



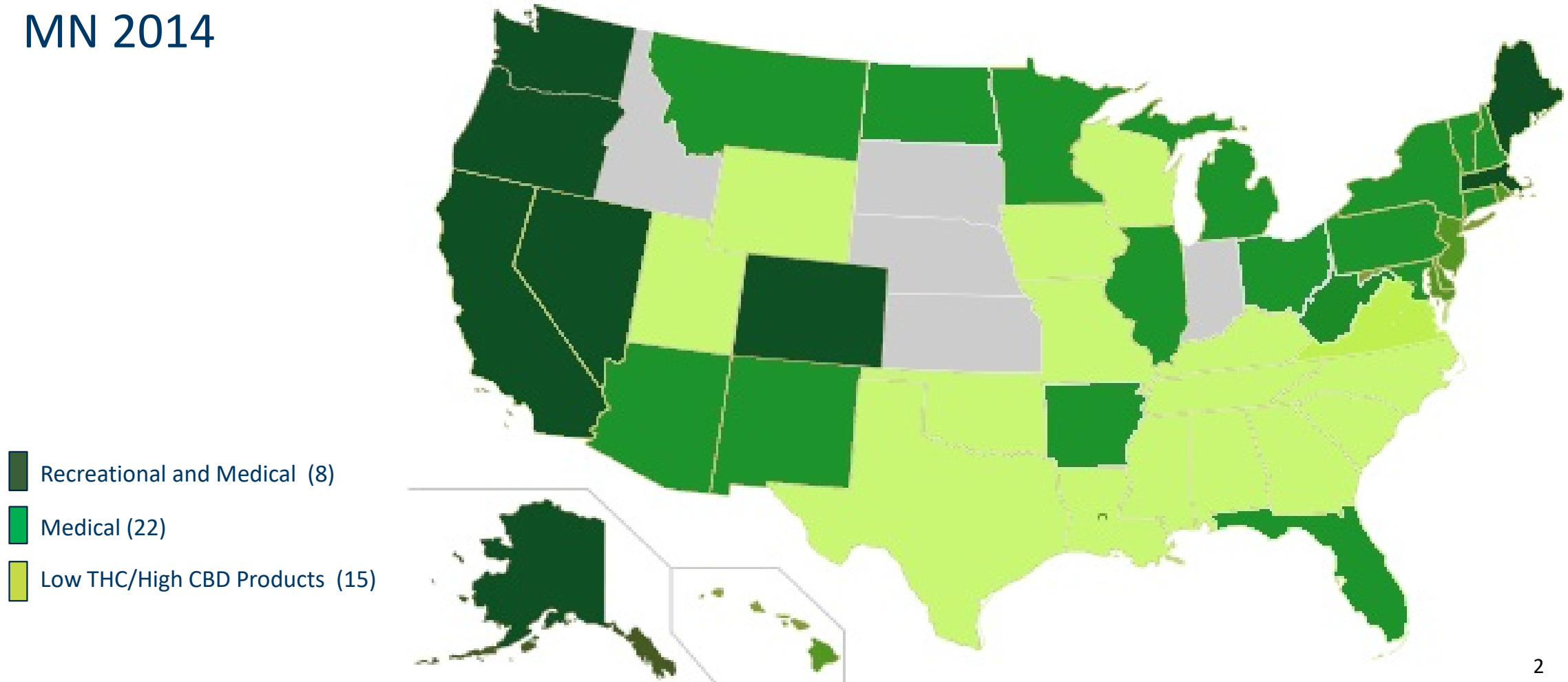
Minnesota's Medical Model

Michelle Larson, PhD | Director

AFDO – June 13, 2018

Office of Medical Cannabis

Most states have some variety of medical cannabis program:
MN 2014



Minnesota's program:

- No smokeable or plant form marijuana (only liquids and oils in capsule, tincture, or vaporized form. Topical preparations of oils allowed starting August, 2017)
- Two manufacturer's vertically integrated
- Commitment to learning from experience with the program (reports and observational studies on effectiveness, side effects, etc.)

Qualifying Medical Conditions

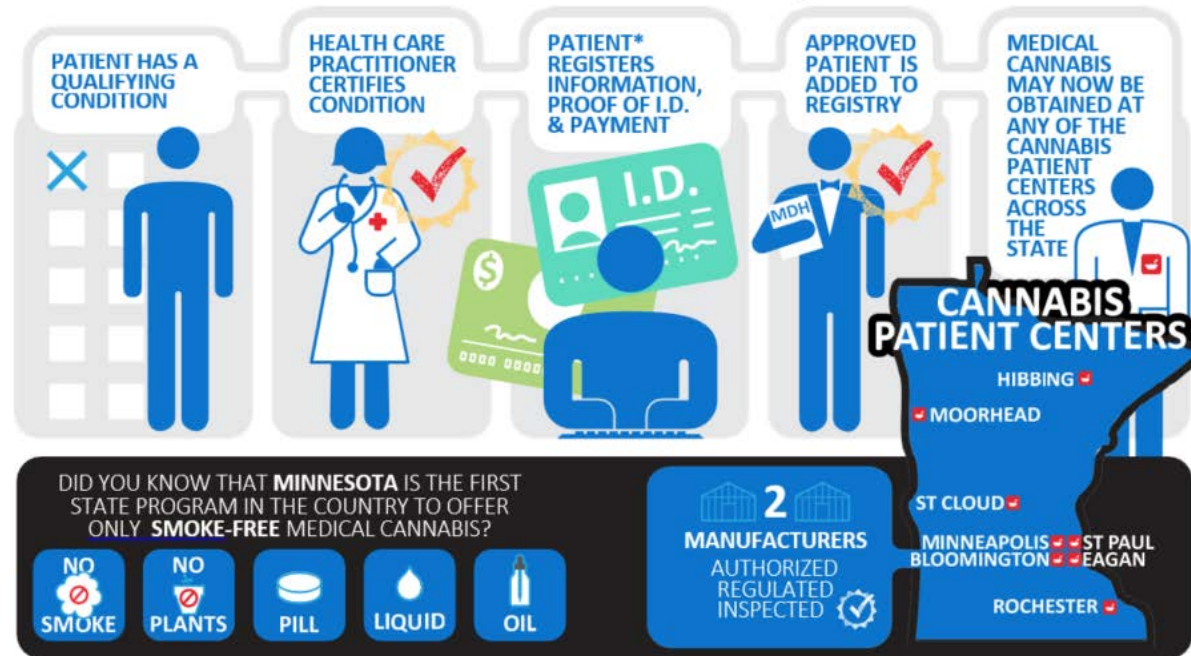
- Cancer – with severe or chronic pain, or nausea, or cachexia
- Glaucoma
- HIV/AIDS
- Tourette's Syndrome
- Amyotrophic Lateral Sclerosis
- Seizures, including those characteristic of epilepsy

Qualifying Medical Conditions (continued)

- Severe and persistent muscle spasms, including those characteristic of multiple sclerosis
- Inflammatory Bowel Disease, including Crohn's Disease
- Terminal Illness with life-expectancy < 1 year – with severe or chronic pain, or N/V, or cachexia
- Intractable Pain (effective August 1, 2016)
- PTSD (effective August 1, 2017)
- Autism and obstructive sleep apnea (effective July 1, 2018)

Office of Medical Cannabis

Overview of MN Medical Cannabis Program



*Care-giver may represent a patient by applying and meeting conditions including a background check.

MDH Minnesota Department of Health

9622 Active Patients (as of April 12, 2018)

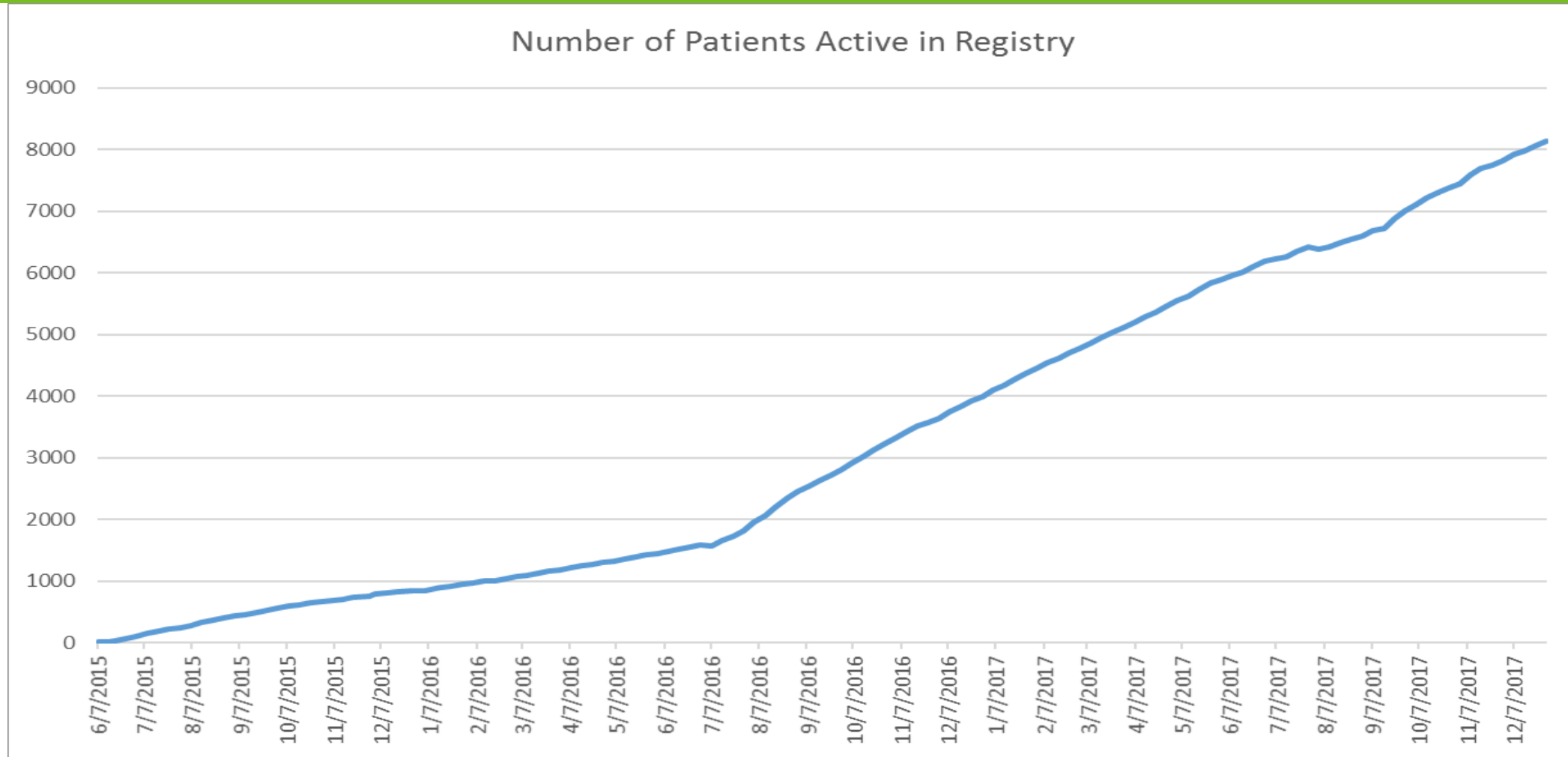
- 66% Intractable pain
- 15% Severe and persistent muscle spasms
- 14% PTSD
- 10% Cancer
- 5% Seizures
- 4% Inflammatory bowel disease
- 1% Terminal illness, Tourette syndrome, HIV/AIDS, Glaucoma
- < 1%: ALS

Note: 14% of patients >1 condition

9252 Active Patients (as of April 12, 2018)

| | | |
|------------------|---------|-------|
| Age distribution | 0-4 | (<1%) |
| | 5-17 | (2%) |
| | 18-24 | (4%) |
| | 25-35 | (16%) |
| | 36-49 | (28%) |
| | 50-64 | (33%) |
| | 65+ | (18%) |
| Gender: M/F | 49%/51% | |

Weekly Number of Active Patients



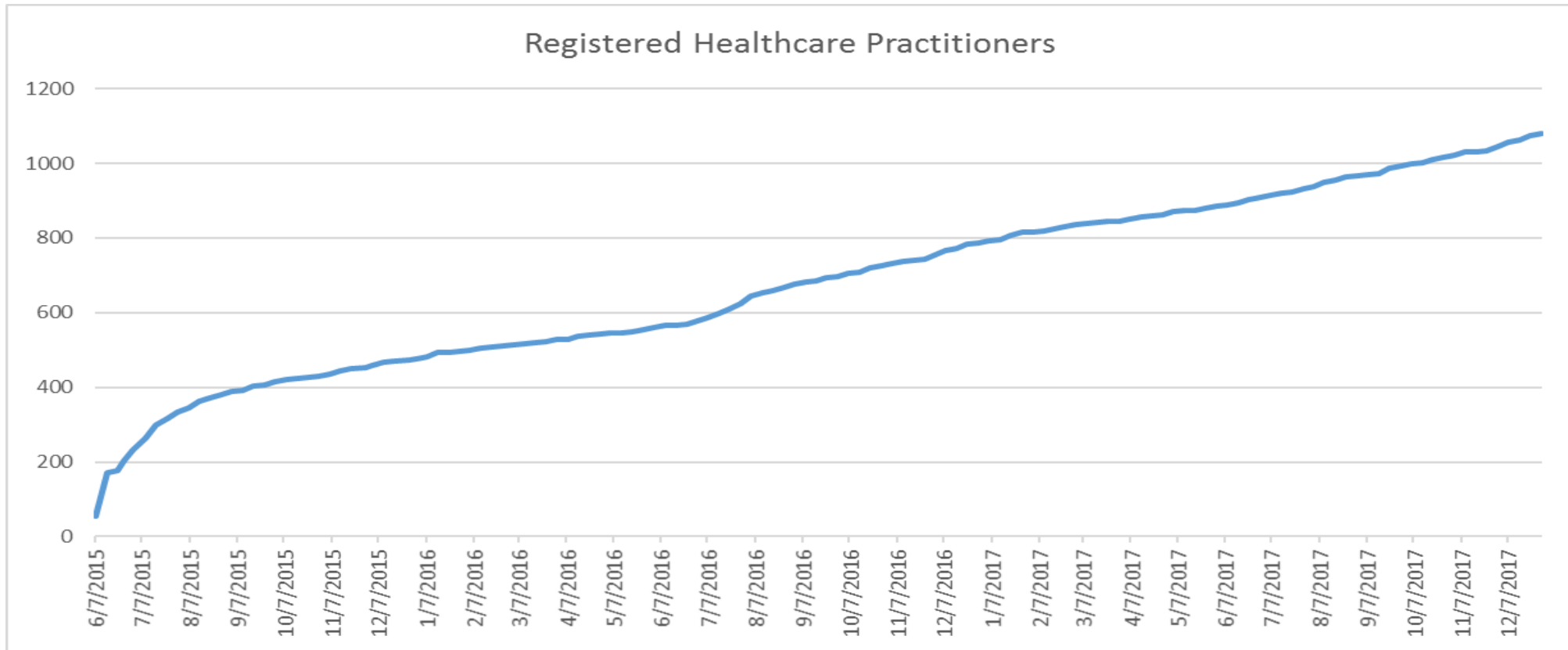
Registered Health Care Practitioners

As of April 12, 2018:

1177 registered

- 77% physicians
- 16% advanced practice registered nurses
- 7% physician assistants

Cumulative Number of Registered HCPs



Product Composition

- Different medical cannabis products in MN are characterized by different ratios of THC:CBD and mode of delivery (capsule/oral suspension, tincture, oil for vaporization, topical)
- The two manufacturers each determine their product line, which will evolve over time. But each specific product is to remain consistent as long as it is produced.
- Current products listed on the two companies' web sites (links on Office of Medical Cannabis web site).

Laboratory Testing

- Content – cannabinoid profile
- Contamination:
 - Metals
 - Pesticides
 - Microbials
 - Residual solvents
- Consistency and stability

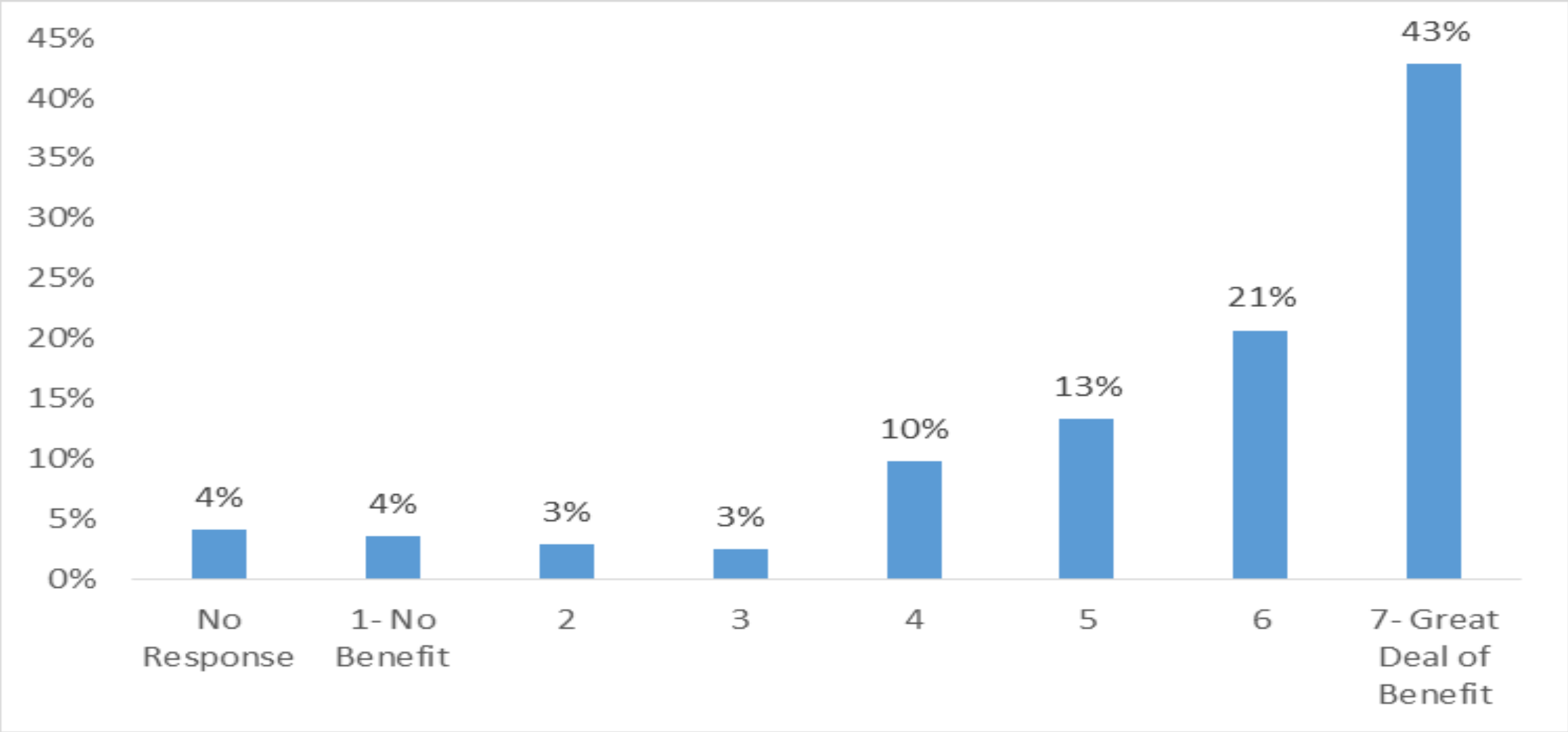
Adverse Event Reporting

- “Serious adverse incident” means any adverse incident that results in or would lead, without intervention, to hospitalization, significant disability, life-threatening situation, or death
- Required reporting of serious adverse incidents: patient, patient’s certifying health care practitioner, patient’s registered caregiver, parent/legal guardian
- Contact manufacturer to report (or contact MDH if manufacturer unknown)
- Manufacturer must investigate each report and submit to MDH a report documenting their findings

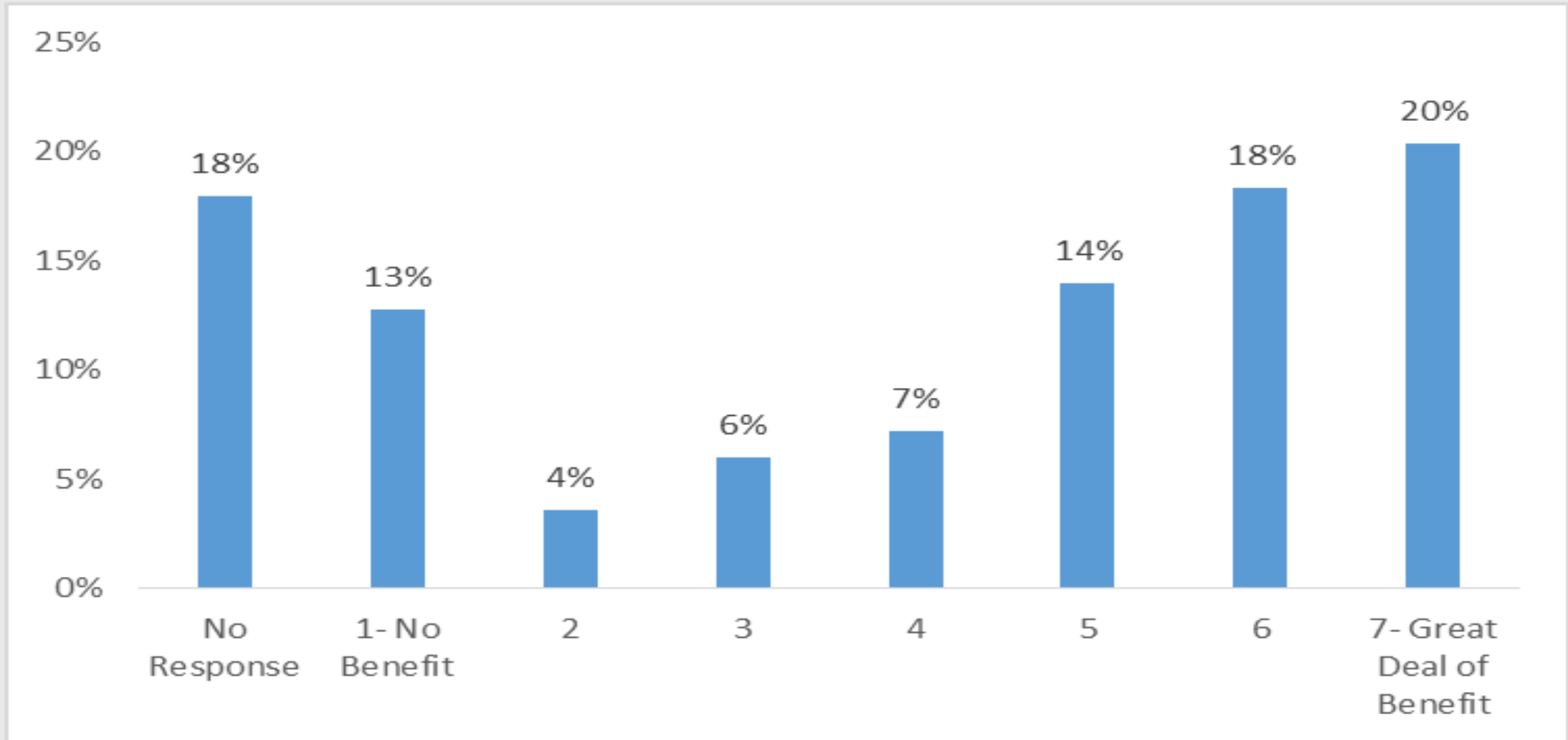
Learning from Participants' Experience

- Observational study from data reported by patient and their certifying health care practitioner
 - Patient-reported data at time of each medical cannabis purchase
 - Surveys
- Adverse event reporting

Patient-Reported Benefit (first year cohort)



Health Care Practitioner-Reported Benefit (first year cohort)



≥30% Symptom Reduction (first year cohort)

| Condition | Standard 8 Symptom Measure | # of Patients Reporting at Moderate to Severe Levels at Baseline | % of Patients Reporting at Moderate to Severe Levels at Baseline | % of Patients Achieving ≥30% Symptom Improvement within 4 months of First Purchase out of all Moderate to Severe Baseline Scorers (n) | # of Patients with Data in 4-mo Period Following Initial ≥30% Symptom Improvement | % of Patients Who Achieved ≥30% Symptom Improvement that Maintained it for at Least 4 months (n) | % of Patients that Both Achieved ≥30% Symptom Improvement and Retained that Degree of Improvement for at Least 4 months |
|---|----------------------------|--|--|---|---|--|---|
| All Patients - Collapsed Across Conditions (n = 1512) | Anxiety | 1185 | 78.4 | 53.8 (638) | 460 | 53.1 (339) | 28.6 |
| | Appetite Lack | 963 | 63.7 | 53.7 (517) | 383 | 57.1 (295) | 30.6 |
| | Depression | 1000 | 66.1 | 56.8 (568) | 419 | 56.7 (322) | 32.2 |
| | Disturbed Sleep | 1323 | 87.5 | 50.3 (665) | 519 | 52.0 (346) | 26.2 |
| | Fatigue | 1381 | 91.3 | 40.2 (555) | 415 | 48.6 (270) | 19.6 |
| | Nausea | 864 | 57.1 | 55.6 (480) | 362 | 59.2 (284) | 32.9 |
| | Pain | 1312 | 86.8 | 36.3 (476) | 329 | 45.0 (214) | 16.3 |
| | Vomiting | 480 | 31.7 | 60.2 (289) | 213 | 57.8 (167) | 34.8 |

≥30% Symptom Reduction (first year cohort)

| Condition | Condition-Specific Symptom Measure | # of Patients Included in Analysis | % of Patients Achieving Threshold Symptom Improvement within 4 months of First Purchase (n) | # of Patients with Data in 4-mo Period Following Initial Threshold Symptom Improvement | % of Patients Who Achieved Threshold Symptom Improvement that Maintained it for at Least 4 months (n) | % of Patients that Both Achieved Threshold Symptom Improvement and Retained that Degree of Improvement for at Least 4 months |
|------------------------------------|------------------------------------|------------------------------------|---|--|---|--|
| Muscle Spasms | Weekly Spasms Frequency | 629 | 48.0 (302) | 225 | 57.6 (174) | 27.6 |
| | 0-10 Spasticity Scale | 618 | 36.4 (225) | 197 | 47.1 (106) | 17.2 |
| Cancer: Nausea/Vomiting | Chemo-Induced Nausea | 147 | 37.4 (55) | 29 | 34.5 (19) | 12.9 |
| | Chemo-Induced Vomiting | 77 | 41.6 (32) | 20 | 56.3 (18) | 23.4 |
| Cancer: Cachexia/Wasting | Weight | 147 | 13.6 (20) | 15 | 45.0 (9) | 6.1 |
| Seizures | Weekly Seizure Frequency | 262 | 68.3 (179) | 150 | 70.9 (127) | 48.5 |
| Crohn's Disease | # Liquid Stools | 41 | 51.2 (21) | 17 | 57.1 (12) | 29.3 |
| | Abdominal Pain | 73 | 53.4 (39) | 29 | 35.9 (14) | 19.2 |
| | General Well-Being | 15 | 46.7 (7) | 5 | 28.6 (2) | 13.3 |
| | Measures Combined | 102 | 51.0 (52) | 41 | 42.3 (22) | 21.6 |
| | Weight | 102 | 20.6 (21) | 18 | 57.1 (12) | 11.8 |
| Terminal Illness: Cachexia/Wasting | Weight | 29 | 20.7 (6) | 5 | 50.0 (3) | 10.3 |
| HIV/AIDS | Weight | 48 | 14.6 (7) | 3 | 42.9 (3) | 6.3 |
| Tourette Syndrome | Weekly Tic Frequency | 28 | 60.7 (17) | 15 | 76.5 (13) | 46.4 |
| ALS | Weekly Spasms Frequency | 18 | 33.3 (6) | 4 | 66.7 (4) | 22.2 |
| | 0-10 Spasticity Scale | 15 | 20.0 (3) | 3 | 100.0 (3) | 20.0 |

Patients Certified for Intractable Pain (Aug-Dec, 2016)

- PEG Scale (patient-reported 3-item scale assessing pain intensity and interference with enjoyment of life and general activity):
 - 42% achieved $\geq 30\%$ reduction; 22% both achieved and maintained $\geq 30\%$ reduction, on average, over next four months
- Clinician pain scale assessment (six months):
 - 41% achieved $\geq 30\%$ reduction
- Among patients using opioid medications when they started medical cannabis, 64% were able to reduce or eliminate opioid usage after six months (data from healthcare provider surveys)

Patient Survey Comments

- “After serving in the Marines from 2005-2009 my body has many ailments (arthritis, IBS, pinch nerve, fused disk, and others) and my PTSD was not always easy to handle. This program helps me a great deal in living a normal life that is comfortable and being able to continue my professional career. Before medical marijuana I was miss work too often and also miss out on life’s daily joys. Now I can do much more.”
- “At first it helped a lot but my seizures have returned.”
- “Within 1 week of use, my tics disappeared and have stayed gone even with occasional use. This has never happened previously in my life, so it is very effective”

Patient Survey Comments (continued)

- “My back pain is manageable and my spasms have stopped once I use the medication. I have also found that I sleep better at night and my agitation has stabilized. I seem to be getting along with this medication and it has given me absolutely no problems, but rather benefits. I am also doing very well in school now that I can focus on the capstone courses that I am taking at [name of college] instead of having to shift and turn and be constantly bothered by my pain and spasms.”
- “I did feel I was more comfortable socially (taking continuing education classes on my own), when normally I would not have considered due to social anxiety. However, I was taking it for pain which it did not help”

Patient Survey Comments (continued)

- “I am able to participate in social activities again without feeling drugged all the time. Prescription pain medications had many negative side effects which the cannabis does not have for me. I have been able to discontinue the use of 60 mg of morphine and 15-20 mg of oxycodone per day. I’m a different person, much happier (even my granddaughter noticed the change!).”
- “Medical cannabis has not made a difference to me. I have never used it before and was a little hesitant to try. When I did I found that I had no relief of pain and I didn’t like the way I felt so I discontinued use.”

Adverse Effects (first year cohort)

- 15% of patients reported ≥ 1 adverse effect
- Of all reported adverse effects:
 - 47% mild (symptoms do not interfere with daily activities)
 - 44% moderate (symptoms may interfere with daily activities)
 - 9% severe (symptoms interrupt usual daily activities)
- As of May 8, 2018: two reports of serious adverse events – both cannabinoid hyperemesis syndrome. Both patients recovered fully after discontinuing the high THC products they were using.

Thank you!

Michelle Larson

Michelle.Larson@state.mn.us

<http://www.health.state.mn.us/topics/cannabis/>