



The Cannabis model in Canada and the USA

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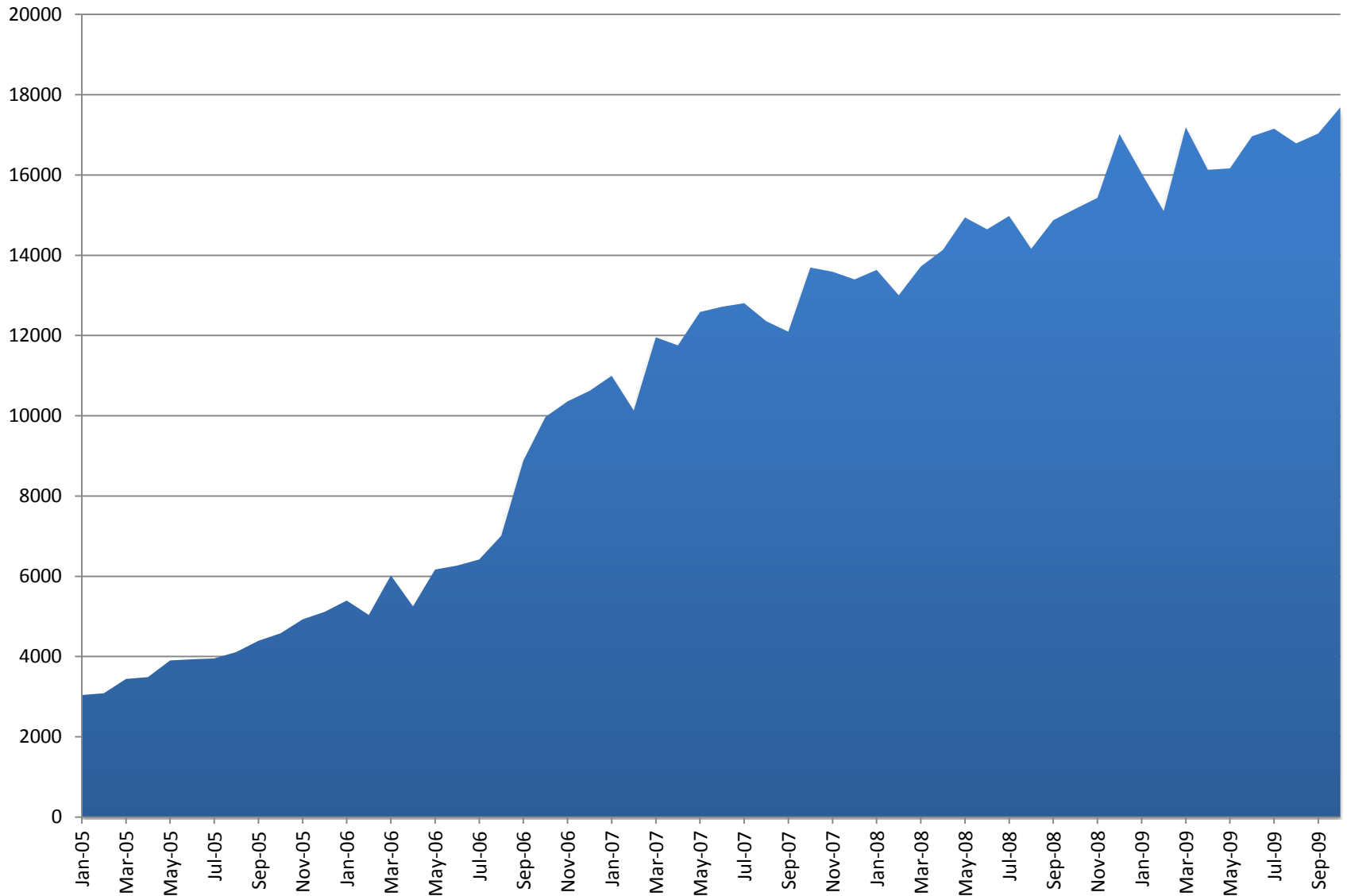
Outline

- Canada
 - Cannabinoid medicines
 - Existing regulatory framework
 - Proposed new regulations
- USA
 - Overview of state programs and issues
- Discussion of key elements and issues

Cannabinoids in Canada

- THC/CBD (2.5mg THC + 2.7mg CBD)
 - Oromucosal spray
 - Approved for multiple sclerosis-associated neuropathic pain, spasticity and advanced cancer pain
- Nabilone (0.25 - 1.0mg)
 - Oral capsule
 - Approved for chemotherapy-induced nausea and vomiting
- Dronabinol/THC (2.5 - 10mg)
 - Oral capsule
 - Approved for chemotherapy-induced nausea and vomiting and anorexia associated with HIV/AIDS
- Herbal cannabis (12.5% THC)
 - Via Marihuana Medical Access Regulations (MMAR-Health Canada)

Total cannabinoid prescriptions Canada 2005-2009



Issues in cannabinoid prescribing

- Cost
 - Coverage by provincial formularies
 - Nabilone (generic 2012)
 - Coverage by private insurance
 - Nabiximols
 - Dronabinol
- Off-label use
- Abuse potential very low
 - Ware & St-Arnaud (Addiction 2010)
 - Ware et al (IASP 2012)

Canada's Medical Marijuana Access Regulations (MMAR)

- Authorization process elements
 - Statement of symptom/disease complex
 - Category 1 & 2
 - Acknowledge that cannabis is not approved
 - State that conventional treatments “tried or considered”
 - Specialist “aware that cannabis is being used” (Category 2 only)
 - Submit to Health Canada for ‘license to possess’

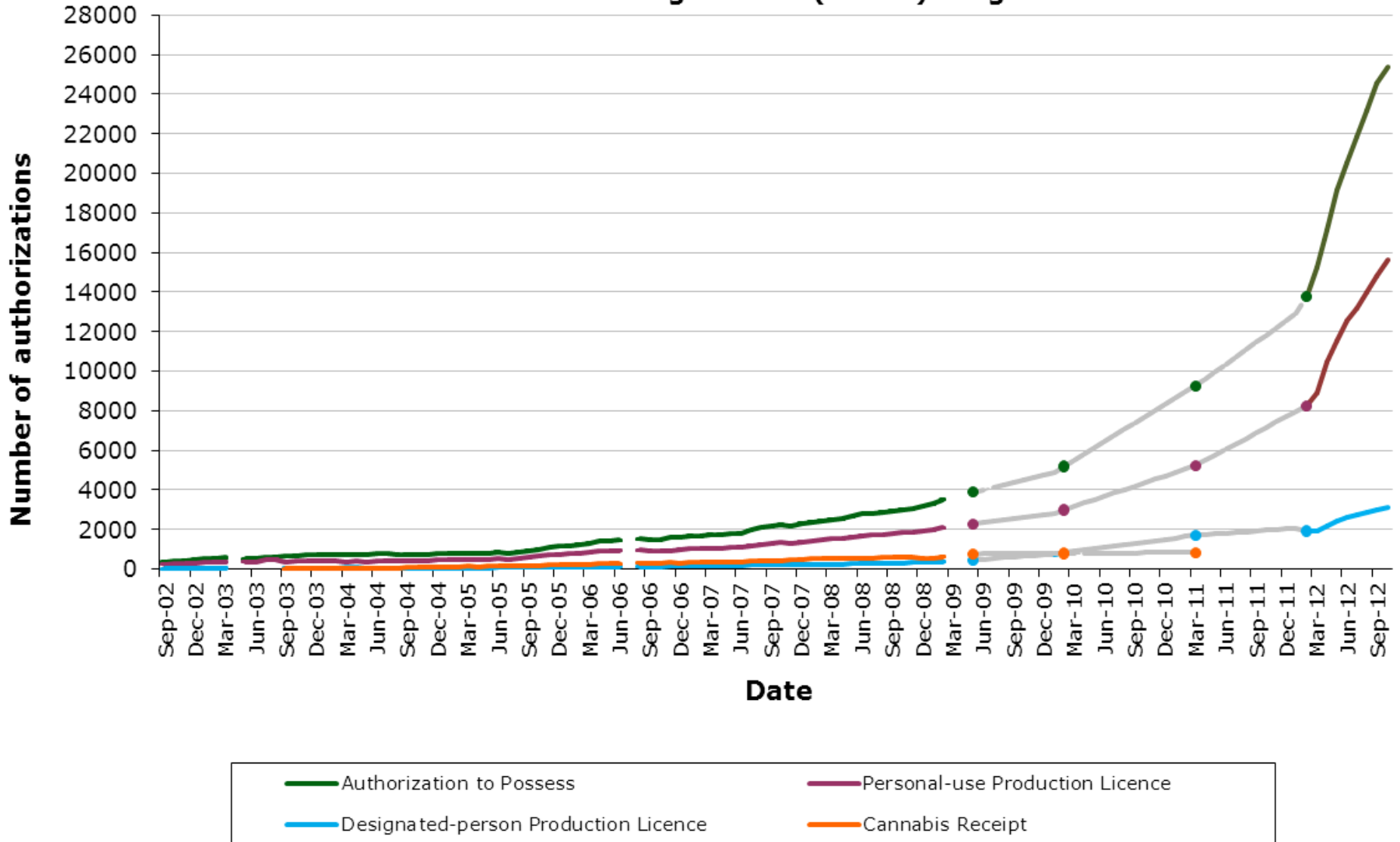
Canada's MMAR: access

- Authorization users: supply options
 - License to produce
 - Designated production license
 - Purchase from Health Canada/Prairie Plant Systems (PPS)
 - 12% THC
 - Single strain
 - Tested for heavy metals/contaminants
 - Gamma irradiated
 - Sent by registered mail directly to patient
- No insurance coverage
 - May claim tax credit for medical expense (PPS only)

Other MMAR resources

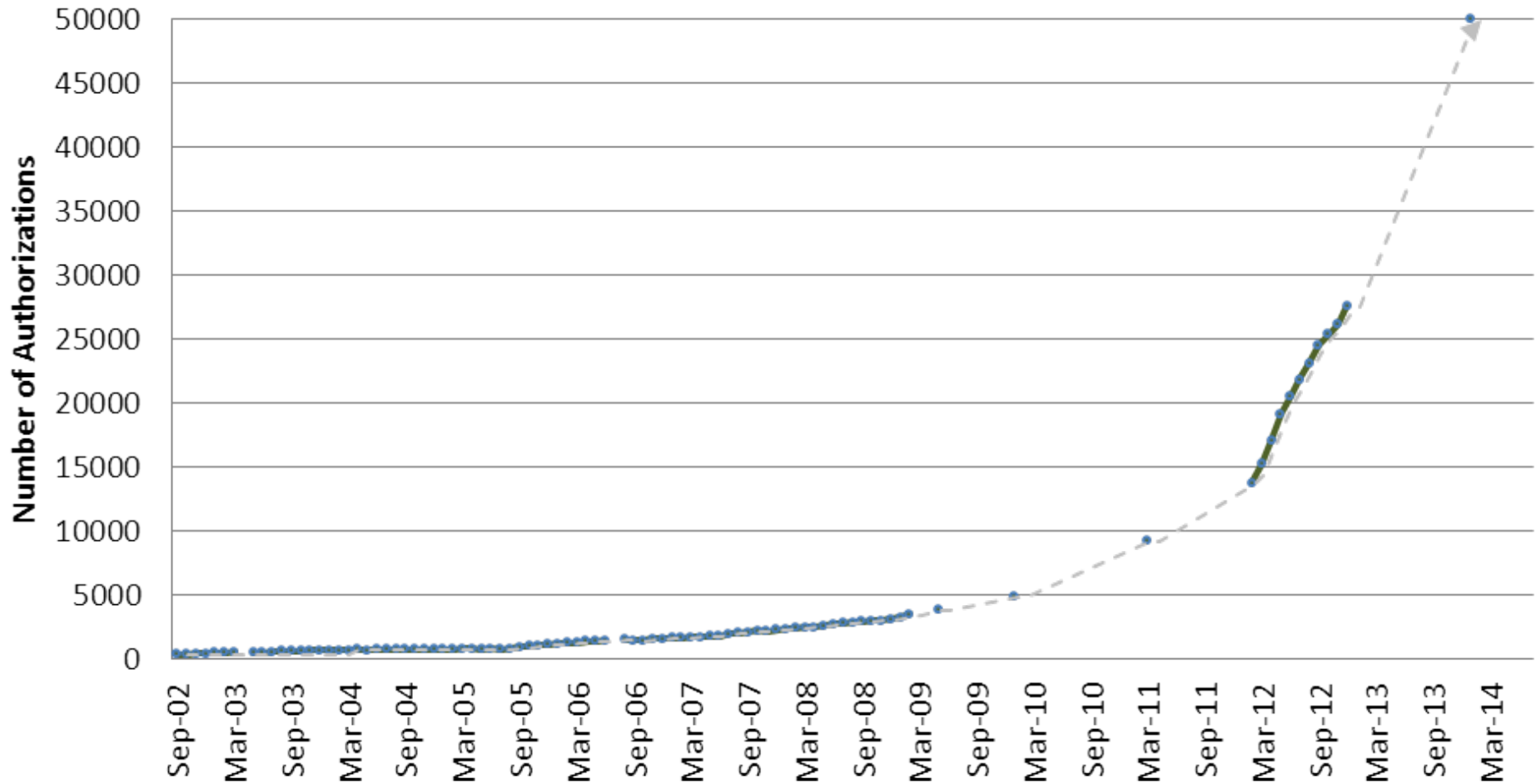
- Vapourizer approved as medical device
 - Volcano Medic[®] (Storz & Bickel)
- Information for Health Care Professionals
 - Health Canada Expert Advisory Committee
 - www.hc-gc.ca
 - Search “marihuana”

Authorizations to possess marihuana under Health Canada's Marihuana Medical Access Regulations (MMAR) Program



Source: Health Canada January 2013

Growth Rate of Authorizations to Possess Marihuana for Medical Purposes under Health Canada's Marihuana Medical Access Regulations Program



Source: Health Canada January 2013

The Marijuana Medical Regulations Policy (MMRP) 2013

- Reasons for change:
 - Security/safety
 - Proliferation of ‘grow-ops’ in homes
 - Access
 - Court challenges to existing MMAR
 - Long history of courts driving regulatory change
 - Abuse of MMAR
 - Organized crime approaches to solicit licenses
 - MDs “selling” licenses

The Marijuana Medical Regulations Policy (MMRP) 2013

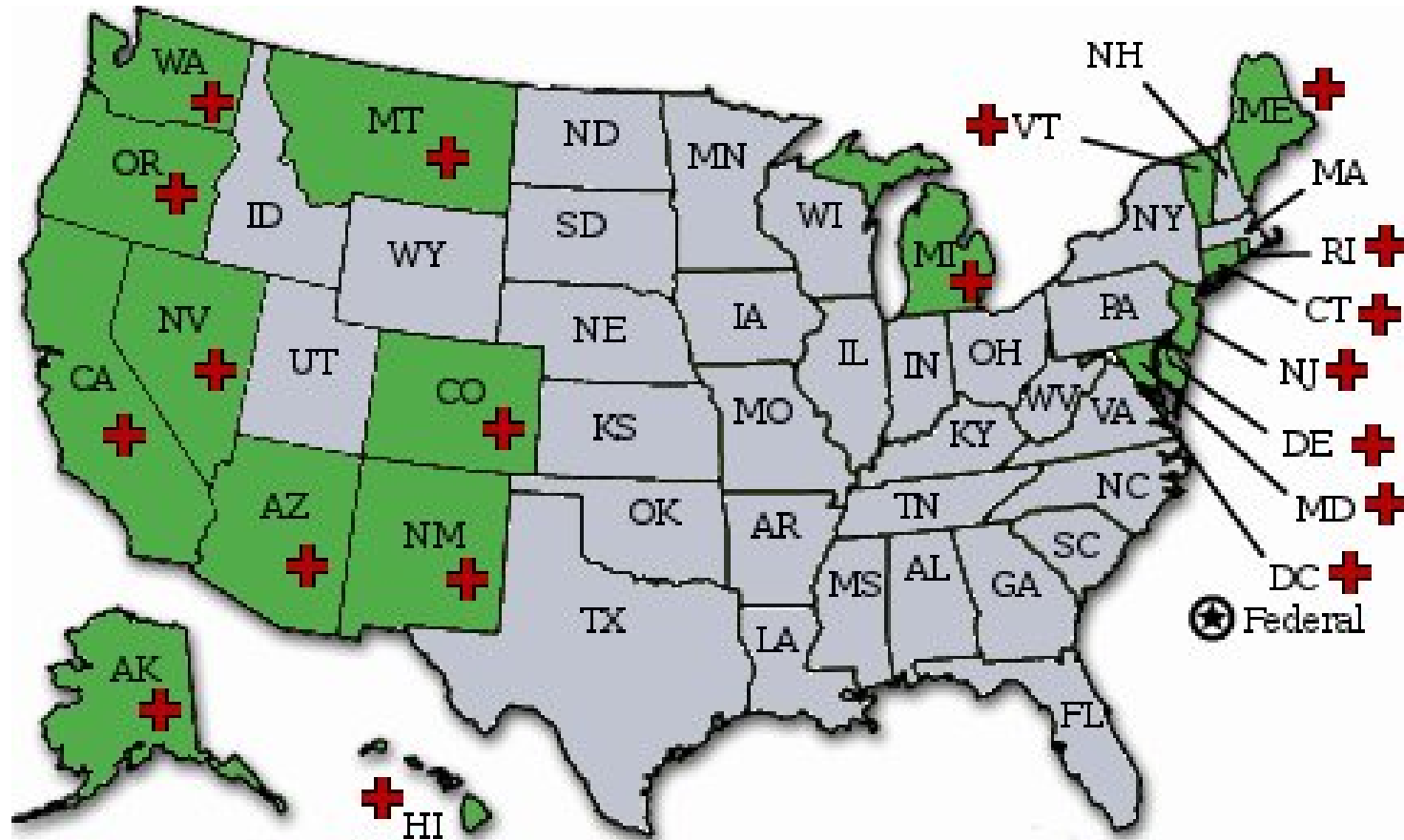
- No more licenses issued
 - “prescription” model
- Multiple licensed commercial producers
- MDs and nurse practitioners may prescribe (and pharmacists?)
- Distribution direct or through pharmacies
- Come into effect March 2014
- <http://www.gazette.gc.ca/rp-pr/p1/2012/2012-12-15/html/reg4-eng.html#reg>

Education of health care professionals

- Canadian Consortium for the Investigation of Cannabinoids (www.ccic.net)
- Accredited cannabinoid education (ACE) programs for over 3000 HCPs in last 2 years
 - Small group
 - Online
 - Interactive
- Informed by needs assessments, expert faculty
- Programs across Canada and USA, European Symposia
- International Association for Cannabinoid Medicine (IACM)
 - 7th Conference on Cannabinoids
 - 27-28 September 2013
 - Holiday Inn, Cologne, Germany
 - www.cannabis-med.org



Medical cannabis in the USA



Source: www.safeaccessnow.org

Jurisdiction	Year legalized	Amount allowed per card holder	New application fee (\$)	Dispensaries allowed
Alaska	1998	1 oz and 6 plants (no more than 3 mature)	25	No
Arizona	2010	2.5 oz, 0-12 plants	150	Yes
California	1996	8 oz, 18 plants (6 mature, 12 immature)*	66**	Yes
Colorado	2000	2 oz and 6 plants (no more than 3 mature)	90	Yes
Hawaii	2000	7 plants (3 mature, 4 immature) and 1 usable oz from each mature plant	25	No
Maine	1999	2.5 oz and 6 plants	100	Yes
Michigan	2008	2.5 oz and 12 plants	100	No
Montana	2004	1 oz, 6 plants	25	No
Nevada	2000	1 oz, 7 plants (3 mature, 4 immature)	150+	No
New Jersey	2010	2 oz	200	Yes
New Mexico	2007	6 oz, 18 plants (4 mature, 12 seedlings)	0‡	Yes
Oregon	1998	24 oz 24 plants (6 mature, 18 seedlings)	100	No
Rhode Island	2006	2.5 oz, 12 plants	75	Yes
Vermont	2004	2 oz, 9 plants (2 mature, 7 immature)	50	No
Washington	1998	24 oz and 15 plants	No registration program	No
Washington, DC	2010	2 oz	Not established	No

Source: Daniel Bowles MD, personal 2011

Table 1. Diseases and Conditions for Which Medical Marijuana Use Is Permitted According to State Laws.*

Qualifying Diseases and Debilitating Conditions	Alaska	California	Colorado	Hawaii	Maine	Michigan	Montana	Nevada	New Jersey	New Mexico†	Oregon	Rhode Island	Vermont	Washington
Cancer	X	X	X	X	X	X	X	X	X (if terminal)	X	X	X	X‡§	X
Glaucoma	X	X	X	X	X	X	X	X	X‡	X	X	X		X‡
HIV/AIDS	X	X	X	X	X	X	X	X	X	X	X	X	X‡§	X
Hepatitis C						X						X		X‡
Alzheimer's disease						X					X	X		
Nail-patella syndrome						X								
Amyotrophic lateral sclerosis						X			X					
Cachexia, or wasting syndrome§	X	X	X	X	X¶	X	X	X	X¶		X	X	X	X‡
Severe or chronic pain§	X	X	X	X		X	X	X	X¶		X	X	X	X‡
Severe nausea§	X	X	X	X	X¶	X	X	X	X¶		X	X	X	X‡
Seizures§	X	X	X	X	X	X	X	X	X‡	X (epilepsy)	X	X	X	X
Intractable spasticity									X‡					X‡
Anorexia		X												X‡
Severe muscle spasms	X	X	X	X	X	X	X	X			X	X		X‡
Multiple sclerosis									X	X			X	X
Spinal cord damage, with neurologic indication of muscular spasticity										X				
Appetite loss					X¶									X‡
Cramping														X‡
Arthritis		X												
Migraine		X												
Muscular dystrophy									X					
Inflammatory bowel or Crohn's disease						X			X					X‡
Admission to hospice care or terminal illness									X	X				
Any other chronic or persistent medical condition		X**												
Any other medical condition approved by state agency	X		X	X	X	X	X	X	X	X	X	X		X



US issues

- Proliferation of “pot docs”
 - Unregulated, untrained, unethical
- Federal law trumps state law
- Doctors afraid of legal ramifications
 - DEA licenses
- High profile dispensaries and court challenges
- Washington and Colorado have legalized cannabis
 - What will Barack Obama do now?





Global issues

- Approved ‘indications’ vary widely
- Education lacking
 - Health care professionals
 - “bona fide relationship” with practitioner
 - Cannabis is a means to improved health, not the end
 - Public/patients
 - Alternative delivery
- Research **desperately** needed
 - Monitoring
 - Strain differences
 - Other herbal preparations...

A proposal...

- Cannabis exists between folk and academic medicine
 - With enormous range of potential therapeutic applications
 - No chance of ‘approval’ for all of these
- Global advisory panel on medical cannabis policy
 - Harmonize regulatory approaches
 - Transfer knowledge
 - Sharing experience