# The Difference Between Medical Marijuana and Marijuana-Based Medicines A Guide for Journalists and Policymakers

# National Families in Action January 2015

# 1. How the Food and Drug Administration Protects Us from Unsafe, Ineffective Drugs

## Before a medicine maker can market a new drug to the public, he must establish:

That the drug is safe:

 Must test in animals to make sure it's safe for human use and shows preliminary evidence of effectiveness.

That the drug is effective:

- Must test in healthy humans for safety, then in sick humans to determine if the drug does what its maker says it will do.
- Conducts randomized controlled trials (RCTs) to determine safety and efficacy in humans.

A precise dose and regimen (length of time the drug should be taken).

## Once these proofs are established:

FDA approves the new drug.

- Medicine maker can market and distribute it.
- Doctors can prescribe it.
- Pharmacies can sell it.

A reporting system is in place:

• To recall the drug if side-effects appear that did not show up in human testing (clinical trials).

# 2. Medical Marijuana

## Is legalized by voters via initiatives advocates place on the ballot or by elected officials.

Few are scientists, pharmacologists, or doctors licensed to practice medicine.

- Few are trained or qualified to create medicines.
- Legalizing marijuana for medical use has no scientific basis to support such action.

## No producers of legalized medical marijuana have submitted their drugs to FDA for approval.

Doctors cannot *prescribe* medical marijuana. Laws call for doctors to either:

- Recommend medical marijuana, or
- Certify that a patient has a disease or symptom which laws claim medical marijuana treats or relieves

Patients have no guarantees that medical marijuana is:

- Safe, or
- Effective.

Pharmacies cannot sell medical marijuana, and pharmacists cannot dispense it.

• No recall system is in place if side-effects emerge.

Anyone can claim a specific marijuana strain or compound will treat:

- Almost any symptom or disease (see Leafly).
- Medical marijuana has been legislated to treat more than 50 diseases in 23 states.<sup>1</sup>

# 3. Marijuana-Based Medicines

## Are created by researchers and pharmacologists:

Who are trained and qualified to develop and test marijuana-based medicines for FDA approval.

## Approved by FDA in the 1980s

Dronabinol (trade name Marinol®) and Nabilone (trade name Cesamet®)

Synthetic (man-made) THC

 Reduce chemotherapy-related nausea and AIDs wasting in patients who do not respond to standard medicines.

#### In FDA clinical trials

Nabiximols (trade name Sativex®)

- A mouth spray consisting of highly purified cannabidiol (CBD) and THC
- Extracted from marijuana grown without the use of pesticides in computer-controlled glasshouses by GW Pharmaceuticals in Great Britain
- · Approved in 27 countries to treat multiple sclerosis
- In Phase III trials in US to treat advanced cancer pain

## CBD (trade name Epidiolex®)

- A highly purified CBD oil
- Extracted from marijuana grown by GW Pharmaceuticals
- In clinical trials in US to treat intractable seizures in children with rare forms of epilepsy
- Through FDA expanded access programs, Epidiolex® is provided to children with epilepsy while clinical trials proceed.

## Expected to enter FDA clinical trials in 2015

Insys Therapeutics' CBD candidate

- A synthetic (man-made) CBD oil made with pure chemicals
- To reduce intractable seizures in children with rare forms of epilepsy

## There is no need to legalize marijuana-based medicines.

They are legal for patients to possess and use:

- In research studies and during clinical trials, and
- With a prescription once FDA approves them.

Medical Marijuana vs. FDA Approved Marijuana-Based Medicines	
Legalized Medical Marijuana	FDA Approved Marijuana-Based Medicines
No Proven Safety No Proven Efficacy No Established Dose or Regimen No Randomized Controlled Trials No Recall System Doctors Recommend or Certify Dispensaries Sell Budtenders Dispense	Safe Effective Established Dose and Regimen Randomized Controlled Trials Recall System Doctors Prescribe Pharmacies Sell Pharmacists Dispense

### Cannabidiol (CBD) Oil

In 2014, 11 states legalized Charlotte's Web or cannabidiol oil (CBD) for children with epilepsy.

- Legalized CBD oil is not a marijuana-based medicine.
- It has not been approved by FDA as safe or effective.

To date, a few states are administering Epidiolex® to these children:

- In clinical trials and via FDA expanded access programs.
- Epidiolex® is a marijuana-based medicine seeking FDA approval.
- It is not medical marijuana.

Journalists should use correct terms:

• To distinguish between marijuana-based medicines, i.e. Epidiolex, and medical marijuana, i.e., Charlotte's Web oil, when reporting this story.

<sup>&</sup>lt;sup>1</sup> Some medical marijuana states include a provision that enables citizens to petition state agencies to add additional diseases they believe medical marijuana treats.

## States Have Legalized Medical Marijuana to Treat The Following Diseases as of 1.1.2015

#### Alaska

Cachexia Cancer Chronic Pain Glaucoma HIV or AIDS Multiple Sclerosis Nausea Seizures

## Arizona

Alzheimer's Disease
Amyotrophic Lateral Sclerosis
(Lou Gehrig's disease)
Cachexia or wasting
syndrome
Cancer
Chronic pain
Crohn's Disease
Glaucoma
Hepatitis C
HIV or AIDS
Multiple Sclerosis
Nausea
PTSD

# Seizures California

California
Arthritis
Cachexia
Cancer
Chronic pain
HIV or AIDS
Epilepsy
Migraine
Multiple Sclerosis
Any debilitating illness where
the medical use of marijuana
has been "deemed
appropriate and has been
recommended by a
physician"

#### Colorado

Cachexia
Cancer
Chronic pain
Chronic nervous system
disorders
Epilepsy
Glaucoma
HIV or AIDS
Multiple Sclerosis
Nausea

## Connecticut

Cachexia
Cancer
Crohn's disease
Epilepsy
Glaucoma
HIV or AIDS
Intractable spasticity
Multiple Sclerosis
Parkinson's Disease
Posttraumatic Stress
Disorder (PTSD)
Other medical conditions may
be approved by the
Department of Consumer
Protection

#### Delaware

Alzheimer's disease Amyotrophic Lateral Sclerosis Cachexia Cancer Chronic pain HIV/AIDS Nausea Post-traumatic Stress Disorder (PTSD) Seizures Severe and persistent muscle

#### **District of Columbia**

Any debilitating condition as recommended by a DC licensed doctor

#### Hawaii

Cachexia
Cancer
Chronic pain
Crohn's disease
Epilepsy and other disorders
characterized by seizures
Glaucoma
HIV or AIDS
Multiple sclerosis and other
disorders characterized by

# Nausea Illinois

muscle spasticity

Alzheimer's disease Amyotrophic Lateral Sclerosis (ALS) Arnold Chiari malformation Cachexia/wasting syndrome Cancer Causalgia Chronic Inflammatory Demyelinating Polyneuropathy Crohn's Disease Dystonia Fibromyalgia Glaucoma Hepatitis C HIV/AIDS Hydrocephalus Hydromyelia Interstitial Cystitis Lupus Multiple Sclerosis Muscular Dystrophy Myasthenia Gravis Myoclonus

# Nail patella syndrome

Neurofibromatosis
Parkinson's disease
Reflex Sympathetic
Dystrophy (RSD)
Rheumatoid Arthritis
Sjogren's syndrome
Spinal cord disease
Spinal cord injury

Spinocerebellar Ataxia (SCA) Syringomyelia

Tarlov cysts
Tourette's synd

Tourette's syndrome Traumatic brain injury and post-concussion syndrome

#### Maine

Alzheimer's disease
Amyotrophic Lateral Sclerosis
Cachexia or wasting
syndrome
Cancer
Chronic pain
Crohn's disease
Epilepsy
Glaucoma
Hepatitis C
HIV or AIDS

Huntington's disease Inflammatory bowel disease Multiple Sclerosis

Nausea

Nail-patella syndrome Parkinson's disease Post-traumatic stress disorder (PTSD)

#### Maryland

Nail-patella syndrome Parkinson's disease Post-traumatic stress disorder (PTSD)

Cachexia, Anorexia, or

## Massachusetts

Nausea

Wasting Syndrome Chronic Pain Nausea Seizures Severe or persistent muscle spasms Michigan Alzheimer's disease Amyotrophic Lateral Sclerosis Cachexia or wasting syndrome Cancer Chronic pain Crohn's disease Glaucoma HIV or AIDS

Nausea Post-traumatic stress disorder (PTSD)

Hepatitis C

Nail patella

Seizures Severe and persistent muscle spasms

#### Minnesota

Amyotrophic Lateral Sclerosis
Cancer/cachexia
Glaucoma
HIV/AIDS
Seizures
Severe and persistent muscle
spasms
Terminal illness
Tourette's Syndrome

#### Montana

Cachexia or wasting syndrome Chronic pain Nausea Seizures Severe or persistent muscle spasms

#### Nevada

AIDS
Cachexia
Cancer
Glaucoma
Post-traumatic stress
disorder (PTSD)
Persistent muscle spasms or
seizures
Severe nausea or pain
Other conditions are subject
to approval

#### **New Hampshire**

Cancer Crohn's disease Hepatitis C Muscular Dystrophy Multiple Sclerosis

#### **New Jersey**

Cancer
Glaucoma
HIV/AIDS
Inflammatory bowel disease
Lou Gehrig's disease
Multiple Sclerosis
Muscular Dystrophy
Seizure and/or spasticity
disorders
Any terminal illness if a
doctor has determined the
patient will die within a year

#### **New Mexico**

Amyotrophic Lateral Sclerosis (Lou Gehrig's disease) Anorexia/cachexia Arthritis Cancer Chronic pain Crohn's disease **Epilepsy** Glaucoma Hepatitis C HIV/AIDS Hospice patients Huntington's disease Intractable nausea/vomiting Multiple sclerosis Painful peripheral neuropathy Parkinson's disease Post-traumatic Stress Disorder Spinal cord damage

New York Cancer Epilepsy HIV/AIDS

Huntington's Disease Inflammatory bowel disease Lou Gehrig's disease Parkinson's Disease Multiple Sclerosis Neuropathies Spinal cord damage

Oregon

Alzheimer's disease Cachexia Cancer Chronic pain Epilepsy Glaucoma HIV or AIDS Multiple Sclerosis

Post-traumatic stress
Other conditions are subject

to approval

Nausea

Rhode Island Alzheimer's Disease

Cachexia
Cancer
Chronic pain
Glaucoma
Hepatitis C
Nausea
Seizures

Severe and persistent muscle spasms

Other conditions are subject to approval

Vermont

Cachexia or wasting syndrome Cancer HIV or AIDS Multiple Sclerosis Seizures Severe pain Severe nausea

Washington Cachexia

Cancera
Cancer
Cancer
Crohn's disease
Epilepsy
Glaucoma
Hepatitis C
HIV or AIDS
Intractable pain
Muscle spasms, and/or
spasticity
Multiple Sclerosis
Nausea

Seizures Other conditions are subject to approval The following states legalized medical marijuana CBD oil

only in 2104:
Alabama
Florida
lowa
Kentucky
Mississippi
Missouri
North Carolina
South Carolina
Tennessee
Utah
Wisconsin

Source: National Organization for the Reform of Marijuana Laws (NORML)

## **About National Families in Action**