IN THE WEEDS: EXPLORING THE SCIENCE AROUND MEDICAL MARIJUANA AND THE OPERATION OF A STATE PROGRAM
In the Weeds: Exploring the Science of Medical Marijuana and Operation of a State Program

Sue Rusche
President and CEO, National Families in Action
The Marijuana Report.Org
Key elements of medical marijuana (MMJ)

- MMJ makers have not submitted their products to the Food and Drug Administration (FDA) for approval to market them to the public.

- No guarantee marijuana medicines are pure, safe, or effective.

- Marijuana is renowned for containing mold, mildew, pesticides, and sometimes pathogens.

- Doctors cannot prescribe, only recommend MMJ.
Marijuana medicines doctors can prescribe

- Marinol
- Cesamet
  - Synthetic THC
  - FDA approved in 1980s
- Sativex
- Epidiolex
  - Undergoing FDA trials in US
  - Both have FDA fast track status
A Guide to Medical Marijuana

Thousands of Marijuana Medicines
Why Can Doctors *Prescribe* Only Two?

By Sue Rusche
President and CEO, National Families in Action
April, 2014
MMJ states that keep data

- Average age of patients is 30 to 40
- Less than 5 percent have cancer or AIDS
- 90 to 95 percent chronic pain
MMJ edibles appeal to children

Marijuana threatens the healthy development of adolescents and young adults because it impairs their developing brains.

Adolescent marijuana use is linked to the development of mental illnesses, including schizophrenia, in those with family histories of mental illness.
Persistent marijuana use that begins before age 18 and continues to mid-life results in an average 8-point drop in IQ, enough to propel an average person to the bottom third of the IQ scale.

Colorado toddlers and preschoolers are being treated for overdoses after eating marijuana edibles.
Marijuana addicts 1 in 6 children. Like the tobacco and alcohol industries, a marijuana industry targets kids to increase its addicted customer base – and profits.
Fact Sheet: Marijuana Effects

State of the Science

Marijuana use has been associated with substantial adverse effects, some of which have been determined with a high level of confidence. *So say leading scientists who conducted a review of research in the New England Journal of Medicine. Adverse effects are summarized in this table, quoted from the article:

<table>
<thead>
<tr>
<th>Effects of short-term use</th>
<th>Effects of long-term or heavy use</th>
</tr>
</thead>
<tbody>
<tr>
<td>Impaired short-term memory, making it difficult to learn and to retain information</td>
<td></td>
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<tr>
<td>Impaired motor coordination, interfering with driving skills and increasing the risk of injuries</td>
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<tr>
<td>Altered judgment, increasing the risk of sexual behaviors that facilitate the transmission of sexually transmitted diseases</td>
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<tr>
<td>In high doses, paranoia and psychosis</td>
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<tr>
<td>Addiction (in about 9% of users overall; 17% of those who begin use in adolescence, and 25 to 50% of those who are daily users)*</td>
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<tr>
<td>Altered brain development*</td>
<td></td>
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<tr>
<td>Poor educational outcome, with increased likelihood of dropping out of school*</td>
<td></td>
</tr>
<tr>
<td>Cognitive impairment, with lower IQ among those who were frequent users during adolescence*</td>
<td></td>
</tr>
<tr>
<td>Diminished life satisfaction and achievement (determined on the basis of subjective and objective measures as compared with such ratings in the general population)*</td>
<td></td>
</tr>
<tr>
<td>Symptoms of chronic bronchitis</td>
<td></td>
</tr>
<tr>
<td>Increased risk of chronic psychotic disorders (including schizophrenia) in persons with a predisposition to such disorders*</td>
<td></td>
</tr>
</tbody>
</table>

* The effect is strongly associated with initial marijuana use early in adolescence.

Fact Sheet: Medical Marijuana

State of the Science

In the June 5, 2014 issue of the New England Journal of Medicine, the authors who are leading scientists state: "There is also a need to improve our understanding of how to harness the potential medical benefits of the marijuana plant without exposing people who are sick to its inherent harms.*

They note that the Institute of Medicine acknowledged the potential benefits of smoking marijuana in stimulating appetite, combating chemotherapy-induced nausea, severe pain, and some forms of spasticity, but point out that the Institute stressed research efforts should focus on "the therapeutic potential of synthetic or pharmacologically pure cannabinoids," components unique to the cannabis plant.

"Some physicians continue to prescribe marijuana for medicinal purposes despite limited evidence of a benefit. This practice raises particular concern with regard to long-term use by vulnerable populations," they warn.

They include a table summarizing what is known—and not known—which we reproduce here without footnotes:

Clinical Conditions with Symptoms That May Be Relieved by Treatment with Marijuana or Other Cannabinoids.

**Glaucus**

Early evidence of the benefits of marijuana in patients with glaucoma (a disease associated with increased pressure in the eye) may be consistent with its ability to effect a transient decrease in intracranial pressure, but other, standard treatments are currently more effective.

**Nausea**

Treatment of the nausea and vomiting associated with chemotherapy was one of the first medical uses of THC and other cannabinoids. THC is an effective antiemetic agent in patients undergoing chemotherapy, but patients often state that marijuana is more effective in suppressing nausea. Other, unidentified compounds in marijuana may enhance the effect of THC (as appears to be the case with THC and cannabidiol, which act through different antiemetic mechanisms). Paradoxically, increased vomiting (hyperemesis) has been reported with repeated marijuana use.
These reports, toolkits & fact sheets are all available from

Marijuana Studies Program
The Marijuana Report.org
National Families in Action
In partnership with Project SAM, Treatment Research Institute, and others.

Alcohol
Alcohol Taxes Should Be Tripled
5/27/14—According to a Pew study, most people see marijuana's relative harmfulness as a reason for to regulate marijuana as lightly as alcohol is regulated. When asked if alcohol would still be more harmful to society than marijuana if marijuana were just as easy to get, a hold of 63 percent said that yes, it would be. Read

Lawmakers begin plans to ban powdered alcohol
4/30/14—The definition of a mixed drink could change if a new product, freeze-dried alcohol, wins federal approval in coming months. Minnesota state Rep. Joe Atkins (D) introduced new legislation that would ban sales of powdered alcohol, known as Palcohol, while a similar bill is moving through Vermont's legislature. Read

Marijuana & Education
'Cannabis College' students banking on medical marijuana
5/20/14—When you think about a college degree you think of things like economics, communications or pol sci. But a group of students in Tampa is learning something that right now is actually illegal to do in the State of Florida. They're learning how to cultivate marijuana. Read

Drug arrests increase 156% at Michigan State University
5/19/14—Michigan State University arrested 261 people for drugs in 2012, a 156 percent increase from two years earlier, the East Lansing school says. The university had more drug arrests than any state school in 2012, the last year for which figures are available, the Lansing State Journal reported. Read

Medical Legalization
Can marijuana heal a wounded warrior?
6/25/14—According to the VA, 20 percent of veterans returning from Afghanistan and Iraq suffer from post-traumatic stress. Current treatments range from therapy to prescription drugs, but the group wants to replace pills with pot, according to veteran and Grow4Vets founder Roger Martin. However, critics are still dubious, given the fact there is little to no scientific proof that pot actually helps with post-traumatic stress disorder. Read

Mining's new joint venture
6/19/14—As a result of the shift in the Canadian mining business, a couple dozen mining companies are now trying out a new business—the cannabis business. Canada started granting its first commercial permits to grow marijuana for medicinal purposes late last year. Since then, at least thirty junior mining enterprises have started diversifying into medical marijuana or have announced plans to do so. Read

Marijuana & Workplace
Reno policy allows up to .08 BAC for firefighters
6/22/14—Reno firefighters can show up to work with up to a .08 percent blood alcohol level or more than twice the legal driving limit of a variety of illegal drugs in their system without facing discipline under a 12-year-old policy negotiated by the city and the fire union. Read
Overview and Disclaimer

- National Background
- AZ’s Proposition 203 and DHS Rules

DISCLAIMER!

THIS PRESENTATION IS NOT LEGAL ADVICE AND DO NOT RELY ON IT AS SUCH. SELLING AND POSSESSING MARIJUANA IS AGAINST FEDERAL LAW!
National MMJ Background

- California started the modern MMJ movement with Proposition 215 in 1996. Now there are 21 States and D.C.
- 5 other states with CBD only laws
  - CBD only laws are not sufficient. Leaves many people suffering unnecessarily (nausea, appetite, pain)
- 2 other states with MMJ laws which ban smoking
  - Smoking often is the easiest way to titrate effective does and takes effect immediately
National MMJ Background

- MMJ and its benefits are REAL and the evidence increasingly supports this.

- Federal Government restrictions prevent research into this important medicine (Catch-22).
  - The only reason research of the benefits of cannabis has taken place is because of State programs or other countries.
    - CA, CO, Israel

- NIDA monopoly on study drug.
  - Possibly starting to open up.
National MMJ Background

- The conflict between State MMJ laws and the Federal Controlled Substances Act remains.

- In 2013 DOJ issued the Cole memo which states that DOJ will not interfere in State programs so long as it is well regulated and doesn’t affect other Federal priorities (e.g. selling to minors, connections to cartels etc.)

- Still not a legal defense if DOJ changes their minds
Proposition 203

- 2010 - Arizona’s Medical Marijuana Program approved by only 4,000 votes; it was the 3rd time over 2 decades that AZ has voted for MMJ
  - AZ legislature overturned the first one leading to the Voter Protection Act (now requires ¾ majority and furthering the purpose for legislature to touch a citizen’s initiative)
- Federal lawsuit filed by Governor and AG delayed implementation of the Dispensary program--thrown out on procedural grounds for lack of jurisdiction
- Lawsuit then filed in State court by County Attorney the court upheld the MMJ Act and Dispensary program. (bottom line MMJ laws NOT Federally preempted)
Proposition 203

- Allows patients to qualify for legal protection if they have a "DEBILITATING MEDICAL CONDITION" Which means one or more of the following:
  - CANCER, GLAUCOMA, HIV, AIDS, HEPATITIS C, ALS, CROHN'S DISEASE, AGITATION OF ALZHEIMER'S DISEASE OR THE TREATMENT OF THESE CONDITIONS.
  - or, A CHRONIC OR DEBILITATING DISEASE OR MEDICAL CONDITION OR ITS TREATMENT THAT PRODUCES ONE OR MORE OF THE FOLLOWING:
    - CACHEXIA, WASTING SYNDROME; SEVERE AND CHRONIC PAIN; SEVERE NAUSEA; SEIZURES, INCLUDING THOSE CHARACTERISTIC OF EPILEPSY; OR SEVERE AND PERSISTENT MUSCLE SPASMS, INCLUDING THOSE CHARACTERISTIC OF MULTIPLE SCLEROSIS.
  - or ANY OTHER MEDICAL CONDITION OR IT’S TREATMENT ADDED BY THE DEPARTMENT—Nearly impossible standard to add conditions but PTSD may make it
Proposition 203

In order to qualify for legal protection the patient must:

- Get a doctors recommendation (MD, NMD, DO)
- Obtain and maintain a patient card from DHS
- Possess only the allowable amount (2.5 ounces every 2 weeks) (12 plants if growing) (allowable amount of concentrates?)
- Swear not provide the MMJ to a non-patient nor sell to another patient (what is a “transfer for value”?)
Proposition 203

- The law initially allowed patients and caregivers to cultivate their own medicine until dispensaries began to open.
- The 2-year delay in dispensaries meant every patient or caregiver could grow if they wanted to.
- Approximately 35,000 patients elected to grow or designated a caregiver to grow for them.
- This led to a proliferation of unlicensed, unregulated “compassion clubs”—Still dealing with this problem today! Lesson: make sure patients have access to medicine ASAP when legal protections are enacted.
Proposition 203

- Dispensaries are Safe and Regulated
- Must comply with numerous security and inventory control regulations
- Employees must pass criminal background checks
- Dispensaries must employee or contract with a Medical Director (MD NMD or DO) who is available to help answer your questions. (the efficacy of this requirement is questionable)
- Most reputable dispensaries test their medicine for potency and purity (i.e. no pesticides, mold, fungus)—although not currently required by DHS
Proposition 203--Dispensaries
Proposition 203--Dispensaries
MMJ and the Future

- MMJ consistently polls at over 70% approval
- The barriers to research are starting to weaken
- MMJ may be an integral part of a new “wellness” approach to medicine!
  - Inhibiting or reversing cancer/tumor growth
  - Preventing Alzheimer’s (HHS patent no. 6630507)
- Increasingly finding new ways to get some benefits without the “high” if desired
  - Juicing raw plant
  - CBD
Important takeaways:

- *If you are strictly compliant with State MMJ laws, your risk at the Federal level is practically non-existent (but theoretically Federal arrest still possible)*

- *Providing sufficient access concurrently with legal protections is vital to ensuring a program with sufficient regulatory oversight—otherwise patients will find a supply of their own*
Important takeaways:

- AZ currently has approximately 48,000 patients (appears to be consistent with a truly medical program)
- These are capital intensive and difficult business to run correctly. By increasing barriers to entry you encourage strict compliance
- If you have any questions at all consult an expert (legal, medical, MMJ)
Questions?

www.roselawgroup.com
M. Ryan Hurley
480-240-5585
AN FDA-APPROVED INVESTIGATION OF THE SAFETY AND EFFICACY OF MEDICAL MARIJUANA IN VETERANS WITH CHRONIC, TREATMENT-RESISTANT POSTTRAUMATIC STRESS DISORDER

• By Sue Sisley, M.D.
• Principal Investigator
NO PERSONAL, PROFESSIONAL NOR FINANCIAL INTEREST IN MARIJUANA

• I have NO personal experience with MJ

• I do NOT write Qualifying Patient certifications for MJ

• I do NOT receive money from MJ Dispensaries or other MJ Industries.
STUDY OBJECTIVES

• To investigate the safety and efficacy of five different potencies of marijuana
  • (0% or 12% THC or 6% CBD/<1% THC 6% THC/6% CBD),

as treatment in veterans diagnosed with chronic, treatment-resistant, service-related PTSD

• And to compare the safety and efficacy of two substance delivery methods:
  1) smoking or
  2) vaporizing.
• Schedule I
  • No medical benefit and high potential for abuse

• Schedule II
  • Medical benefit, strong abuse potential

• Schedule III
  • Accepted medical use, less abuse potential than above
<table>
<thead>
<tr>
<th>Schedule</th>
<th>Drugs</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Schedule I</strong></td>
<td>Ecstasy, China White, GHB, Heroin (synthetic and natural), Lysergic Acid Diethylamide (LSD), Marijuana, Mescaline, Peyote, Psilocin and Psilocybin (constituents of magic mushrooms)</td>
</tr>
<tr>
<td><strong>Schedule II</strong></td>
<td>Amphetamine, Cocaine and Crack, Codeine, Fentanyl, Hydrocodone, Meperidine (Demerol®), Methadone, Methylphenidate (Ritalin), Morphine, Opium, Oxycodone (OxyContin®, Percocet®), Phencyclidine (PCP)</td>
</tr>
<tr>
<td><strong>Schedule III</strong></td>
<td>Anabolic steroids, Barbiturates, Ketamine, LSD precursors</td>
</tr>
<tr>
<td><strong>Schedule IV</strong></td>
<td>Alprazolam (Xanax®), Clonazepam (Klonopin®, Clonopin®), Diazepam (Valium®), Flunitrazepam (Rohypnol), Lorazepam (Ativan®), Triazolam (Halcion®), Zolpidem (Ambien®)</td>
</tr>
<tr>
<td><strong>Schedule V</strong></td>
<td>Codeine preparations—200 mg/ml or 100 g (Cosanyl, Robitussin A-C®, Cheracol®, Cerose®, Pediacof®)</td>
</tr>
</tbody>
</table>
“NIDA MONOPOLY”

• The National Institute of Drug Abuse holds a government-enforced monopoly on the legal supply of research marijuana.

• Marijuana is the only Schedule 1 drug for which the federal government not only controls the supply, but also requires a special review of all scientific protocols by a NIDA/Public Health Service (PHS) review panel.
Since 1968 the DEA has licensed only one Cannabis-production facility in the US, housed at the University of Mississippi.

If NIDA decides not to sell Marijuana to a group of researchers, their study becomes impossible to conduct.

Unlike the 30-day timetable that the FDA must follow when reviewing research protocols, the NIDA/PHS review process has NO DEADLINE.
NIDA MONOPOLY

• We unsuccessfully tried to purchase 10 grams of marijuana from NIDA for 7 years for vaporizer research.

• An LSD study looking at Tx of End-of-Life Anxiety has NO delay once FDA-approval obtained. No 2nd review required by DEA/NIDA—only Cannabis is subject to these multiple redundant reviews by PHS and NIDA.
Marijuana May Be Studied for Combat Disorder

By DAN FROSCH

DENVER — For years now, some veterans groups and marijuana advocates have argued that the therapeutic benefits of the drug can help soothe the psychological wounds of battle. But with only anecdotal evidence as support, their claims have yet to gain widespread acceptance in medical circles.

Now, however, researchers are seeking federal approval for what is believed to be the first study to examine the effects of marijuana on veterans with chronic post-traumatic stress disorder.

The proposal, from the Multidisciplinary Association for Psychedelic Studies in Santa Cruz, Calif., and a researcher at the University of Arizona College of Medicine, would look at the possibility of using marijuana, among other substances.

"There is a widely accepted need for a new treatment of PTSD," said Rick Doblin, who wants to do research on marijuana.

condition, according to the state's health department. It is unclear how many are veterans.

One recent Army veteran from Texas who fought in Iraq for 18 months beginning in 2006, said he used marijuana three times a day in lieu of the painkillers and antidepressants he was prescribed after returning home. He asked that his name not be used because Texas does not allow medical marijuana.

The veteran, who said he had been shot in the leg and suffered numerous head injuries from explosions while deployed as a Humvee gunner, said marijuana helped quiet his physical and psychological pain, while not causing the weight loss and sleep deprivation brought on by his prescription medications.

"I have cancer, but I'm not okay."
WHY STUDY NEW TREATMENTS FOR PTSD?

• PTSD plagues between 6 and 10% of the US population at some point during their lifetime

• Approximately 18% of soldiers returning from combat in the Iraq war will have PTSD

• In 2010, the U.S. Veterans Administration spent about $5.5 billion on PTSD disability payments to about 275,000 veterans
“Drugs widely prescribed to treat severe PTSD symptoms for veterans are no more effective than placebos and come with serious side effects.”
WHY STUDY NEW TREATMENTS FOR PTSD?

A significant percentage of PTSD patients fail to respond adequately to FDA-approved treatments, suggesting a need to develop innovative treatments.
WHY STUDY NEW TREATMENTS FOR PTSD?

• Numerous anecdotal reports of marijuana used successfully for PTSD by veterans

• One recent Army veteran from Texas who fought in Iraq for 18 months beginning in 2006, said he used marijuana three times a day in lieu of the painkillers and antidepressants he was prescribed after returning home. (The New York Times, July 18, 2011)
WHY STUDY NEW TREATMENTS FOR PTSD?

- The Endocannabinoid System has been suggested to be involved in regulating sleep, anxiety, attention to and response to stressful situations; may be involved in the extinction of conditioned fear; modulate GABAergic transmission and enhance the release of endogenous opioids.

- Exogenous cannabinoids trigger the Endocannabinoid System
WHY MARIJUANA FOR PTSD?

• At present, there are NO PUBLISHED DATA from a randomized, placebo-controlled, study of the risks AND benefits of marijuana for subjects with chronic treatment-resistant PTSD from any cause.
TIMELINE

- November 12, 2010
  - Protocol submitted to the FDA

- Morning April 28, 2011
  - Protocol approved by FDA

- Afternoon April 28, 2011
  - Protocol sent to DEA
LATEST DEVELOPMENTS

- 3 years later and still no reply from DEA/NIDA until April 2014 when PHS Public Health Service issues Letter of APPROVAL arrived 2 days after CNN Dr. Gupta Weeds 2 documentary airs.

- 1 week after PHS greenlights the study, NIDA informs us via email that they have NO MARIJUANA STUDY DRUG to sell: No strains outlined in our FDA approved protocol despite written assurances back in 2011 that they had every strain we needed to conduct the study. Maybe they never believed the study would ever get the approval.

- NIDA has NO TRACK RECORD of successfully growing any high-CBD strains of Marijuana which is an essential arm of our PTSD study.
Huge barrels store the end product, a ground-up mix of buds, leaves and stems that will eventually be machine rolled into joints, packaged in metal containers, and sent to the four remaining medical-marijuana patients still supplied by the federal government.
NIDA MARIJUANA CIGARETTES
UNROLLED NIDA MARIJUANA: MOSTLY LEAF
STEMS AND SEEDS IN 3 NIDA-SUPPLIED MARIJUANA CIGARETTES
HYPOTHESES

• Marijuana will ease the symptoms of PTSD, specifically reducing nightmares, improving sleep, and improving mood as measured in by the Clinician Administered PTSD Scale (CAPS)

• Marijuana, in a dose dependent manner, will ease the symptoms of PTSD

• Marijuana with *6% THC/6% CBD and *6% CBD alone will be more effective than marijuana with 6% THC alone
SAFETY MEASURES

• Two 4-hour long sessions on two consecutive days as an added safety measure prior to initiation of treatment phase for 2 reasons:

  • To monitor and collect data on any Adverse Events/serious side effects.
  • To train study subjects in standardized delivery method for either smoking or vaporizing Marijuana Study Drug
### MARIJUANA DOSES

#### Stage 1

<table>
<thead>
<tr>
<th>Dose</th>
<th>Number of Participants receiving dose</th>
<th>Smoked marijuana</th>
<th>Vaporized Marijuana</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 % THC marijuana</td>
<td>14</td>
<td>7</td>
<td>7</td>
</tr>
<tr>
<td>6 % THC marijuana</td>
<td>14</td>
<td>7</td>
<td>7</td>
</tr>
<tr>
<td>6 % CBD marijuana</td>
<td>14</td>
<td>7</td>
<td>7</td>
</tr>
<tr>
<td>6 % THC/6 % CBD marijuana</td>
<td>14</td>
<td>7</td>
<td>7</td>
</tr>
<tr>
<td>12 % THC marijuana</td>
<td>14</td>
<td>7</td>
<td>7</td>
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</tbody>
</table>

#### Stage 2

<table>
<thead>
<tr>
<th>Dose</th>
<th>Number of Participants receiving dose</th>
<th>Smoked* Marijuana</th>
<th>Vaporized* Marijuana</th>
</tr>
</thead>
<tbody>
<tr>
<td>12 % THC marijuana</td>
<td>23</td>
<td>11</td>
<td>12</td>
</tr>
<tr>
<td>6 % CBD marijuana</td>
<td>23</td>
<td>11</td>
<td>12</td>
</tr>
<tr>
<td>6 % THC/6% CBD marijuana</td>
<td>24</td>
<td>12</td>
<td>12</td>
</tr>
</tbody>
</table>
MARIJUANA ADMINISTRATION

• Method 1: Participant smokes pre-rolled marijuana cigarette, weighing 0.9 grams

• Method 2: Participant vaporizes material from pre-rolled cigarette in a Volcano vaporizer

• Vaporize: to convert into vapor, by the application of hot air with no combustion
BENEFITS OF VAPORIZING

- No products of combustion, smoke, or taste of smoke

- Vapor still contains particulate matter from the plant, but compared to smoking it is much safer
TREATMENT PROCESS

- Investigator will contact subject via telephone on a daily basis during the first week of Stage 1 and first week of Stage 2.
- Participant will meet with investigator at the study site once a week during the self-administration period and abstinence period.
- Study duration = 15 months.

Screening/Baseline

4-hour Introductory Sessions

Stage 1

- 4 weeks Self-administration
- Stage 1 Evaluation

2 Weeks Marijuana Abstinence

Stage 2

- 4-weeks Self-administration
- Stage 2 Evaluation

2 Weeks Marijuana Abstinence

Stage 3

- Optional self-administration of unused marijuana

Follow-up

12 Months
ENSURING SAFETY

• Storage box with combination lock

• Subjects **required to return unused amounts to investigators during each weekly visit**

• Should subjects request it, all unused marijuana will be returned to them at the end of Stage 2, reducing likelihood of unnecessary use or diversion

• Investigators provide subjects with portable video cameras, and subjects are asked to record their use of marijuana.

• Participant designates **an secondary verifier** who the investigator will telephone weekly

• Research staff **will contact subject via telephone daily for the first week of marijuana self-administration**

• Subjects provided with 1 week supply at a time (2 grams per day)
NIDA: CONTINUING SAGA

• In January 2011 NIDA wrote to us indicating that they were confident they could provide the marijuana we needed containing a balanced THC/CBD ratio, about 5-6% THC and 5-6% CBD.

• On May 9, 2014, they wrote to us again to say that they did not have that strain and would need to grow it, and that it wouldn't be ready until the fall.

• NIDA will then need to dry, process, and package the marijuana into rolled cigarettes, which is where we got our January 2015 estimate.

• Since NIDA claims they're FINALLY attempting to grow this new equal ratio THC/CBD variety, we have also requested that they simultaneously produce a CBD-only strain, which would contain roughly 6% CBD with less than 1% THC.
On May 27 they told us "We are targeting to obtain the cannabis varieties that you are looking for but it is too early to commit their availability in advance."

NIDA is required under the Controlled Substances Act of 1970 to provide an "adequate and uninterrupted supply of these substances under adequately competitive conditions" of marijuana for research, which they have now admitted in writing they are INCAPABLE OF PROVIDING.
In 2001, MAPS began helping Prof. Lyle Craker, director of the Medicinal Plant Program at the University of Massachusetts at Amherst, to apply to the DEA for a license to open a marijuana-production facility for FDA-approved research.

Craker’s proposed facility would focus on providing medical-grade marijuana, including strains with high-CBD, for FDA-approved studies.
• In February 2007, the DEA’s Administrative Law Judge, Mary Ellen Bittner, issued a recommendation affirming that it would be in the public interest for DEA to grant Prof Craker a license.

• According to Bittner’s ruling, federal officials had repeatedly refused to provide marijuana on reasonable cannabis-research requests in a timely manner or had denied them outright, creating a clear need to end the NIDA monopoly.
• Judge Bittner’s recommendation was ignored for nearly two years.

• Six days before President Obama was inaugurated, Acting DEA Administrator Michelle Leonhard officially rejected the recommendation and denied Craker’s license.
NIDA MONOPOLY

- On December 15, MAPS filed with the First Circuit Court of Appeals.

- On March 22, 2012, after three requests for delays, DEA responded.

- In 2013 Court denied the Appeal, and we are forced to continue dealing with sole legal supplier, NIDA Monopoly for Marijuana Study Drug.
ARMA AND MCMS RESOLUTIONS TO ELIMINATE BARRIERS TO MJ RESEARCH

- THE ARIZONA MEDICAL ASSOCIATION, INC.
- HOUSE OF DELEGATES
- DATE: 5/15/12
- SUBJECT: NIDA’S SOLE AUTHORITY AND BARRIERS TO THE ADVANCEMENT OF ESSENTIAL CANNABIS RESEARCH
- ASSIGNED TO: REFERENCE COMMITTEE ON REPORTS AND RESOLUTIONS
• **RESOLVED**, That the Arizona Medical Association should urge the following policy to our Arizona congressional delegation through our local government relations department.

• Once the protocol for privately-funded marijuana research has been reviewed and approved by the Food and Drug Administration FDA and relevant Independent Review Board IRB and the practitioner has obtained registration from the Drug Enforcement Administration DEA, the National Institute of Drug Abuse NIDA shall, without further evaluation of the research protocol, supply marijuana for the research, at cost, upon the practitioner’s proper application.
"A SCIENTIST WHO IS ALSO A HUMAN BEING CANNOT REST WHILE KNOWLEDGE WHICH MIGHT BE USED TO REDUCE SUFFERING RESTS ON THE SHELF..."

- ALBERT B. SABIN, MD
B. AUGUST 26, 1906