Real Medicines have Real Risks
An Explanation of Marijuana’s Potential Health Hazards

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Medical Director, Best Practices for Schizophrenia Treatment (BeST) Center
Disclosures

- No connection to cannabis industry or pro-cannabis lobby
- No connection to any anti-cannabis organization
- Received $962.46 (in meals at lunch/dinner lectures) from pharmaceutical industry between 2013 to 2018
- Always signed petitions for, and voted in favor of measures to make cannabis legal
- Believe that informed adults should who choose to use cannabis should be free to do so legally
  - But they should not have to learn about risk the hard way
The ‘What’ and ‘Why’ of This Talk

Objectives

• Discuss major pharmacological actions or cannabis
• Identify cannabis’ most significant health risks
• Explain how these risks relate to cannabis pharmacology

Why?

• Because every real medicine comes with risks
• A lot of people underestimate the risks from cannabis
Underestimating Cannabis Risk
Public Perception of Cannabis Risk Potential

- Perception of “great risk” from weekly marijuana use dropped from 50.4% in 2002 to 33.3% in 2014\(^1\)
- Aside from legal problems, at least half of Americans report little concern for serious risks\(^2\)
- **65%** of teens are not worried that cannabis might damage health\(^3\)
- **30%** believe that smoking or vaping cannabis will actually prevent health problems\(^1\)

Why Is Cannabis Risk Under-Appeciated?

Don’t Think Much About It
• Most people don’t use cannabis ➔ no strong reason to consider safety.

Turned Off By Propaganda
• To the extent that risk has been discussed, it’s been in the context of “drugs are bad… just say no” prohibition campaigns ➔ messages seen as agenda-pushing and fear-mongering, possibly not taken seriously.

No Personal Experience of Harm
• Majority of those who have used cannabis are infrequent consumers of low-potency products ➔ many within this group will not have experienced adverse effects.

”Natural” Brand Image
• Prefixes like “recreational” or “medical” may also deflect perceived risk
Why Is Cannabis Risk Under-Appreciated?

Bias Toward Positive Experience Among Advocates
• The most motivated, vocal advocates are people for whom cannabis works really well. Have received high benefit/low risk
• Those who have experienced adverse effects less numerous and less likely to participate in public discussion

Bad For Business
• Makes it harder to change laws or sell product to acknowledge potentially harmful risks

No Obligation to Disclose Risks
• Unlike for any other medicine, there is no consistent regulation that requires producers, vendors, advertisers, or recommenders to disclose risks

Most State Governments Are Silent On Possible Risks
Officially-Recognized Benefits
(Medical Benefits of Marijuana, State-By-State)

Number of Benefits Suggested to Consumers by State Medical Marijuana Programs

21 Medical Benefits in Ohio


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Officially-Recognized Risks (Risks of Disclosed to the Public by State Medical Marijuana Programs)

Number of Risks Disclosed to Consumers on State Medical Marijuana Program Websites

No risks disclosed to the public by Ohio state medical marijuana program and 23 other websites
Marijuana Is Believed Safer Than Aspirin

US Adults Agreeing That [Drug] Has Potentially Serious Side Effects

- 74% for Aspirin
- 51% for Marijuana

National survey, March 2019
How Drugs Work
When it comes to drugs, you can’t have the good without inviting the bad…

- Drugs are molecules whose shapes allow them to distort the chemistry of life.
- Medicines are drugs that:
  1) don’t usually kill us, and
  2) distort life chemistry in ways that may be useful
Potential Benefits are Inseparable From Risks

Drugs Distort Life Processes

Diseases Distort Life Processes

Medicinal Drugs Counteract Disease Distortion

But Usually Never Stop There

The body can’t tell the difference between medical or recreational use

Real Medicines Have Real Risks

The body can’t tell if a drug came from a plant or a factory
Aspirin Distorts a Fundamental Reaction

Turns off an enzyme that converts an omega-6 fatty acid into prostaglandin chemical messenger molecules
### Effects of Aspirin’s Distortion

<table>
<thead>
<tr>
<th>Location</th>
<th>Action of Prostaglandins</th>
<th>Effect of Reducing Prostaglandins</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nerve endings</td>
<td>Activate small-diameter fibers</td>
<td>Analgesia, pain reduction</td>
</tr>
<tr>
<td>Brain, hypothalamus</td>
<td>Thermoregulation</td>
<td>Antipyretic, fever reduction</td>
</tr>
<tr>
<td>Interstitial fluid</td>
<td>Recruit immune cells</td>
<td>Anti-inflammation</td>
</tr>
<tr>
<td>Blood cells</td>
<td>Cell adhesion</td>
<td>Decrease risk of blood clots -&gt; heart attack, thromboembolic stroke</td>
</tr>
<tr>
<td>Colon</td>
<td>Cell growth</td>
<td>Decrease risk of polyps and certain forms of colon cancer</td>
</tr>
</tbody>
</table>

A single biochemical pathway interacts with a wide array of seemingly different body functions.
# Other Effects of Aspirin’s Distortion

<table>
<thead>
<tr>
<th>Location</th>
<th>Action of Prostaglandins</th>
<th>Effect of Reducing Prostaglandins</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stomach</td>
<td>Mucus secretion</td>
<td>Occult bleeding, gastritis, ulcer, overt bleeding</td>
</tr>
<tr>
<td>Lung</td>
<td>Tension of muscles lining the airways</td>
<td>Provoke asthma attack</td>
</tr>
<tr>
<td>Blood</td>
<td>Cell adhesion</td>
<td>Bruising, increased bleeding time, hemorrhagic stroke</td>
</tr>
<tr>
<td>Brain</td>
<td>Regulate the release of dopamine</td>
<td>Psychosis</td>
</tr>
</tbody>
</table>

The actions of a drug that make it useful as a medicine are the same actions that make it potentially harmful.
Cannabis Pharmacology
Definitions

Cannabis  A genus of flowering plants in the family Cannabaceae. Includes C. sativa, C. indica, C. ruderalis

Marijuana  Colloquial name for cannabis.

Hemp  Cannabis with very low THC content

THC  Tetrahydrocannabinol. A CB1 receptor partial agonist. The intoxicating constituent of cannabis. Historically ≈ 4% of plant weight, now > 20% strains are available

CBD  Cannabidiol. A neuro-active yet non-intoxicating constituent of cannabis.

State Definitions of cannabis or marijuana may allow *any form of THC at any concentration* to be called cannabis, marijuana, or medical marijuana.

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Phytocannabinoids and Endocannabinoids

• Contains about 500 chemicals
• About 60 of those chemicals are unique to Cannabaceae, and are called phytocannabinoids*
• The brain makes its own endocannabinoids*
• THC is psychoactive because it activates the receptors the brain makes to detect endocannabinoids

*phyto = Greek word for plant
*endogenous cannabinoids
Neurobiology 101

- State of consciousness, thoughts, moods, memories, decisions are based on the electrical activity of large networks of nerve cells.

- Electrical activity is regulated by chemical messages (neurotransmitters) released by activated cells at specialized points of contact (synapses).

- Neurotransmitters make receiving cells either more excitable or less excitable.

If the brain is like a computer, This is its basic computational unit

Releasing Side

| GLU + | GABA - |

Receiving Side

Output depends on the balance of + vs - inputs

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Primary Actions of THC

- THC activates a specialized protein known as the CB1 receptor
- CB1 is located on the releasing side of the synapse
- When activated, the CB1 receptor turns down the release of glutamate or GABA

Diagram:
- THC activates CB1, weakening excitation by releasing glutamate (GLU)
- CB1 is activated by THC, weakening inhibition by releasing GABA (GABA)

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Glutamate

- Most abundant neurotransmitter in the brain. More than 50% of synapses use glutamate.

- Too much glutamate release is neurotoxic

- Just-right glutamate release is critical to sculpting the circuits that serve learning and memory

- Many anticonvulsant medications reduce the release of glutamate

- Blocking the glutamate signal can lead to dissociation or psychosis

- THC reduces glutamate output
GABA

• Second-most abundant neurotransmitter in the brain. 30% to 40% of synapses in the brain are GABA connections

• Increasing GABA signal promotes sleep, reduces anxiety, stops seizures, relaxes muscles

• Many neurological and psychiatric medications boost GABA signal

• THC reduces GABA output
Clinical effects of THC derive from:

- Function of the brain region with CB1 receptors
- Whether net effect is to stimulate or inhibit the region
- Number and sensitivity of receptors
- Patterns of interaction between brain regions (varies between individuals)
- Genetic makeup of the individual
- Concentration of drug and rate of change of concentration

Many sites of action = Many Possible Benefits = Many Possible Risks
The endocannabinoid system is involved in the formation of the placenta\(^1\)

CB1 receptors in fetal brain are detected by gestational week #14\(^2\)

EC system is very active in fine-tuning connections within cerebral cortex and between cortical (reasoning) and limbic (emotional) structures\(^3\)

Cannabis Risks
Several Opportunities for Risk

• THC disrupts the strength of the brains #1 and #2 neurotransmitter signals

• CB1 receptors are present in brain regions that control perception, mood, memory, coordination, nausea, reward

• Endocannabinoid system is present from embryonic stage of development and is active in sculpting brain development throughout childhood and adolescence
Who Decides Which Possible Benefits or Risks Are Credible?

- FDA usually makes these decisions, but is not involved in this facet of cannabis debate.

- In 1 year in the US, between $10 billion to $30 billion is spent on cannabis

- High incentive for businesses, investors, entrepreneurs to enter this market

- Spending on political lobbying rose by 3,400% from 2014 to 2018

- Numerous conflicts of interest at play

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Independent, Non-Partisan Review

• National Academies of Sciences, Engineering and Medicine

• Congressionally-chartered to provide objective analysis of complex problems

• Considered more than 10,700 studies for inclusion

• Published in 2017

• Full text available at https://www.nap.edu/read/24625/chapter/1
# National Academies Assessment of Medical Benefits

<table>
<thead>
<tr>
<th>Condition</th>
<th>Level of Evidence to Support Conclusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chronic pain in adults</td>
<td>Conclusive</td>
</tr>
<tr>
<td>Nausea or vomiting caused by chemotherapy</td>
<td>Conclusive</td>
</tr>
<tr>
<td>Patient-reported muscle spasms from multiple sclerosis</td>
<td>Conclusive</td>
</tr>
<tr>
<td>Sleep disturbances in obstructive sleep apnea</td>
<td>Moderate</td>
</tr>
<tr>
<td>Fibromyalgia, chronic pain</td>
<td>Moderate</td>
</tr>
<tr>
<td>Multiple sclerosis</td>
<td>Moderate</td>
</tr>
</tbody>
</table>

**Conclusive Evidence:**
“Strong evidence from randomized controlled trials to support the conclusion that cannabis or cannabinoids are an effective treatment.”

**Moderate Evidence:**
“There is some evidence to support the conclusion that cannabis or cannabinoids are an effective treatment.”
## Conclusions About Medical Benefits

### National Academies v State of Ohio

<table>
<thead>
<tr>
<th>Conditions with at least moderate evidence per National Academies of Sciences, Engineering and Medicine</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chronic pain</td>
</tr>
<tr>
<td>Nausea or vomiting</td>
</tr>
<tr>
<td>Multiple sclerosis</td>
</tr>
<tr>
<td>Sleep disturbances in OSA</td>
</tr>
<tr>
<td>Fibromyalgia</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Medical Uses Approved by the State of Ohio</th>
</tr>
</thead>
<tbody>
<tr>
<td>AIDS</td>
</tr>
<tr>
<td>Amyotrophic lateral sclerosis</td>
</tr>
<tr>
<td>Alzheimer’s disease</td>
</tr>
<tr>
<td>Cancer</td>
</tr>
<tr>
<td>Chronic traumatic encephalopathy</td>
</tr>
<tr>
<td>Seizure disorders</td>
</tr>
<tr>
<td>Fibromyalgia</td>
</tr>
<tr>
<td>Glaucoma</td>
</tr>
<tr>
<td>Hepatitis C</td>
</tr>
<tr>
<td>Inflammatory bowel disease</td>
</tr>
<tr>
<td>Multiple sclerosis</td>
</tr>
<tr>
<td>Chronic pain</td>
</tr>
<tr>
<td>Parkinson’s disease</td>
</tr>
<tr>
<td>HIV Positive</td>
</tr>
<tr>
<td>PTSD</td>
</tr>
<tr>
<td>Sickle cell anemia</td>
</tr>
<tr>
<td>Spinal cord disease or injury</td>
</tr>
<tr>
<td>Tourette’s syndrome</td>
</tr>
<tr>
<td>Traumatic brain injury</td>
</tr>
<tr>
<td>Ulcerative colitis</td>
</tr>
</tbody>
</table>

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*Promoting Innovation. Restoring Lives.*

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### National Academies Assessment of Risks

<table>
<thead>
<tr>
<th>Condition</th>
<th>Level of Evidence to Support Conclusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Respiratory symptoms, bronchitis (if smoked)</td>
<td>Substantial</td>
</tr>
<tr>
<td>Increased risk of motor vehicle accidents</td>
<td>Substantial</td>
</tr>
<tr>
<td>Lower birth weight of babies if cannabis used in pregnancy</td>
<td>Substantial</td>
</tr>
<tr>
<td>Development of schizophrenia or other psychoses</td>
<td>Substantial</td>
</tr>
<tr>
<td>Problematic cannabis use (e.g., addiction)</td>
<td>Substantial</td>
</tr>
</tbody>
</table>

**Substantial Evidence:**

“Several supportive findings from good-quality studies with very few or no credible opposing findings”
<table>
<thead>
<tr>
<th>Condition</th>
<th>Level of Evidence to Support Conclusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Accidental overdose in children</td>
<td>Moderate</td>
</tr>
<tr>
<td>Impairments of learning, memory, or attention</td>
<td>Moderate</td>
</tr>
<tr>
<td>Increased symptoms of mania in setting of bipolar disease</td>
<td>Moderate</td>
</tr>
<tr>
<td>Increased risk of developing depressive disorders</td>
<td>Moderate</td>
</tr>
<tr>
<td>Increased incidence of suicidal ideation or attempts</td>
<td>Moderate</td>
</tr>
<tr>
<td>Increased incidence of social anxiety disorder</td>
<td>Moderate</td>
</tr>
<tr>
<td>Worsening of the negative symptoms of schizophrenia</td>
<td>Moderate</td>
</tr>
<tr>
<td>Development of an other-than-cannabis substance use disorder</td>
<td>Moderate</td>
</tr>
</tbody>
</table>

**Moderate Evidence:**

“Several supportive findings from good- to fair-quality studies with very few or no credible opposing findings”
Risks Publicized by the Government of Canada

Marijuana Packaging in Canada is required to carry warnings about:

- Lung health
- Pregnancy risks
- Vehicle accidents
- Addiction risks
- Increased risk for psychosis or schizophrenia
- Special vulnerability of adolescents

Full list of required warnings:
THC Adverse Effects from USA Clinical Trials

- Exacerbates mania, depression or schizophrenia
- Paranoid reaction, abnormal thinking, hallucination (ie, psychosis)
- Impaired cognition
- Impairs mental/physical activities required for complex tasks (like driving)
- Blood pressure, pulse effects
- Seizures and seizure-like activity
- Paradoxical nausea, vomiting or abdominal pain

Marinol (dronabinol, THC) prescribing information
https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/018651s029lbl.pdf
CBD Adverse Effects from USA Clinical Trials

Per FDA Prescribing Information for Epidiolex:

**Warnings**
- Hepatocellular injury
- Somnolence and sedation
- Suicidal behavior and ideation

**> 10% prevalence**
- Somnolence
- Decreased appetite
- Diarrhea
- Transaminase elevations
- Fatigue
- Malaise
- Asthenia
- Rash
- Insomnia
- Sleep disorder
- Poor quality sleep
- Infections

**Other CNS Effects**
- Irritability, agitation
  - 5% to 9% for CBD
  - 2% for placebo
- Aggression, anger
  - 3% to 5% for CBD
  - < 1% for placebo
- Drooling
  - 1% to 4% for CBD
  - < 1% for placebo
- Gait disturbance
  - 2% to 3% for CBD
  - <1% for placebo
Cannabinoid Hyperemesis Syndrome

• Severe, intractable, frequent episodes of abdominal pain, nausea, vomiting
• Affected people find relief from hot showers, baths
• Can be life threatening (and there have been fatalities) due to complications from repetitive vomiting
• Occurs in long-term, regular cannabis users
• “New disorder” first described in 2014
Cannabinoid Hyperemesis Syndrome

- Ibn Wahshiyah, Arabic physician, 1000 AD described “continuous wretching and death” among hashish users
- THC prescribing information describes paradoxical abdominal pain, nausea, vomiting
- CB1 receptors in brainstem regulate nausea/vomiting. They change in number and density with long-term cannabis use.
How Big Is The Risk?

- Cyclical vomiting diagnoses doubled in Colorado within 2 years of the 2009 liberalization of cannabis laws (Kim, 2015, Acad Emerg Med 22:694-9)

- 7-fold higher likelihood that a diagnosis of persistent vomiting is present among people with a cannabis use disorder (Patel, 2019, Psychosomatics doi: 10.1016/j.psym.2019.07.003)

- 30% of daily or near-daily cannabis users reported CHS-like symptoms in a survey conducted in New York City (Habboushe, 2018, Basic Clin Pharmacol Toxicol 122:660-2)
The Important Lessons of CHS

• Like many other medications, marijuana can have paradoxical effects

• Risk profile can change over time

• There are some problems with the talking point that ‘we know all about cannabis risk because people have been using it for 5,000 years’
Most Common Adverse Effects in New Zealand Survey

• Community survey of 1,000 adults (18 – 35 years old)

• 38% reported having used cannabis

• Most common adverse effects
  – Anxiety or panic attacks (22%)
  – Psychotic symptoms (15%)

How Can Cannabis Cause Anxiety?

THC activates CB1 receptor

Activated CB1 receptor turns down GABA release

GABA inhibits activity within anxiety centers in the brain

Reducing GABA signal can activate brain’s anxiety centers
How Can Cannabis Cause Psychosis?

The Chemical Effects of Cannabis resemble the Biochemistry of Psychosis

Cannabis triggers dopamine release.¹

Most people with psychosis or schizophrenia release too much dopamine.

DOPAMINE
Dopamine is a chemical signal for significance. Misperceiving significance can lead to psychosis.

Cannabis reduces glutamate release.²

Many people with psychosis or schizophrenia have weak glutamate signals.

GLUTAMATE
Glutamate is the brain’s most abundant neurotransmitter. It’s especially important in the networks that form perceptions. Other drugs that reduce glutamate signals (like ketamine or PCP) can produce psychosis.

Cannabis reduces the level of protective anandamide.³

Low anandamide levels correspond to more severe symptoms of psychosis in people with schizophrenia.⁴

ANANDAMIDE
Named after the Sanskrit word for bliss, anandamide reduces brain inflammation and protects the brain against schizophrenia.

Frequent exposure makes the hallucination-producing 2A-type of serotonin receptor more sensitive.⁵

Many people with schizophrenia have abnormal 2A-type serotonin receptors.

SEROTONIN
Serotonin is part of the brain circuits that create perception. Drugs like LSD or psilocybin produce their hallucinations by turning on the 2A-type of serotonin receptor.

Sources:
2. Sánchez-Bítape, P., Rodríguez-Murillo, M., & Garés, J. The cannabinoid receptor 1 associates with NMDA receptors to produce glutamatergic hypofunction: implications in psychosis and schizophrenia. Front Pharmacol 4, 169 (2014).
Findings Consistent With Causality

Cannabis Causes Schizophrenia-Like Changes in Animals

Giving THC to animals changes their:
- Emotional response
- Social behavior
- Motivation
- Activity
- Brain function

In ways that resemble schizophrenia in people.⁶

Schizophrenia Risk Goes up with More Frequent Cannabis Use

Based on 10 separate studies, frequent cannabis users have nearly 4 times greater risk for schizophrenia.⁷

Cannabis Causes Schizophrenia-Like Changes in People

THC causes psychosis in healthy human beings and usually worsens symptoms in people with schizophrenia.⁸

Canadian Warning Label

The government of Canada requires this health warning on all cannabis packages.

References:
Pregnancy Concerns

Increased risk of:¹

- Low birth weight (less than 5.5 lbs) (OR: 1.7)
- Small for gestational age (OR: 2.2)
- Admission to the NICU (OR: 2.0)

Lower levels of dopamine receptors in the fetal brain:²

Psychosis-prone thinking in children exposed to cannabis in utero³


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Pregnancy Concerns

Longitudinal studies of children exposed to cannabis in utero find:

Pregnancy Concerns

Substance Use During Pregnancy
US Data: 2002 - 2016

70% of dispensaries in Colorado recommended cannabis for pregnant women with nausea; less than a third recommended checking with their doctor first


Based on data from the National Survey on Drug Use and Health
Cannabis Use Disorder

• Describes problematic relationship to cannabis, usually involving difficulty in controlling or cutting down use and/or using cannabis in situations where its use is causing problems

• May develop biochemically (effects on brain’s reward system) or psychologically (as a coping strategy)

• Among people who have used cannabis in the prior year, 12% to 30% will meet criteria for cannabis use disorder (Hasin, 2016, JAMA Psychiatry 72:1235-42)

• Among adolescents, 20% of those who try marijuana will meet CUD criteria within 3 years (Han, 2018, Addiction 114:698-707)
Depression and Suicide

• THC depletes serotonin levels in brain regions involved in mood (rodent study: Sagredo (2006) Naunyn Schmied Arch Pharmacol 372:313-7)


• Cannabis users with depression have poorer rates of treatment response (Bahorik (2018) J Affect Disord 241:8-14)

• 62% higher risk of depression among regular cannabis consumers (Lev-Ran (2014) Psychol Med 44:797-810)

• 250% higher risk of suicide among cannabis consumers (Borges (2016) J Affect Disord 195:63-74)
Health Risks Disclosed to Ohio Medical Marijuana Consumers

• 21 benefits, zero risks described on the Ohio Medical Marijuana Program Website
• Package warnings:
  – This product may cause impairment and may be habit forming
  – There may be health risks associated with consumption of this product
  – Should not be used by women who are pregnant or breastfeeding
  – Marijuana can impair concentration, coordination and judgment. Do not operate a vehicle or machinery under the influence of this drug

http://codes.ohio.gov/oac/3796:6-3-09
But Medical Marijuana Is Safer
Ohio Definition of Medical Marijuana

"Marihuana" means all parts of a plant of the genus cannabis, whether growing or not; the seeds of a plant of that type; the resin extracted from a part of a plant of that type; and every compound, manufacture, salt, derivative, mixture, or preparation of a plant of that type or of its seeds or resin.

http://codes.ohio.gov/orc/3719.01v1

As with many other medical marijuana state laws,
- The only thing that defines medical marijuana is the intention of the user
- No regulation of THC/CBD ratios
- Many extremely unnatural forms of THC are included
- FDA max dose of THC 20 mg/day
- Ohio purchase limit of THC: 110 mg/day (oral) to 590 mg/day (vaping)
Obfuscating Risk
Discrediting Risk Is (Superficially) Easy

- “If this were true, we would have already known about it because people have used cannabis for thousands of years”
- “Correlation does not prove causation”
- “Existing data are inconclusive… we need more studies before we can say that the risk is real”

Points 2 and 3 were widely used by the tobacco industry to dispute cancer risk data
The Conclusive Study

20,000 Young, Healthy Non-Smokers

Random Assignment

10,000 Smoke Every Day

10,000 Placebo-Smoke Every Day

10-Year Follow Up

How Many New Cases of Cancer Have We Caused?

Obviously, can never be done
Questions To Ask

• Is there a biochemical mechanism that can explain the identified risk?
• Can we create the adverse effect by giving the drug to animals?
• Can we create the adverse event in human volunteers under laboratory conditions?
• Is the event more likely among people with greater exposure to the drug?
• What’s the harm in warning people about the possibility?
• How might the person/organization making the claim benefit from others believing it?
Final Words

• Any drug with medicinal value automatically carries the possibility that some who use it will be harmed.

• Modern regulations require the people who make, sell, or recommend drugs to disclose risks.

• Ethics dictate that consumers be informed of risks.

• Prudence requires that we err on the side of caution when deploying marijuana policy reform.

• States that adopt medical marijuana programs should disclose and publicize the scientifically-credible risks.
For printable PDFs of slides or infographics

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