

# MN Office of Medical Cannabis Research and Analytics Update

**Task Force on Medical Cannabis  
January 6, 2017**

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# Covered in today's presentation:

- Current counts of program statistics
- Early look at components of report on enrollees during first year of program (report will be completed end of March)
- Very early look at patients certified for intractable pain (report on first six months of intractable pain enrollees by end of 2017)

# Research Data

- Separate from transactional registry
- Deidentified to protect patient privacy
- Security policies (examples: no remote access; no loading data onto PC; other)

# As of December 23, 2016:

## 3936 Active Patients

- 56% Intractable pain
- 24% Severe and persistent muscle spasms
- 14% Cancer
- 8% Seizures
- 4% Inflammatory Bowel Disease
- 2% Terminal Illness
- 2% HIV/AIDS
- ≤ 1% each: Tourette syndrome, Glaucoma, ALS

**Note: 12% of patients > 1 condition**

# As of December 23, 2016:

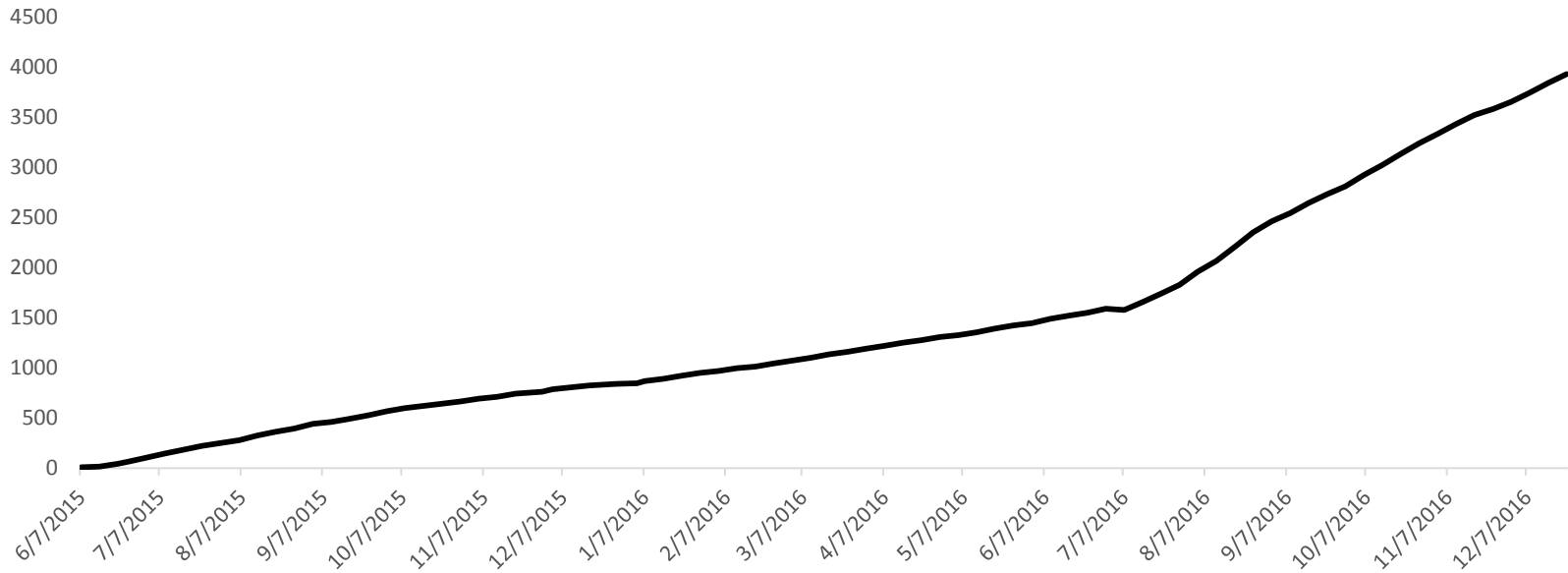
3936 Active Patients

## Age distribution

- 0-4 (<1%)
- 5-17 (3%)
- 8-24 (4%)
- 25-35 (14%)
- 36-49 (24%)
- 50-64 (36%)
- 65+ (18%)

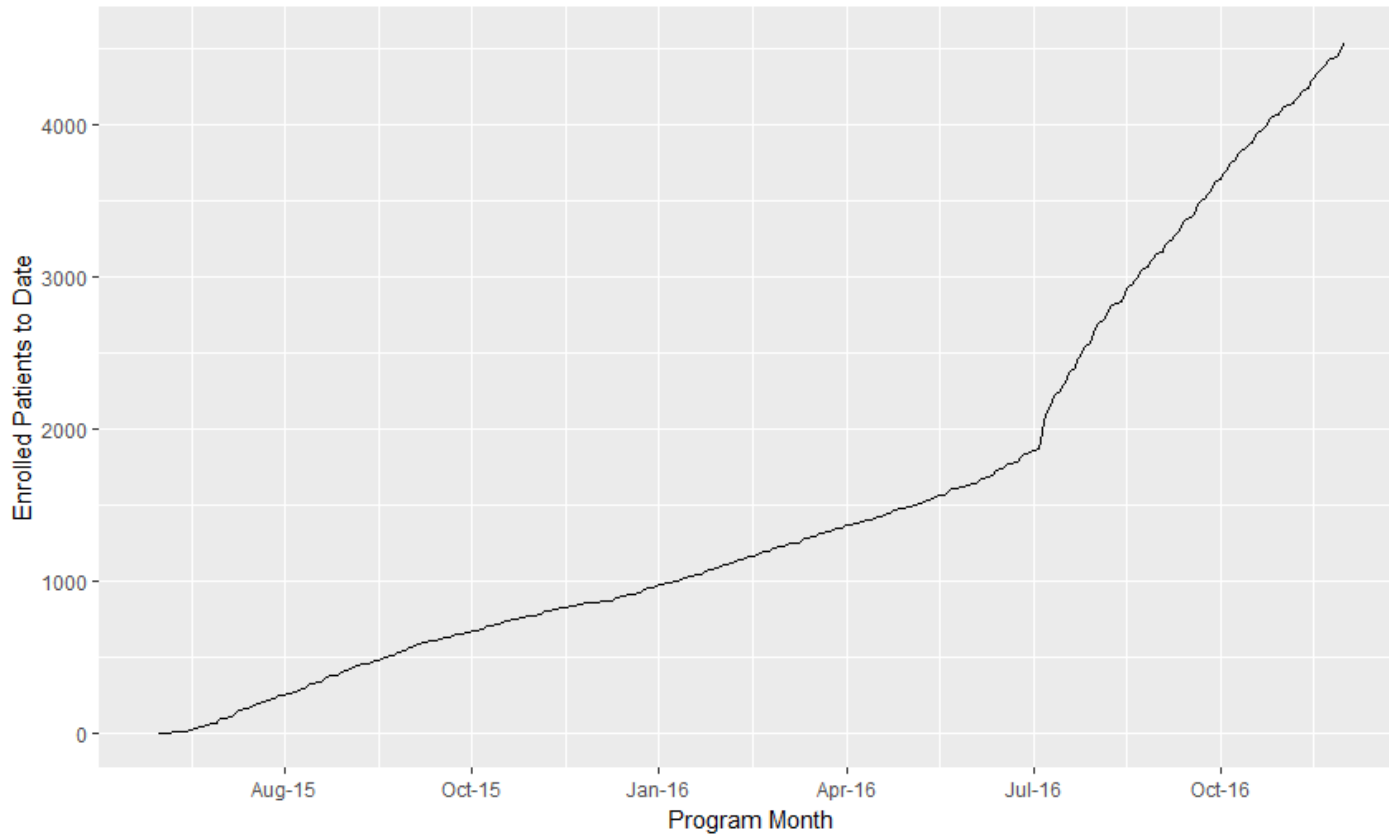
# Active Patient Count

Number of Patients Active in Registry: June 2015-December 2016



# Total Patient Enrollment

Cumulative Count of Patients Enrolled in Program



# As of December 23, 2016:

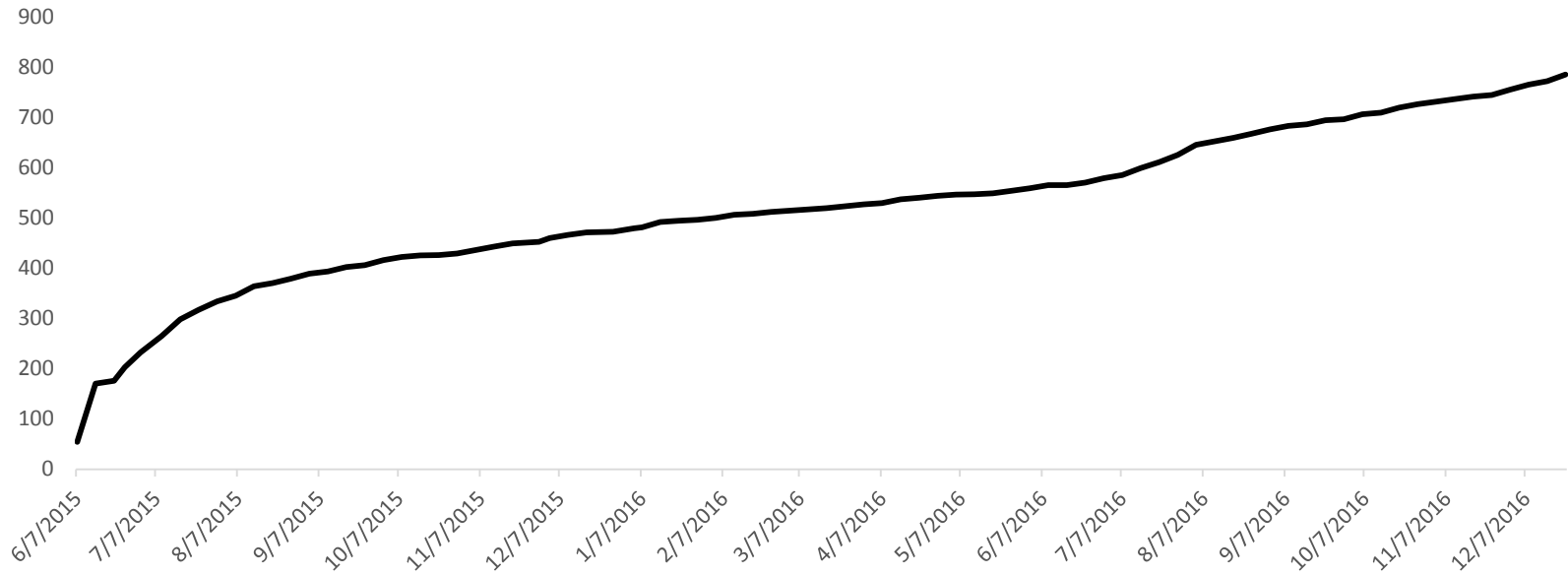
786 Health Care Practitioners Registered:

- 81% Physicians
- 14% Advanced Practice Registered Nurses
- 6% Physician Assistants



# Healthcare Provider Enrollment

Registered Healthcare Practitioners: June 2015-December 2016



# Report on enrollees during the first year of the program – components:

- Description of patients, registered caregivers, and health care practitioners
- Purchasing patterns (including duration of participation)
- Medical Cannabis Use Patterns
- Changes in symptoms (and description of medical cannabis used when clinically significant improvement achieved)
- Side effects
- Survey results on benefits and harms – includes appendices with direct words of patients and their certifying health care practitioners

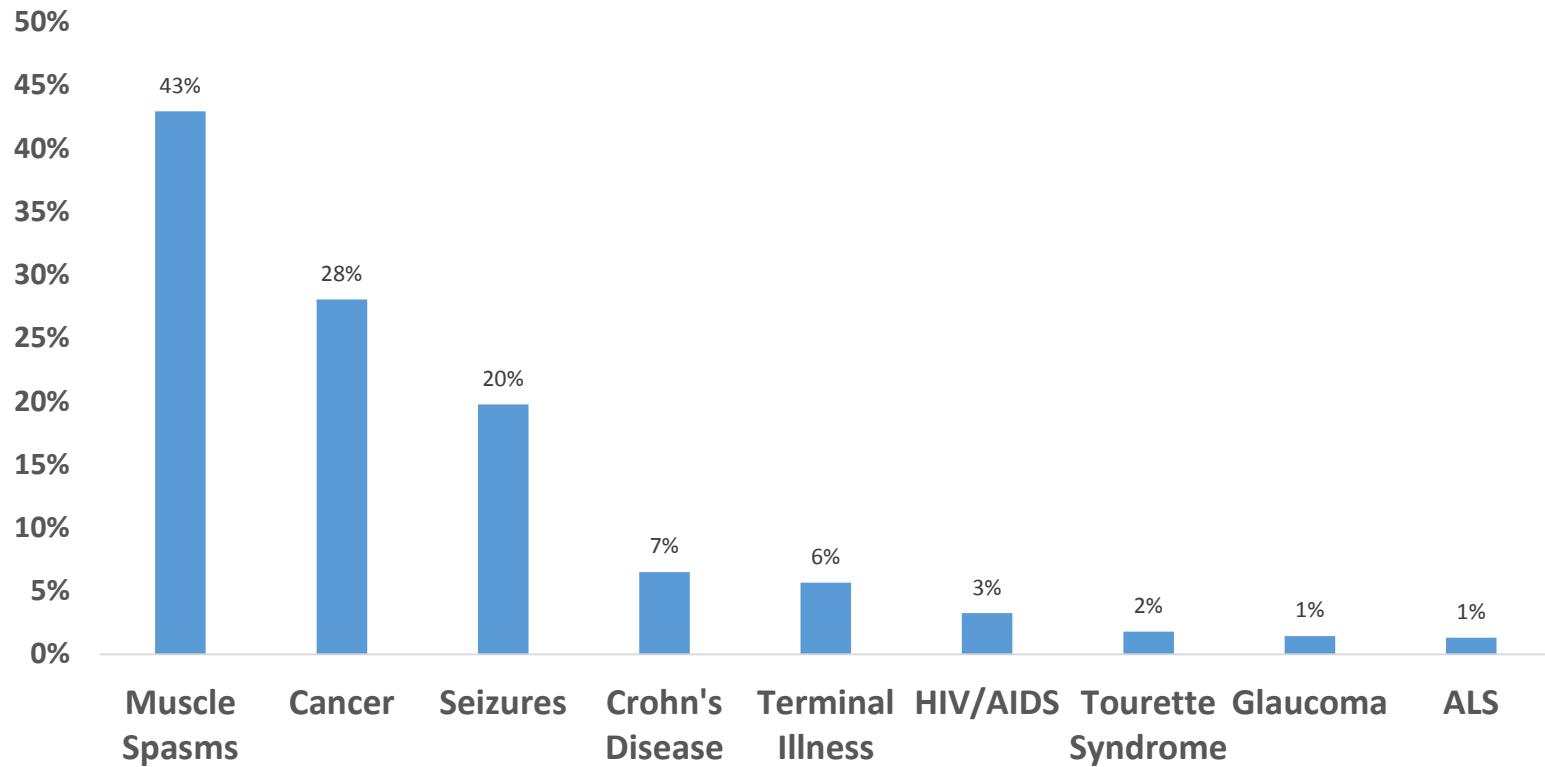
# Minnesota Medical Cannabis Program

**Patient, Certifying Healthcare Provider and  
Caregiver Statistics  
July 2015-June 2016**

# Program Year One Descriptives

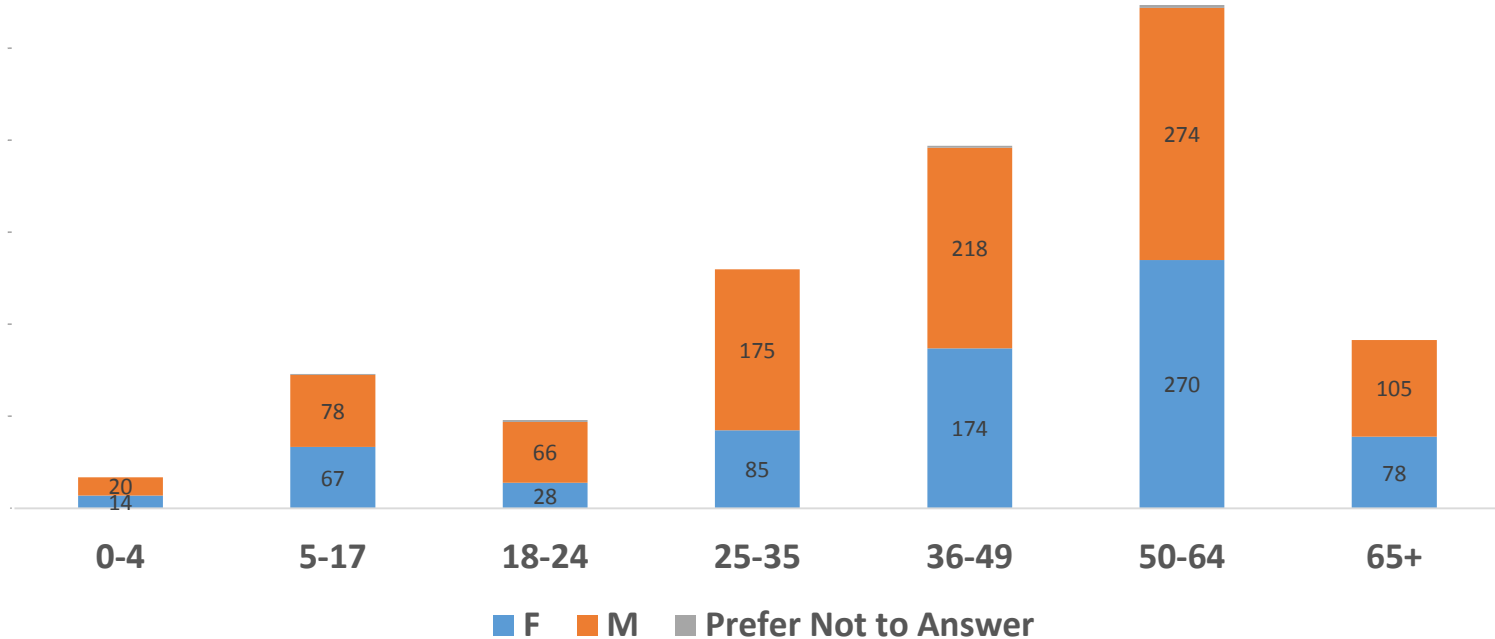
# Program Year One: 1660 Patients

## Enrolled Patients by Qualifying Condition



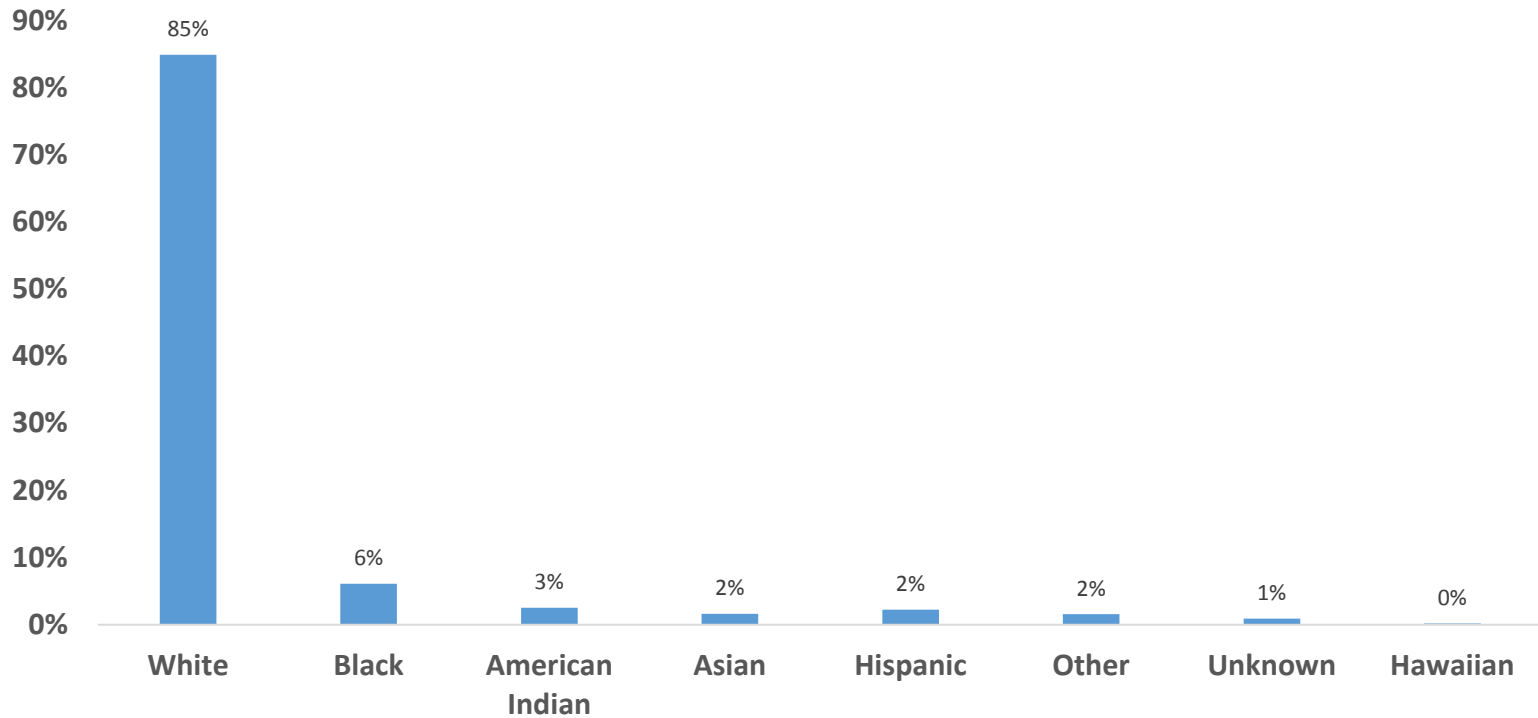
# Program Year One: 1660 Patients

Enrolled Patients by Age and Gender



# Program Year One: 1660 Patients

Enrolled Patient Race/Ethnicity

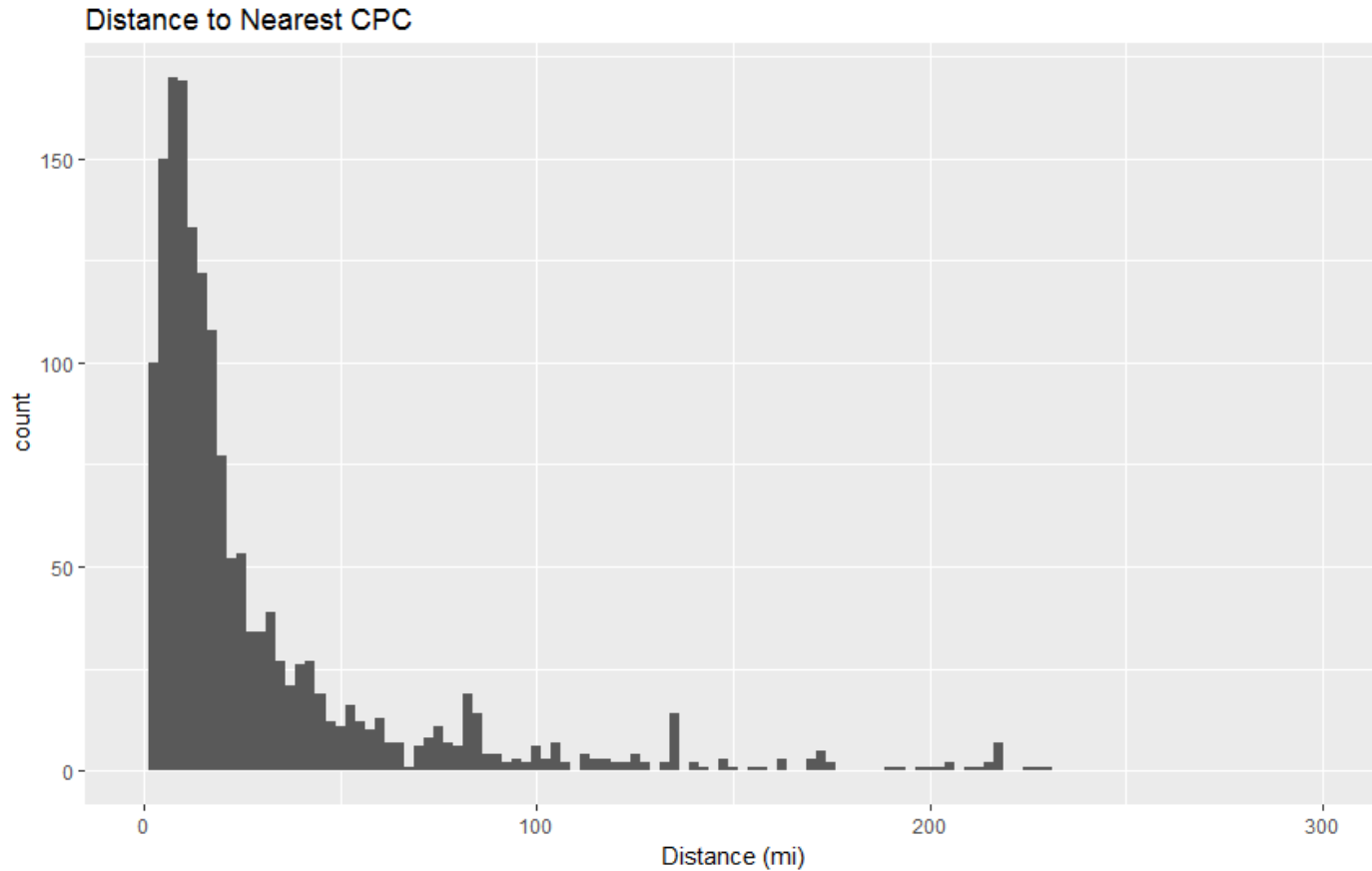


# Program Year One: Patients with Caregivers

<b>CONDITION</b>	<b>% Allowed Caregivers Per HCP</b>	<b>% With Registered Caregivers</b>	<b>% with Registered Parents/ Legal Guardians</b>
<b>All Conditions</b>	41%	11%	17%
<b>Cancer</b>	40%	15%	5%
<b>Terminal Illness</b>	56%	15%	11%
<b>Glaucoma</b>	33%	13%	0%
<b>HIV/AIDS</b>	11%	2%	0%
<b>Tourette Syndrome</b>	40%	7%	53%
<b>ALS</b>	77%	32%	5%
<b>Seizures</b>	66%	10%	65%
<b>Muscle Spasms</b>	29%	10%	4%
<b>Crohn's Disease</b>	20%	6%	3%



# One-Way Distance to Nearest Patient Center



# Product Types Purchased (July 2015- Dec 2016)

Vapor	Capsule/Oral Solution	Tincture	N	%
x	x		542	33%
x	x	x	223	13%
	x		219	13%
x			213	13%
	x	x	197	12%
		x	66	4%
x		x	66	4%
			134	8%

# Registered Healthcare Practitioners

HCP TYPE	N	%	MALE: N(%)	MEAN AGE (SD)
Physicians	475	82%	341 (72%)	50.3 (11.3)
Nurses	77	13%	9 (12%)	47.0 (9.4)
PAs	28	5%	6 (21%)	39.5 (9.6)
<b>Total</b>	<b>580</b>	<b>100%</b>	<b>356 (61%)</b>	<b>49.4 (11.3)</b>

# Registered Physician Specialties

Registered Physician Specialties	N
Primary Care	177
<i>Family Medicine</i>	108
<i>Internal Medicine</i>	60
<i>Pediatrics</i>	8
Oncology	80
Neurology	62
Specialized Pediatrics	29
Hospice/Palliative Medicine	24
Physical Medicine and Rehabilitation	21
Gastroenterology	10
Psychiatry	10
Ophthalmology	9
Surgery	8
Infectious Disease	6
Pain Medicine	5
Radiology/Radiation Oncology	5
Nephrology	3
Rheumatology	2
Emergency Medicine	2
Geriatric Medicine	2
Obstetrics and Gynecology	2
Sports Medicine	2
Anesthesiology	1
Dermatology	1
Public Health and Preventive Medicine	1
Sleep Medicine	1

# Patient and HCP Surveys: First 6 Months

# Patient/Healthcare Practitioner Surveys

- Short survey asking patients and their healthcare practitioners about benefits and harms associated with medical cannabis
- Initial survey schedule: sent to patients and their healthcare practitioners 3 months after the patient's first medical cannabis purchase
- Revised survey schedule: sent to patients 3 months after the patient's first medical cannabis purchase; sent to patients and their healthcare practitioners every 6 months the patient is enrolled in the program

# Benefits and Negative Effects

- Patients and HCPs asked to quantify benefits/harms related to medical cannabis use:

1. How much benefit, if any, have you experienced from taking medical cannabis?  
(1- no benefit; 4- some benefit; 7- a great deal of benefit)

1

2

3

4

5

6

7

4. How much negative impact, if any, have you experienced by taking medical cannabis? (For this question, please do not consider the financial costs)  
(1-no negative effects, 4-some negative effects, 7-great deal of negative effects)

1

2

3

4

5

6

7

- Patients and HCPs asked to describe the benefit(s)/harm(s) from medical cannabis

# Patient/Healthcare Practitioner Surveys: First 6 Months

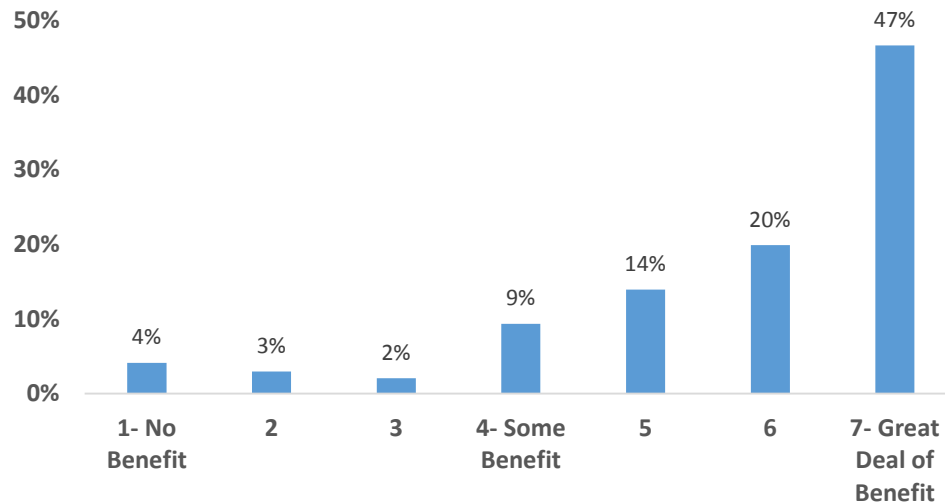
Patients who purchased medical cannabis July  
2015-December 2015

- **774 patients** and their certifying HCPs were sent surveys 3 months after the patient's first purchase
- **437 (56%) patient surveys** were completed
- **251 (32%) HCP surveys** were completed

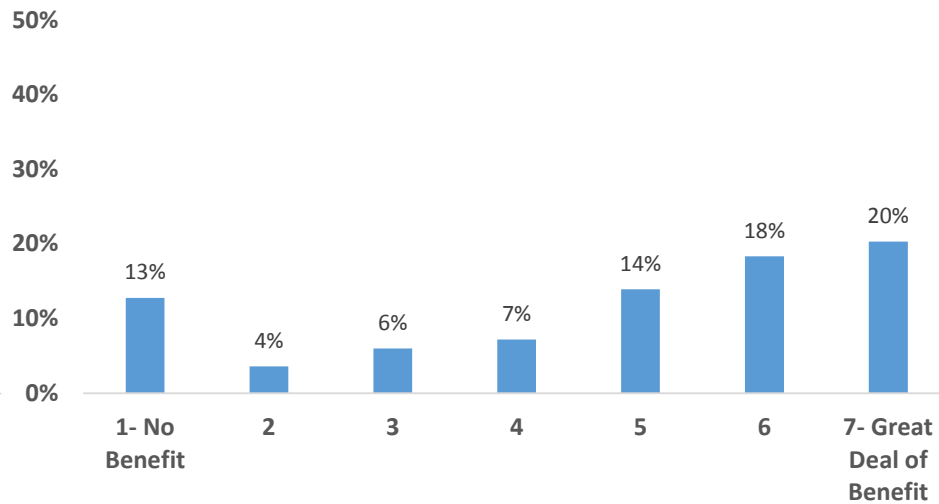


# 3-Month Survey: Perception of Benefit

Patient-Perceived Benefit: All Conditions (N=437)

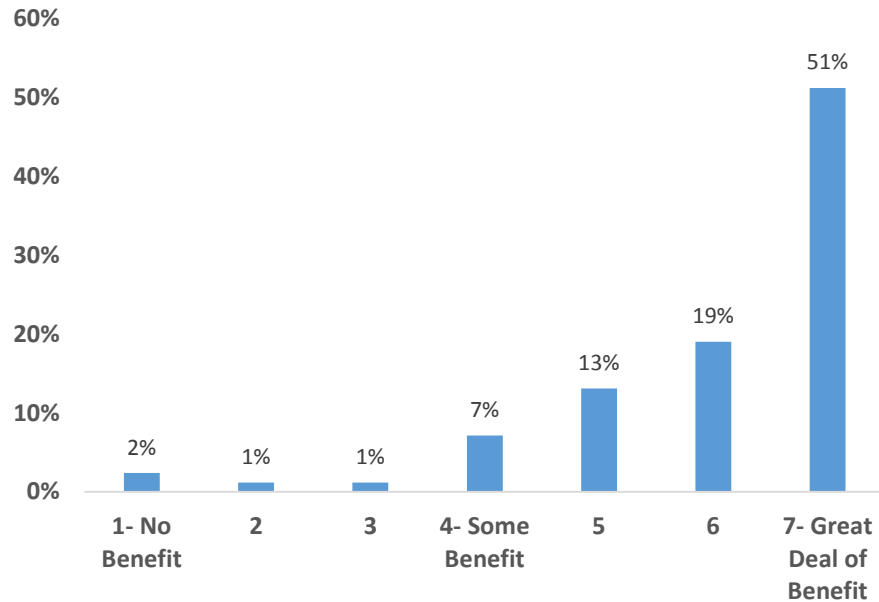


HCP-Perceived Benefit: All Conditions (N=251)

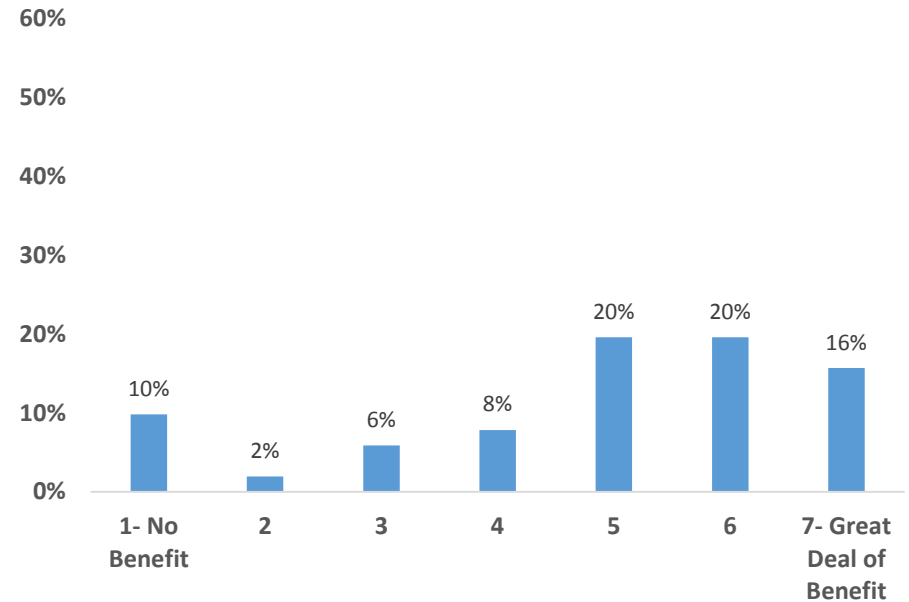


# Perceived Benefits in Cancer Patients

Patient-Perceived Benefit: Cancer (N=84)



HCP-Perceived Benefit: Cancer (N=51)



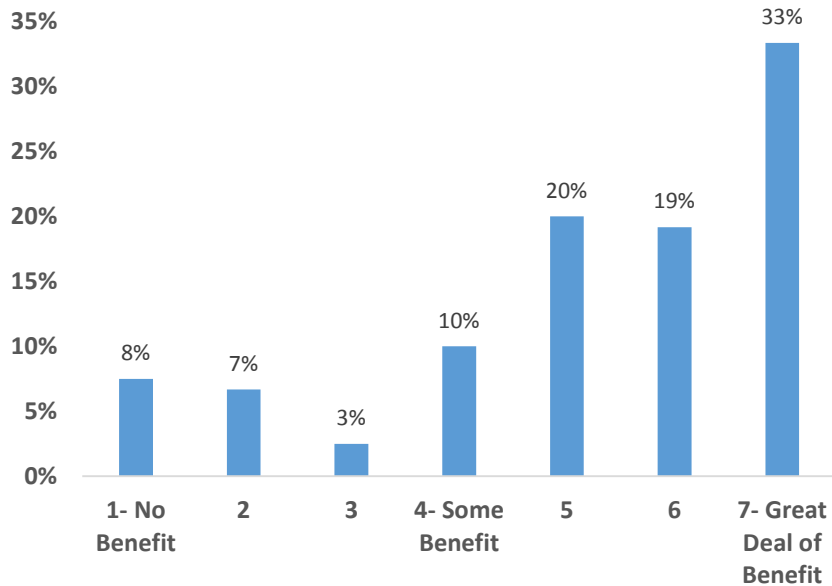
# Patient Comments

**“I was able to get off all my anti nausea medication which allowed me to Get off all the anti constipation medication. Prior to being in the cannabis program I had no appetite and had lost 35 lbs I have been able to put back on 15 lbs. My quality of life after chemotherapy treatments turned around substantial. An added bonus was the pain relief from a chronic back pain, it has helped significantly with my pain management.”**

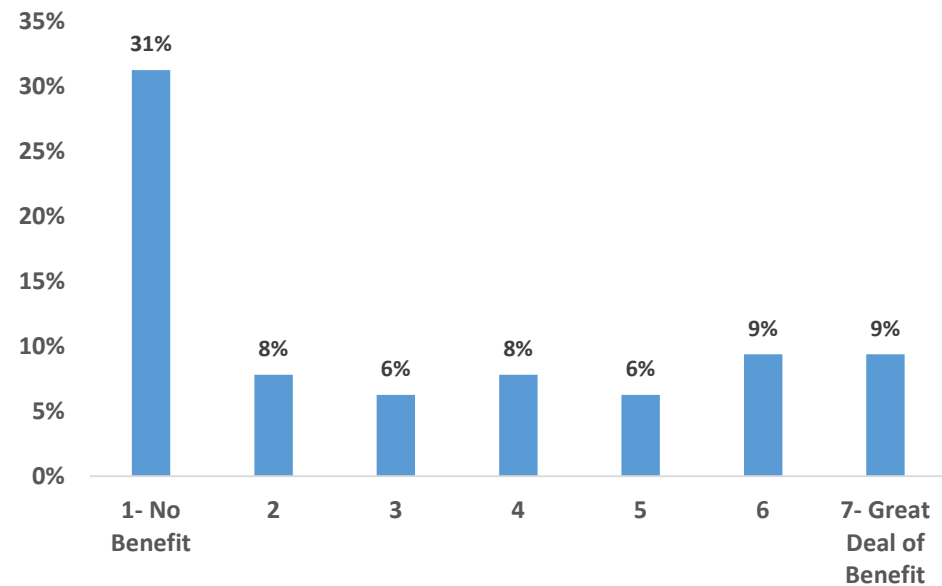
**“One benefit was it helped with my nausea and vomiting but not as well as I would have hoped. I had to puff on the vape pen consistantly to relieve me of the nauseated feeling instead of the 1 to 2 puff recommended dose.”**

# Perceived Benefits in Seizure Patients

Patient-Perceived Benefit: Seizures (N=120)



HCP-Perceived Benefit: Seizures (N=64)



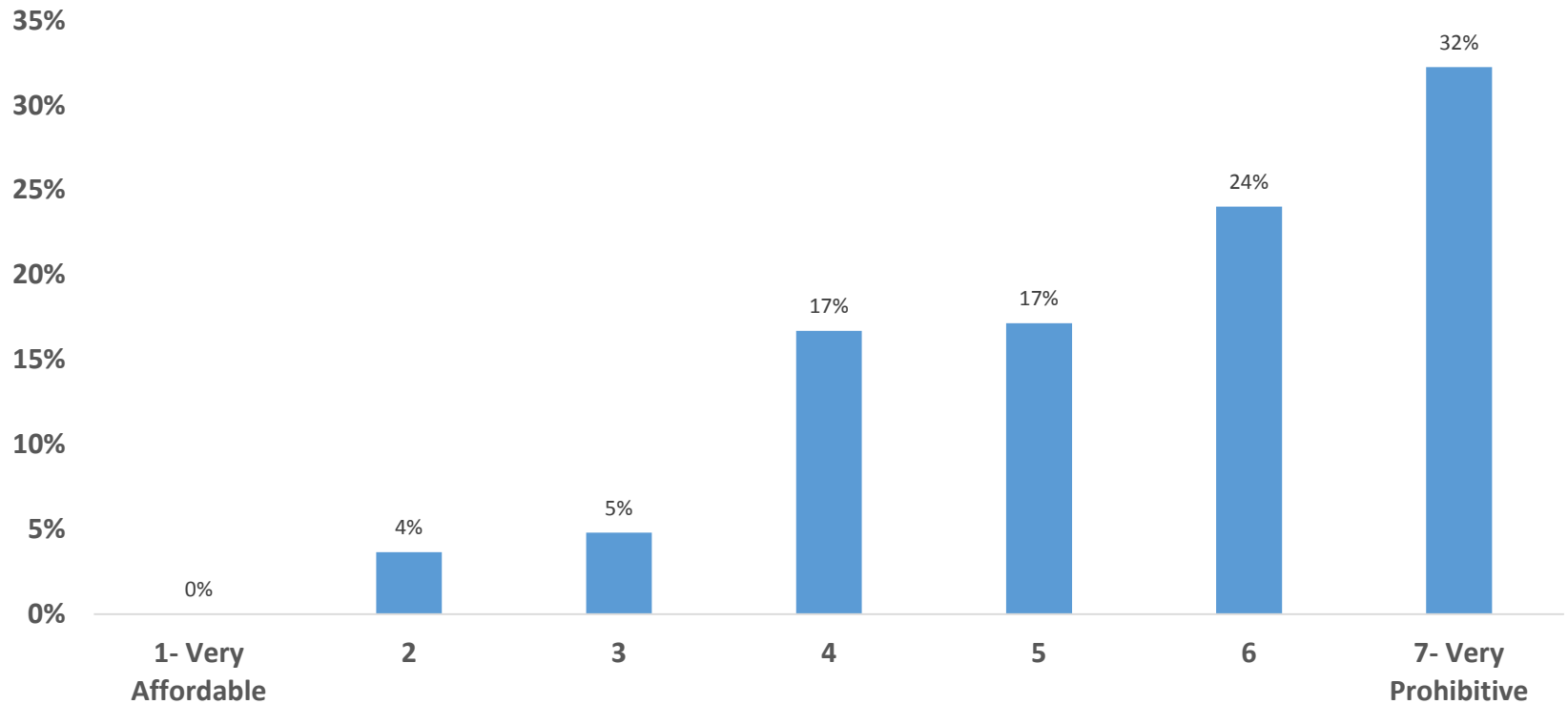
# Patient Comments

**“98% seizure reduction, elimination of persistent headaches, and we were able to wean 75% of child's benzodiazepines, meaning that her Quality of Life has significantly improved, as have all of her abilities.”**

**“My daughter went for the full month of September with NO seizures when she first started on cannabis. October and November were not so good. This past month we tried a different formula to see if we can get better control. Still more adjustments are needed.”**

# Attitudes Toward Cost

“Do you find the cost of medical cannabis to be affordable or prohibitive?”



# Minnesota Medical Cannabis Program

## **Patient Self-Evaluation Data – Early Look**

# Patient Self-Evaluation

Patients complete a Patient Self-Evaluation prior to purchasing medical cannabis

- Negative side effects
- Symptom changes




# Patient Self-Evaluation

Patients complete a Patient Self-Evaluation prior to purchasing medical cannabis

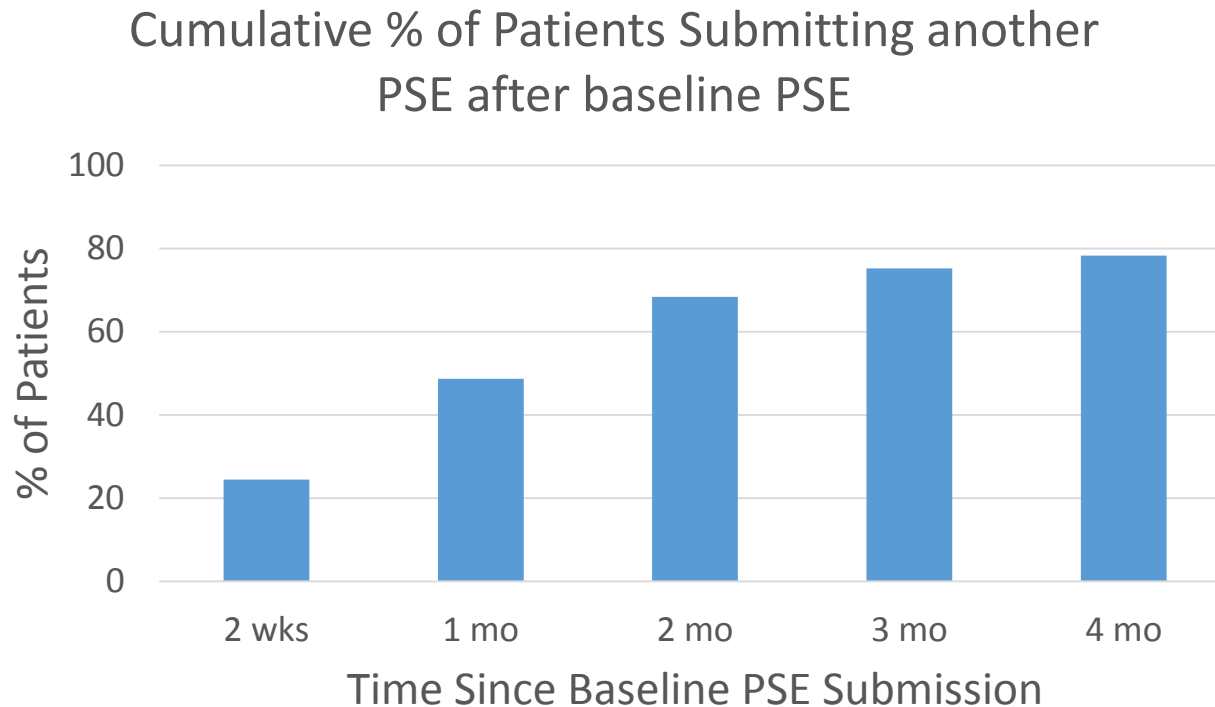
- **Negative side effects**
- Symptom changes

# Side Effect Reporting

- What side effect(s) might be attributed to medical cannabis?
  
- How severely is side effect experienced?
  - Mild: Symptoms do not interfere with daily activities
  - Moderate: Symptoms may interfere with daily activities
  - Severe: Symptoms interrupt usual daily activities
  
-  Any additional comments on side effect?

# What percentage of patients reported negative side effects within the 4 months following their first medical cannabis purchase?

## Why within 4 months?

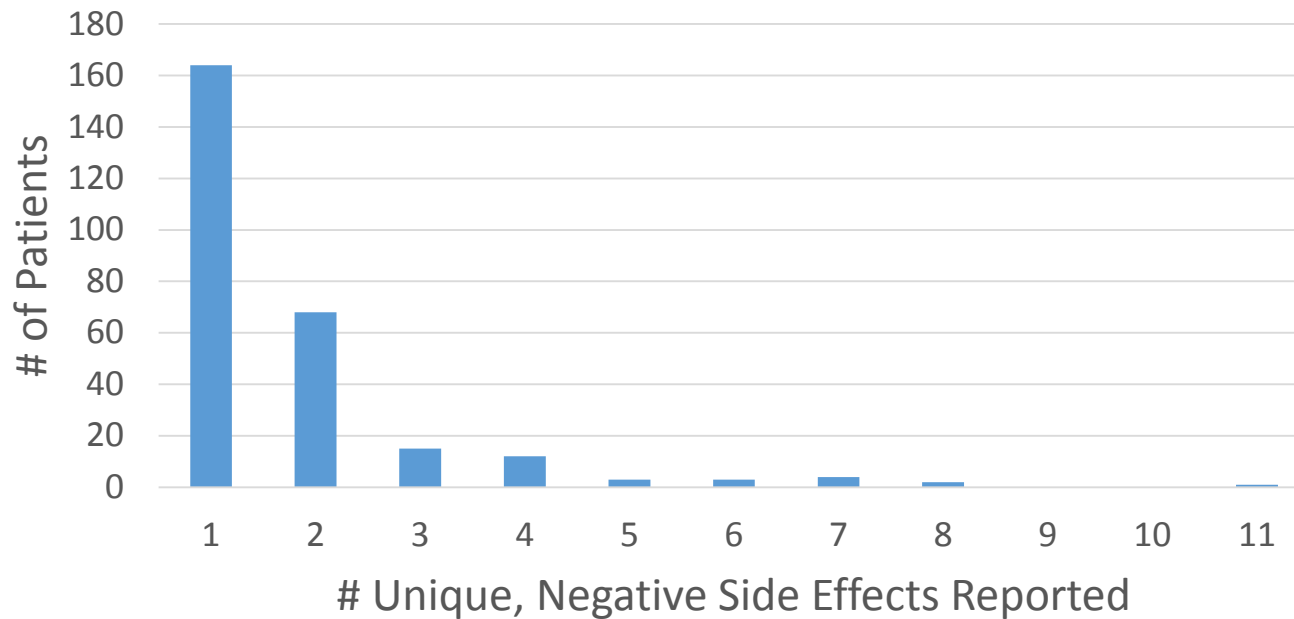


# What percentage of patients reported negative side effects within the 4 months following their first medical cannabis purchase?

Out of the **1502** patients in the 1<sup>st</sup> cohort who could potentially report negative side effects, only 272 **(18.1)% reported any cases**

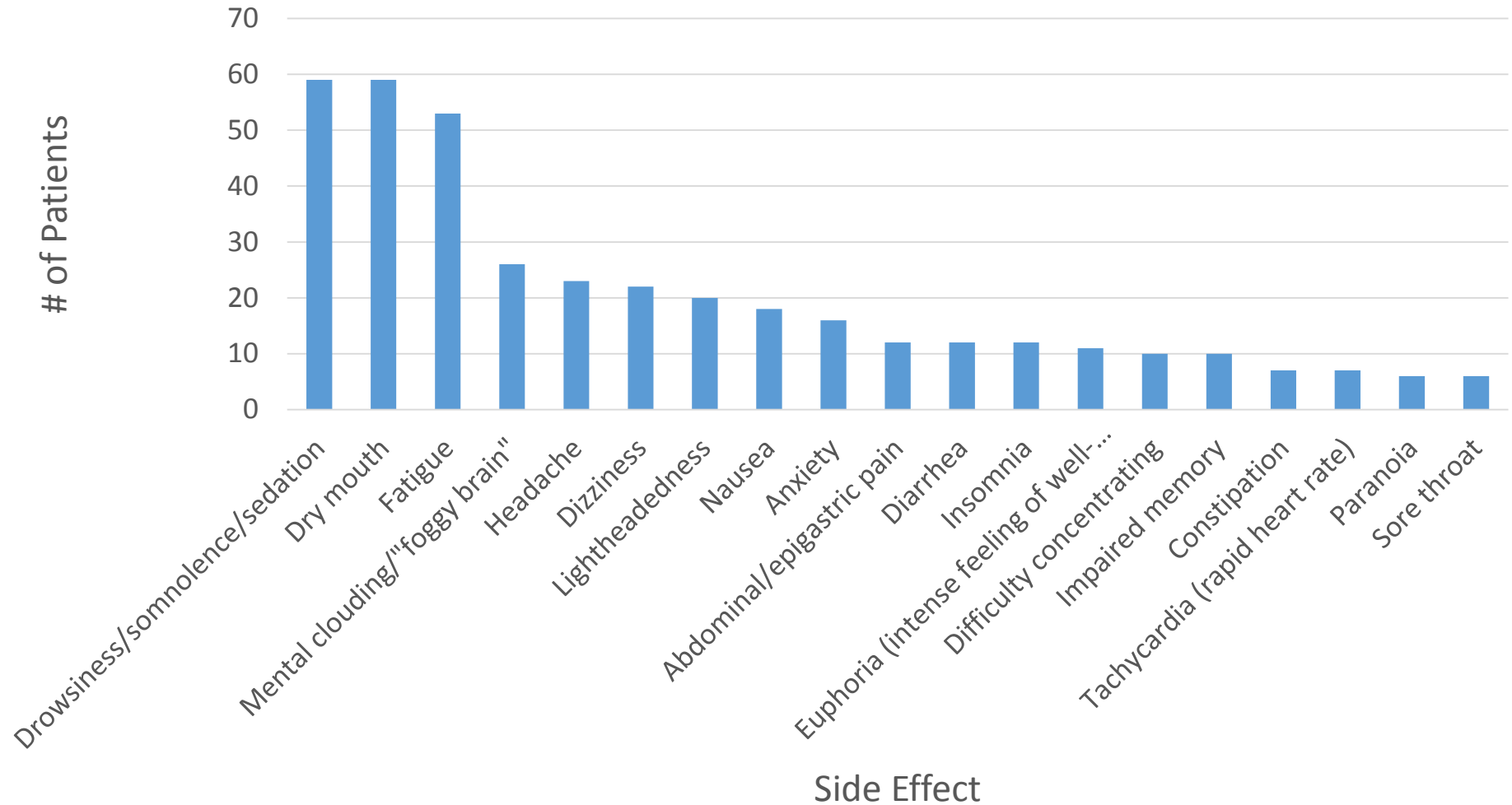
# How many different, negative side effects do patients report?

Frequency Distribution of Patients by Number of Unique Side Effects Reported



# Most Commonly Reported Negative Side Effects <sup>38</sup>

Number of Patients Reporting Listed Side Effects



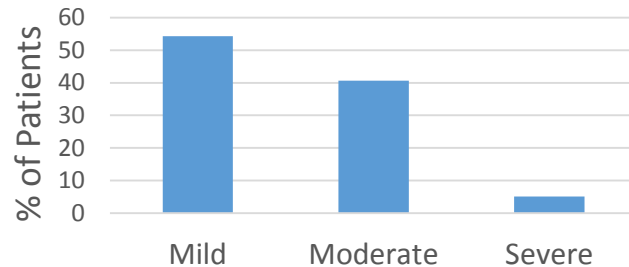
<b>Side Effect</b>	<b># Patients Reported</b>
Asthenia (muscle weakness)	5
Chest pain	5
Confusion	5
Disorientation	4
Eye redness	4
Increased agitation	4
Lethargy	4
Blurred Vision	3
Decreased muscle coordination/balance	3
Increased seizures	3
Numbness	3
Panic attack	3
Personality/mood change	3
Tinnitus (ringing perception in the ears)	3
"Stoned" feeling	2
Body stiffness	2
Coughing/lung irritation	2
Decreased appetite	2
Dry eyes	2
Feeling cold	2
Tremors	2

<b>Side Effect</b>	<b># Patients Reported</b>
"Wired" feeling	1
Bloating	1
Burping	1
Change in quality of seizures	1
Chest colds	1
Cognitive change	1
Cramping with bowel movement	1
Dysphoria (intense feeling of unease or unpleasantness)	1
Exacerbation of lymphedema	1
Eye muscle twitching	1
Hives	1
Hyperactive bowel sounds	1
Hypomania	1
Increase in mucus secretions	1
Increased aggression	1
Increased urine output	1
Increased yelling	1
Mouth irritation/burning	1
Rash on face	1
Repressed immune system	1
Sleep disturbance	1
Sneezing	1
Thrush	1
Urinary retention	1
Vomiting	1
Worsening acne	1

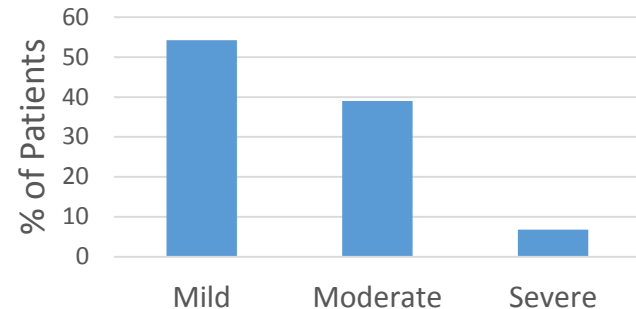
# Negative Side Effect Severity

**90.6%** of all unique reported side effects are of mild to moderate severity

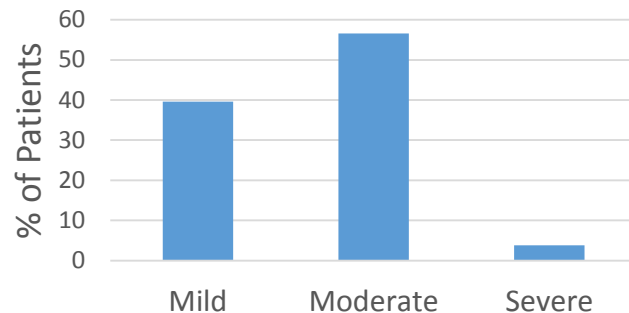
Drowsiness/somnolence/sedation  
(n = 59)



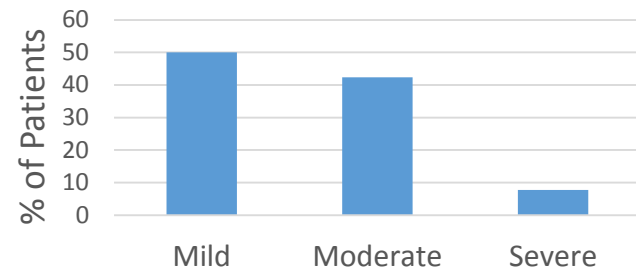
Dry mouth (n = 59)



Fatigue (n = 53)



Mental clouding/"foggy brain"  
(n = 26)





# Patient Self-Evaluation

Patients complete a Patient Self-Evaluation prior to purchasing medical cannabis

- Negative side effects
- **Symptom changes**

# Symptom Changes on Patient Self-Evaluation

- Standard 8 symptoms
  - 0-10 numerical rating scale

e.g.,

Your disturbed sleep at its worst \*



- Condition-Specific symptoms

**What percentage of patients who experienced moderate to severe symptoms achieved  $\geq 30\%$  reduction by the 4<sup>th</sup> month since their first medical cannabis purchase?**

# Symptom Changes – Early Look

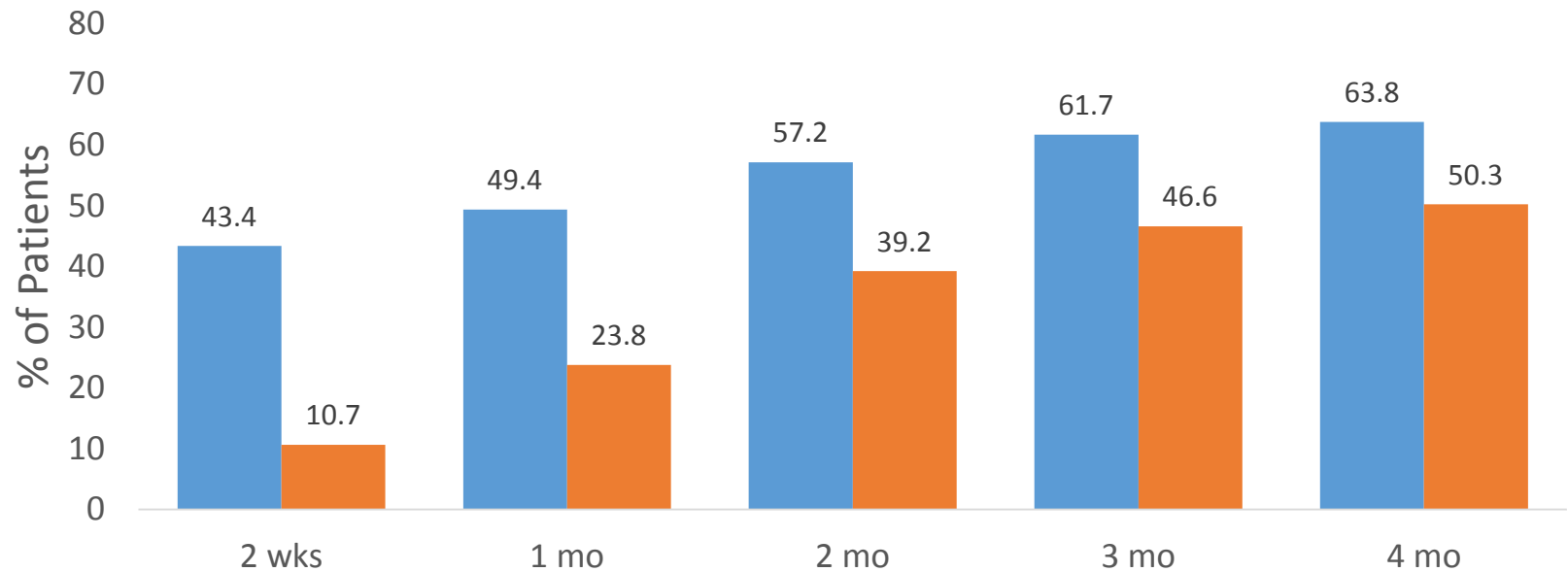
**1512** out of 1660 (91.1%) patients enrolled in the 1<sup>st</sup> year have made some type of medical cannabis purchase AND have at least been enrolled for 4 months since their first medical cannabis purchase

# Symptom Changes: Disturbed Sleep (Standard 8)

- **87.5%** of respondents (1323/1512) rated sleep disturbance at moderate to severe levels at baseline

# Symptom Changes: Disturbed Sleep (Standard 8)

Cumulative 30% Symptom Reduction



■ Of all Moderate to Severe scoring patients submitting data by this time point

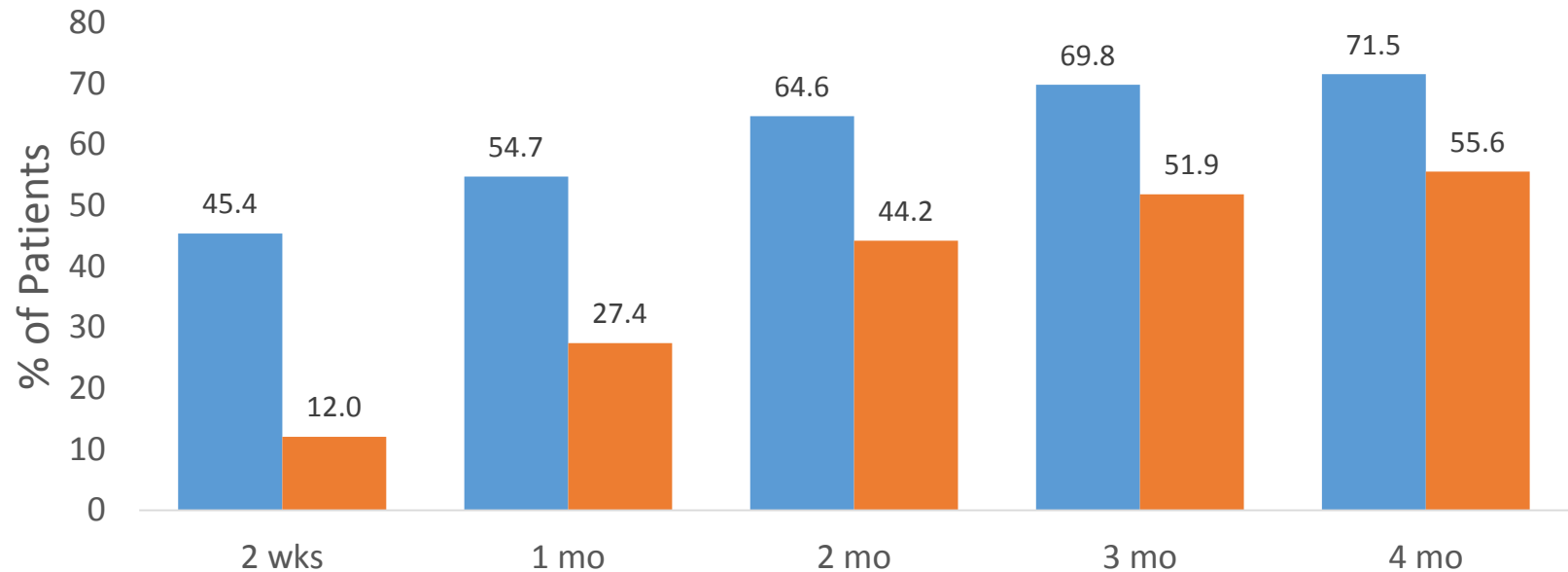
■ Of all Moderate to Severe scoring patients

# Symptom Changes: Nausea (Standard 8)

- **57.1%** of respondents (864/1512) rated nausea at moderate to severe levels at baseline

# Symptom Changes: Nausea (Standard 8)

Cumulative 30% Symptom Reduction



■ Of all Moderate to Severe scoring patients submitting data by this time point

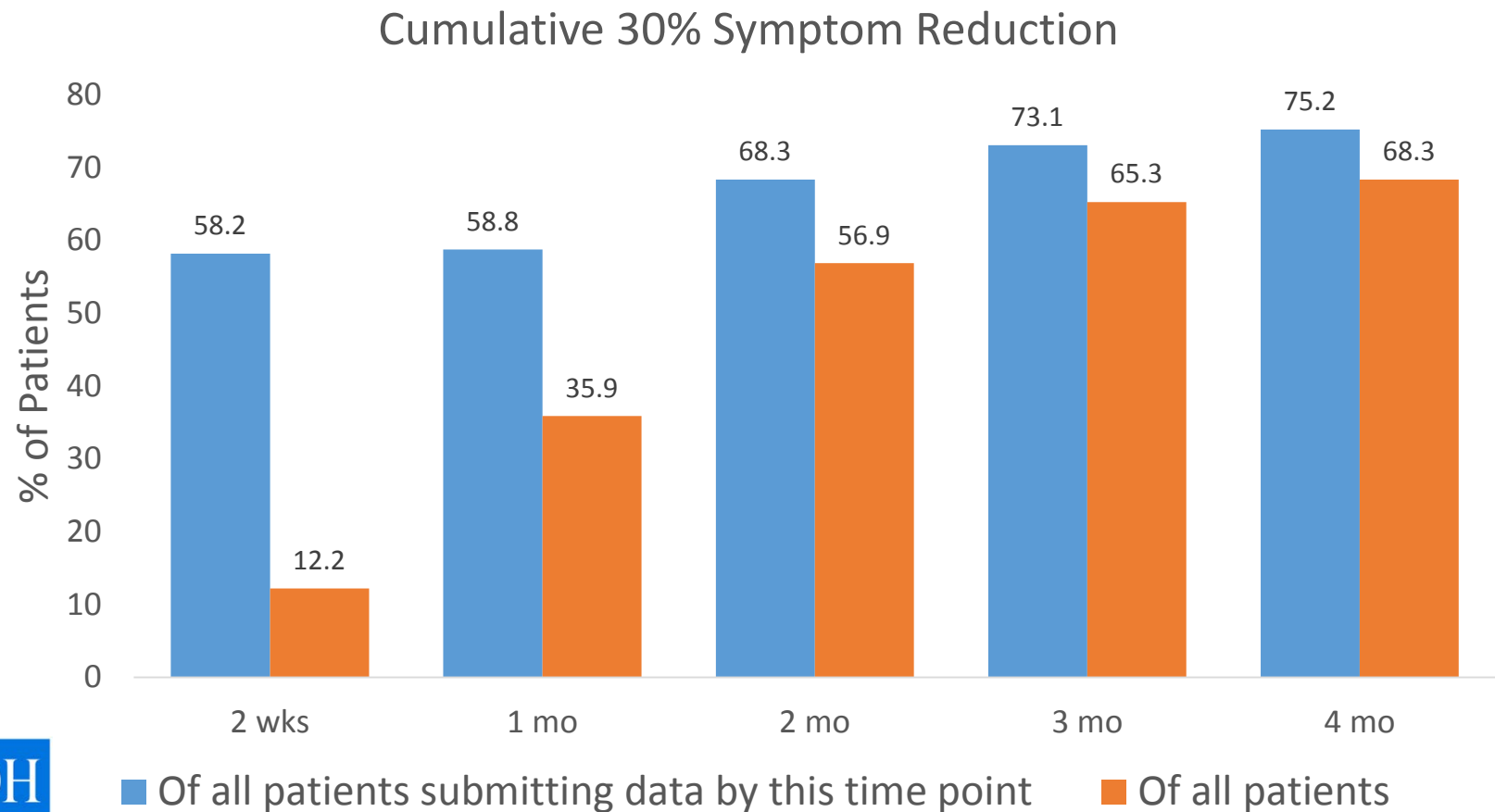
■ Of all Moderate to Severe scoring patients



# Symptom Changes: Weekly Seizure Frequency (Condition-Specific)

- 328 (19.8%) seizure patients enrolled within 1<sup>st</sup> program year
- **262** (79.9%) of them had weekly seizure responses at baseline

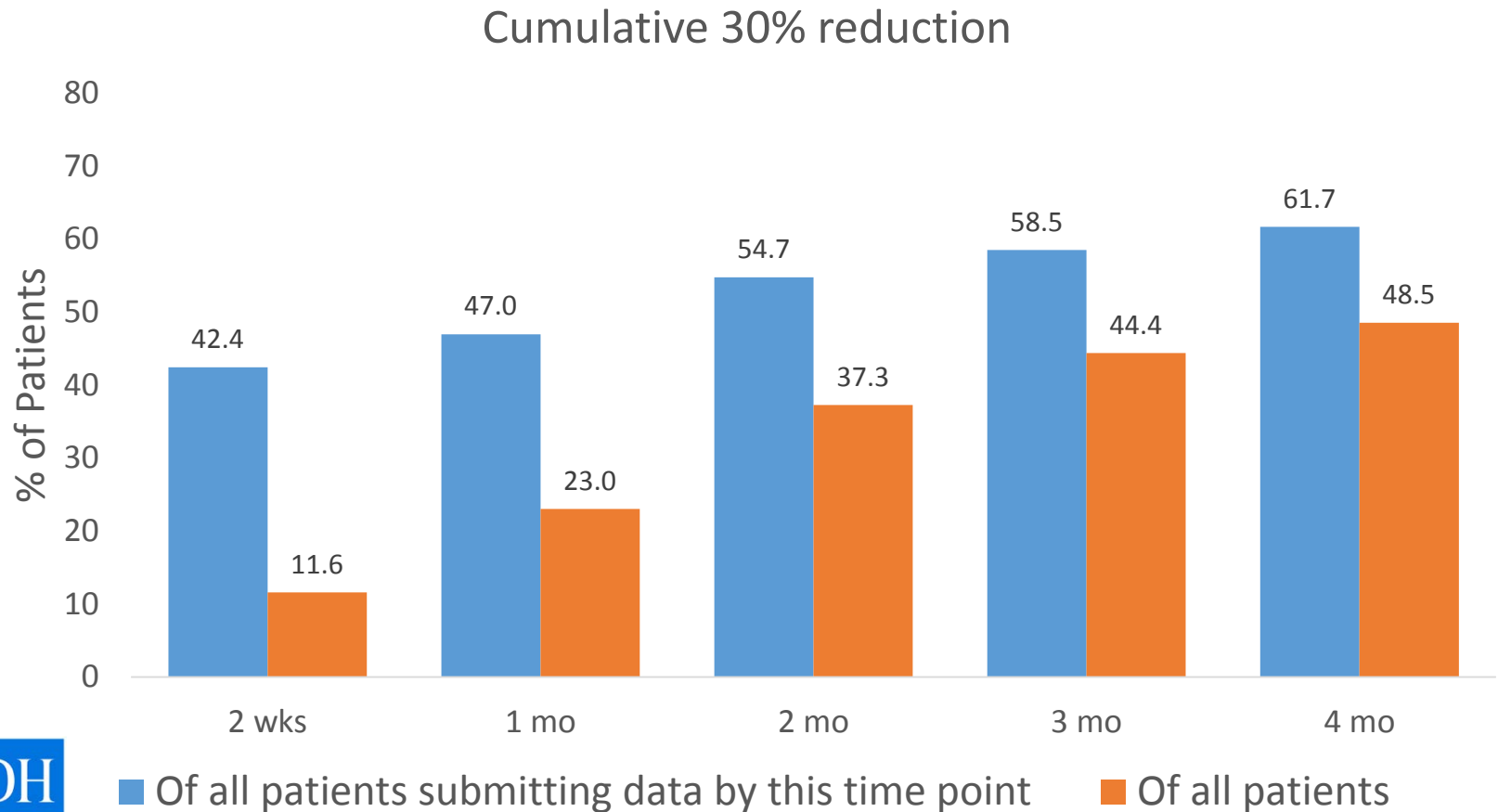
# Symptom Changes: Weekly Seizure Frequency (Condition-Specific)



# Symptom Changes: Weekly Spasms Frequency (Condition-Specific)

- 733 (44.2%) muscle spasm and/or ALS patients enrolled within 1<sup>st</sup> program year
  - 713 Muscle Spasm patients
  - 22 ALS
- **604** (82.4%) of them had weekly spasms responses at baseline

# Symptom Changes: Weekly Spasms Frequency (Condition-Specific)



# Symptom Changes

Additional information in 1<sup>st</sup> year report:

- Description of medical cannabis products patients purchased when patient first achieved 30% symptom reduction
- Description of symptom scores *after* achieving first 30% reduction

# Preliminary Intractable Pain Results

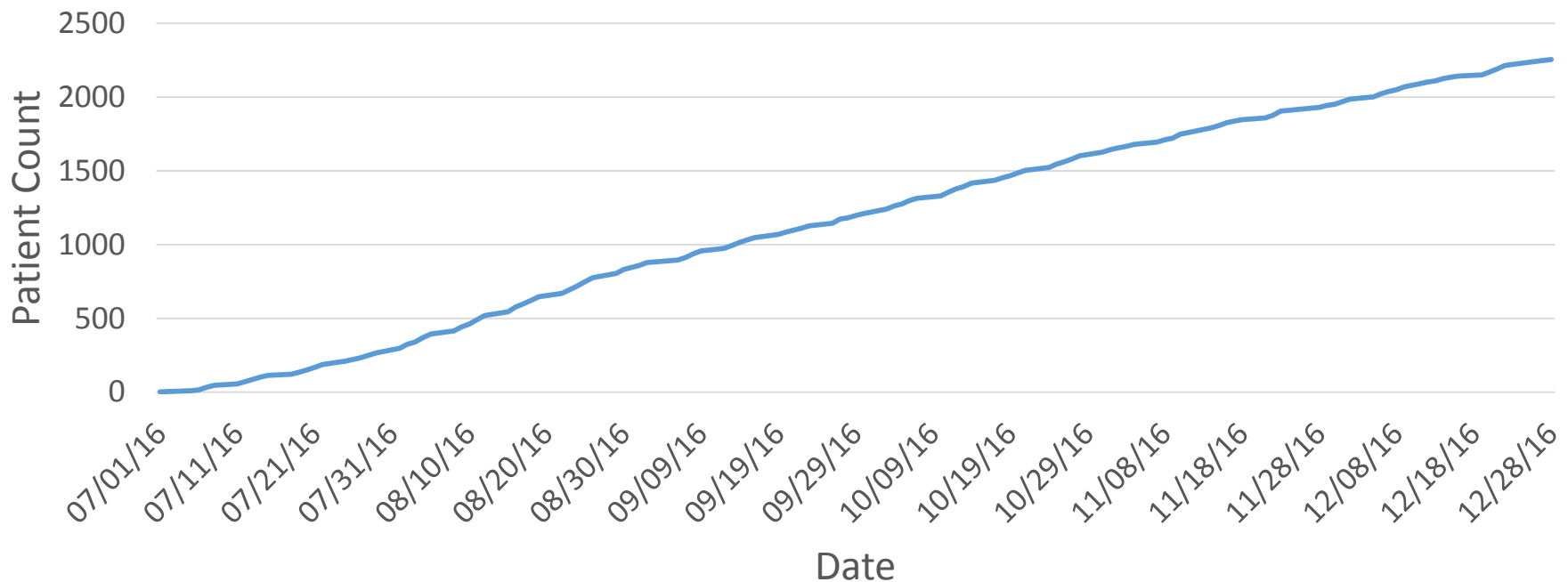
# Intractable Pain Enrollments

**2255 IP patients in Approved status** (as of Dec. 28<sup>th</sup>, 2016)

- **Most common IP causes:**
  - Back pain
    - Axial
    - Radicular
  - Fibromyalgia/myofascial pain
  - Arthritis: osteoarthritis
  - Neuropathy that is not of HIV, diabetic, or post-herpetic origin

# Patients Approved for Intractable Pain

Cumulative Number of Intractable Pain Patients Approved for the Medical Cannabis Program



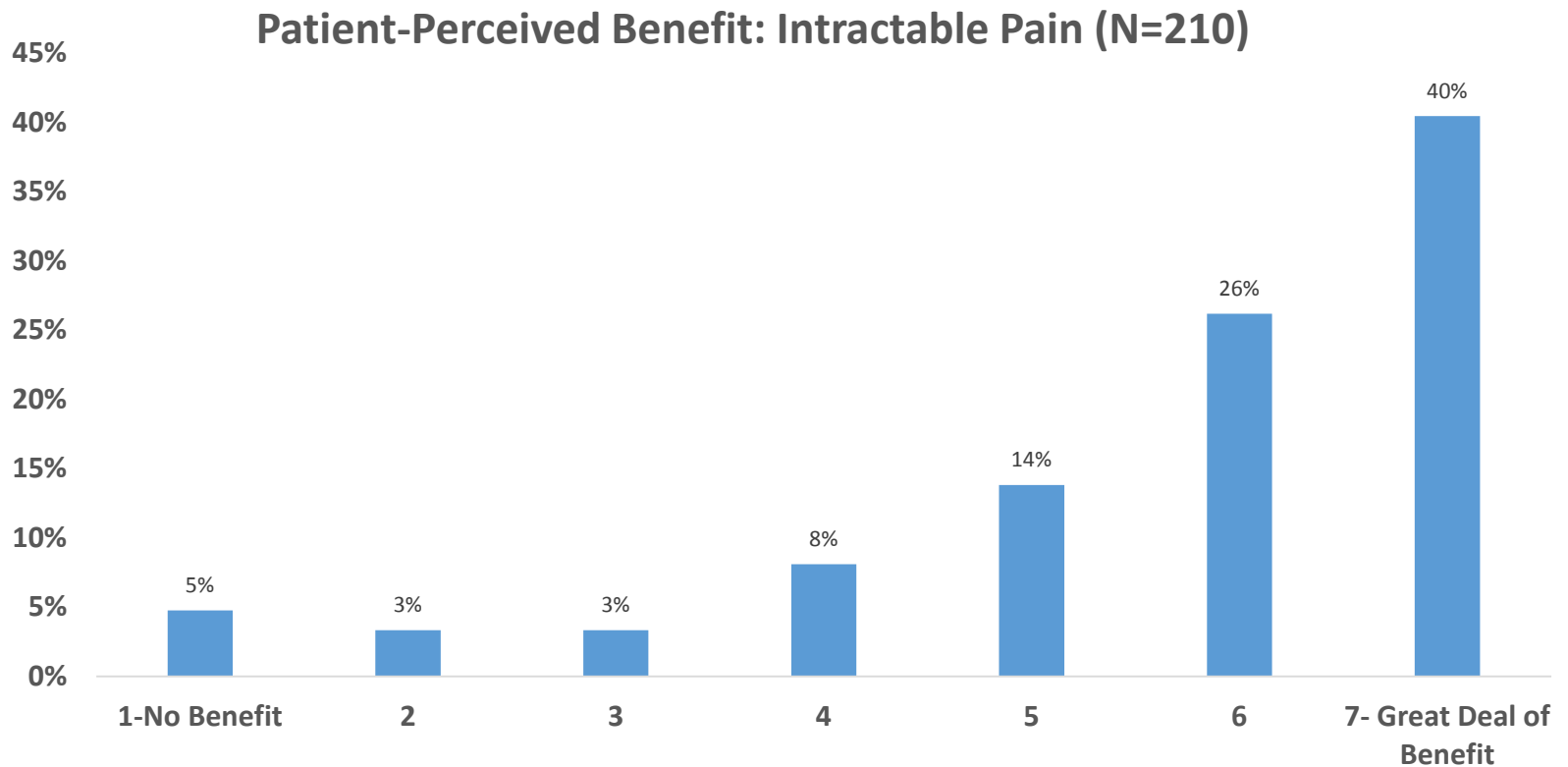
2255 IP patients currently active as of Dec. 28, 2016



# Preliminary Intractable Pain Patient Survey Results

- **382 patients** certified for Intractable Pain began purchasing medical cannabis between **8/1/16 and 8/12/16**
- **210 (55%)** completed a survey 3 months after their first purchase

# Patient Perception of Benefit: Intractable Pain



# Perceived Benefits from Medical Cannabis

<b>Benefit Types</b>	<b>N (%)</b>
Pain Reduction	133 (63%)
Sleep Improvement	58 (28%)
Reduction of Other Medications/Related Side Effects	38 (18%)
Anxiety Reduction	33 (16%)
Quality of Life Improvement	20 (10%)
Mobility/Functional Improvement	16 (8%)
Appetite Improvement	16 (8%)
Nausea/Vomiting Reduction	14 (7%)
Spasm Reduction	11 (5%)
Improved Mood/Attitude	9 (4%)
Improved GI Function	2 (1%)
Improved Alertness/Cognition	1 (0%)
Crohn's Symptoms Reduction	1 (0%)

# Patient Comments

- “1. I can play with my daughter without needing breaks or not being able to at all.**
- 2. I can go to school/work because I can be on my feet without needing to rest every hour or more.**
- 3. I can sleep through the night!**
- 4. I can take my daughter to the zoo or park etc without worrying about if I'll be able to get through it without needing breaks.**
- 5. I can get right up when I wake up without needing an hour or more to get the energy to move.**
- 6. My anxiety has been better, so my life is overall easier to manage**
- 7. It helps with my ovarian cyst pains I get monthly**
- 8. I don't have migraines anymore**
- 9. I can make plans again**
- 10. I'm not nauseous all the time.**

**Honestly, I could keep going and going. The benefits I've experienced are overwhelming. I still have pain, but, it doesn't dictate my life. I feel like I finally have my life back.”**

**“Minimized leg cramps. Helps with daily pain but wish it worked better for how expensive it is.”**

# For more information:

**Office of Medical Cannabis web site:**  
<http://www.health.state.mn.us/topics/cannabis/>

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