

# Cannafest Conference, 2013 Prague

## Cannabis in Israel – by Boaz Wachtel



**ISRAEL and...**

**The United States**



*Maps drawn to same scale.  
Israel shown in blue.*

- The 100th smallest country,
- 8 million people,
- less than 1/1000th of the world's population,
- One of the highest ratio of university degrees to the population in the world.
- One of the highest scientific papers and patents filed per capita.
- In proportion to its population, Israel has the largest number of startup companies in the world.
- Advanced socialized, affordable, National Health care system.
- Where THC was first Isolated in 1966 by Professor Rafel Meschulam and where Professor Lumir Hanuš and American molecular pharmacologist William Anthony Devane first described in 1992 the structure of [Anandamide](#), an endogenous [cannabinoid neurotransmitter](#).
- Professor Lumir Hanus was born, educated and still woks in your beautiful country.

# A medical cannabis flower



Source: Canndoc Ltd. Israel

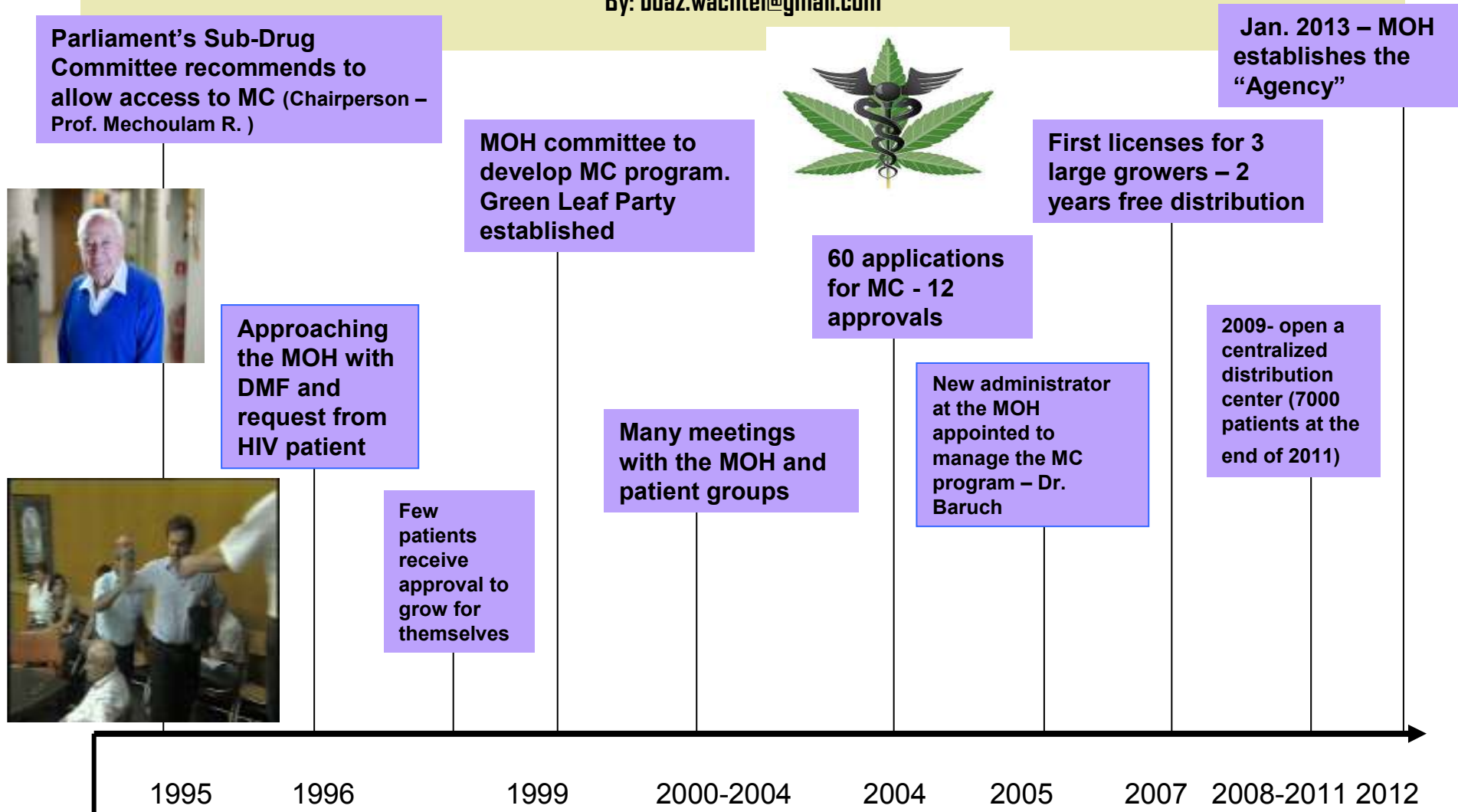
## ***Israel's National Medical Cannabis program: a model to follow?***

- **Israel's national Medical Cannabis program evolved in the last 15 years from an activist's efforts to a full fledged National medical Cannabis program serving over 13,000 patients with cannabis grown by 8 growing groups.**
- **Israel is the third country in the world to establish a National Medical Cannabis Program/Agency, after Holland and Canada.**
- **According to recent developments, the Czech republic would be the forth country to launch a compassionate and just medical cannabis program (we hope).**
- **The Dutch where the first to implement a “designated medical cannabis Agency” as instructed by UN drug conventions.**

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# ISRAEL'S MEDICAL CANNABIS PROGRAM - TIME LINE/EVOLUTION

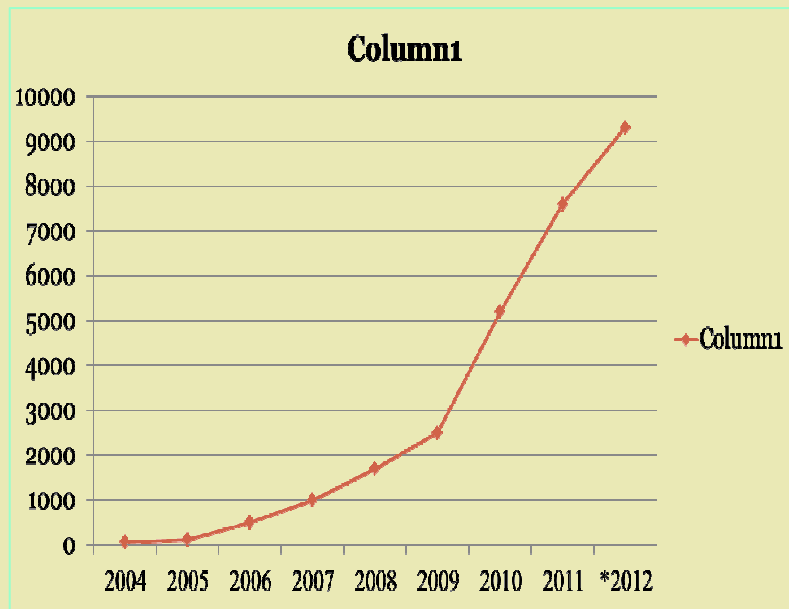
By: boaz.wachtel@gmail.com



**August 2011: The Israeli cabinet approved medical marijuana guidelines that will govern the supply of marijuana for medical and research purposes. In so doing, it explicitly agreed that marijuana does indeed have medical uses that are necessary in certain cases. “The Health Ministry will — in coordination with the Israel Police and the Israel Anti-Drug Authority — oversee the foregoing and will also be responsible for supplies from imports and local cultivation,” according to a statement from Prime Minister Binyamin Netanyahu’s office**

# Medical Cannabis (MC) program

13,000 + patients with permits  
served by 8 licensed growers



## Physician Perspective (Dr. Y Baruch – former head of MC program)

On one side:

- A lot of patients benefit greatly from the use.
- Another medicine in the pharmacopeia.
- Higher safety than opioids (no death due to OD).

On the other side:

- Mainly in chronic pain Clinic – fear of becoming a cannabis Clinic

## Patient's Perspective

- Cannabis is better tolerated than opioids.
- No risk of Overdose and death.
- A different mechanism of work – can help where other medications did not.
- A social trend.
- What strain to use? Who decides?
- Should self growing be allowed?


# Indications

**Medical Grade Cannabis is a last resort treatment**

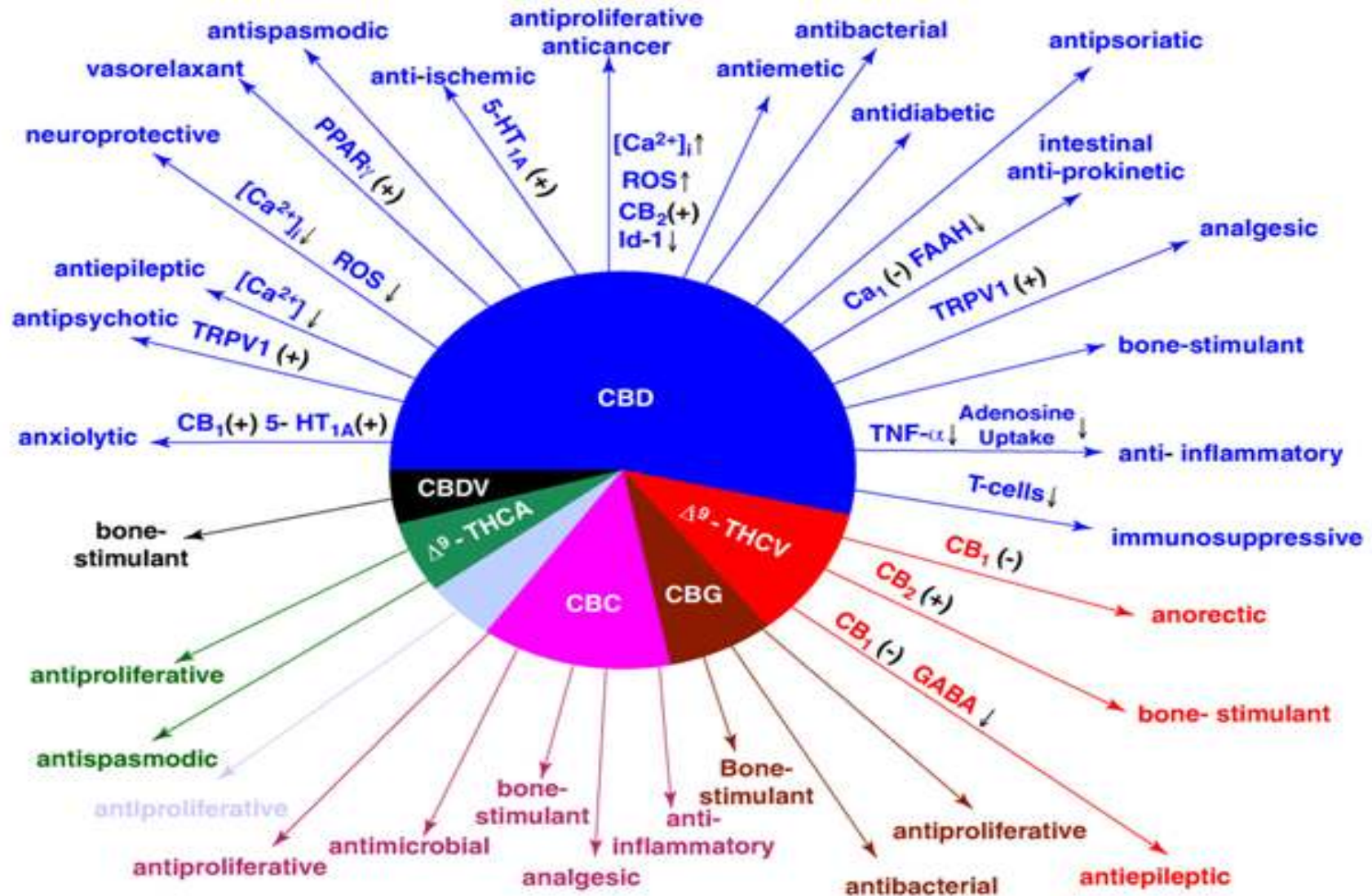
(From Dr. Y. Baruch's presentation – former head of the MC program)

- Chronic Pain Due to a Proven Organic Etiology
- Orphan Diseases
- HIV patients with loss of body weight >10% or CD4 < 400
- Inflammatory Bowel Disease (as opposed to Irritable Bowel Syndrome)
- Multiple Sclerosis
- Parkinson's Disease
- Malignant Tumor in Various Stages of the Disease
- Other conditions under the “exceptional clause”

**Number of patients per indication  
Israel Medical Cannabis Program – November 2011**

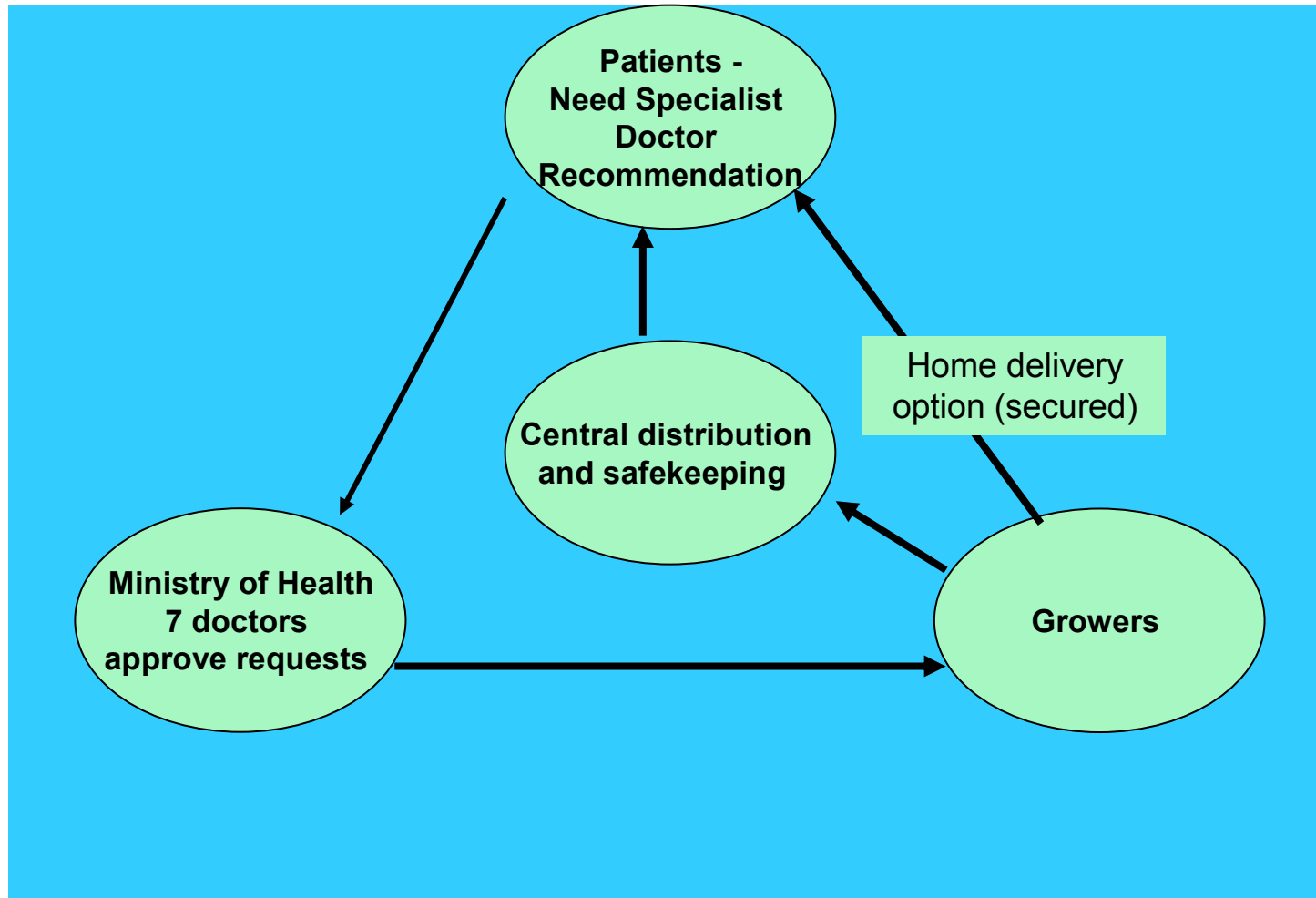
<b>indications</b>	<b># of Patients</b>
pain	2400
cancer	2000
Multiple sclerosis	150
Neurological disorders	120
Various diseases	100
Psychiatry (mostly war-related PTSD) 	82
Parkinson	70
Gastro	70
ALS	20
DIABETES	15

**Summary of recent research findings:**  
**RAPHAEL MECHOULAM, ET AL. " NON-PHYSCHOTROPIC PLANT CANNABINOIDS: NEW THERAPEUTIC OPPORTUNTIES FROM AN ANCIENT HERB", TRENDS IN PHARMACOLOGICAL SCIENCE, 1-13 (2009)**

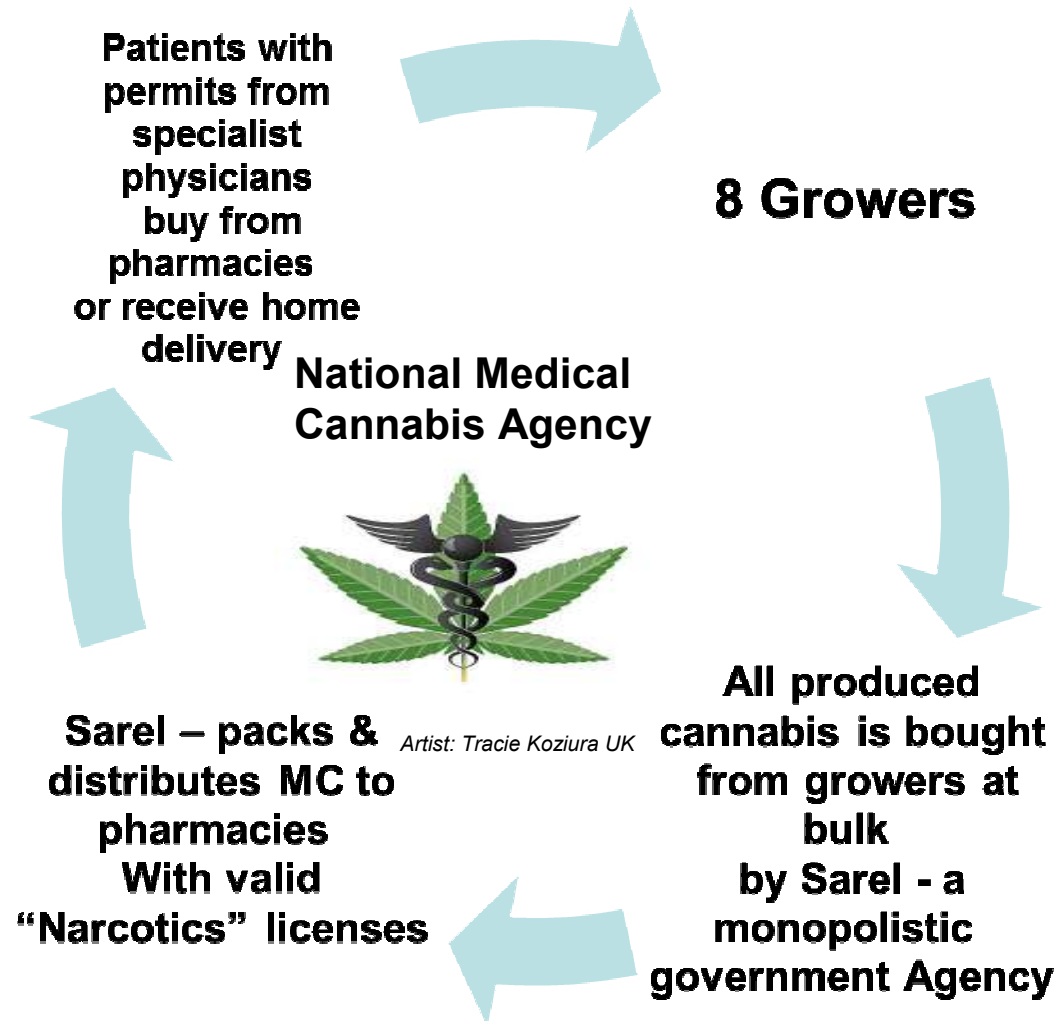




## Medical Cannabis Flow Chart – Israel (2004-2011)



# Flow Chart of Medical Cannabis (New) National MC Agency (2012 - Israel)



## After the establishment of the National MC Agency

- Sarel – the monopolistic arm of the agency.
- Sarel will buy all the crop (through tenders among growers).
- Distribution to pharmacies already licensed to handle control substances.
- Option of home delivery (additional fee).
- Option of trial and error to try and decide which strain (among different growers) gives the best result to the specific patient.
- (Source – Dr. Y Baruch – former Director of the MC program)

**The first legal 50 plants for medicinal use, Galilee, Israel (2007)**



# Greenhouse – equipment

Greenhouse cover. Darkening curtain. Eco-lights. Heating/cooling



Source: Canndoc Ltd. Israel

Growing tables



**Many varieties are grown – these in a growing operation located in the desert (courtesy Cannadoc Ltd)**

**Patients pay 110 \$ per month regardless of the quantity (30-100 grams) of dried flowers he/she receives**

## Consumption options for patients (Israel)

1. Cleaned & dried Cannabis flowers
2. Oil – in small bottles with peptide  
A trade off exists between the number of bottles and the weight of dried flowers a patient receives
3. Cannabis lased brownies
4. Cannabis Salve (ointment)
5. Cannabis lased brownies
6. Ready made joints

Vaporizers (rent or sale – are approved for use in oncology wards in hospitals)



Various cannabis products at the MECRAJ distribution and training center available to Israeli medicinal cannabis patients. From top, a cannabis tincture, baked cannabis cookies, cannabis salve, and cannabis cigarettes rolled with organic paper.  
Photo: ©2013 Moshe Yareh

# Medical Cannabis Education

- Educate the public: Press articles, TV, Internet.
- Patient Education: A cornerstone of successful MC program - personal interviews + take home media kit with FAQ's. Hotline for patients questions
- Physicians and nurses: prepare a curriculum for medical and nursing students, organize conferences, add to continuing education credits.
- Politicians: invite them for conferences, send patients to meet them, pressure to include MC in national healthcare insurance programs.





### **The Quiet Giant: Israel's Discreet and Successful Medicinal Cannabis Program**

by Lindsay Stafford Mader

American Botanical Council ;2012 *.HerbalGram*



## Member Advisory

# HerbalGram Publishes First Cannabis Cover in its 30-Year History

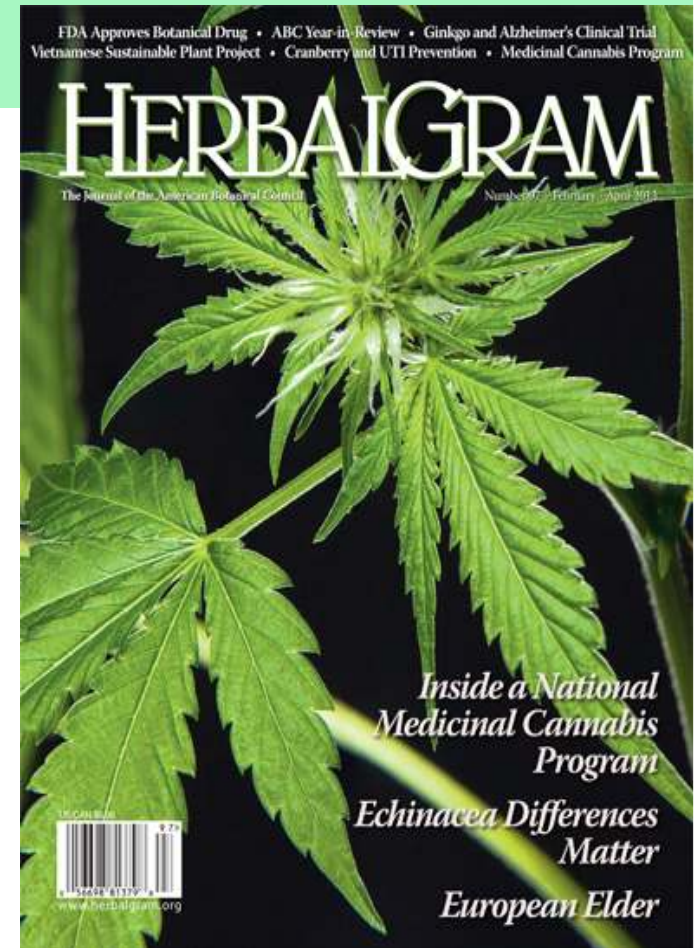
AUSTIN, Texas, February 7, 2013 (*HerbalGram*, the journal of the American Botanical Council (ABC), has unveiled its first cannabis cover in 30 years of publishing history. The beautiful cover image of *Cannabis sativa*, photographed by Johnny Wiggs, accompanies the issue's cover story on the federal medicinal cannabis program in Israel, written by associate editor Lindsay Stafford Mader. The cannabis cover represents an important milestone for ABC and is symbolic of the progress being made by the global medicinal cannabis community .

According to ABC Founder and Executive Director Mark Blumenthal:

There is obvious growing social demand for and acceptance of medicinal cannabis, and for this, and other reasons, ABC has increased its cannabis coverage in recent years. Now, more than 20 years since our first cannabis story, we have decided to recognize this important plant with the first-ever *HerbalGram* cannabis cover....

**Other herb organizations also are dealing with cannabis. The American Herbal Pharmacopoeia is developing a Standards Monograph and Therapeutic Compendium — the first of its kind in North America — and the American Herbal Products Association's Cannabis Committee just released draft recommendations for regulators on the legal dispensation of medicinal cannabis.**

As members of the medicinal cannabis community continue to work on quality standards, scientific research, and legal advocacy, ABC will maintain its medicinal cannabis coverage. From our perspective, cannabis is just another medicinal plant — one with a compelling history and an apparently promising future.



## Patients' Intake questions – Israel

### Intake Interview – Israel



- What are you suffering from?
- How bad is it (1-10)?
- For how long?
- What kind of medications have you been using?
- Do you have experience with cannabis? Do you know how to roll joints?
- Have you ever smoked cigarettes?
- Do you have kids or minors in your house?
- Do you have someone to take your cannabis from the distribution center?
- Do you have someone to be with you in the house while you smoke the MC?
- These are the possible side effects (\*)
- **Psychotic episodes**
- **Panic attacks**
- **Generalized Anxiety Disorder**
- **A-motivational Disorder**
- (\*)The side effects are quoted from a presentation of Dr. Y. Baruch, the director of the MC program and a psychiatrist

Some insight:

## **Promising Results – unpublished, interim results, Open Pilot Study MEDICAL CANNABIS AS TREATMENT FOR CHRONIC COMBAT PTSD**

**Collaborative research between the Ministry of Health and the M. of Defense**

**Principle Investigator - Dr. Yehuda Baruch, MD, Director, Abarbanel Mental Hospital, Israel**

**Presented by Dr. Masiach at: Patients Out of Time Conference, Tucson, Arizona April 28, 2012**

- **This open pilot study was designed to test (29 subjects) the effects of smoked cannabis on symptoms of chronic combat PTSD (Post Traumatic Stress Syndrome)**
- **Smoked medical indica cannabis of roughly 23% THC and less than 1% CBD was dispensed to the subjects: at an amount of no more than 100 grams per month (based on their licenses limit and set at a high level to thwart undue distress)**
- **Cannabis was added to subjects' standing treatment**
- **Subjects were instructed to smoke the cannabis daily at times, frequencies and amounts of their own choosing until they felt relaxed.**

## Smoked Cannabis PTSD pilot research results

- **After cannabis treatment, a significant decrease in the total CAPS score and in the three subsections of the test was seen. Specifically, the severity of intrusive symptoms, which are most characteristic of PTSD, dropped by 51% within two months of treatment, the severity of the avoidant symptoms dropped by 38% within two months of treatment, and the severity of the increased arousal symptoms dropped by 43% within two months of treatment initiation.**
- **There was also a significant improvement in self-reported emotional distress and work-social function, according to subject reports. Within two months of initiation of treatment, there was an improvement of 35%.**
- **A marked improvement was also indicated by the assessment of the subjects' general condition by the evaluating psychiatrists, using the General Assessment Score Test (DSM-IV). Specifically, an improvement of 45% was seen in the general evaluation of the subject's psychological state after two months of treatment.**

## **How to improve the MC program in Israel?**

- **Every doctor should be allowed to give a prescription for MC and not just a few specialists . (They are allowed to prescribe morphine so why not cannabis?)**
- **Better quality control in real time before the MC reaches patients**
- **Grow under GMP (Good Manufacturing Practice) and the guidelines for cannabis cultivation, derived from the general rules for Good Agricultural Practice of the Working Group on Herbal Medicinal Products of the European Medicines Evaluation Agency (EMA).**
- **Reduce THC levels and increase CBD levels**
- **Have the national medical insurance companies pay for the MC**
- **Improve MC education for doctors, nurses and patients.**
- **Prepare MC curriculum to be taught in medical and nurse schools**
- **Allow for distribution through pharmacies and not in a few limited locations**
- **Increase government funding for MC research**

## **Self production vs. Imports**

- **Holland is the only country in the world that legally exports medical cannabis (80KG, 2011)**
- **It is possible for an EU patient to import Dutch MC to an EU country with a Doctor's prescription but some countries try to resist this legally binding option.**
- **The Dutch MC (Bedrocan) is very expensive and the quality is not satisfactory. Today there are less the(some patients say). Less then 1000 patients left in the MC program. Reasons.....**
- **Local growing is a cheaper option, with better quality, and is legal (according to UN conventions) under a MC research program at a first stage and later when establishing a designated MC Agency.**
- **The threat of leakage to the black market is a poor excuse why not to grow MC in any given country. The black market world wide is already saturated with Cannabis.**
- **Due to the very limited number of growers, security measures can be taken by the police to prevent any leakage to the black market.**

## Cost of medical cannabis (& extract medications) in various countries

(In US Dollars)

USA	CANADA	Holland	Israel	Approved cannabis extract medications
<p>\$ 10 – \$21 gr. (average is \$17 per gram) \$300- \$630 for 30 gr.</p>	<p>.rg 4.67\$ grams 30 rfo 140\$</p>	<p>USD \$ 10 gr. variety SIMM 18 per gr. (2005) \$ 11 + per gr. for variety Bedrocan</p> <p>The prices are built up as follows:</p> <ol style="list-style-type: none"> <li>the OMC's selling price per gram SIMM 18: \$ <u>8.68</u> Bedrocan: \$ <u>10.07</u></li> <li>the pharmacy's fee: \$ <u>7.44</u> per prescription</li> <li>+3. 6% tax</li> </ol> <p>Exported: in Germany \$ 23.3 gr. \$ 700 for 30 gr.</p>	<p>\$ <u>3.3 gr.</u> \$ <u>100 per 30-100 Gr.</u></p>	<p>Sativax spray (UK) cost per patient per month – 500 UK pounds = <u>803 USD per month.</u></p> <hr/> <p>Marinol/ Dronabinol (synthetic THC pills) The average dose is 12.5mg per day = \$1.81 per milligram X 30 days= \$ 678 per month</p>

Sativax: Now approved in the UK, Spain, Germany, Denmark, the Czech Republic, Sweden, New Zealand and Canada





## Problems with the Dutch and MC program

- In 2001 Holland was the first country to establish a “Office of Medical Cannabis” (OMC)
- Prior to that, a Dutch pioneer by the name of Marcel De Wit sold through his company ‘Maripharm’ MGC to over 1000 pharmacies serving at its pick almost 15,000 patients.
- The Dutch issued a tender and two companies were chosen: Bedrocan and Hortipharm. Due to restrictions on number of strains (Bedrocan today has only 4), bad selection of strains and excessive price many patients stopped buying the MC from the pharmacies and purchase different strains in coffee shops. Today there are less then 1000 patients buying the MGC in pharmacies. As a result of low demand, Hortipharm went bankrupt and only Bedrocan supplies in Holland. This is what they supply:
  - There are four varieties of medicinal cannabis available through Dutch pharmacies: Cannabis Flos Bedrocan®, Bedrobinol®, Bediol® and Bedica® can be prescribed by doctors for both humans and animals.
  - Each variety has its own predetermined strength and composition.
  - |   | Variety    | THC content | CBD content |
|---|------------|-------------|-------------|
| • | Bedrocan   | 19%         | < 1%        |
| • | Bedrobinol | 12%         | < 1%        |
| • | Bediol     | about 6%    | about 7,5%  |

# Working with the authorities

## Advice from an international MC activist

1. Authorities are addicted to the “status-quo drug” and are not impressed by facts, truth or acts of compassion.
2. Talk the language authorities talk – point to how their & the country’s interests will be served, (electoral support, savings money on other medications etc.)
3. Be brief. Prepare a book of abstracts to show that Cannabis is well researched/studied, safe and effective medicine.
4. Lay out a plan that would not cost the state too much money, if at all.

## Working with the authorities

5. Talk about other countries' MC programs (Holland, Canada, Israel and 17 states in the US). This will give them confidence that they are not the first country to allow MC and that they will join a relatively enlightened group of nations that operate MC programs.
6. Organize the patients and have them join the meetings to personalize the issue.
7. Optimism and tenacity are necessary to run the marathon against the authorities.
8. Be prepared to pay a personal cost in terms of public perception initially. Later on you may be perceived as a folk hero. Don't hold your breath as other people will jump on the "credit wagon".
9. Build up media contacts. Put up MC testimonials on **YouTube**, have a list of interested reporters ready to write on it. Don't use all your ammunition at once. Remember – this is a marathon.

10 common reasons used by governments **why not** to launch a Medical Cannabis program:

- 1. Cannabis has no medical value**
- 2. Not enough research/clinical results**
- 3. Conventional treatments are good enough**
- 4. Cannabis is addictive, damaging and illegal**
- 5. No medicine has been approved in the form of smoking**
- 6. Prohibited by UN Drug conventions**
- 7. No good way to control the production and distribution**
- 8. The police/public is against it**
- 9. It is a cover for cannabis legalization**
- 10. During times of recession the government cant fund such a program**

**Below is what the man in charged on “access to controlled medicine” at the World Health Organization, wrote me when I confronted him with the subject**

2. “The best way to offer medicinal cannabis to patients is without any doubt a professional production respecting all pharmaceutical quality requirements like for any other medicine (warranting a constant strength and absence of heavy metals, pesticides and microbiological contamination) and a distribution through pharmacies. The Single Convention requires a government monopoly if the government wants to produce inside the country, but import is simpler because it can be done without such a monopoly and government involvement. (See art 28 of the convention). See also the policy guidelines published by WHO:

[http://www.who.int/medicines/areas/quality\\_safety/guide\\_nocp\\_sanend/en/index.html](http://www.who.int/medicines/areas/quality_safety/guide_nocp_sanend/en/index.html). These guidelines do not recommend any exceptional position for controlled medicines as compared to other medicines”.

**Dr. William Scholten team Leader, Access to Controlled Medicine, Access and Rational Use, Department of Essential Medicines and Health Products, World Health Organization, Geneva, Switzerland.**

# Background—the indispensability of controlled medicines

- At the 53rd session of the Commission on Narcotic Drugs (CND) held in March 2010, the Commission adopted Resolution 53/4  
**“Promoting adequate availability of internationally controlled licit drugs for medical and scientific purposes while preventing their diversion and abuse”.**
- The Commission recalled the recognition of parties to the Single Convention on Narcotic Drugs 1961 as amended by the 1972 Protocol **that the medical use of narcotic drugs continued to be indispensable for the relief of pain and suffering and that adequate provision must be made to ensure their availability for such purposes.**
- It also recalled the recognition of parties to the Convention on Psychotropic Substances 1971 **that the use of psychotropic substances for medical and scientific purposes is indispensable and that their availability for such purposes should not be unduly restricted.**

**UNITED NATIONS OFFICE ON DRUGS AND CRIME**

**Vienna**

***Ensuring availability of controlled medications for the relief of pain and  
preventing diversion and abuse***

***Striking the right balance to achieve  
the optimal public health outcome***

**Discussion paper based on a scientific workshop**

**January 18 – 19, 2011**

**UNODC, Vienna**

**UNITED NATIONS**

**New York, 2011**



**Ensuring availability of controlled medications for  
"the relief of pain"**

**A Global Tragedy led by the UN drug policies and  
caused by inaction of politicians**



**“The tragedy of the inadequate availability of opioid analgesics is well expressed by the INCB:**

**“Although medical science has the capacity to provide relief for most forms of moderate to severe pain, over 80 per cent of the world population will have insufficient analgesia, or no analgesia at all, if they suffer from such pain.”**

**WHO estimates that each year 5.5 million terminal cancer patients and 1 million end-stage HIV/AIDS patients as well as many other people with chronic, non-malignant pain suffer un- or under-treated moderate to severe pain, including 800,000 patients with lethal injuries caused by accidents and violence, patients with chronic illnesses, patients recovering from surgery, and 110 million women in labour giving birth each year.**



**Altogether, WHO estimates that annually tens of millions of people are not treated adequately for their moderate to severe pain.**

**Unrelieved pain affects the quality of life of individuals and their families, friends and communities, and can through cause wider losses to society, such as reduced productivity of both patients and their caregivers. Inadequate pain treatment may also lead to the seeking of additional medical intervention.**

**Global inequalities in access to pain relief are stark, with, for example, 90 per cent of the global consumption of morphine, fentanyl and oxycodone registered in 2009 occurring in Australia, Canada, New Zealand, the United States and several European countries.”**

# The Truth about Morphine availability

From Wikipedia

- “According to a 2005 estimate by the [International Narcotics Control Board](#), six countries (Australia, Canada, France, Germany, the United Kingdom, and the United States) consume 79 percent of the world’s morphine. The less affluent countries, accounting for 80 percent of the world's population, consumed only about 6 percent of the global morphine supply. Some countries import virtually no morphine, and in others the drug is rarely available even for relieving severe pain while dying.

- Experts in pain management attribute the under-distribution of morphine to an unwarranted fear of the drug's potential for addiction and abuse. While morphine is clearly addictive, Western doctors believe it is worthwhile to use the drug and then wean the patient off when the treatment is over.<sup>[88]</sup>

<sup>^</sup> Donald G. McNeil Jr. (2007-09-10). ["Drugs Banned, Many of World’s Poor Suffer in Pain"](#). New York Times. Retrieved 2007-09-11.

## Current Legal Production of Opium

Legal growing of opium for medicinal use currently takes place in India, Turkey, and Australia. **Two thousand tons of opium** are produced annually and this **supplies the world** with the raw material needed to make medicinal products. From *Mallinckrodt site*



# *Mallinckrodt*

- Mallinckrodt is the largest U.S. supplier, by prescription, of opioid pain medications.
- **The most famous federally approved cannabis grower, Dr. Mahmoud El Sohly, has also testified he has begun legally selling THC extracted from his marijuana farm at the [University of Mississippi](#) to the drug company Mallinckrodt. The [National Institute on Drug Abuse](#) at the University of Mississippi supplied Mallinckrodt with [marijuana](#) to produce a generic version of [Marinol](#) until the project ended in 2010**

## Researchers Find Study of Medical Marijuana Discouraged

By GARDINER HARRIS

Published: January 18, 2010

# The New York Times

But federal officials have repeatedly failed to act on marijuana research requests in a timely manner or have denied them, according to a 2007 ruling by an administrative law judge at the Drug Enforcement Administration. **While refusing to approve a second marijuana producer, the government allowed the University of Mississippi to supply Mallinckrodt, a drug maker, with enough marijuana to eventually produce a generic version of Marinol.**

## Inventors

[Mahmoud A. Elsohly](#), [Samir A. Ross](#)

<b>Publication number</b>	US6365416 B1
<b>Publication type</b>	Grant
<b>Application number</b>	US 09/178,962
<b>Publication date</b>	Apr 2, 2002
<b>Filing date</b>	Oct 26, 1998
<b>Priority date</b>	Oct 26, 1998
<b>Fee status</b>	Paid
<b>Also published as</b>	<a href="#">CA2348028A1</a> , <a href="#">5 More »</a>
<b>Original Assignee</b>	<a href="#">The University Of Mississippi</a>

# Method of preparing delta-9-tetrahydrocannabinol

US Patent 6365416 B1

## ABSTRACT

A method of preparing THC using extraction of plant material with a non-polar solvent followed by vacuum distillation and chromatography.

# Text from the Patent filing of

Mahmoud A. Elsohly, Samir A. Ross

- “Regardless of which formulation is to be used for THC or a pro-drug thereof, a source for the raw material is critical. The currently-approved capsule formulation is prepared from synthetic THC which is extremely expensive to produce. It is thought that should an economic process be developed for isolation of THC from the natural material (cannabis), then the cost of the raw material could be brought down significantly, making it possible to develop such formulations at a reasonable cost to the public. The consequence of this would be the availability of alternative therapies involving THC (or a prodrug thereof) which would help in suppressing the public outcry for approval of marijuana as a medicine”.



MARINOL® Capsule is formulated with the following inactive ingredients:

- Each FD&C Blue No. 1 (5 mg), FD&C Red No. 40 (5 mg), FD&C Yellow No. 6 (5 mg and 10 mg), gelatin, glycerin, methylparaben, propylparaben, sesame oil, and **titanium dioxide.**



## Canadian Centre for Occupational Health & Safety

[www.ccohs.ca](http://www.ccohs.ca)

- **Titanium Dioxide Classified as Possibly Carcinogenic to Humans**
- Titanium dioxide **has recently been classified by the International Agency for Research on Cancer (IARC) as an IARC Group 2B carcinogen "possibly carcinogen to humans"**. Titanium dioxide accounts for 70% of the total production volume of pigments worldwide. It is widely used to provide whiteness and opacity to products such as paints, plastics, papers, inks, foods, and toothpastes. It is also used in cosmetic and skin care products, and it is present in almost every sunblock, where it helps protect the skin from ultraviolet light.

*This report contains the collective views of an international group of experts and does not necessarily represent the decisions or the stated policy of the World Health Organization*

**WHO Technical Report Series**

**808**

# **WHO EXPERT COMMITTEE ON DRUG DEPENDENCE**

Twenty-seventh Report

## 4. **Dronabinol**

.....➔ Dronabinol (INN; CAS 1972-08-3), chemically (6aR,10aR)-6a,7,8,10a-tetrahydro-6,6,9-trimethyl-3-pentyl-6H-dibenzo[b,d]pyran-1-ol, is one of the stereochemical variants of *delta*-9-tetrahydrocannabinol, the active principle of cannabis. Dronabinol is included in Schedule I of the Convention on Psychotropic Substances, 1971. Dronabinol was reviewed by the twenty-sixth meeting of the WHO Expert Committee on Drug Dependence (2) in response to a notification by the Government of the United States of America, requesting the transfer of *delta*-9-tetrahydrocannabinols (*delta*-9-THC) from Schedule I to Schedule II of the Convention. At that time the Committee rated the abuse liability of dronabinol as high, although few public health and social problems were associated with its therapeutic use, and rated its therapeutic usefulness as moderate to high as an antiemetic adjunct to cancer chemotherapy in selected cases. Based on the above assessment, the Committee recommended rescheduling of dronabinol from Schedule I to Schedule II.

====➔ The United Nations Commission on Narcotic Drugs did not endorse this recommendation. Some delegations pointed out that the value of dronabinol in therapy did not seem to counterbalance its high potential for abuse, which would constitute a serious disadvantage if dronabinol were moved to Schedule II. It was suggested, however, that WHO should continue collecting data on its therapeutic usefulness for another review.

The Committee reviewed additional data compiled on therapeutic usefulness, and reconsidered the abuse potential and the possible implications of rescheduling, bearing in mind the concerns expressed by the Commission on Narcotic Drugs.

**B1**

Boaz, 18/02/2013

# UN Drug Related Organs

- Earlier treaties had only controlled opium, coca, and derivatives such as morphine, heroin and cocaine. The Single Convention, adopted in 1961, consolidated those treaties and broadened their scope to include **cannabis** and drugs whose effects are similar to those of the drugs specified.
- The Commission on Narcotic Drugs and the World Health Organization were empowered to add, remove, and transfer drugs among the treaty's four Schedules of controlled substances.
- The International Narcotics Control Board (INCB) was put in charge of administering controls on drug production, international trade, and dispensation.
- The United Nations Office on Drugs and Crime (UNODC) was delegated the Board's day-to-day work of monitoring the situation in each country and working with national authorities to ensure compliance with the Single Convention.
- This treaty has since been supplemented by the [Convention on Psychotropic Substances](#), which controls LSD, Ecstasy, and other psychoactive pharmaceuticals, and the [United Nations Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances](#), which strengthens provisions against money laundering and other drug-related offenses.

*Article 28-* **SINGLE CONVENTION  
ON NARCOTIC DRUGS, 1961**

As amended by the 1972 Protocol amending UNITED  
NATIONS

- Articles 1, 2, 4, 9, 12, 19, and 49 contain provisions relating to "medical and scientific" use of controlled substances. **In almost all cases, parties are permitted to allow dispensing and use of controlled substances under a prescription, subject to record-keeping requirements and other restrictions.**

## SINGLE CONVENTION ON NARCOTIC DRUGS, 1961

Final Act of the United Nations Conference for the Adoption of a Single Convention on Narcotic Drugs

### Article 23

#### NATIONAL OPIUM AGENCIES

1. A Party that permits the cultivation of the opium poppy for the production of opium shall establish, if it has not already done so, and maintain, one or more government agencies (hereafter in this article referred to as the Agency) to carry out the functions required under this article.
2. Each such Party shall apply the following provisions to the cultivation of the opium poppy for the production of opium and to opium:
  - a) The Agency shall designate the areas in which, and the plots of land on which, cultivation of the opium poppy for the purpose of producing opium shall be permitted.
  - b) Only cultivators licensed by the Agency shall be authorized to engage in such cultivation.
  - c) Each licence shall specify the extent of the land on which the cultivation is permitted.
  - d) All cultivators of the opium poppy shall be required to deliver their total crops of opium to the Agency. The Agency shall purchase and take physical possession of such crops as soon as possible, but not later than four months after the end of the harvest.
  - e) The Agency shall, in respect of opium, have the exclusive right of importing, exporting, wholesale trading and maintaining stocks other than those held by manufacturers of opium alkaloids, medicinal opium or opium preparations. Parties need not extend this exclusive right to medicinal opium and opium preparations.

### Article 28

#### CONTROL OF CANNABIS

1. If a Party permits the cultivation of the cannabis plant for the production of cannabis or cannabis resin, it shall apply thereto the system of controls as provided in article 23 respecting the control of the opium poppy.
2. This Convention shall not apply to the cultivation of the cannabis plant exclusively for industrial purposes (fibre and seed) or horticultural purposes.
3. The Parties shall adopt such measures as may be necessary to prevent the misuse of, and illicit traffic in, the leaves of the cannabis plant.

**Article 28- SINGLE CONVENTION  
ON  
NARCOTIC DRUGS, 1961  
As amended by the 1972 Protocol amending UNITED NATIONS  
CONTROL OF CANNABIS**



1. If a Party permits the cultivation of the cannabis plant for the production of cannabis or cannabis resin, it shall apply thereto the system of controls as provided in **article 23** respecting the control of the opium poppy.
2. **This Convention shall not apply to the cultivation of the cannabis plant exclusively for industrial purposes (fiber and seed) or horticultural purposes.**
3. The Parties shall adopt such measures as may be necessary to prevent the misuse of, and illicit traffic in, the leaves of the cannabis plant.



## Article 23

# NATIONAL ~~OPIUM~~ (Cannabis) AGENCIES

1. A Party that permits the cultivation of the (~~opium poppy~~) CANNABIS for the production of (~~opium~~) CANNABIS shall establish, if it has not already done so, and maintain, one or more government agencies (hereafter in this article referred to as the **Agency**) to carry out the functions required under this article.
2. Each such Party shall apply the following provisions to the cultivation of (~~the opium poppy~~) CANNABIS for the production of (~~opium and to opium~~) CANNABIS:
  - a) The Agency shall designate the areas in which, and the plots of land on which, cultivation of the (~~opium poppy~~) CANNABIS for the purpose of producing (~~opium~~) CANNABIS shall be permitted.
  - b) Only cultivators licensed by the Agency shall be authorized to engage in such cultivation.
  - c) Each license shall specify the extent of the land on which the cultivation is permitted.

## *Article 23*

d) All cultivators of (~~the opium poppy~~) CANNABIS shall be required to deliver their total crops of (~~opium~~) CANNABIS to the Agency. The Agency shall purchase and take physical possession of such crops as soon as possible, but not later than four months after the end of the harvest.

e) The Agency shall, in respect of (~~opium~~) CANNABIS, have the exclusive right of importing, exporting, wholesale trading and maintaining stocks other than those held by manufacturers of (~~opium~~) CANNABIS alkaloids, medicinal (~~opium~~) CANNABIS or (~~opium~~) CANNABIS preparations. Parties need not extend this exclusive right to medicinal (~~opium~~) CANNABIS and (~~opium~~) CANNABIS preparations.

## **Regulatory environment permits and requires the establishment of a MC Agency**

- Under UN conventions MC can be grown and consumed as part of a medical and scientific research program.**
- This requires establishing an “agency”.**
- If the authorities refuse to approve the MC research program take them to court to fulfill their obligation to UN drug conventions and their expose their cruelty to reduce pain and suffering among sick people**

# Thank you