) • No NIST standards or performance testing
Market risks for exceeding spec limits	• State requirements $\pm 10\%$ tolerance • 100mg total package, 5 mg/serving [4.5-5.5] mg per piece	• Cannot sell if exceeds upper limit • Customer reluctance to purchase below lower limit; discount

REPRODUCIBILITY DISCUSSIONS WITH CLIENTS

- Show the state of the market ($\pm 4\%$ at 1 SD)
- Build a system variation study (Gage R&R)
 - Weight accuracy (ingredients) $\pm 1\text{-}2\%$ at 1 SD
 - Dispense accuracy (automated) $\pm 0.4\%$ at 1SD
 - Emulsion accuracy: $\pm 7\%$
- Work with lab for their RSD results from ISO 17025
 - Typical is $\pm 5\text{-}7\%$ 'R&R'
- Propagate errors

$$TSD = \sqrt{\sum SD^2}$$

- TSD $\sim 9.9\%$ Process is incapable



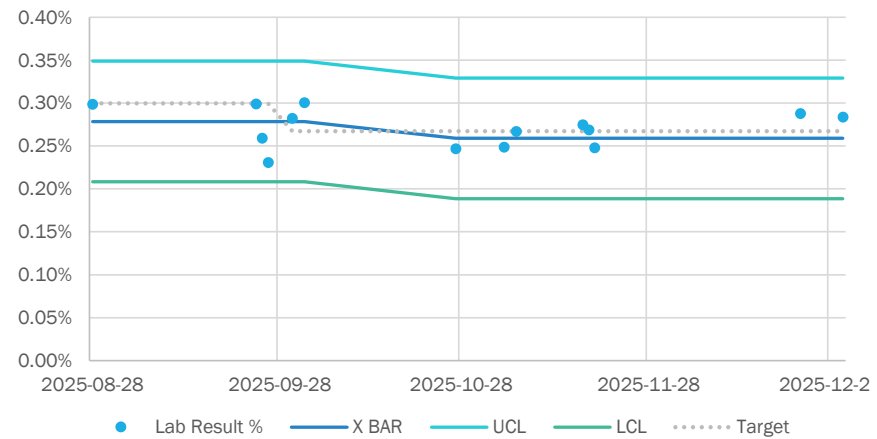
MONITOR DEEMING MONITOR

Set up automated Excel or other
XmR charting.

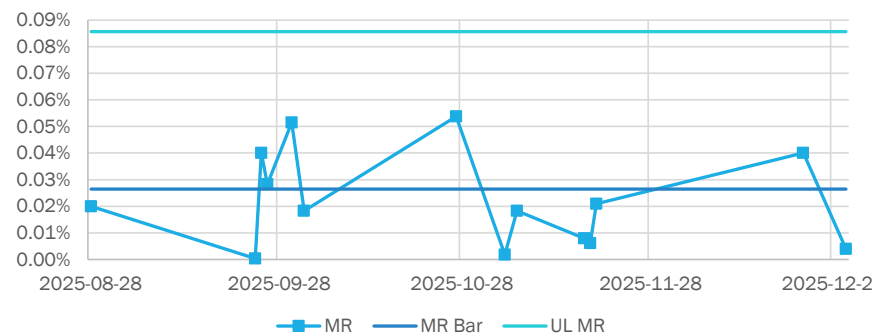
Train on interpretation

Share with management and lab

X lab results



MR Lab results



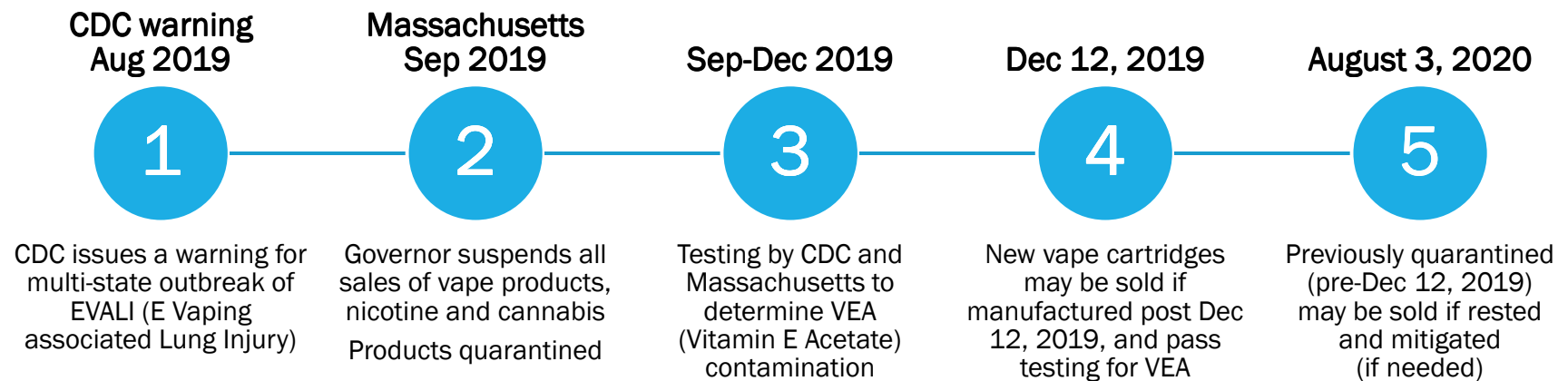
THE POWER OF KNOWLEDGE SAFER VAPE PENS

*Data are random and
miscellaneous, knowledge is
orderly and cumulative*

Donald Wheeler
Understanding Variation



THE EVALI CRISIS



CLIENT CHALLENGE—NO VEA; WHERE IS THE LEAD COMING FROM?



Approximately 60,000
quarantined vape pens to retest



No VEA (Vitamin E Acetate) used
in any formulation



Problem:

9% of retested samples showed
Pb (lead) above state limit of
500ppb

36% tested positive for Pb, yet
below state limit

No lead detected in original pens

A CAPA OPPORTUNITY

Impact Assessment



- ☐ Get everyone at the table: Labs, vape hardware suppliers
- ☐ Contacted other manufacturers to understand scope of the problem

Root cause analysis



- ☐ Obtain vape hardware certifications; multiple suppliers
- ☐ Analyze pre and post fill data for trends or other correlation

Corrective Actions



- ☐ What can be done to eliminate the problem
- ☐ How to implement industry wide?

Client Name: [REDACTED]

Address: [REDACTED]

Supplier: [REDACTED]

Materials: Lead-free copper

Contact person: /

Element	Material	Concentration
Arsenic(As)	7440-38-2	0.0441%
Iron (Fe)	7439-89-6	0.0196%
Lead(Pb)	7439-92-1	0.0069%
Bismuth(Bi)	7440-69-9	1.4221%

FIRST FINDINGS

Distributors received products from multiple suppliers

Supplier certifications, when available, were contradictory

0.0069% Lead (pb) is 69,000 ppb!

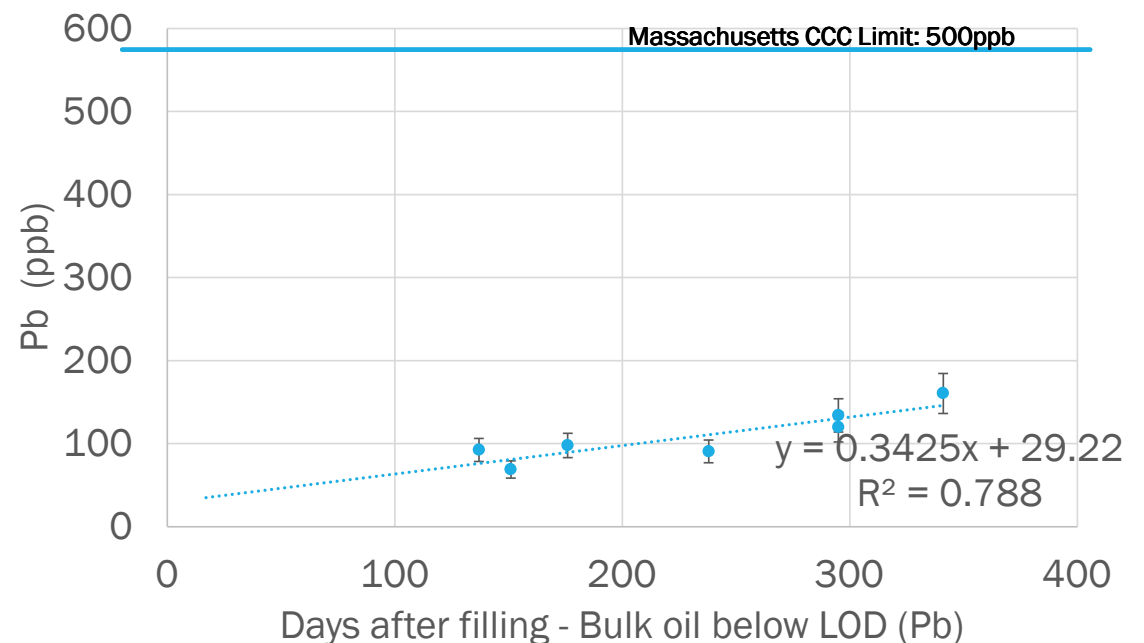
SECOND FINDING

Lead leached into vape fluid over time (about 3 ppb/week)

Chemistry:

- Vapes were designed for nicotine salts with different pH than cannabinoids
- Vapes are intended for short term use—cartridge used within a week.

Pb in THC vape pens after controlled storage (20-25C)



CONSUMER AND INDUSTRY ISSUES



- Consumers usually stored THC cartridges for long period in their cars
 - Temperature excursions in the center console
 - Stored for up to 6 months
- Similar lead contamination was noted by Canadian processors—Valens Company (now SNDL)



CORRECTIVE ACTION PLAN

- Manufacturers should implement purchasing controls and documentation compliant with 21 CFR 820.50, adding zero lead limits as an essential requirement
 - Support with EPA metals detection methods for solid waste (can be completed in any laboratory)
- Establish shelf-life limits and clearly communicate storage requirements to the consumer
- Establish accelerated aging testing for any vape lot to confirm compliance at end of shelf life
- Test for compliance for all specifications at end of shelf life.

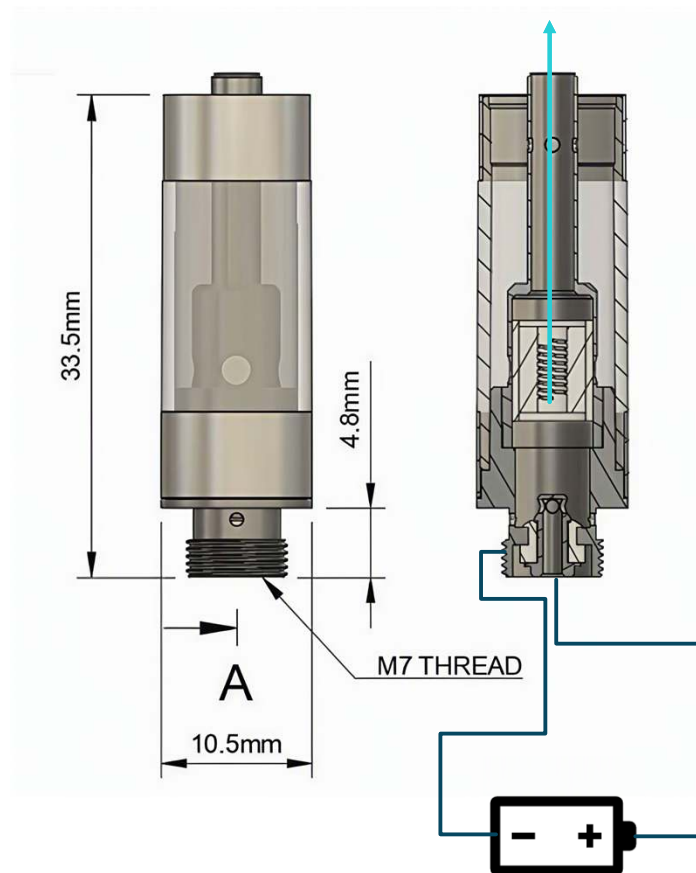
EPA LEACHATE TEST

Test Method 1311 (modified)

Analyze test liquid (citric acid)
using ICMS mass spectrometry.

Easy to implement

No cannabis or extracts involved



Fill with citric acid 5%
w/w and leach at room
temperature (20-25C) for
24-48 hours.

ACCELERATED AGING

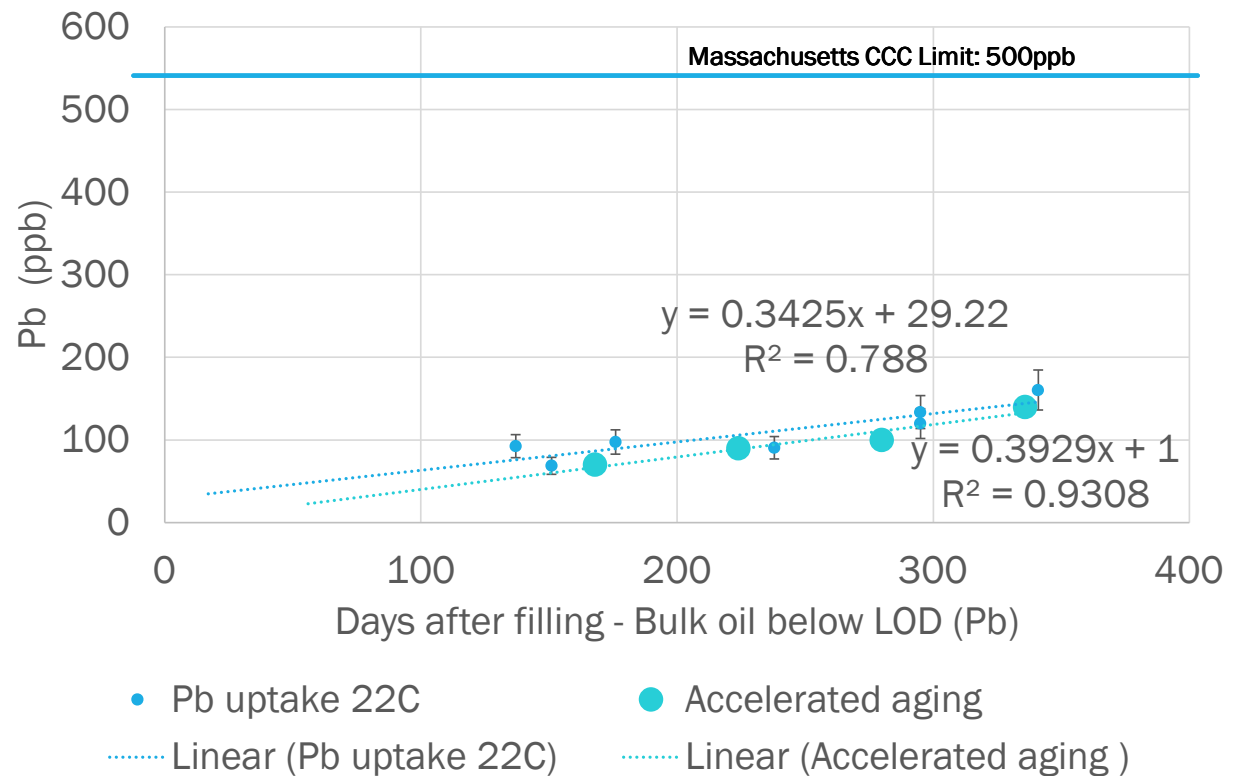
Use FDA consensus method based on ASTM F 1980

Full shelf-life testing may be impractical for market requirements

Use conservative factor of 2 for testing. ΔT of 10C doubles rate or halves time for testing (30C rise cuts time by factor of 8)

$$\text{Relative rate} = e^{0.693(T_1 - T_0)/10}$$

Vape pen Pb after controlled storage (20-25C) and accelerated aging at 50C



ACTION PLAN IMPLEMENTATION

- Communicated to the FDA, AOAC and Health Canada at the AOAC round table on March 10, 2020
 - Dr. Houssain Al Arabi, Ph.D, Valens Canada, Francis J. Boero, Ph.D., Gavenum LLC, Mr. Adam Sanders, Cultivate LLC
 - (Covid controls announced on March 11—actions were placed on the back burner...)
- Nevertheless
 - Massachusetts CCC implemented new rules by 2021 requiring certification of components (purchasing controls)
 - Colorado MED (Marijuana Enforcement Division) implemented shelf-life testing and testing of vaporizer emission (Jan 2022)

QUALITY JOURNEYS

- Covid Kaizen
- Lean for gummy production
- Gemba walks
- Control charts and process capability
- Power of information in vape pens

Why are we here?

- States are decriminalizing and regulating to reduce social harms (incarceration, enforcement costs) **and**, obtain tax revenue
- Current regulations make products safe
- Safe ≠ Harmless
- The current system needs significant work



THANKS

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