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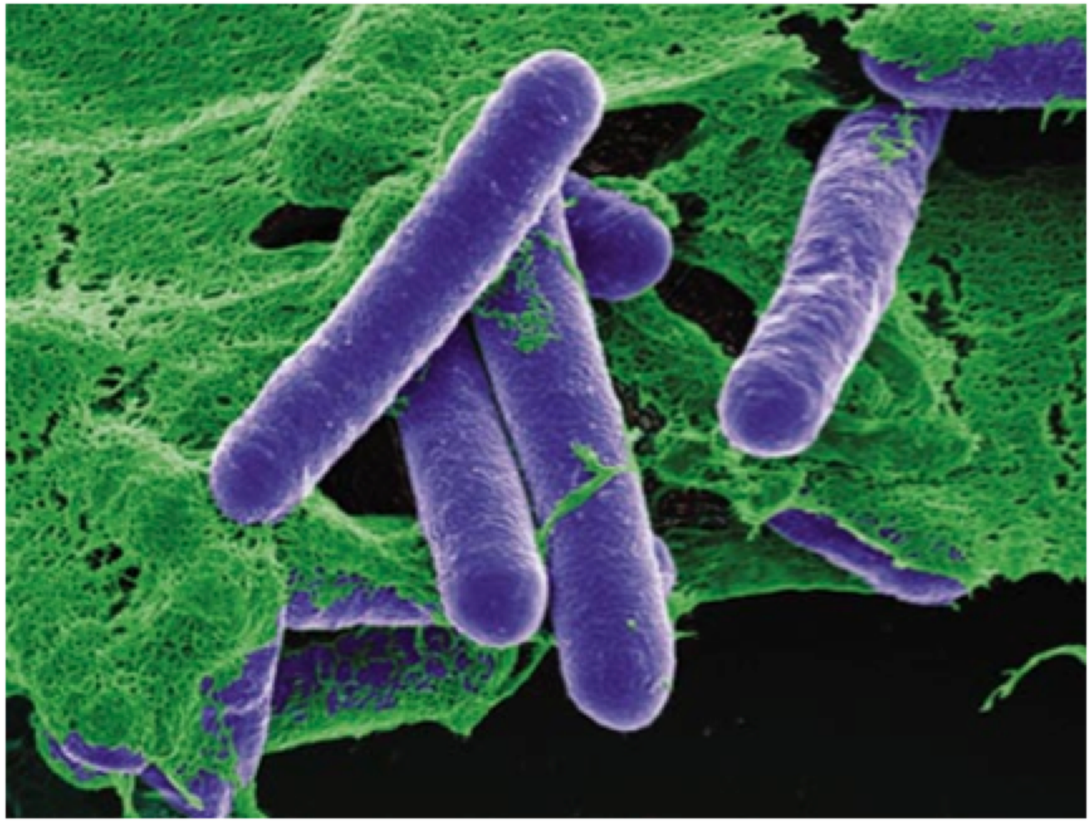
Balancing risk and therapeutic potential with illicit drugs

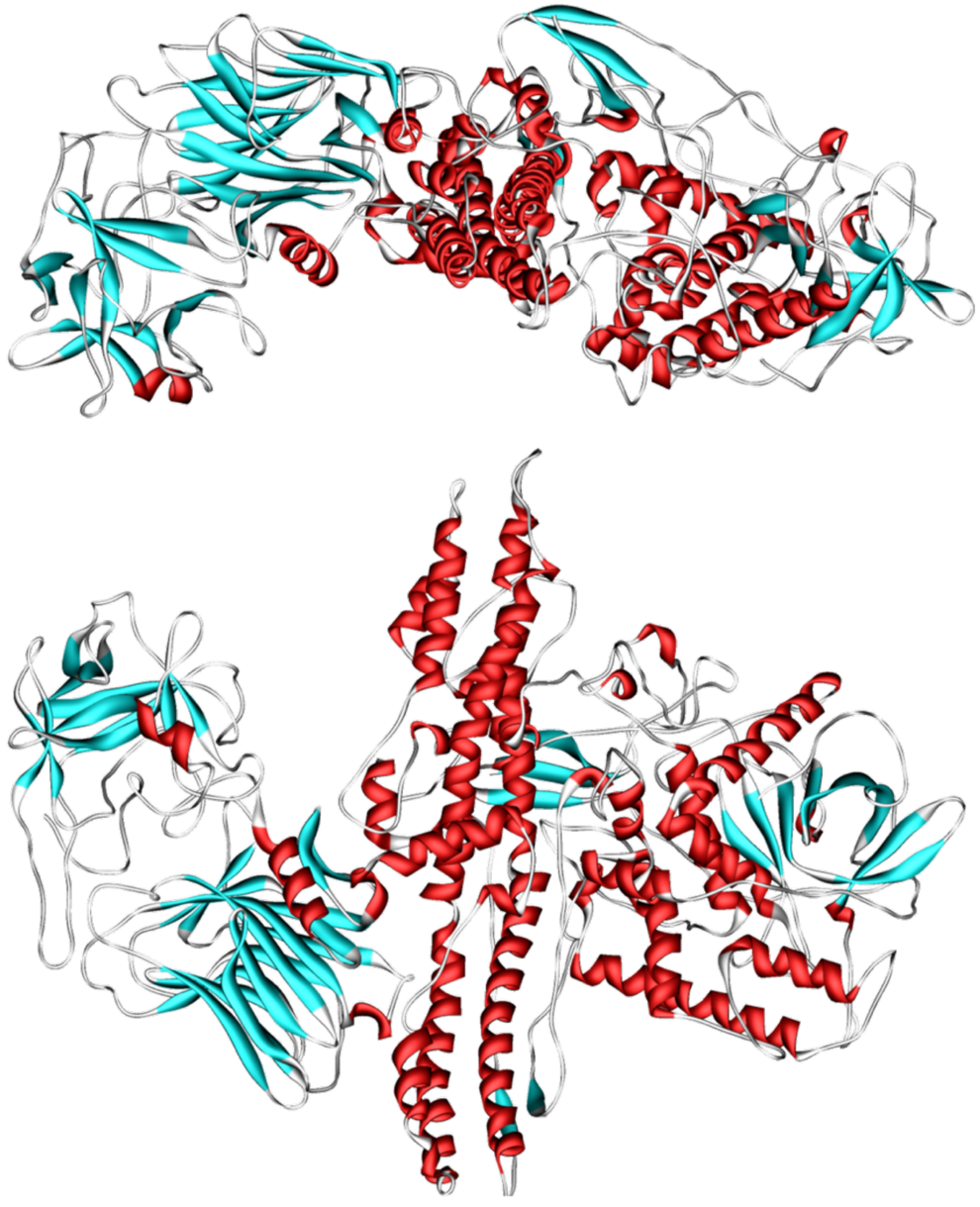
Andreas Wahl Blomkvist, M.D.

Balancing risk and therapeutic potential with illicit drugs

… is principally no different than with drugs in general

Even the most deadly substances in the world can safely be used therapeutically

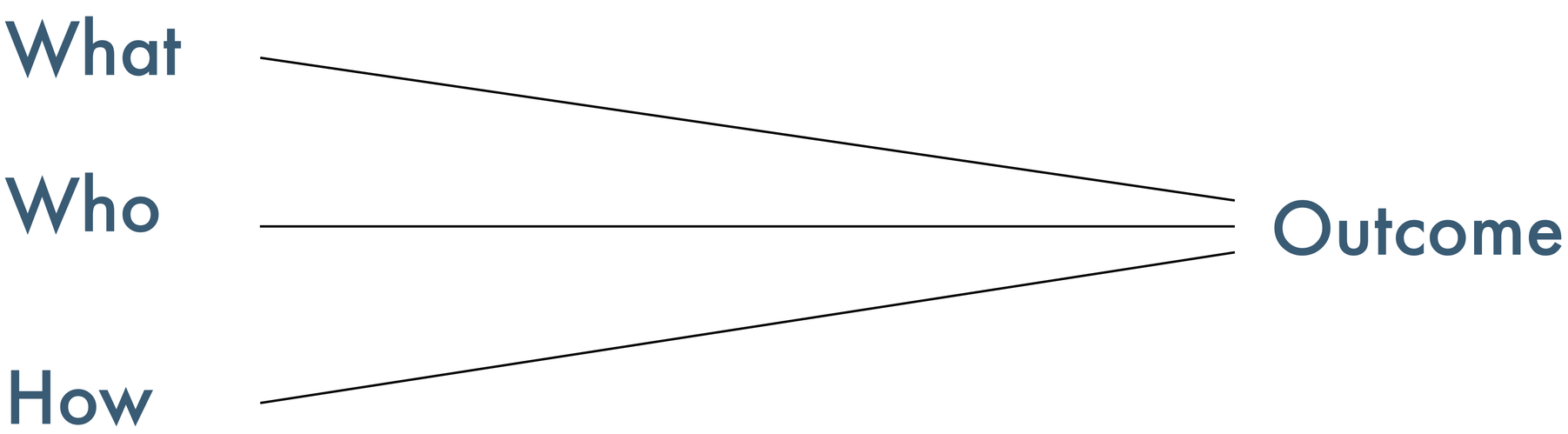




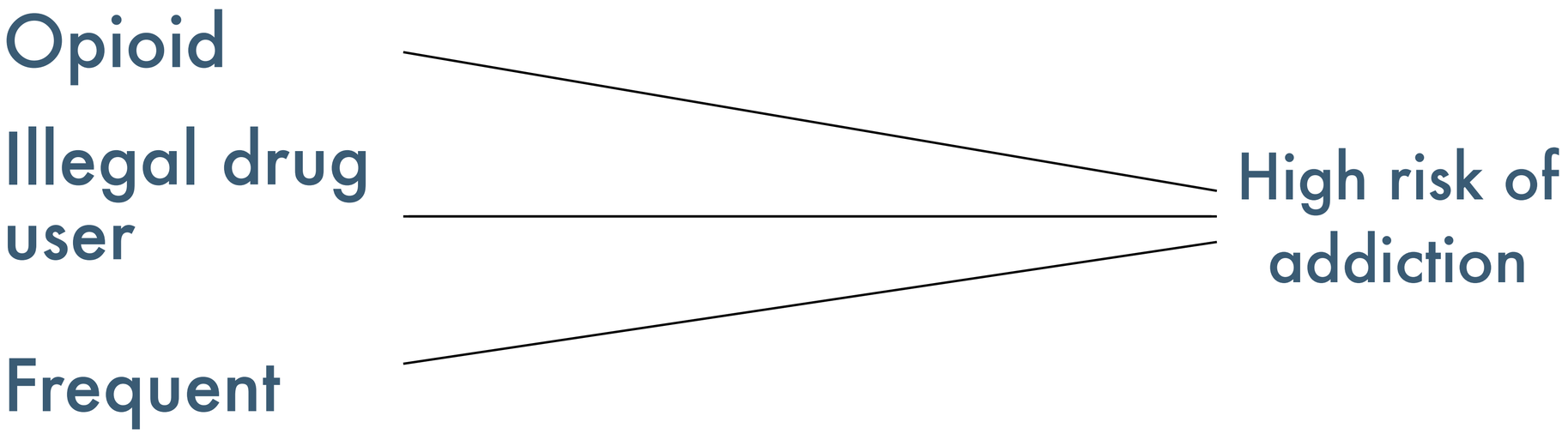
Cosmetics, muscle spasticity, strabismus, overactive bladder, migraine, chronic pain conditions

- Drugs are not inherently harmful or beneficial
- The effects of drugs depends on *how* we use them
- One cannot directly compare medical use with recreational use

Predictors of outcome



Predictors of outcome

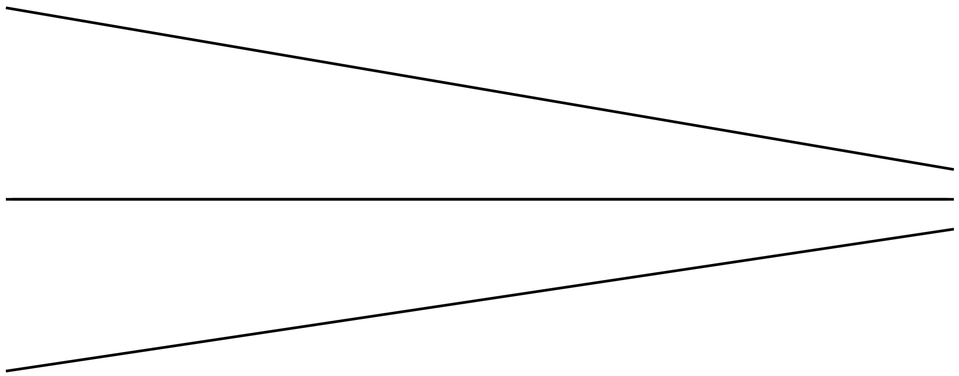


Predictors of outcome

Opioid

Patients

As prescribed



Little or no increased risk of addiction

Cannabis

DRUG ABUSE AND DEPENDENCE

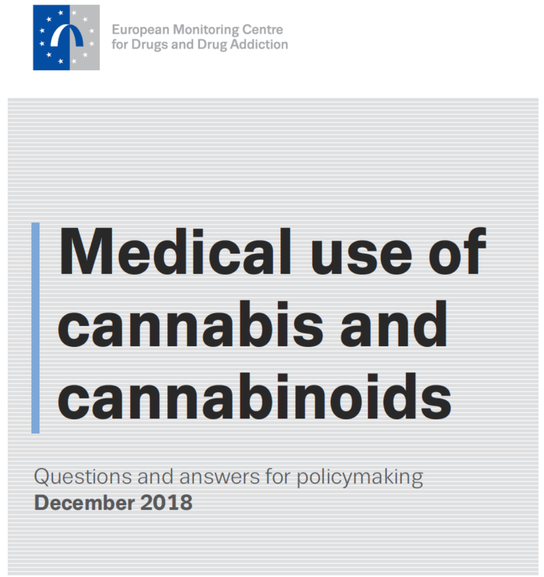
MARINOL® (Dronabinol) Capsules is one of the psychoactive compounds present in cannabis, and is abusable and controlled [Schedule III (CIII)] under the Controlled Substances Act. Both psychological and physiological dependence have been noted in healthy individuals receiving dronabinol, but addiction is uncommon and has only been seen after prolonged high dose administration.

Chronic abuse of cannabis has been associated with decrements in motivation, cognition, judgement, and perception. The etiology of these impairments is unknown, but may be associated with the complex process of addiction rather than an isolated effect of the drug. No such decrements in psychological, social or neurological status have been associated with the administration of MARINOL® Capsules for therapeutic purposes.

In an open-label study in patients with AIDS who received MARINOL® Capsules for up to five months, no abuse, diversion or systematic change in personality or social functioning were observed despite the inclusion of a substantial number of patients with a past history of drug abuse.

What are the long-term risks?

There is less evidence about the risks of long-term medical use of cannabinoids, but in general those reported are similar to those reported for short-term use. Over time, more people report adverse events, but these are generally mild to moderate. More research is needed, however, including on the long-term use of CBD to treat intractable childhood epilepsy.

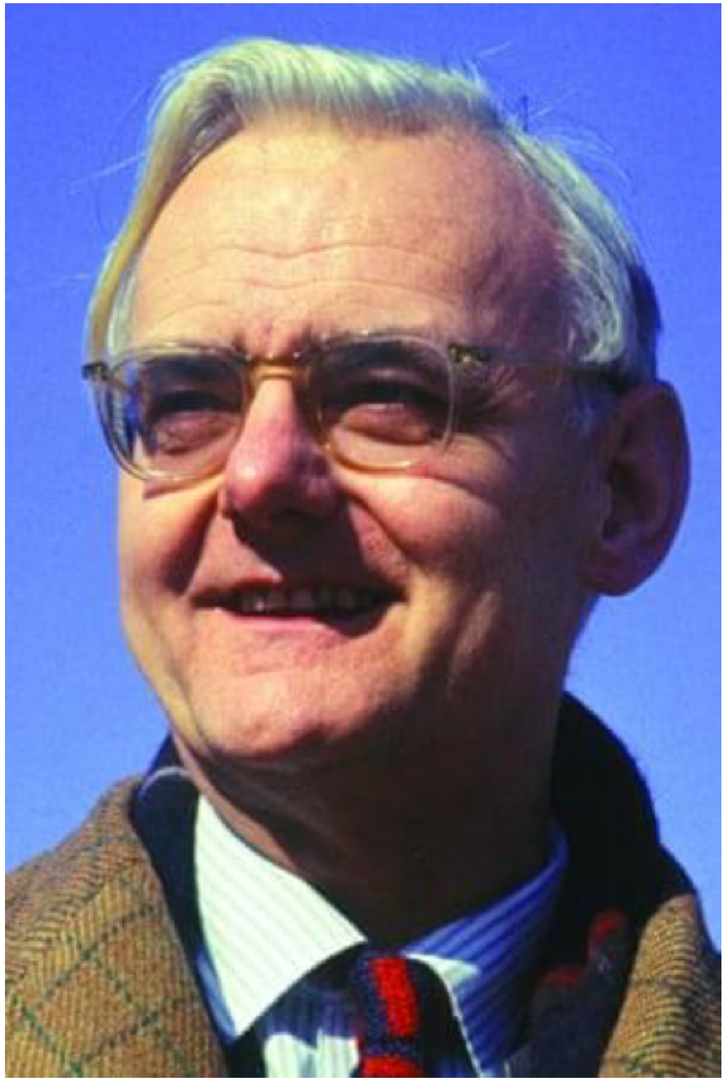


What are the short-term risks?

The short-term adverse effects of medical cannabinoids and cannabis have been evaluated in the randomised controlled clinical trials summarised above. Follow-up in trials of THC for nausea and vomiting ranged from 1 to 6 days, and in trials of cannabinoids to stimulate appetite and reduce pain and muscle spasticity it ranged from 8 to 15 weeks (Whiting et al., 2015). In general, the short-term adverse events reported were similar to those of other commonly used medicines and related to symptoms such as dizziness, dry mouth, disorientation, nausea, euphoria, confusion and somnolence. Serious adverse events were rare.

Learning the hard way with LSD

- What: LSD
- Who: Alcohol use disorder
- How:
  - Preparations
  - Aesthetic environment
  - Supporting monitors



Learning the hard way with LSD

- What: LSD
- Who: Alcohol use disorder
- How:
  - Neutral room
  - Blindfolded and/or restrained
  - Extensive questionnaires during session

Most researched “illegal medicine”

- **Cannabis**
  - Nausea and vomiting associated with chemotherapy (>20 trials)
  - Appetite stimulant (4 trials)
  - Muscle spasticity (14 trials)
  - Chronic pain (including neuropathic pain; 28 trials)
  - Intractable childhood epilepsy (CBD, 6 trials)
- **Psychedelics (primarily psilocybin)**
  - Cancer-related psychological distress (4 trials, 104 patients)
  - Depression (2 trials, 18 patients)
  - Addiction (nicotine (15 patients) and alcohol (10 patients))
- **MDMA**
  - PTSD (5-6 trials)
- **Ketamine**
  - Depression (>20 trials)
  - Suicidal ideation (11 trials)
  - Addiction

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PMCID: PMC5367557
PMID: 27909165

Psilocybin produces substantial and sustained decreases in depression and anxiety in patients with life-threatening cancer: A randomized double-blind trial

Roland R Griffiths,[1,2] Matthew W Johnson,[1] Michael A Carducci,[3] Annie Umbricht,[1] William A Richards,[1] Brian D Richards,[1] Mary P Cosimano,[1] and Margaret A Klinedinst[1]

Balancing risk and benefit with psilocybin

What:

- Psilocybin

Balancing risk and benefit with psilocybin

What:

- Psilocybin

Who:

- Patients
- Range of exclusions criteria

Balancing risk and benefit with psilocybin

What: Who:

- Cardiovascular conditions: uncontrolled hypertension, angina, a clinically significant ECG abnormality (e.g. atrial fibrilation), TIA in the last 6 months, stroke, peripheral or pulmonary vascular disease (no active claudication)
- Blood pressure exceeding 140 systolic or 90 diastolic

Balancing risk and benefit with psilocybin

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- Ps

- Current or past history of meeting DSM-IV criteria for Schizophrenia, Psychotic Disorder (unless substance-induced or due to a medical condition), or Bipolar I or II Disorder
- Current or past history within the last 5 year of meeting DSM-IV criteria for alcohol or drug dependence (excluding caffeine and nicotine).
- Have a first or second degree relative with schizophrenia, psychotic disorder (unless substance induced or due to a medical condition), or bipolar I or II disorder.
- Currently meets DSM-IV criteria for Dissociative Disorder, Anorexia Nervosa, Bulimia Nervosa, or other psychiatric conditions judged to be incompatible with establishment of rapport or safe exposure to psilocybin.

Balancing risk and benefit with psilocybin

What:

- Psilocybin

Who:

- Patients
- Range of exclusions criteria

Balancing risk and benefit with psilocybin

What:

- Psilocybin

Who:

- Patients
- Range of exclusions criteria

How:

- Sufficient dose for mystical experience
- Preparation and integration
- Aesthetic living-room-like environment

Balancing risk and benefit with psilocybin

quality of life, life meaning, and optimism, and decreases in death anxiety. At 6-month follow-up, these changes were sustained, with about 80% of participants continuing to show clinically significant decreases in depressed mood and anxiety. Participants attributed improvements in attitudes about life/self, mood, relationships, and spirituality to the high-dose experience, with >80% endorsing moderately or greater increased well-being/life satisfaction. Community observer ratings showed corresponding changes. Mystical-type psilocybin experience on session day mediated the effect of psilocybin dose on therapeutic outcomes.

Benefits of therapy with psilocybin, MDMA and ketamine

- Low risk for serious adverse events … when used in a controlled setting
- No need for daily dosing for high therapeutic benefit

  - Substantially lower the risk for long-term adverse effects

  - New paradigm in psychiatry

Thank you very much

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