Medical Cannabis
Medical Perspective

Danesh Mazloomdoost, MD
Medical Director
Conflict of Interest

• None
**Herbal treatment:**

- Alzheimer disease,
- Parkinson disease,
- Depression and anxiety,
- Schizophrenia,
- Attention deficit hyperactivity disorder (ADHD),
- Pain,
- Obesity
Is this medicine?
Drug
- Unsafe till proven Safe

Supplement
- Safe until proven Unsafe

Vice
- Unsafe but Recreational (self-medicating)
What is Medicine?

• Indications
• Risks & Benefits
• Dosing
• Poisonings

What is NOT Medicine?

• Indications (?)
• Risks & Benefits (+/-)
• Dosing (?)
• Poisonings (?)
Healing Beyond Medicine

**PRE-CLINICAL**
Testing on animals for toxicity.

**INVESTIGATIONAL NEW DRUG APPLICATION**
Describes the manufacturer's plans for testing the drug in clinical trials. If approved by FDA, the manufacturer becomes the sponsor of an "existing IND."

**CLINICAL TRIALS**

**Phase I**
Clinical trials test for safety and dosing ranges.
- No. of patients: 20 to 80
- Approximately 63.2% moved to phase II

**Phase II**
Clinical trials test for efficacy in the patients that the drug is intended to treat.
- No. of patients: a few dozen to hundreds
- Approximately 30.7% moved to phase III

**Phase III**
Clinical trials test for efficacy in the patients that the drug is intended to treat.
- No. of patients: hundreds to thousands
- Approximately 58.1% moved to the new drug application process

**REVIEW/APPROVAL PROCESS**
Once the drug has successfully completed the phase III trials, the manufacturer generally submits a new drug application to FDA.
- FDA approval results
  - FDA either approves or denies approval for the drug or biologic for marketing and sales in the U.S.

Source: GAO analysis of FDA data and a 2016 collaborative study by Biotechnology Innovation Organization, Biomedtracker, and Amplion. | GAO-17-564
wellward
Regenerative Medicine
Fast-track drugs:
Cancer
Alzheimers
Drug-resistant infection
Drug approval process

• Fast Track – serious conditions & unmet needs
• Breakthrough Therapy – serious condition & superior
• Priority Review – 6 months vs 10 months
1 Pill: 500 ingredients

Studied products:

1. d-9-THC
2. d-8-THC
3. Cannabinol
4. Cannabidiol (CBD)
Rising [THC]

Mehmedic et al., 2010
Rx Marijuana

- Concentrations?
- Combinations?
- Personal Variations?
- Reduce Risks
- Optimize Benefits
# Marijuana vs. Hemp

<table>
<thead>
<tr>
<th>Feature</th>
<th>Marijuana</th>
<th>Hemp</th>
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<tbody>
<tr>
<td>Legal</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>CBD &gt; THC</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Lower risks</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Greater Medical Proof</td>
<td>No</td>
<td>Yes</td>
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Clean-up costs

The New York Times

Johnson & Johnson Ordered to Pay $572 Million in Landmark Opioid Trial

Oklahoma pursued the first case against a drug manufacturer for the national public health disaster, and the ruling may point to what lies ahead in 2,000 more lawsuits.
Healing Beyond Medicine

Acknowledge

- Challenge outdated laws and beliefs
  - Downregulated control status → research
  - Justice & politics
  - Autonomy vs. Responsibility
- Honest conversations
  - Identify special interest agendas
  - Pars fact from fiction
  - Search for truth