FIVE DAYS in MAY 2019

Cannabis: Revelations through Research

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Cannabis Legalization – A Time *of* Prophets or *for* Profits?

May 30, 2019

Dr. Richard Stanwick
Chief Medical Health Officer
Island Health

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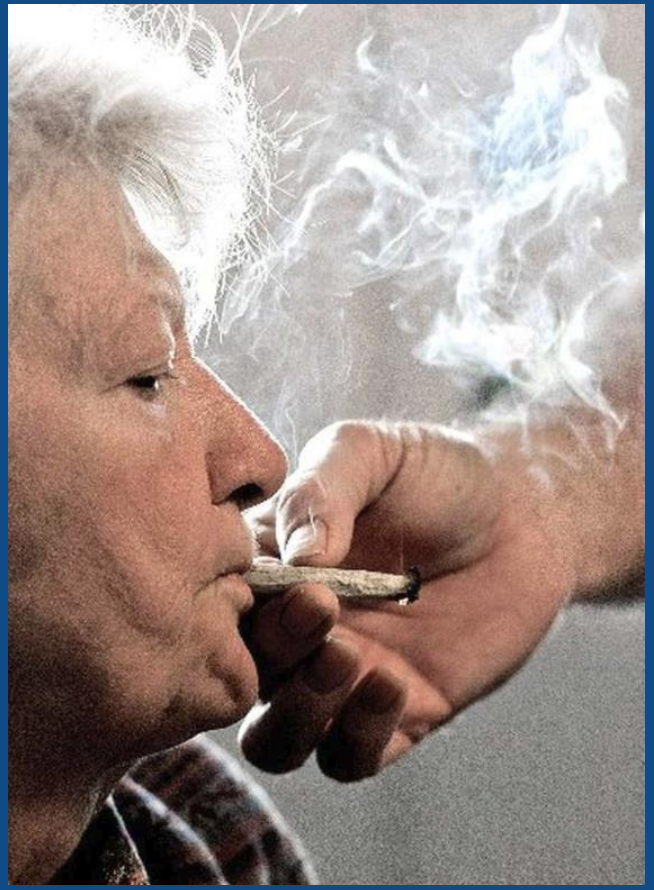


Acknowledgement

We are gathered on the traditional unceded territory of the Lekwungen Speaking Peoples, specifically the Songhees and Esquimalt First Nations.

Hay’sxw’qa Si’em.

What is True about Cannabis?

4/20 is a term for smoking pot adopted by potheads after they learned 420 was the police code for Marijuana Smoking in Progress.

1. True
2. False

What is True about Cannabis?

2. False

"4:20 was the time of day some stoners at San Rafael High in Northern California would get together every day after school to smoke weed and get high." – the *Urban Dictionary* notes there is no police code for smoking pot.

What is True about Cannabis?

A. Cannabis can be a source of heartbreak.
B. Cannabis production will significantly increase BC's carbon footprint.
C. Cannabis plants are nothing to sneeze at.
D. Co-using cannabis and Viagra will give you more than a really stiff upper lip.

1. A and C.
2. B and D.
3. All of the above.
4. None of the above.

What is True about Cannabis?

- French study 2014, increased BP and HR associated with cannabis consumption responsible for about 2% of heart disease observed and 9 MI's.
- Energy consumed by cannabis industry 6X that of pharmaceutical industry in the United States. (The Carbon Footprint of Indoor Cannabis Production." Energy Policy 46 (2012) 58-67).
- Allergic responses to cannabis on the rise, similar to hay fever; anaphylaxis still rare but keep that Epi Pen close.
- Cannabis can inhibit liver enzyme cytochrome P450 which breaks down Viagra resulting pro*long*ed response to the drug.

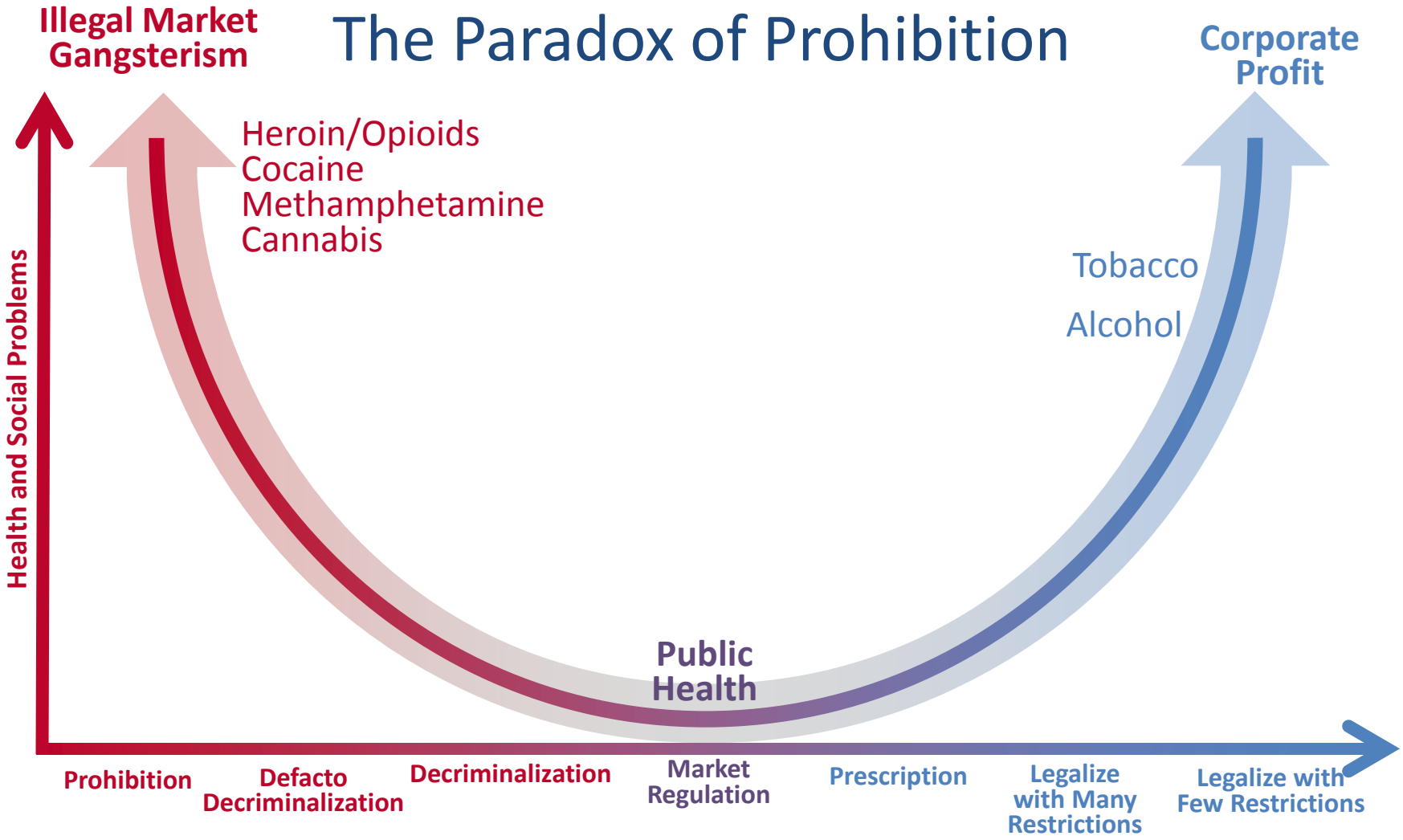
3. All of the Above

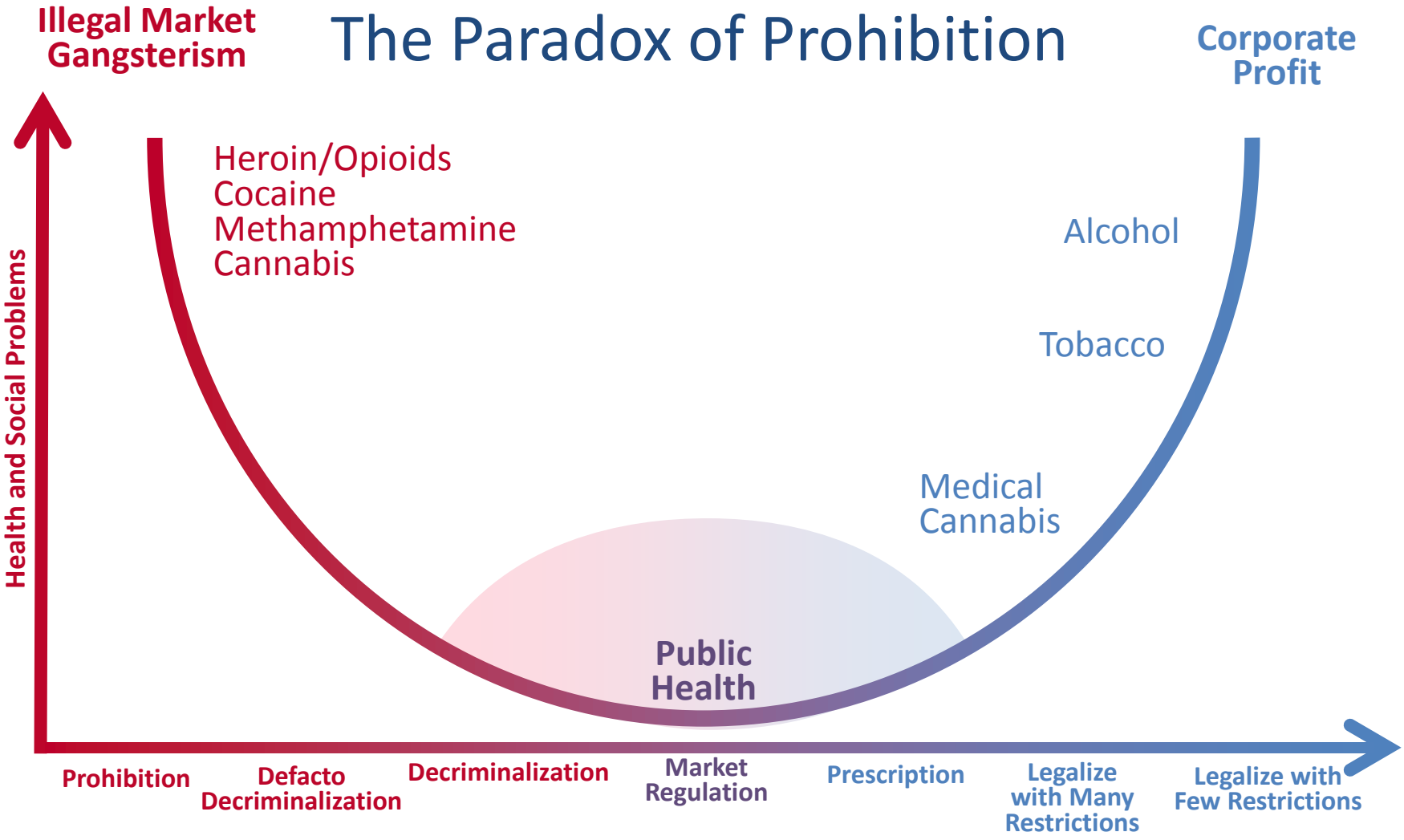
Disclosure

- I have no relevant financial relationships with the manufacturer(s) of any commercial product(s) and/or provider(s) of commercial services referenced in this public presentation.
- I *may* discuss an unapproved or investigative use of a commercial product or device in this presentation.

Learning Objectives

- To describe the elements of influence that go into shaping a public policy, and reference the contribution of health to that process.
- To appreciate the impact arising from the current legislation of cannabis and to anticipate the consequences of “wave two” of legalization.


Illegal Market Gangsterism
The Paradox of Prohibition
Corporate Profit
Heroin/Opioids
Cocaine
Methamphetamine
Cannabis
Tobacco
Alcohol
Health and Social Problems
Public Health
Prohibition
Defacto Decriminalization
Decriminalization
Market Regulation
Prescription
Legalize with Many Restrictions
Legalize with Few Restrictions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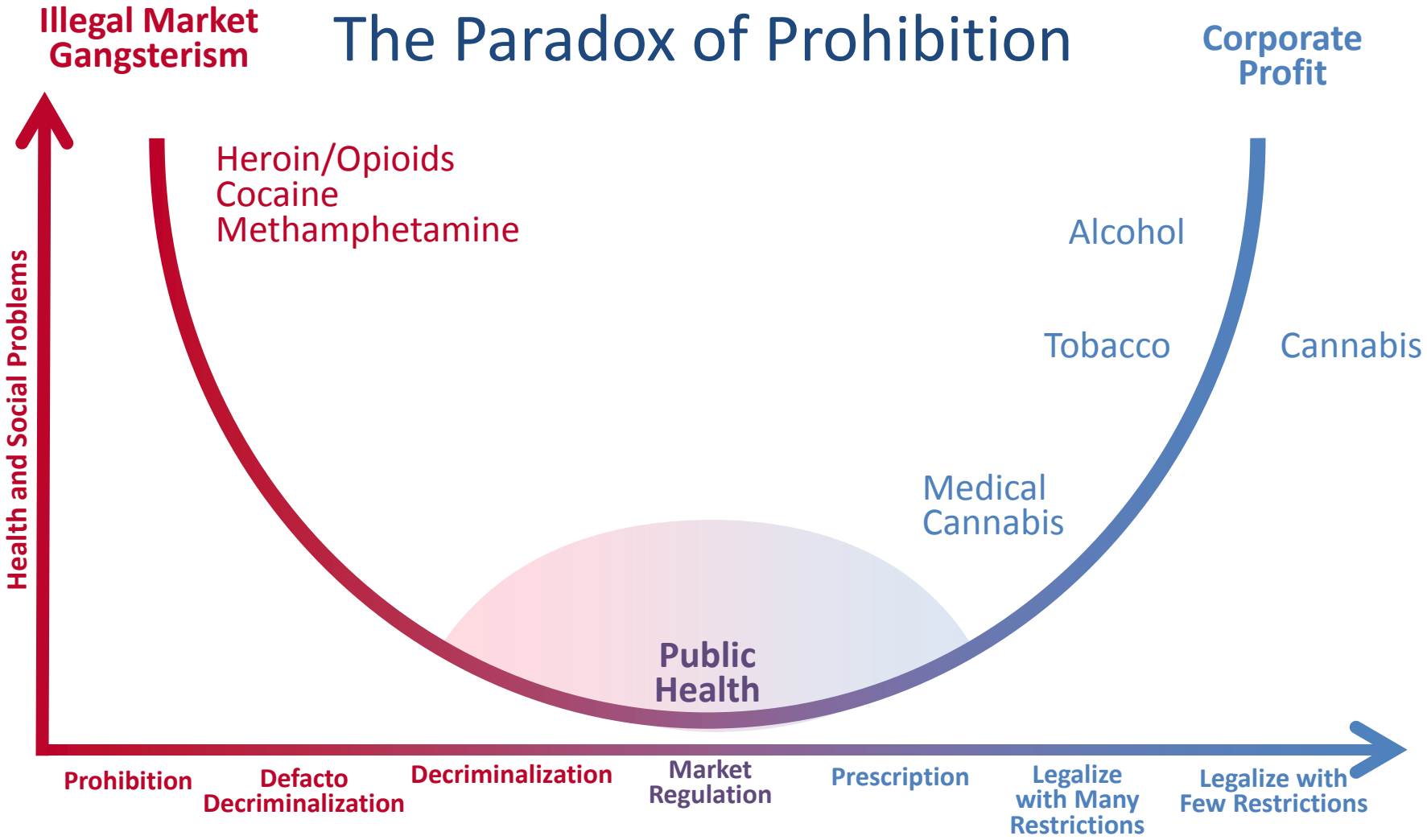
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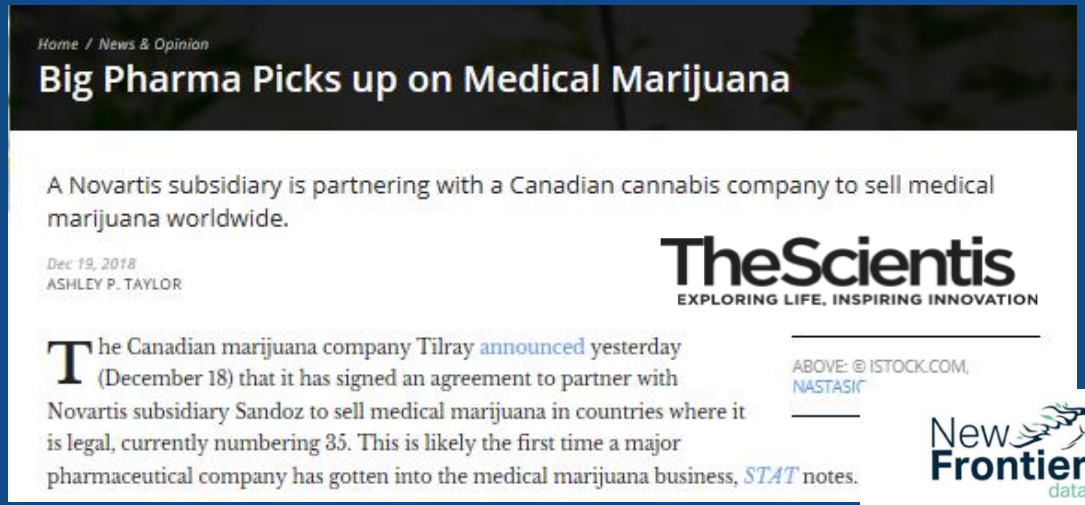
Medical Cannabis



Home / News & Opinion

Big Pharma Picks up on Medical Marijuana

A Novartis subsidiary is partnering with a Canadian cannabis company to sell medical marijuana worldwide.

Dec 19, 2018
ASHLEY P. TAYLOR

TheScientis
EXPLORING LIFE, INSPIRING INNOVATION

The Canadian marijuana company Tilray announced yesterday (December 18) that it has signed an agreement to partner with Novartis subsidiary Sandoz to sell medical marijuana in countries where it is legal, currently numbering 35. This is likely the first time a major pharmaceutical company has gotten into the medical marijuana business, *STAT* notes.

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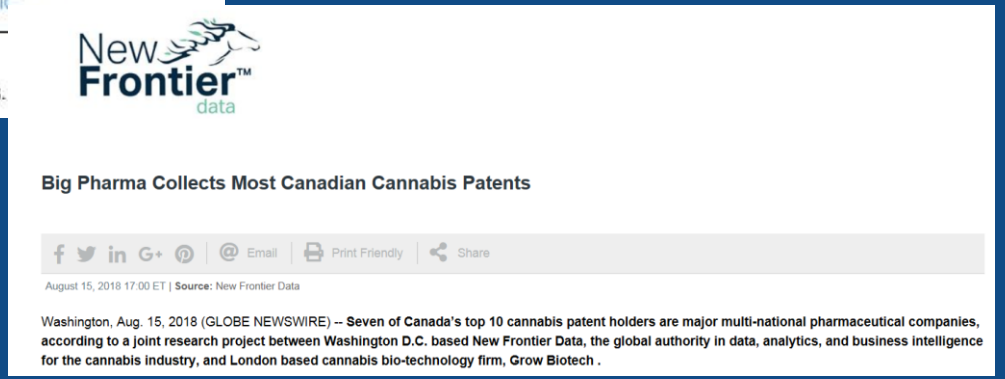


New Frontier™ data

Big Pharma Collects Most Canadian Cannabis Patents

Email | Print Friendly | Share

August 15, 2018 17:00 ET | **Source:** New Frontier Data

Washington, Aug. 15, 2018 (GLOBE NEWSWIRE) -- **Seven of Canada's top 10 cannabis patent holders are major multi-national pharmaceutical companies, according to a joint research project between Washington D.C. based New Frontier Data, the global authority in data, analytics, and business intelligence for the cannabis industry, and London based cannabis bio-technology firm, Grow Biotech .**

Medical Cannabis

CANNABIS »

Shoppers Drug Mart shows up on Health Canada's list of online vendors of medical cannabis

by Charlie Smith on December 9th, 2018 at 10:45 AM

Home » News

London Drugs 'ready' to dispense medical marijuana

Vice-president John Tse says their pharmacists have been training for months

KATYA SLEPIAN/BLACK PRESS / Tri-City News
DECEMBER 8, 2016 12:39 PM

A B.C.-based pharmacy chain is itching to be the first in Canada to sell medical marijuana.

Global NEWS

CANNABIS January 8, 2019 9:49 am Updated: January 10, 2019 7:30 am

Shoppers Drug Mart launches platform to sell medical marijuana online

By Staff The Canadian Press

BRAMPTON, Ont. – Shoppers Drug Mart's e-commerce platform for medical cannabis launched Tuesday, a month after Health Canada licenced the company to sell the product online.

Product information is available nationally, but Shoppers Drug Mart can initially only sell medical cannabis to patients in Ontario.

Shoppers Drug Mart says it has signed supply agreements with 10 licensed producers of dried cannabis and cannabis oil and will provide products and medical accessories.

Global NEWS

HEALTH April 23, 2019 6:24 am Updated: April 23, 2019 11:13 am

Shoppers Drug Mart launches online medical pot portal in Alberta

By The Canadian Press

Medical cannabis users in Alberta can now get their therapeutic pot from Shoppers Drug Mart, with the retail giant opening its second online platform Tuesday in the western province as it pursues the growing market.

The launch follows the January debut of Medical Cannabis by Shoppers Drug Mart in Ontario, where the company says uptake “has been strong.”

Gerald Major, president of the patients’ advocacy group Canadians for Fair Access to Medical Marijuana, says he welcomes Shoppers’ promise to offer a holistic approach to health care, as well as demystify the process of finding the right product.

LONDON DRUGS Blog PROUDLY CANADIAN SINCE 1945

Confused About Cannabis? We Can Help

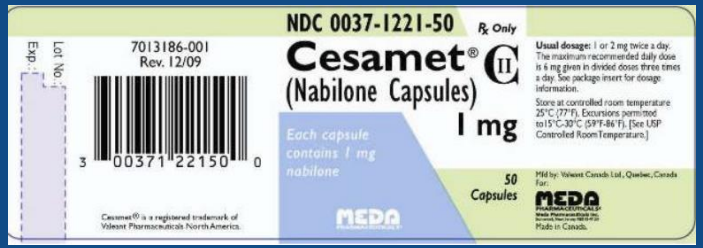
Medication reviews are available at all London Drugs locations. Cannabis Educators are available to meet with patients at the following London Drugs locations. Call the pharmacy to book an appointment.

British Columbia Locations:

- **Broadway and Vine**, Vancouver
- **Marine Way and Byrne**, Vancouver
- **West Broadway**, Vancouver
- **Duncan**, Duncan
- **Nanaimo North Town Centre**, Nanaimo
- **Lansdowne Village**, Kamloops
- **Penticton**, Penticton

Medical Cannabis

- No assigned Drug Identification Number (DIN) as with all therapeutic agents used in mainstream medicine.
- No assigned Natural Product Number (NPN) as with some therapeutic agents used in alternative medicine.



intuit turbotax

MEDICAL & DISABILITY

Surprising Tax Deductible Medical Expenses

Medical Marijuana

If you have a medical marijuana prescription, the CRA allows you to claim money spent on marijuana as a medical expense. To qualify, you must have a receipt, and the purchase must be made from a legal and licensed facility.

You may also claim the cost of marijuana seeds but may not claim any costs related to growing including lights, containers, fertilizers and other items.

LONDON DRUGS Blog PROUDLY CANADIAN SINCE 1945

Confused About Cannabis? We Can Help

What conditions can medical cannabis help? Health Canada recognizes the following:

- Chronic pain
- Severe, resistant nausea and vomiting
- Wasting syndrome and loss of appetite
- Muscle spasm caused by multiple sclerosis (MS), amyotrophic lateral sclerosis (ALS), and spinal cord injury
- Epileptic seizures
- Mobility issues caused by Parkinson's disease, Tourette's syndrome, Huntington's disease, and other movement disorders
- Arthritis
- Glaucoma
- Alzheimer's disease and other forms of dementia
- Insomnia
- Anxiety and depression
- Post-traumatic stress disorder (PTSD)
- Inflammatory bowel diseases (IBD) and irritable bowel syndrome (IBS)

Indications for Medical Marijuana (Dispensaries)

- Alcohol and Opioid Withdrawal Symptoms
- Alzheimer's
- Anorexia
- Anxiety and Depression
- Any condition diagnosed as "debilitating" by a licensed physician
- Arnold-Chiari malformation and syringomyelia
- Arthritis
- Asthma
- Autism
- Cachexia (wasting syndrome)
- Cancer
- Causalgia
- Central and peripheral chronic
- Chronic inflammatory demyelinating polyneuropathy
- Chronic or severe pain
- Crohn's disease
- CRPS (Complex Regional Pain Syndrome Type I)
- CRPS (Complex Regional Pain Syndrome Type II)
- Decompensated cirrhosis
- Dementia
- Diseases of the Liver
- Diseases of the Pancreas
- Dravet syndrome
- Dystonia
- Epilepsy
- Fibromyalgia
- Fibrous dysplasia
- Glaucoma
- Hepatitis C
- HIV/AIDS
- Huntington's Disease
- Hydrocephalus
- Hypertension
- Inflammatory Bowel Diseases
- Inflammatory Skin Diseases
- Interstitial cystitis
- Intractable skeletal muscular spasticity
- Irritable Bowel Syndrome
- Lennox-Gastaut syndrome
- Lou Gehrig's disease (Amyotrophic lateral sclerosis, or ALS)
- Lupus
- Metabolic Syndrome – Obesity, Diabetes
- Migraines
- Mitochondrial disease
- Multiple Sclerosis
- Muscle spasms
- Muscular dystrophy
- Myasthenia gravis
- Myoclonus
- Nail-patella syndrome
- Nausea and Vomiting
- Neurofibromatosis
- Neuropathies
- Osteoarthritis
- Osteoporosis Pain
- Painful peripheral neuropathy
- Parkinson's Disease
- Post-concussion syndrome
- Post-traumatic stress disorder
- Residual limb pain
- Rheumatoid Arthritis
- Schizophrenia and Psychosis
- Seizure disorders
- Sickle cell disease
- Sjogren's syndrome
- Sleep Disorders
- Spastic quadriplegia
- Spasticity disorders
- Spinal Cord Injury or Disease (including but not limited to arachnoiditis, Tarlov cysts, hydromyelia & syringomelia)
- Spinocerebellar ataxia (SCA)
- Terminal illness
- Tourette's Syndrome
- Traumatic brain injury (TBI)
- Ulcerative Colitis

Cannabis Prophets from the Time of the Greeks?

Oracle of Delphi

TIMES COLONIST

Saturday's 4/20 event shifts to lawn of legislature

Katie DeRosa / Times Colonist
APRIL 18, 2019 06:00 AM

The grassroots activists who fought for legalization have been left in the dust as the industry has been taken over by corporate interests, Smith said.

"They're not trying to include the grassroots people who paved the way for legalization in the first place."

"The fact that we have nowhere we can smoke is one of the things we're protesting," said Ted Smith, founder of the Cannabis Buyer's Club and the master of ceremonies at Vancouver's first 4/20 event in 1995.

Organizers originally wanted to host a festival-type event with live bands at Royal Athletic Park, but it was impossible to obtain a permit because cannabis consumption would violate the Capital Regional District's clean-air bylaw, Smith said.

"The way legalization is set up is completely backwards, especially for British Columbia, because we have a vested industry here that is getting shut out of this new marketplace," said Smith. "Right now, somebody comes here from somewhere else to check out B.C. bud because we are so famous for it. Well, not only do we sell them the only legal products, which are from anywhere in Canada, they are not B.C. specific at all, but then we kick them to the curb to smoke it."

Smith said the model isn't conducive to a good economy and that B.C. should be building cannabis tourism.

Now, the only law being broken by sparking up a joint is the Capital Regional District's Clean Air Bylaw.

That too should change, Smith said.

"We all should have the ability to go to a lounge here in Victoria to smoke cannabis but the Clean Air Bylaw will not allow that.

"It became legal but it became like drinking and driving. So now everybody is like, 'Are you smoking and driving?' That end of things really changed."

Constituents of Tobacco and Cannabis Smoke

Table 4. Various Analytes Including Tobacco-Specific Compounds and Heavy Metals Determined in Sidestream Smoke from Tobacco and Marijuana under Two Smoking Conditions[a]

	ISO		extreme	
	tobacco	marijuana	tobacco	marijuana
tar (mg/cig)	24.3 ± 1.8	49.7 ± 2.5*	17.2 ± 1.8	30.8 ± 1.6*
NO (μg/cig)	1101 ± 47	2087 ± 152*	1419 ± 124	2631 ± 241*
NOx (μg/cig)	1172 ± 44	2284 ± 229*	1521 ± 153	2880 ± 323*
CO (mg/cig)	61.7 ± 2.0	54.0 ± 3.7*	61.6 ± 2.9	50.6 ± 3.9*
nicotine (mg/cig)	4.77 ± 0.26	0.065 ± 0.018*	3.11 ± 0.23	0.074 ± 0.029*
ammonia (μg/cig)	5568 ± 322	14270 ± 472*	3919 ± 327	10743 ± 675*
HCN (μg/cig)	83.8 ± 7.8	685 ± 28*	103 ± 10	678 ± 72*
NNN	41 ± 4.8	<0.634*	28 ± 2.0	0.634–2.0*
NAT	17.4 ± 1.4	<2.34*	10.2 ± 1.1	<2.34*
NAB	2.71 ± 0.52	<0.793*	0.79–2.5	<0.793
NNK	92 ± 11.7	<4.65*	61 ± 5.1	<4.65*
mercury	8.32 ± 0.57	<4.40*	6.31 ± 0.61	<4.40*
cadmium	478 ± 19	4.0–13.4*	360 ± 20	4.0–13.4*
lead	34.5–115	<34.5	34.5–115	<34.5
chromium	31.0–103	31.0–103	<31.0	31.0–103
nickel	35.5–118	35.5–118	<35.5	<35.5
arsenic	<11.3	<11.3	<11.3	<11.3
selenium	<17.5	<17.5	<17.5	<17.5

[a] Values are provided ± standard deviations. For tar, nicotine, and CO, $n = 20$. For all others, $n = 7$. Units are ng/cigarette unless noted differently. *$P < 0.05$ vs tobacco. Values shown with "<" were below the limit of detection; values shown as a range were above the limit of detection but below the limit of quantitation.

Table 5. Miscellaneous Organics Determined in Mainstream and Sidestream Smoke from Tobacco and Marijuana under Two Smoking Conditions[a]

	ISO		extreme	
	tobacco	marijuana	tobacco	marijuana
	mainstream			
pyridine	31.1 ± 1.7	34.6 ± 4.3	59 ± 4.9	93.0 ± 8.9*
quinoline	1.31 ± 0.08	1.06 ± 0.26*	2.22 ± 0.22	2.68 ± 0.34*
1,3-butadiene	64.8 ± 2.2	79.5 ± 7.4*	124 ± 7	138 ± 17
isoprene	286 ± 15	74.0 ± 6.5*	540 ± 18	132 ± 19*
acrylonitrile	13 ± 1.2	36.6 ± 4.3*	24 ± 0.9	66.9 ± 9.5*
benzene	62.2 ± 3.5	58.3 ± 5.9	94.6 ± 2.6	84.4 ± 8.9*
toluene	103 ± 6	124 ± 15*	169 ± 3	199 ± 25*
styrene	15 ± 0.6	17.2 ± 2.3*	28.6 ± 2.0	44.7 ± 4.2*
	sidestream			
pyridine	265 ± 11	307 ± 14*	225 ± 9	278 ± 22*
quinoline	9.94 ± 0.92	11.3 ± 0.7*	8.53 ± 0.54	9.82 ± 1.10*
1,3-butadiene	372 ± 12	412 ± 27*	269 ± 13	420 ± 22*
isoprene	1459 ± 82	656 ± 40*	1153 ± 51	614 ± 31*
acrylonitrile	102 ± 4	295 ± 21*	73.8 ± 4.7	273 ± 17*
benzene	290 ± 11	341 ± 12*	203 ± 11	328 ± 18*
toluene	516 ± 20	704 ± 29*	393 ± 32	729 ± 28*
styrene	105 ± 10	162 ± 10*	85.2 ± 10.6	175 ± 9*

[a] Values are provided ± standard deviations; $n = 7$. Units are μg/cigarette. *$P < 0.05$ vs tobacco.

marijuana was ammonia. In marijuana smoke, ammonia was found at levels about 20-fold those in tobacco in mainstream smoke (Table 3) and about 3 fold greater in sidestream smoke (Table 4), although the absolute values were very much greater in sidestream smoke. The amount of ammonia produced during combustion of tobacco has been related to the amount of nitrate fertilizer applied during growth (*30*). The simplest explanation for the very high levels of ammonia found in marijuana smoke may be that the marijuana used for this study contained more nitrate than the tobacco sample. The marijuana plants were grown on soil-less growth medium. All fertilizers were commercially available and consisted of water-soluble hydroponic vegetable fertilizers used for horticulture and contained nitrogen

Table 6. Aromatic Amines Determined in Mainstream and Sidestream Smoke from Tobacco and Marijuana under Two Smoking Conditions[a]

	ISO		extreme	
	tobacco	marijuana	tobacco	marijuana
	mainstream			
1-aminonaphthalene	24.9 ± 2.6	84.4 ± 13.2*	35.1 ± 5.7	178 ± 17*
2-aminonaphthalene	9.38 ± 0.62	33.6 ± 3.5*	12.9 ± 1.2	66.3 ± 6.8*
3-aminobiphenyl	2.22 ± 0.18	9.15 ± 0.63*	3.68 ± 0.44	18.8 ± 1.8*
4-aminobiphenyl	1.56 ± 0.13	6.17 ± 0.44*	2.54 ± 0.17	13.5 ± 1.5*
	sidestream			
1-aminonaphthalene	195 ± 16	305 ± 21*	144 ± 8	266 ± 23*
2-aminonaphthalene	136 ± 7	177 ± 19*	79.4 ± 7.4	139 ± 12*
3-aminobiphenyl	33 ± 2.1	50.4 ± 3.7*	19.7 ± 1.6	40.6 ± 2.4*
4-aminobiphenyl	23.2 ± 1.8	31.2 ± 2.8*	13.9 ± 1.3	27.3 ± 2.2

[a] Values are provided ± standard deviations; $n = 7$. Units are ng/cigarette. *$P < 0.05$ vs tobacco.

Table 7. Selected Carbonyl Compounds Determined in Mainstream and Sidestream Smoke from Tobacco and Marijuana under Two Smoking Conditions[a]

	ISO		extreme	
	tobacco	marijuana	tobacco	marijuana
	mainstream			
formaldehyde	200 ± 28	25.1 ± 2.7*	543 ± 91	66.5 ± 11.8*
acetaldehyde	872 ± 101	448 ± 44*	1555 ± 222	1021 ± 99*
acetone	454 ± 44	237 ± 23*	826 ± 93	514 ± 32*
acrolein	125 ± 13	54.3 ± 4.5*	251 ± 32	148 ± 13*
propionaldehyde	72.1 ± 8.1	32.3 ± 3.2*	97.8 ± 14.4	74.0 ± 6.4*
crotonaldehyde	62.9 ± 7.3	23.1 ± 1.5*	127 ± 17	56.7 ± 7.7*
methyl ethyl ketone	135 ± 16	62.4 ± 5.5*	265 ± 27	140 ± 7*
butyraldehyde	47.1 ± 5.7	46.5 ± 3.8	77.1 ± 10.0	110 ± 8*
	sidestream			
formaldehyde	886 ± 47	383 ± 27*	662 ± 29	202 ± 34*
acetaldehyde	1587 ± 45	1170 ± 69*	1383 ± 37	896 ± 112*
acetone	828 ± 22	566 ± 34*	720 ± 22	405 ± 54*
acrolein	437 ± 10	304 ± 20*	316 ± 12	179 ± 24*
propionaldehyde	121 ± 6	120 ± 6	116 ± 5	93.4 ± 11.7*
crotonaldehyde	106 ± 3	49.9 ± 3.8*	97.5 ± 8.7	42.9 ± 4.7*
methyl ethyl ketone	222 ± 9	160 ± 11*	202 ± 17	116 ± 13*
butyraldehyde	67.1 ± 2.7	173 ± 12*	60.2 ± 1.7	139 ± 13*

[a] Values are provided ± standard deviations; $n = 7$. Units are μg/cigarette. *$P < 0.05$ vs tobacco.

in the form of both nitrate and ammoniacal nitrogen. However, it is not known to what extent the differences in the growing conditions between the marijuana and the tobacco, including the types of fertilizers used, influenced the levels of nitrates in the plants. The temperature of combustion can also influence the production of ammonia. Burning tobacco results in a reduction of nitrate to ammonia, which is released to a greater extent during sidestream smoke formation (*31*), suggesting that lower combustion temperatures favor the production of ammonia. Combustion temperature differences between marijuana and tobacco may have also contributed to the differences in ammonia yield, but this was not verified.

Tobacco-specific nitrosamines were not found in the marijuana smoke (Tables 3 and 4). This result was expected, given that these compounds are derived from nicotine. Arsenic and lead were also noticeably absent from the marijuana smoke, which is consistent with the certificate of analysis provided with the plant material (data not shown). Again, this could be a function of the relatively controlled growth conditions.

NO and NO_x were significantly elevated in the marijuana smoke under both smoking regimes and in mainstream (Table 3) and sidestream smoke (Table 4). A logical explanation would be that these are arising from the nitrate present in the fertilizer and would be consistent with the very high ammonia yields.

Table 9. PAHs and Aza-arenes Determined in Mainstream Smoke from Tobacco and Marijuana under Two Smoking Conditions[a]

		ISO		extreme	
no.		tobacco	marijuana	tobacco	marijuana
1	naphthalene	2907 ± 159	2070 ± 290*	4908 ± 456	4459 ± 646
2	1-methylnaphthalene	2789 ± 176	2057 ± 302*	4888 ± 491	4409 ± 604
3	2-methylnaphthalene	2093 ± 137	1292 ± 189*	3666 ± 374	2917 ± 477*
4	acenaphthylene	385 ± 22	235 ± 31*	711 ± 51	459 ± 60*
5	acenaphthene	172 ± 10	91.2 ± 10.2*	309 ± 22	213 ± 48*
6	fluorene	769 ± 42	366 ± 37*	1369 ± 100	659 ± 64*
7	phenanthrene	293 ± 14	273 ± 23	515 ± 32	476 ± 45
8	anthracene	91.8 ± 5.4	70.9 ± 6.7*	162 ± 13	136 ± 9*
9	fluoranthene	96.8 ± 3.7	65.6 ± 6.5*	171 ± 11	117 ± 12*
10	pyrene	88.8 ± 4.3	45.6 ± 4.4*	154 ± 12	82.3 ± 11.2*
11	benzo(a)anthracene	30.5 ± 2.5	26.2 ± 3.4*	52 ± 5.8	43.1 ± 7.9*
12	chrysene	38.8 ± 2.3	26.2 ± 1.4*	61.7 ± 7.4	56.3 ± 7.9
13	benzo(b)fluoranthene	10.8 ± 0.6	7.18 ± 1.12*	21.9 ± 3.1	16.2 ± 3.6*
14	benzo(k)fluoranthene	3.42 ± 0.32	1.52 ± 0.26*	7.45 ± 1.47	4.54 ± 0.96*
15	benzo(e)pyrene	11 ± 0.6	6.15 ± 0.37*	19.2 ± 1.3	12.6 ± 2.7*
16	benzo(a)pyrene	14.3 ± 1.2	8.67 ± 1.12*	25.1 ± 2.5	15.5 ± 2.9*
17	perylene	3.9 ± 0.46	3.72 ± 0.79	10.8 ± 2.3	6.10 ± 0.82*
18	indeno(1,2,3,-cd)pyrene	4.58 ± 0.89	3.60 ± 0.48*	10.1 ± 0.9	8.65 ± 3.11
19	dibenz(a,h)anthracene	1.15 ± 0.21	1.41 ± 0.19*	4.84 ± 1.05	2.83 ± 0.59*
20	benzo(g,h,i)perylene	3.77 ± 0.66	2.56 ± 0.36*	7.17 ± 1.02	6.03 ± 2.34
21	5-methylchrysene	<0.035	<0.035	<0.071	<0.071
22	benzo(b)fluoranthene	11.5 ± 1.4	6.47 ± 0.86*	19.1 ± 1.7	17.6 ± 1.4
23	benzo(j)fluoranthene	5.81 ± 0.44	4.27 ± 0.83*	13.3 ± 1.8	12.2 ± 2.1
24	dibenz(a,h)acridine	<0.314	<0.314	<0.628	<0.628
25	dibenz(a,j)acridine	<0.260	<0.260	<0.519	<0.519
26	7H-dibenzo(c,g)carbazole	<0.139	<0.139	<0.278	<0.278
27	dibenz(a,j)pyrene	<0.317	<0.317	<0.634	<0.634
28	dibenz(a,c)pyrene	0.531 ± 0.198	0.156–0.522	<0.313	<0.313
29	dibenz(a,j)pyrene	0.987 ± 0.145	0.164–0.548*	2.55 ± 0.60	<0.329*
30	dibenz(a,h)pyrene	0.177–0.589	<0.177	<0.354	<0.354

[a] Values are provided ± standard deviations; $n = 7$. Units are ng/cigarette. *$P < 0.05$ vs tobacco. Values shown with "<" were below the limit of detection; values shown as a range were above the limit of detection but below the limit of quantitation.

Table 10. PAHs and Aza-arenes Determined in Sidestream Smoke from Tobacco and Marijuana under Two Smoking Conditions[a]

		ISO		extreme	
no.		tobacco	marijuana	tobacco	marijuana
1	naphthalene	6861 ± 419	16748 ± 2396*	10111 ± 758	14398 ± 2614*
2	1-methylnaphthalene	6265 ± 365	14812 ± 1511*	7115 ± 787	11016 ± 2954*
3	2-methylnaphthalene	6513 ± 306	11832 ± 1078*	7137 ± 778	9030 ± 2236
4	acenaphthylene	2684 ± 184	4056 ± 452*	2171 ± 123	2876 ± 571*
5	acenaphthene	960 ± 31	1345 ± 101*	791 ± 51	873 ± 163
6	fluorene	1429 ± 71	1073 ± 72*	1242 ± 56	873 ± 67*
7	phenanthrene	2818 ± 112	4933 ± 306*	2117 ± 98	3113 ± 477*
8	anthracene	755 ± 38	1135 ± 75*	542 ± 26	693 ± 111*
9	fluoranthene	699 ± 26	952 ± 61*	520 ± 24	619 ± 78*
10	pyrene	528 ± 35	609 ± 60*	377 ± 25	398 ± 38
11	benzo(a)anthracene	159 ± 8	245 ± 16*	113 ± 7	170 ± 21*
12	chrysene	401 ± 21	488 ± 28*	291 ± 18	331 ± 27*
13	benzo(b)fluoranthene	98.4 ± 8.4	114 ± 7*	79.8 ± 4.3	80.3 ± 8.0
14	benzo(k)fluoranthene	25.8 ± 4.1	27.3 ± 2.8	19.3 ± 3.1	19.7 ± 2.2
15	benzo(e)pyrene	94.9 ± 6.9	87.9 ± 7.5	72.9 ± 3.8	63.1 ± 6.2*
16	benzo(a)pyrene	91.7 ± 7.1	101 ± 9*	62.7 ± 4.2	69.7 ± 6.3*
17	perylene	23.6 ± 2.9	26.4 ± 4.7	16.4 ± 1.7	19.9 ± 2.7*
18	indeno(1,2,3,-cd)pyrene	41.7 ± 5.7	45.9 ± 6.8	32.8 ± 6.6	27.4 ± 3.3
19	dibenz(a,h)anthracene	13.8 ± 3.1	15.6 ± 3.2	13.9 ± 2.8	10.8 ± 1.2*
20	benzo(g,h,i)perylene	44.7 ± 8.0	41.8 ± 9.6	32.8 ± 7.2	30 ± 5.0
21	5-methylchrysene	<0.354	<0.354	<0.354	<0.354
22	benzo(b)fluoranthene	118 ± 9	102 ± 11*	90.4 ± 5.6	86.7 ± 12.5
23	benzo(j)fluoranthene	102 ± 7	120 ± 16*	72.3 ± 6.2	124 ± 14*
24	dibenz(a,h)acridine	<3.138	<3.138	<3.138	<3.138
25	dibenz(a,j)acridine	<2.597	<2.597	<2.597	<2.597
26	7H-dibenzo(c,g)carbazole	<1.389	<1.389	<1.389	<1.389
27	dibenz(a,l)pyrene	<3.172	<3.172	<3.172	<3.172
28	dibenz(a,e)pyrene	<1.565	<1.565	<1.565	<1.565
29	dibenz(a,i)pyrene	<1.644	<1.644	<1.644	<1.644
30	dibenz(a,h)pyrene	<1.768	<1.768	<1.768	<1.768

[a] Values are provided ± standard deviations; $n = 7$. Units are ng/cigarette. *$P < 0.05$ vs tobacco. Values shown with "<" were below the limit of detection.

island health

Dried plant smoke: similar chemicals in varied proportions

Sample comparisons of components of tobacco and marijuana secondhand smoke

	tobacco	marijuana		tobacco	marijuana
tar (mg/cig)	24.3 ± 1.8	49.7 ± 2.5*	naphthalene (ng/cig)	6861 ± 419	16748 ± 2396*
NO (μg/cig)	1101 ± 47	2087 ± 152*	formaldehyde (μg/cig)	888 ± 47	383 ± 27*
CO (mg/cig)	61.7 ± 2.0	54.0 ± 3.7*	acetaldehyde (μg/cig)	1587 ± 45	1170 ± 69*
nicotine (mg/cig)	4.77 ± 0.26	0.065 ± 0.018*	acrolein (μg/cig)	437 ± 10	304 ± 20*
ammonia (μg/cig)	5568 ± 322	14270 ± 472*	methyl ethyl ketone (μg/cig)	222 ± 9	160 ± 11*
HCN (μg/cig)	83.8 ± 7.8	685 ± 29*	phenol (μg/cig)	264 ± 13	260 ± 11
pyridine (μg/cig)	265 ± 11	307 ± 14*	*m* + *p*-cresols (μg/cig)	64.6 ± 2.5	104 ± 6*
benzene (μg/cig)	290 ± 11	341 ± 12*	pyrene (ng/cig)	528 ± 35	609 ± 60*
toluene (μg/cig)	516 ± 20	704 ± 29*	benzo(e)pyrene (ng/cig)	94.9 ± 6.9	87.9 ± 7.5
styrene (μg/cig)	105 ± 10	162 ± 10*	anthracene (ng/cig)	755 ± 38	1135 ± 75*

From Moir *et al.*, 2008. Subset of 65 components analyzed under standard tobacco smoking conditions

Exposure

- Public Health cannot accept an individual or group of individuals improving their own wellbeing by generating an established hazard that puts the health of the public at risk. Actions addressed under the *Cannabis Control and Licensing Act* of BC.
- Allows for second hand smoke exposure of health care and hotel workers.

Smoke + Psychoactive Substance =

BYLAW NO. 3962

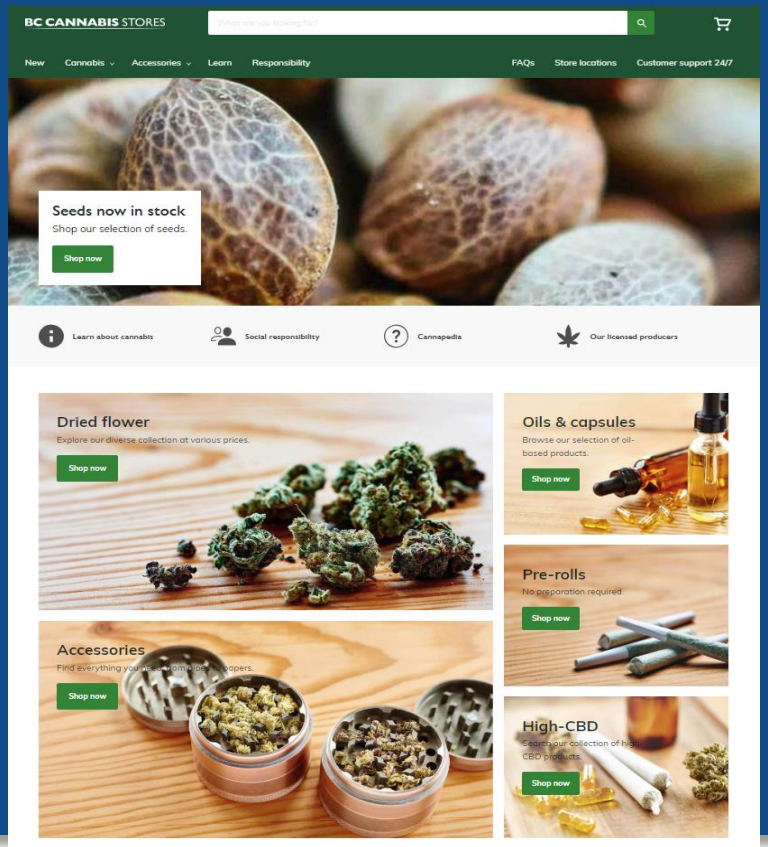
CAPITAL REGIONAL DISTRICT
CLEAN AIR BYLAW NO. 1, 2014

ADOPTED September 10, 2014
Includes all amending bylaws adopted up to January 9, 2019
(Bylaws No. 4237 & 4272)

Improving Health Outcomes For All Populations

Recreational Cannabis

> *"If you have a joint and you're smoking it for your private pleasure, you shouldn't be hassled."*
>
> ~ Prime Minister Pierre Elliot Trudeau, 1977



Government of Canada | Gouvernement du Canada

Why is the Canadian government legalizing marijuana?

Three main reasons.

1. To keep cannabis out of the hands of youth by better preventing them from accessing it.
2. To displace the illegal cannabis market.
3. To protect public health and safety with product quality and safety requirements for cannabis.

Justin Trudeau, Prime Minister of Canada

- “ young people have easier access to cannabis now, in Canada, than they do in just about any other countries in the world. [Of] 29 different countries studied by the U.N., Canada was number one in terms of underage access to marijuana. And whatever you might think or studies seen about cannabis being less harmful than alcohol or even cigarettes, the fact is it is bad for the developing brain and we need to make sure that it’s harder for underage Canadians to access marijuana. And that will happen under a controlled and regulated regime.”

“The most disingenuous element of legalization is that it will keep it out of the hands of children,” said Dr. Benedikt Fischer, a senior scientist at the Center for Addiction and Mental Health in Toronto. “It is a big experiment, in many ways.”

Like Breeds Like?

Tag Line – *Gentlemen we're not in this business for our health.*

OTTAWA CITIZEN

Cannabis companies pushing the boundaries as they promote recreational products that are expected to be legal soon

JACQUIE MILLER Updated: June 20, 2018

Tweed Marijuana in Smiths Falls sponsored a runway show at Mens Fashion Week in Toronto this spring featuring duds designed with tweed or inspired by cannabis. 9 / OTTWP

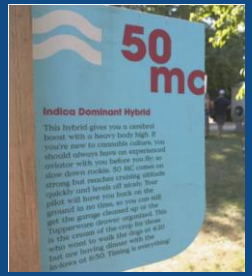
www.islandhealth.ca

TRAILER PARK BUDS

island health

newstrike

CANNABIS



THE TRAGICALLY HIP

We are happy to announce that we have become partners with one of Canada's newest, soon to be public, licensed producers of medicinal marijuana. The company is called Newstrike and, after much discussion and assessment on our part, we've decided that this company – and the many creative people in it – are a perfect fit for The Hip.

Up Cannabis Reveals Strains Named After Tragically Hip Songs

"Grace, Too" will get a nod with a strain simply called Grace, and "Fifty Mission Cap" will become ingestible as 50MC. "Morning Moon" and "Eldorado," meanwhile, directly lift song titles from *We Are the Same* and *Fully Completely*, respectively. The fifth is Gems, inspired by *Road Apples* closer "The Last of the Unplucked Gems."

CBC news

Business

Cannabis connoisseur Seth Rogen creates marijuana brand backed by Canopy Growth

Actor-comedian joins screenwriter Evan Goldberg in new venture

The Canadian Press · Posted: Mar 27, 2019 8:58 AM ET | Last Updated: March 27

Rogen, who has also portrayed pothead characters in films such as *Knocked Up* and *The 40-Year-Old-Virgin*, is not the first celebrity associated with cannabis to dabble in the pot industry:

- Tommy Chong, one half of the Cheech & Chong comedy duo, has a line of medicinal cannabis products called Chong's Choice, available in certain states where legal.
- In late 2017, director and actor Kevin Smith and actor Jason Mewes — better known as their stoner movie characters Jay and Silent Bob — entered into a brand licensing agreement with Hamilton, Ont.-based cannabis company Beleave Inc. to develop strains.
- In 2016, rapper Snoop Dogg struck a deal with Canopy to grant the licensed producer the exclusive right to use certain content and brands such as Leafs By Snoop.

"They are founders and owners, not spokespeople for the brand and have been very careful not to confuse that."

Any promotion that could be seen as appealing to young people is also forbidden.

Cannabis and Regulation

NATIONAL POST

The political fight over cannabis is over, but the legal battles have just begun

BRIAN PLATT AND MAURA FORREST

December 17, 2018
10:00 AM EST

It's unlikely that either party will make a big issue of legal weed in next year's federal election campaign. But that's not to say it's all smooth sailing ahead

Health Canada recently said it has already contacted seven regulated parties to "bring specific concerns to their attention" about cannabis promotion, but hasn't identified which companies may have broken the rules. Branch said the industry is hoping the department will soon provide more information about what kind of promotion is allowed. "People are wanting to comply, they're just having a little bit of trouble figuring out how," she said.

Sara Zborovski, a partner with Norton Rose Fulbright, said she expects to see "lots of challenges around the promotion" of marijuana as companies push the envelope on advertising and meet pushback from Health Canada.

LIFT & CO. CANNABIS BUSINESS CONFERENCE & EXPO

January 10 - 13, 2019 - Vancouver

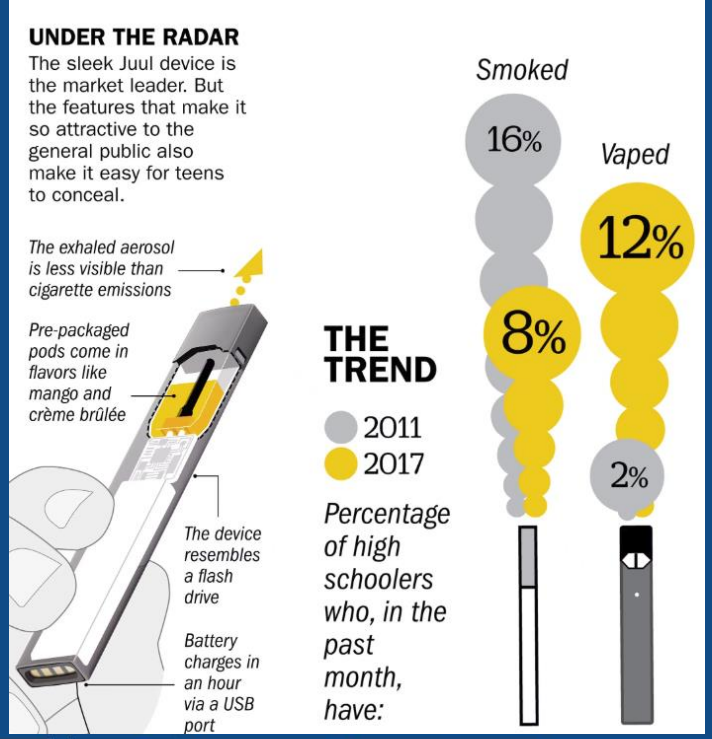
The expo, which highlights over 200 exhibitors from around the world, is considered to be one of the largest of its kind in Canada, playing host to thousands of curious consumers and investors.

As a result of the country's latest legislative shifts around cannabis, Health Canada placed stringent limits on advertising and branding weed products, making these education and brand activation opportunities increasingly important to the fledgling legal industry.

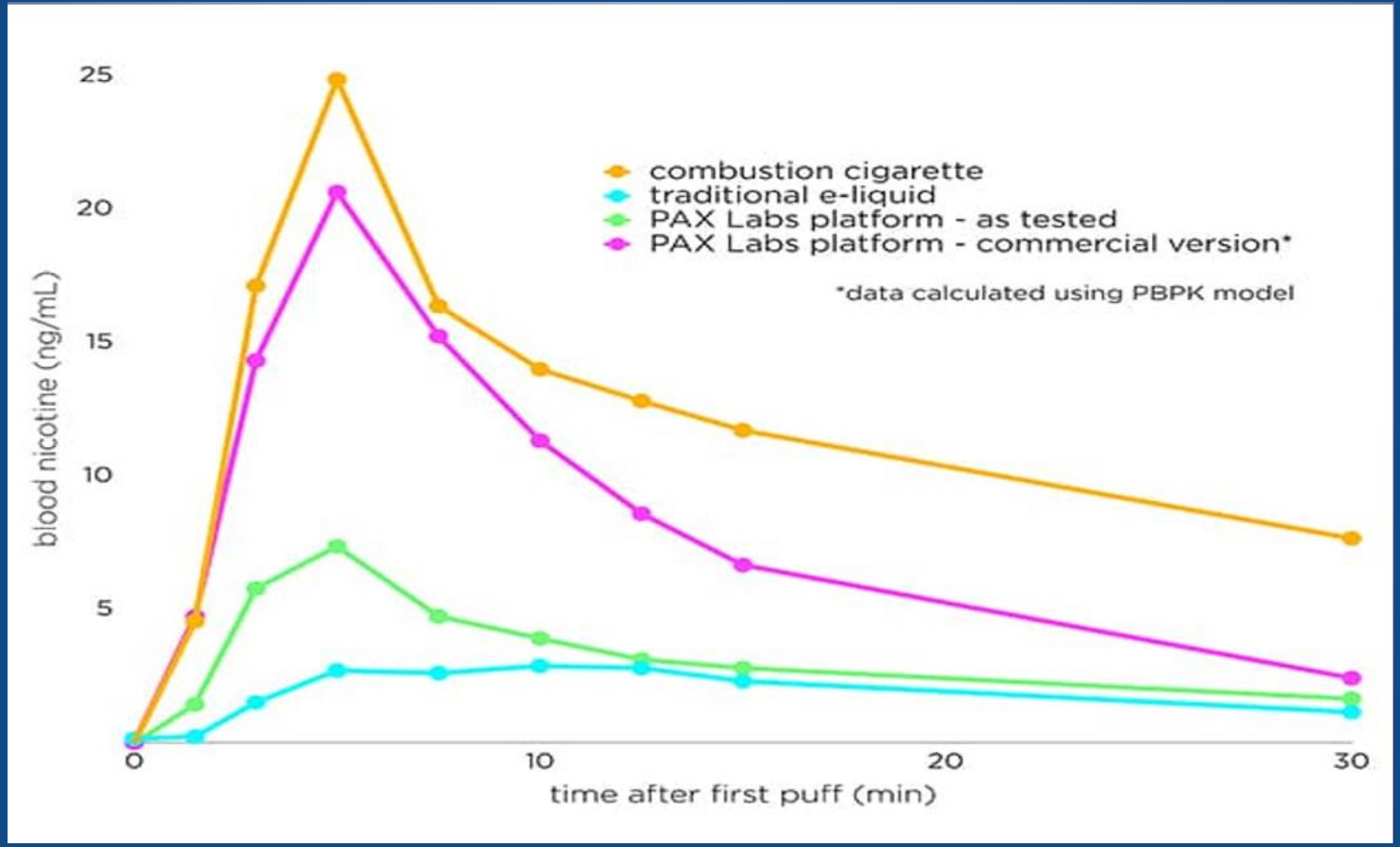
Consumption lounges and lifestyle brands

Under the new legislation, smoke lounges are illegal, sampling is not permitted in retail stores, and landlords can effectively kick tenants out for smoking weed in rental properties. Jeremy Jacob, co-founder of the local dispensary Village Bloomery and president of the Association of Canadian Cannabis Retailers (ACCRES), says the lack of consumption sites is one of the biggest barriers facing consumers today.

THIS IS NOT A FLASH DRIVE.



island health


25
20
15
10
5
blood nicotine (ng/mL)
combustion cigarette
traditional e-liquid
PAX Labs platform - as tested
PAX Labs platform - commercial version*
*data calculated using PBPK model
0
10
20
30
time after first puff (min)

HUFFPOST

NEWS 10/22/2018 15:24 EDT | Updated 10/22/2018 17:59 EDT

Customers Flag Bulky Legal Cannabis Packaging

"We don't want this to be a contributor to the degradation of our environment."

Alex Cooke
Canadian Press

Greg MacLean, who picked up some newly legal cannabis at the Nova Scotia Liquor Corporation last week, was shocked to see how much packaging was used for four grams of weed: two plastic containers, two cardboard boxes, and clear plastic casing, all enclosed in a brown paper bag.

"My initial reaction was a bit of shock that such little amount of plant matter came with so much packaging," he said.

As per Health Canada's guidelines, packaging must prevent contamination of the cannabis, be tamper-proof, and be child-resistant — a step up from the plastic baggies the product was often sold in before legalization.

"Do they really need to have that?" said MacLean, 37. "I mean, no liquor bottles that they sell at the NSLC has a childproof cap on it, and a bottle of vodka would kill a child."

Poison Control Call Records

environmental health services, BCCDC & national collaborating centre for environmental health

BCCDC Grand Rounds+ June 19, 2018

Infused/Enthused About Cannabis?

The alcohol industry may be the key to making drinkable cannabis taste good

Peter Nolan-Smith
Mar 14, 2019 3:31 pm

Molson Coors Brewing Co.

Back in January Molson's noted their concerns about falling beer sales. Earlier this week, Molson Coors Canada announced a joint venture with The Hydropothecary Corporation (TSX:HEXO), a recognized leader in Canadian medical cannabis to develop a line of non-alcoholic, cannabis-infused beverages. Molson Canada is the Canadian arm of beverage giant Molson Coors Brewing Company (NYSE:TAP)(TSX:TPX).

Heineken

Almost two weeks ago, on July 30, Heineken (NASDAQOTH:HEINY) launched Hi-Fi Hops, a cannabis-only beverage in a handful of dispensaries in California under its Lagunitas brand. The beverage is designed to taste like beer but does not contain alcohol.

Currently, the beverage comes in a ten-milligram version with tetrahydrocannabinol (THC), and a hybrid version with five milligrams of THC and five milligrams of CBD. Although the drink costs $8 per can, according to reports sales continue to rise.


Baird Auditorium
Atrium Cafe
Museum Shop

Coming this October

Edibles

Implications

Legalizing a new product for Canadians to consume means that Canada will likely have to make amendments to several other pieces of legislation, including the Food and Drugs Act, the Controlled Drugs and Substances Act, and the Cannabis Act itself. However, lifting the ban on edibles in 2019 doesn't just mean having more marijuana-filled pastries. The law's passage opens up a vast new market filled with everything from cannabis creams and gels to transdermal patches and ingestible capsules.

CBC

Ottawa

Cannabis edibles, drinks will mark '2nd wave' of legalization

Producers developing new products ahead of next October

Leah Hansen · CBC News · Posted: Nov 12, 2018 6:00 AM ET | Last Updated: November 12, 2018

Brand-building starts

Some Canadian companies have been looking to states such as Colorado, where recreational cannabis sales became legal in 2014, to see how producers there are keeping up with demand for edibles.

"It's about getting commercial grade kitchens up and running, because that is not easy," Rosenthal said.

"Creating the next wave of products and facilities to actually churn those out is going to be a challenge."

"We're focusing on everything from different types of edibles to ready-to-serve drinks and vape pens, all the types of products that one might find if they wander into an unlicensed dispensary today."

Absence of evidence of harm is not evidence of absence of harm.

Government of Canada | Gouvernement du Canada

Canadian Institutes of Health Research

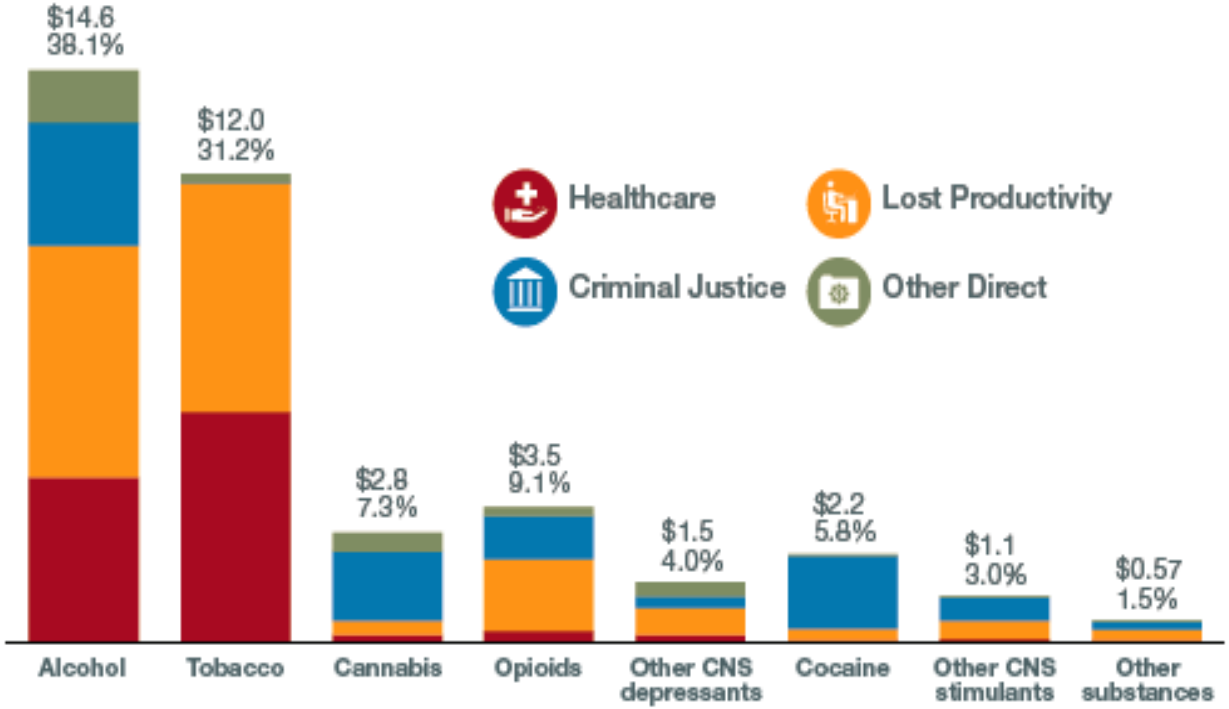
CIHR's cannabis initiative: Meeting the urgent need for more knowledge

Collaboration is essential for comprehensive impact

Rapid-response approaches to build research capacity

Scalable opportunities and new partnerships on the horizon

Costs of Substance Use in Canada



http://csuch-cemusc.ccsa.ca/Resource%20Library/CSUCH-Canadian-Substance-Use-Costs-Harms-Report-2018-en.pdf

Learn About Health
Cannabis

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CANNABIS

Cannabis

FAQs Non-medical Cannabis Edibles

Back to Learn About Health

Cannabis

THANK YOU

Cannabis Substitution Programs: Evidence and Possibilities

Karen Urbanoski, PhD
Canadian Institute on Substance Use Research
School of Public Health and Social Policy
University of Victoria

University of Victoria | Canadian Institute for Substance Use Research | Institut canadien de recherche sur l'usage de substances

"…a conscious choice made by users to use one drug instead of, or in conjunction with another based on: perceived safety, level of addiction potential, effectiveness in relieving symptoms, access and level of acceptance."

Lau N, et al. A safer alternative: Cannabis substitution as harm reduction. Drug Alcohol Rev 2015;34:654–9

Cannabis Substitution

Use of cannabis as a substitute for alcohol, opioids, or other substances, as part of a self-directed management strategy, with a prescription, or through participation in a cannabis substitution program

Criteria for (alcohol) substitution therapy

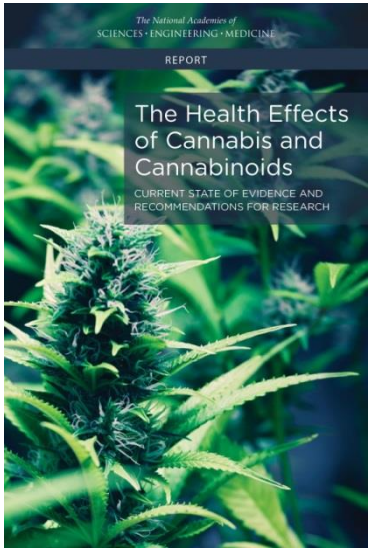
1. It should reduce alcohol use and related harms.
2. It should ideally be free of harms, or at least less harmful than alcohol.
3. Misuse should be less than that of alcohol.
4. It should be shown that it can substitute for alcohol and not be used along with alcohol.
5. It should be safer in overdose than alcohol.
6. It should ideally not potentiate the effects of alcohol especially if either drug is taken in overdose.
7. It should offer significant health economic benefits.

Chick J, Nutt DJ. Substitution therapy for alcoholism: time for a reappraisal? J Psychopharmacol 2012;26:205–12.

Evidence

“There is no evidence to support or refute the conclusion that cannabinoids are an effective treatment for achieving abstinence in the use of addictive substances.”

“There is substantial evidence that cannabis is an effective treatment for chronic pain in adults.”



http://www.nationalacademies.org/hmd/Reports/2017/health-effects-of-cannabis-and-cannabinoids.aspx

Evidence

- Anecdotal reports from the community
- Clinical case studies
- Support from observational and ethnographic studies of people who use alcohol and other drugs

Opportunities

- Controlled trials in formal service settings
- Evaluation of grassroots programs
- Observational studies of personal use as a management strategy

University of Victoria | Canadian Institute for Substance Use Research | Institut canadien de recherche sur l'usage de substances

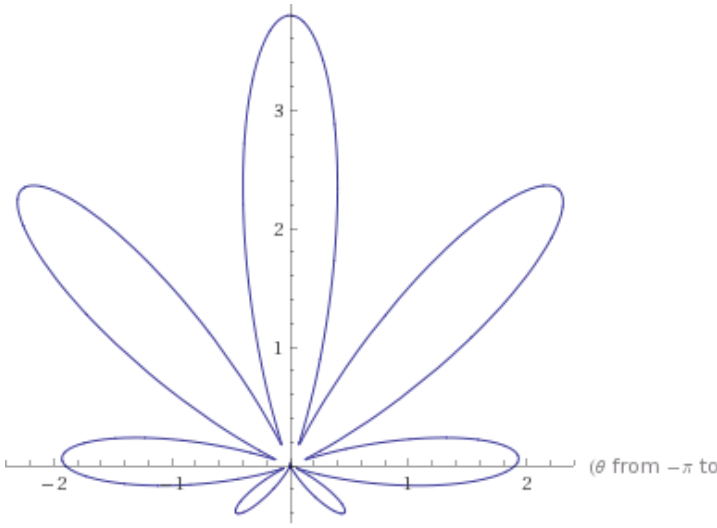
Thank you!

website: cisur.ca email: cisur@uvic.ca Blog: oac.uvic.ca/carbc

UVic.CISUR Uvic_CISUR CARBCUvic

BC Cannabis Research Network

Overview of Current and Planned Research in BC



Island Health Five Days in May

Dr. Brian Emerson, A/Deputy Provincial Health Officer

Ministry of Health

May 30, 2019

BRITISH COLUMBIA

Disclosure

- I have no financial relationships with cannabis or pharmaceutical commercial interests.
- Employee Vancouver Island Health Authority/BC Ministry of Health
- No actual or potential conflicts of interest

Best Brains Exchange

- June 15, 2018 in Victoria, BC at the Ministry of Health
- Collaborators:
  - Canadian Institutes of Health Research
  - Michael Smith Foundation for Health Research
  - BC Centre on Substance Use

Partnerships and Innovation Division

Hlthresearch@gov.bc.ca

- Promote and support a high performing balance of research investment and engagement
- Lead activities related to building and maintaining the Ministry's research infrastructure and culture;
- Manage corporate research and knowledge management
- Primary liaison with the research community, research funders and other parts of government on issues related to research.
- Support the Ministry's research governance structure, a health research agenda and a Research, Evaluation and Knowledge Management Fund

BRITISH COLUMBIA

BC Cannabis Research Network

- The Network is an outcome of the Best Brains Exchange
- Supported by Partnerships and Innovation Division
- Focused on BC, but includes members outside of BC

BRITISH COLUMBIA

Objectives

- Support researchers in connecting, awareness of others' research
- Facilitate research informing practice and policy
- Share information about current and planned research

Meetings to date

- December 2018
  - Canadian Institutes of Health Research - Integrated Cannabis Research Strategy
  - Canadian Centre on Substance Use and Addiction (CCSA) - National Cannabis Research Database
- March 2019
  - Research plan of Dr. Milloy, Professor of Cannabis Science, UBC
  - Update on National Cannabis Research Database

BRITISH COLUMBIA

Participants

- Researchers
- Policy makers
- Research administrators
- Health authorities
- Federal government
- Private sector

Cannabis Research in BC

- Road Safety
- Gender
- Economics
- Youth and young adults
- Pregnancy
- Relation to other substances (opioids and alcohol)
- Neurology
- Mental Health

Institutions

- Many different institutions have received funding in the last few years in BC:
  - University of British Columbia
  - University of Northern BC
  - University of Victoria
  - Centre of Excellence for Women's Health
  - Simon Fraser University
  - University of British Columbia Okanagan

Priorities for Research

- Best Brains Exchange identified three priorities related to the therapeutic use of cannabis:
  - data on cost-effectiveness, including comparisons to other drugs and impact on quality of life;
  - clinical trials looking at prime areas of current use, including pain control, nausea, spasticity and sleep assistance;
  - attention to the current barriers, including the difficulties in the regulation of medical cannabis.

BRITISH COLUMBIA

Policy Research Interests

- Evaluating legalization of non-medical cannabis, both harms and benefits - key role for research as surveillance data does not answer all questions
- Substitution of cannabis for alcohol, prescription and illegal drugs
- Therapeutic potential of cannabis
- What do others think?

BRITISH COLUMBIA

Questions?

Brian Emerson

250-952-1701

brian.emerson@gov.bc.ca

BRITISH COLUMBIA

Canadian Centre
on Substance Use and Addiction

Evidence. Engagement. Impact.

Centre canadien sur
les dépendances et l'usage de substances

Données. Engagement. Résultats.

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National Research, Policy and Knowledge Mobilization

5 Days in May

Rebecca Jesseman

May 30, 2019

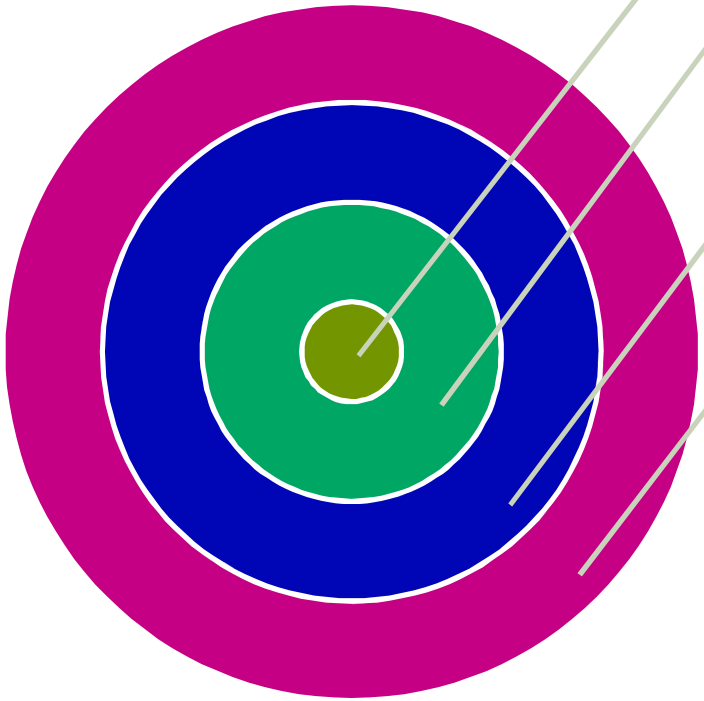
About CCSA

- **Vision:** A healthier Canadian society where evidence transforms approaches to substance use.
- **Mission:** To address issues of substance use in Canada by providing national leadership and harnessing the power of evidence to generate coordinated action.
- **Value Proposition:** Provide national leadership to address substance use in Canada. A trusted counsel, we provide guidance to decision makers by harnessing the power of research, curating knowledge and bringing together diverse perspectives.
- National non-profit organization with a pan-Canadian and international role.

Strategic Core Functions

Cannabis Policy Research

Policy Research Objectives



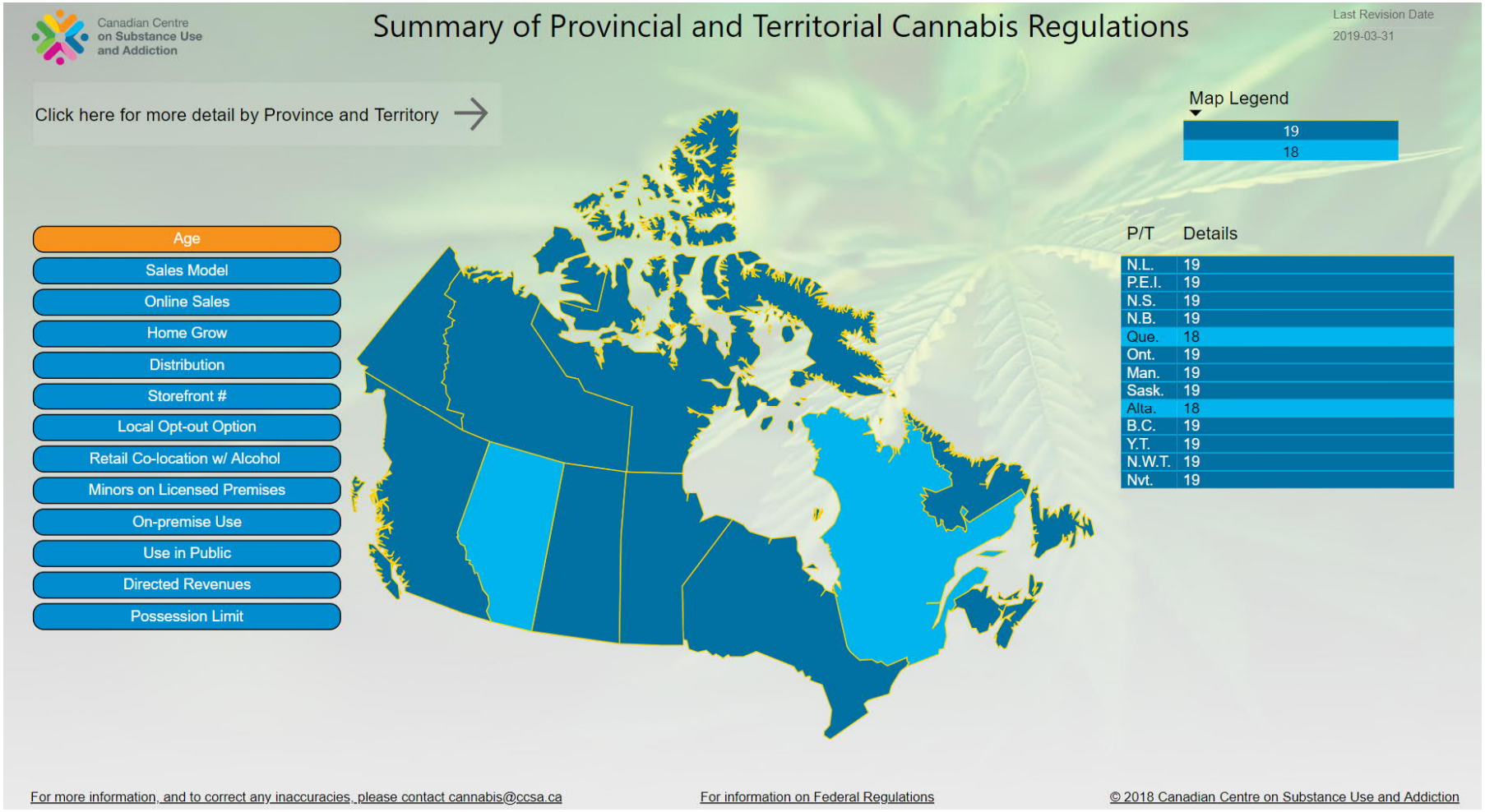
Best Practices

P/T Course Corrections

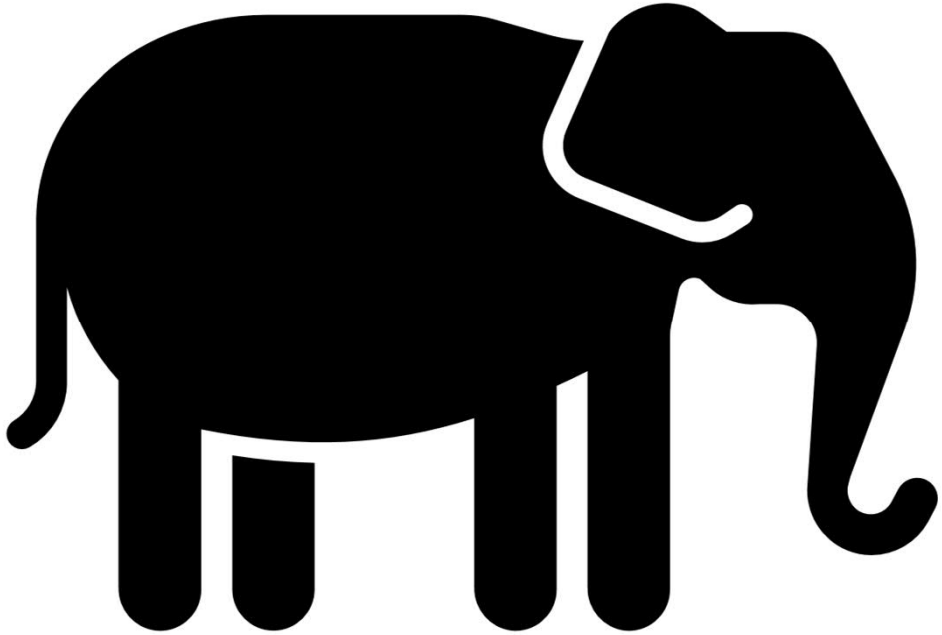
3-Year Health Canada Review

International Models

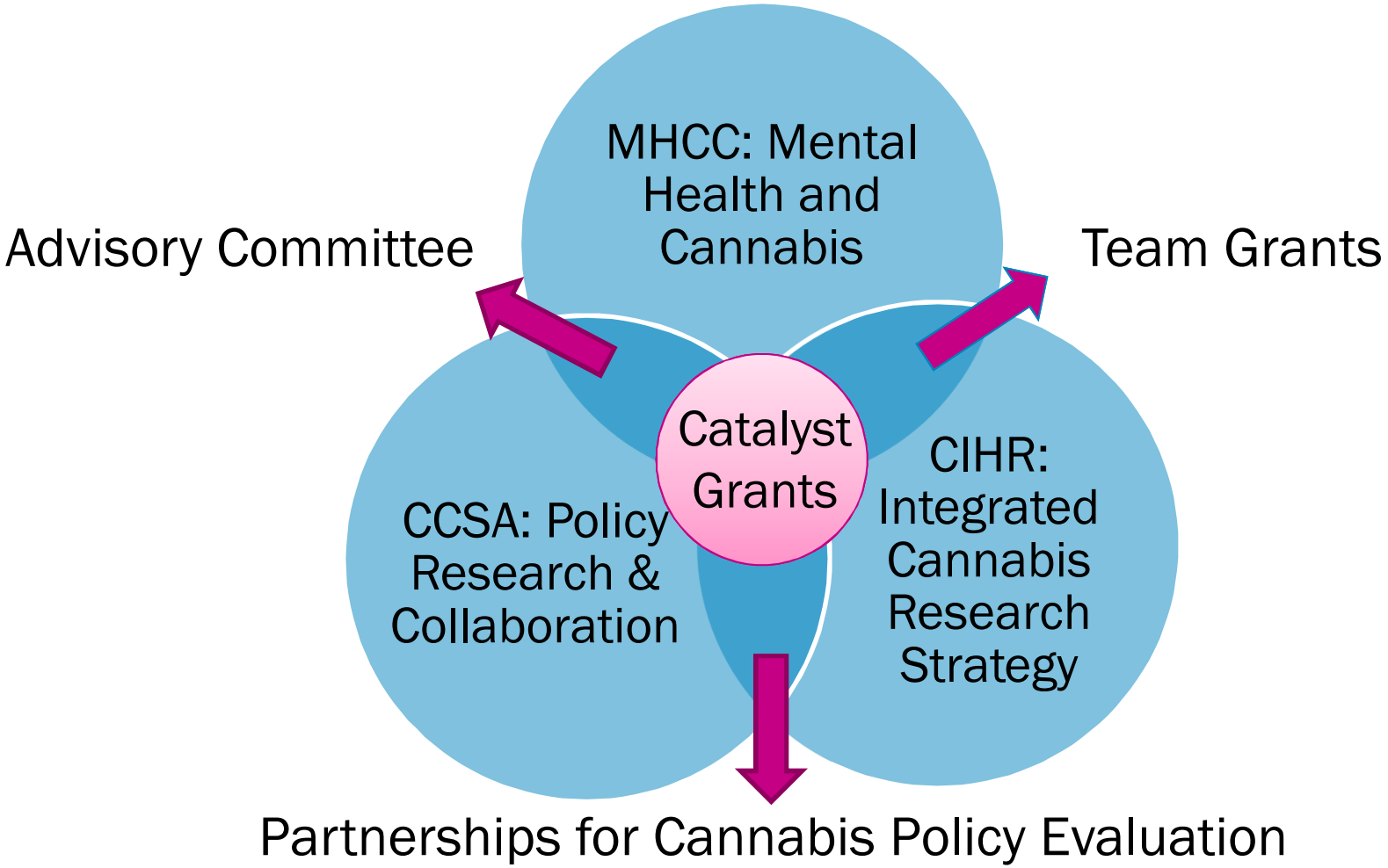
Opportunity: Natural Experiment



Funding

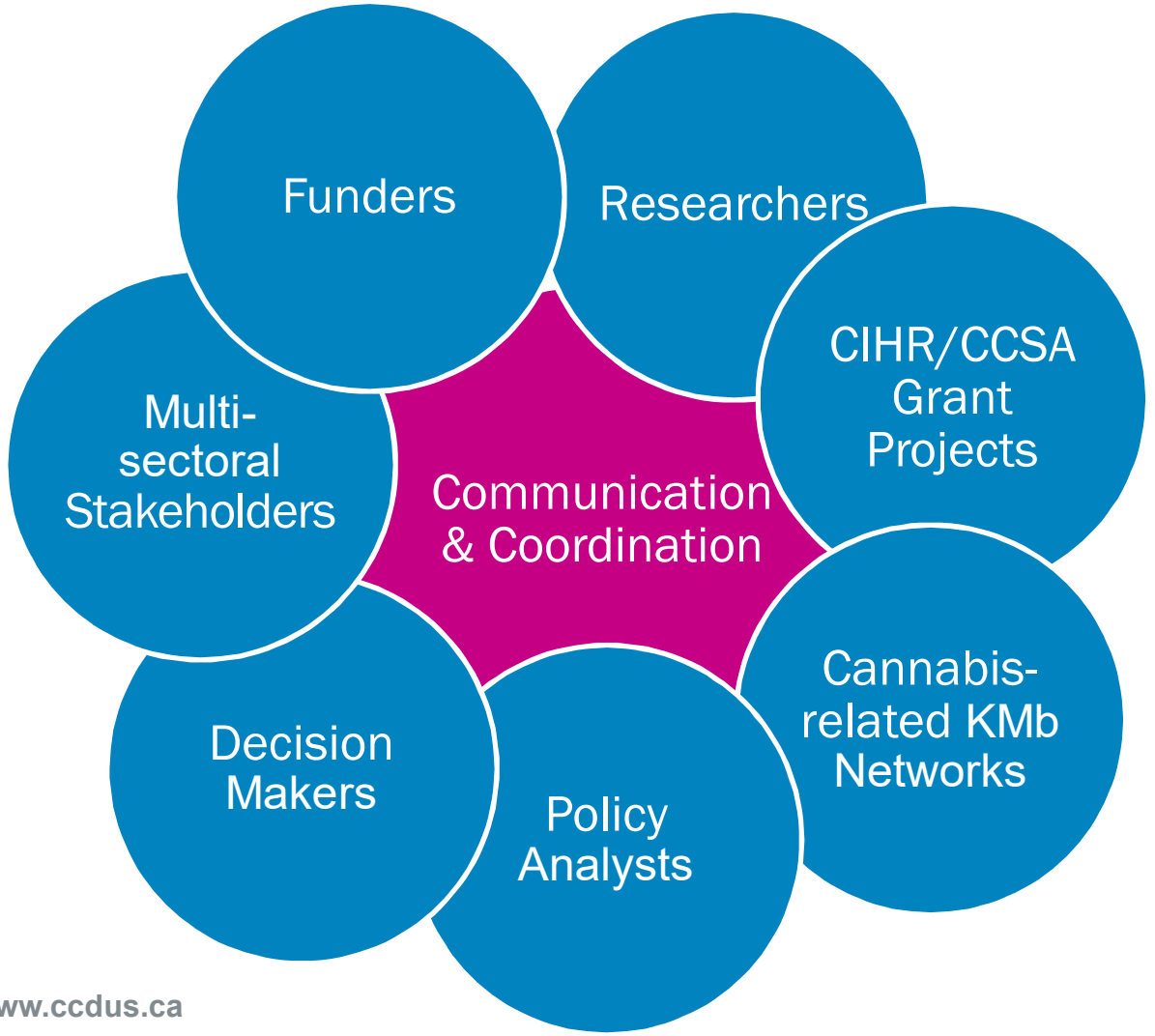


National Collaborations

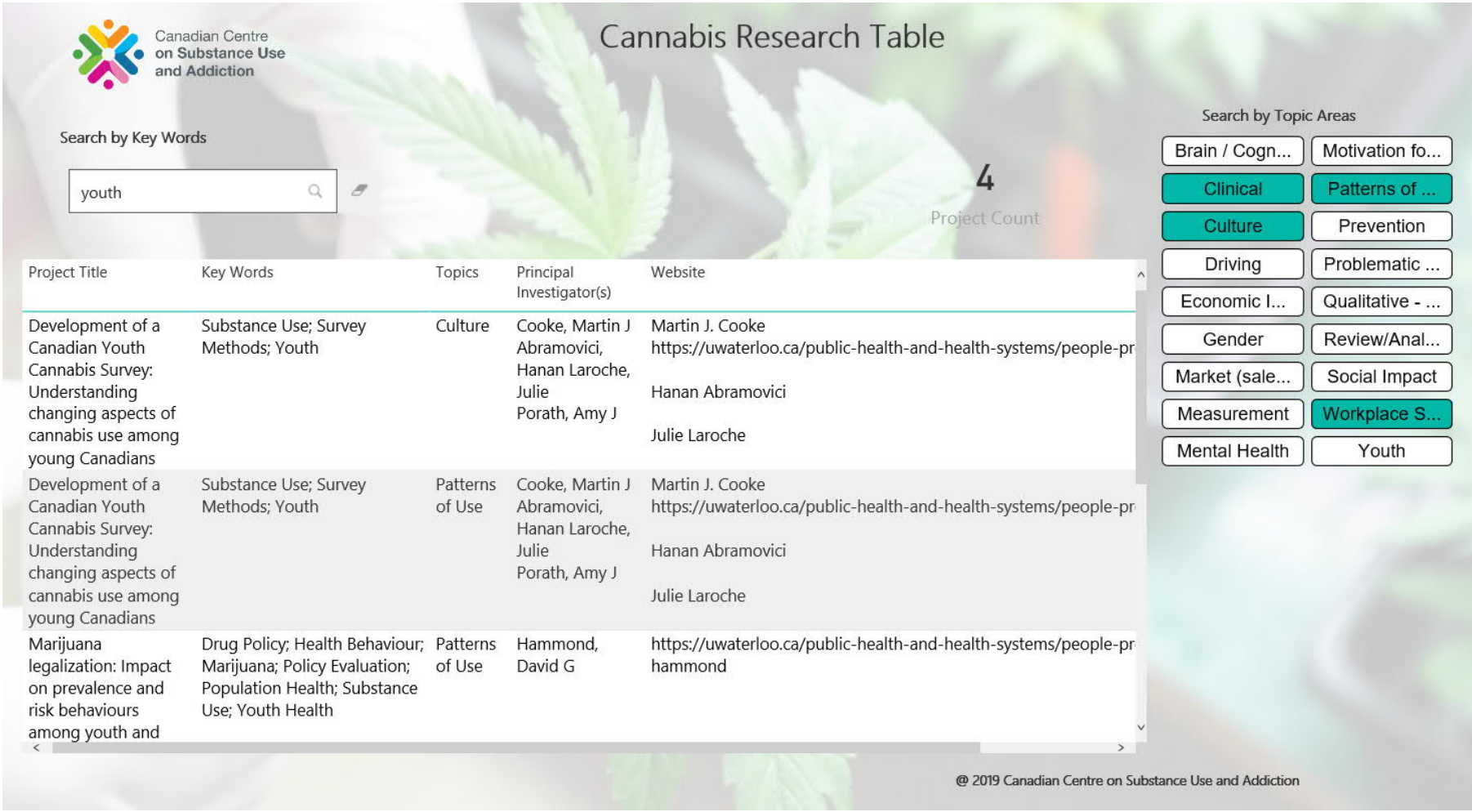


Supporting Collaboration

Cannabis Policy Research "Hub"



Cannabis Research Database



Identifying Research Priorities

- Stakeholder consultations
  - National Research Agenda Meeting, October 2016
  - Policy Research Meeting, December 2018
  - Public Safety Cannabis Symposium, 2019

And ongoing!

Research Opportunities

- Health and social impacts of regulatory approaches
- Consumption patterns, health and social impacts of new products (e.g., edibles, concentrates)
- Impact of regulation on the illegal market
- Equity of impact across populations and domains (i.e., health, social, criminal justice)
- Effective incentives for lower-risk use
- Applicability of evidence from alcohol and tobacco regulation
- Poly-substance use and substitution (risks & benefits)

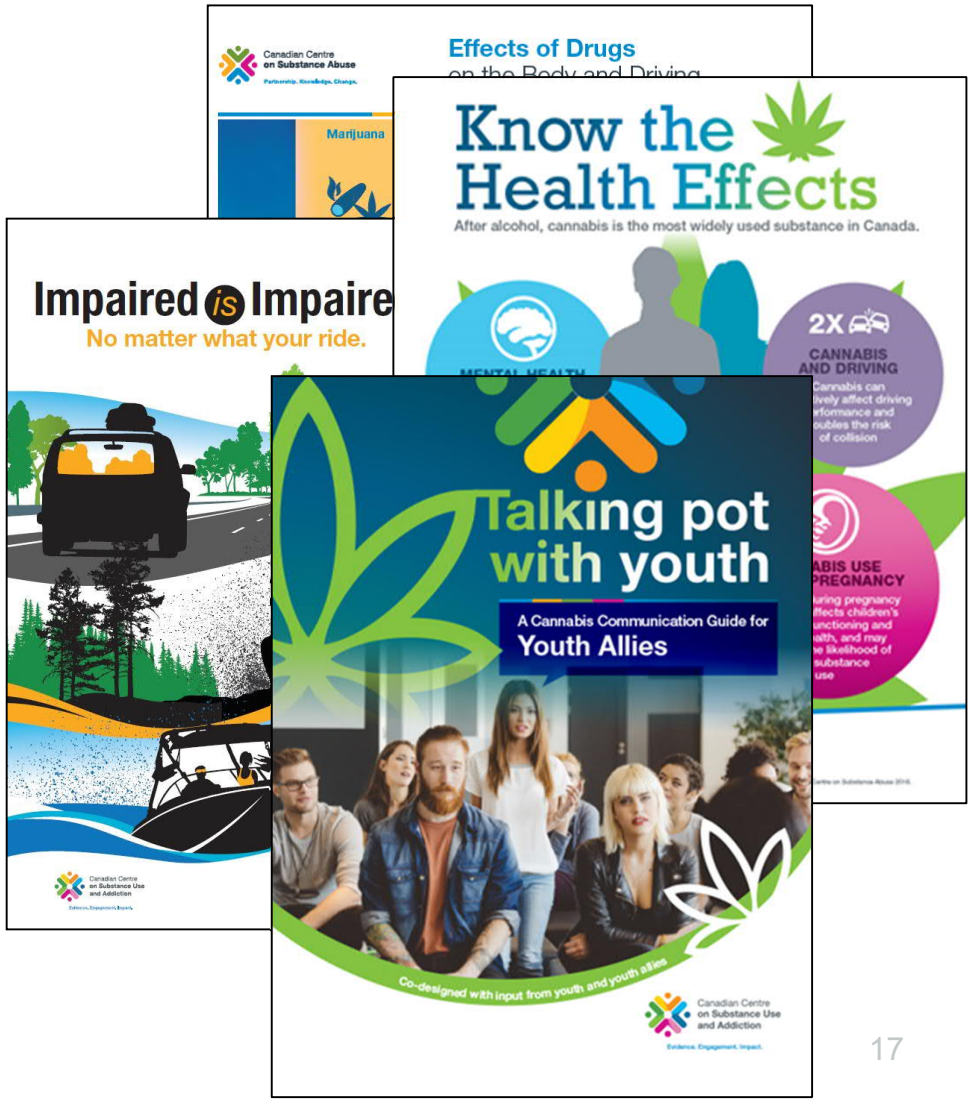
Challenges

- Agreeing on a standard dose
- Provincial and municipal capacity for monitoring and evaluation
- Measuring illegal market impact
- Role of industry
- Processing time for research licenses
- Disaggregation of data
- Coordination of effort — many cooks in the kitchen!

Knowledge Mobilization

Mobilizing Knowledge: Resources

- Cannabis Communication Guide
- Drug-impaired Driving Toolkit and website (coming soon!)
- Infographics



CCSA's Issues of Substance 2019

Evidence and Perspectives, Compassion and Action.

- CCSA's Issues of Substance is Canada's premier conference for the substance use and addiction field
- Registration now open
- #CCSAConference

Questions and Comments

Contact Information

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Medical Cannabis Research:
a patient-centred approach to study design

PIPPA HAWLEY FRCPC (PALL MED)
DIRECTOR OF PSMPC, BC CANCER
CLINICAL PROFESSOR, UBC DEPT. OF MEDICINE

BC CANCER FOUNDATION

Cannabis Overview

- Inhalation not encouraged: oils best
- It is a legitimate thing- don't stigmatize
- It's complicated- a medical authorization is not a prescription
- Doctors usually don't know what to write
- Patients usually don't know what to take
- No face-to-face interaction between legal knowledge-holders and potential consumers

Question 1

Would you participate in a study where there was a 50% chance of never receiving the active product?

1) Yes
2) No

Question 2

Would you participate in a clinical trial where the active product was already widely available?

1) Yes
2) No

Medical Cannabis Research

- 2018/19 survey shows 1 in 4 BC Cancer patients already take cannabis for medical purposes
- Mostly without any medical guidance or oversight
- Benefits and harms are only anecdotally reported
- Lack of partnership with patients about cannabis use has led to conflict between patents and their doctors
- There is an urgent need for good clinical trial evidence to guide health care providers, patients and families

CAFCARS

- Aggregate N-of-1 design
- Each participant gets to try all the study products, in random order, blinded by flavour of coconut and olive oil vehicle
  - All-THC oil
  - All-CBD oil
  - Balanced 1:1 THC:CBD
  - Placebo
- 3 cycles of 4 days of each oil, up to 3 drops every 4 hours, first 2 days considered “washout”, outcomes analyzed only for last 2 days of each period
- Maximum dose of THC in 24hrs would be 15mg

Participants

- 120 STABLE cancer patients with one of four “Most Troublesome” symptoms
  - Pain
  - Nausea
  - Anxiety
  - Sleep disturbance
- Expect to need 150 recruited to allow for “drop-outs”
- Symptoms chosen based on most common symptoms treated by survey respondents that used medical cannabis already
- Not currently taking medical or recreational cannabis
- Not expecting any new treatment that could confound results over the 48 days of the study

Study Goals

- To identify which oil (if any) is most helpful overall and for each symptom
  - For immediate guidance in clinical use
  - To guide future clinical trials
- To establish most promising dosing schedules
- To identify side-effects and any participant characteristics that are associated with increased risk of toxicity
- Establish network of sites for future collaborative research (BCC-VA, -CN, -VI, -AB, Calgary, Winnipeg, Ottawa, Toronto, Kingston)

Outcome Measures

- Patient Global Impression of Change
- Modified Edmonton Symptom Assessment System (ESAS) for symptom severity
- ESAS modified for inclusion of sleep and night sweats
- Medication Log to see if other meds impacted
- Adverse events
- Participant preference at end of study

Other Patient-Centred Features

- Only one visit required at baseline
- No blood tests
- Patient-reported outcomes: individual AND group benefit
- One pharmacy will send out all products by mail
- Participants will be telephoned frequently
- Participants unblinded after participation
- Study products widely available

Thanks to donors,
and to CCTG and PCPCRC for advice

Questions?

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The Force that Through the Green Fuse Drives the Flower: International Medical Cannabis Research

Philippe Lucas PhD(c)
Graduate Researcher, Canadian Institute for Substance Use Research (CISUR)
VP, Global Patient Research & Access, Tilray

Medical & Recreational Cannabis in Canada

Current Landscape

>350,000 Canadians currently authorized, and 18,000 prescribing HCPs.

- 10% month-to-month increase in patients; 12% month-to-month increase in MDs.

Legalization of adult use: **October 17th, 2018.**

On the Near Horizon...

Regulation of non-smoked forms of ingestion

- (ie. edibles & vape pens): **By October 17th, 2019.**

Pharmacy-based access: **2020?**

TILRAY

Cannabis Research, Health Canada Clinical Trial Database

Clinical trials query results.

Drug name	CTA protocol title	Medical condition	Study population	Trial status
CANNABIS	A RANDOMIZED DOUBLE BLIND PLACEBO CONTROLLED, PROOF-OF-CONCEPT, CROSSOVER CLINICAL TRIAL (RCT) OF VAPOURIZED CANNABIS IN ADULTS WITH PAINFUL OSTEOARTHRITIS OF THE KNEE	OSTEOARTHRITIS	ADULT FEMALE, ADULT MALE	ONGOING
CANNABIS	EFFECT OF INHALED VAPORIZED CANNABIS ON PULMONARY FUNCTION, BREATHLESSNESS AND EXERCISE TOLERANCE IN SYMPTOMATIC PATIENTS WITH ADVANCED CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD)	CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD)	ADULT FEMALE, ADULT MALE	ONGOING
CANNABIS	PLACEBO-CONTROLLED, TRIPLE-BLIND, CROSSOVER STUDY OF THE SAFETY AND EFFICACY OF THREE DIFFERENT POTENCIES OF VAPORIZED CANNABIS IN 42 PARTICIPANTS WITH CHRONIC, TREATMENT-RESISTANT POSTTRAUMATIC STRESS DISORDER (PTSD).	POST-TRAUMATIC STRESS DISORDER	ADULT FEMALE, ADULT MALE	ONGOING
CANNABIS (DELTA-9-TETRAHYDROCANNABINOL-CANNABIDIOL)	CANNABINOIDS IN PEOPLE LIVING WITH HIV ON EFFECTIVE ANTIRETROVIRAL THERAPY: A PILOT STUDY TO ASSESS SAFETY, TOLERABILITY AND EFFECT ON IMMUNE ACTIVATION	HUMAN IMMUNODEFICIENCY VIRUS (HIV)	ADULT FEMALE, ADULT MALE	PENDING

4 studies

- Osteoarthritis, COPD, PTSD, HIV

THC Research, Health Canada Clinical Trial Database

Clinical trials query results.

Drug name	CTA protocol title	Medical condition	Study population	Trial status
CANNABIDIOL-DELTA-9-TETRAHYDROCANNABINOL	A DOUBLE-BLIND, PLACEBO-CONTROLLED, PARALLEL-GROUP STUDY OF CANNABIDIOL PLUS TETRAHYDROCANNABINOL (CBD+THC) GIVEN AS ADJUNCTIVE THERAPY IN PATIENTS WITH REFRACTORY SEIZURES	EPILEPSY	ADULT FEMALE, ADULT MALE	ONGOING
CANNABIS (DELTA-9-TETRAHYDROCANNABINOL-CANNABIDIOL)	CANNABINOIDS IN PEOPLE LIVING WITH HIV ON EFFECTIVE ANTIRETROVIRAL THERAPY: A PILOT STUDY TO ASSESS SAFETY, TOLERABILITY AND EFFECT ON IMMUNE ACTIVATION	HUMAN IMMUNODEFICIENCY VIRUS (HIV)	ADULT FEMALE, ADULT MALE	PENDING
CANNIMED OIL (CANNABIDIOL- DELTA-9-TETRAHYDROCANNABINOL)	A PHASE II, RANDOMIZED, OPEN-LABEL, DOUBLE-BLIND, TWO-CENTRE STUDY TO EVALUATE THE TOLERABILITY, SAFETY AND DOSE FINDING OF OIL CANNABIS PREPARATION FOR PAIN IN PARKINSON¿S DISEASE	PARKINSON'S DISEASE	ADULT FEMALE, ADULT MALE	PENDING
CHI-921 (DELTA-9-TETRAHYDROCANNABINOL-CANNABIDIOL)	A DOUBLE-BLIND, RANDOMIZED, PLACEBO-CONTROLLED, MULTI-CENTER, DOSE-TITRATION STUDY ON THE EFFICACY AND SAFETY OF CHI-921 ON SLEEP INITIATION AND MAINTENANCE IN SUBJECTS WITH INSOMNIA	INSOMNIA	ADULT FEMALE, ADULT MALE	PENDING
DELTA-9-TETRAHYDROCANNABINOL-CANNABIDIOL	A DOUBLE-BLIND, RANDOMIZED, PLACEBO-CONTROLLED CROSSOVER PILOT TRIAL OF MEDICAL CANNABIS IN ADULTS WITH TOURETTE SYNDROME.	TOURETTE□S SYNDROME	ADULT FEMALE, ADULT MALE	ONGOING
DELTA-9-TETRAHYDROCANNABINOL-CANNABIDIOL	CANNABIDIOL IN CHILDREN WITH REFRACTORY EPILEPTIC ENCEPHALOPATHY: A PHASE 1 OPEN LABEL DOSE ESCALATION STUDY	DRAVET SYNDROME, REFRACTORY EPILEPTIC ENCEPHALOPATHY	PEDIATRIC	ONGOING
PPP001 (DELTA-9-TETRAHYDROCANNABINOL-CANNABIDIOL)	INHALED PPP001 VERSUS FENTANYL BUCCAL TABLETS FOR THE MANAGEMENT OF BREAKTHROUGH PAIN IN CANCER PATIENTS: AN OPEN-LABEL, CROSSOVER, COMPARISON STUDY FOLLOWED BY A RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED TRIAL	CANCER PAIN	ADULT FEMALE, ADULT MALE	PENDING
PPP001 (DELTA-9-TETRAHYDROCANNABINOL-CANNABIDIOL)	SAFETY AND EFFICACY OF PPP001-KIT FOR IMPROVING HEALTH RELATED QUALITY OF LIFE IN ADVANCED CANCER PATIENTS WITH UNCONTROLLED PAIN: A RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED, PARALLEL GROUP STUDY.	ADVANCED CANCERS, PAIN	ADULT FEMALE, ADULT MALE	ONGOING
PPP005 (DELTA-9-TETRAHYDROCANNABINOL-CANNABIDIOL)	CANNABIS OIL AND RADIATION THERAPY FOR THE MANAGEMENT OF PAIN: ASSESSMENT OF SAFETY AND EFFICACY IN A RANDOMIZED, DOUBLE-BLIND PLACEBO-CONTROLLED PHASE II CLINICAL TRIAL	CANCER PAIN	ADULT FEMALE, ADULT MALE	PENDING
PPP005 (DELTA-9-TETRAHYDROCANNABINOL-CANNABIDIOL)	SAFETY AND EFFICACY OF MEDICAL CANNABIS OIL IN THE TREATMENT OF PATIENTS WITH CHRONIC PAIN: A RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED PILOT STUDY, FOLLOWED BY AN OPEN-LABEL EXTENSION PHASE	PAIN	ADULT FEMALE, ADULT MALE	CLOSED

10 studies (1 listed in “cannabis” search)

- 4 pain (3 cancer pain)
- 2 seizure disorder
- 1 HIV
- 1 Parkinson’s Disease
- 1 Tourette’s

CBD Research, Health Canada Clinical Trial Database

Clinical trials query results.

Drug name	CTA protocol title	Medical condition	Study population	Trial status
CANNABIDIOL	A PHASE 3 RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED, PARALLEL-GROUP STUDY TO ASSESS THE EFFICACY, SAFETY, AND TOLERABILITY OF CANNABIDIOL ORAL SOLUTION AS ADJUNCTIVE THERAPY WITH VIGABATRIN AS INITIAL THERAPY IN PATIENTS WITH INFANTILE SPASMS	INFANTILE SPASM	PEDIATRIC	PENDING
CANNABIDIOL	CANNABIDIOL AND COCAINE DEPENDENCE	DRUG ADDICTION	ADULT FEMALE, ADULT MALE	ONGOING
CANNABIDIOL	CANNABIDIOL AS A NEW INTERVENTION FOR AMPHETAMINE DEPENDENCE: A PROOF-OF-CONCEPT STUDY	ADDICTION	ADULT FEMALE, ADULT MALE	PENDING
CANNABIDIOL-DELTA-9-TETRAHYDROCANNABINOL	A DOUBLE-BLIND, PLACEBO-CONTROLLED, PARALLEL-GROUP STUDY OF CANNABIDIOL PLUS TETRAHYDROCANNABINOL (CBD+THC) GIVEN AS ADJUNCTIVE THERAPY IN PATIENTS WITH REFRACTORY SEIZURES	EPILEPSY	ADULT FEMALE, ADULT MALE	ONGOING
CANNABIDIOL/ ALPRAZOLAM/ DRONABINOL	A SINGLE-DOSE, RANDOMIZED, DOUBLE-BLIND, PLACEBO- AND ACTIVE-CONTROLLED CROSSOVER STUDY TO ASSESS THE ABUSE POTENTIAL OF CANNABIDIOL (CBD; GWP42003-P) IN RECREATIONAL POLYDRUG USERS	ABUSE POTENTIAL	ADULT FEMALE, ADULT MALE	CLOSED
CANNABIS (DELTA-9-TETRAHYDROCANNABINOL-CANNABIDIOL)	CANNABINOIDS IN PEOPLE LIVING WITH HIV ON EFFECTIVE ANTIRETROVIRAL THERAPY: A PILOT STUDY TO ASSESS SAFETY, TOLERABILITY AND EFFECT ON IMMUNE ACTIVATION	HUMAN IMMUNODEFICIENCY VIRUS (HIV)	ADULT FEMALE, ADULT MALE	PENDING
CANNIMED OIL (CANNABIDIOL - DELTA 9-TETRAHYDROCANNABINOL)	A PHASE II, RANDOMIZED, OPEN-LABEL, DOUBLE-BLIND, TWO-CENTRE STUDY TO EVALUATE THE TOLERABILITY, SAFETY AND DOSE FINDING OF OIL CANNABIS PREPARATION FOR PAIN IN PARKINSON¿S DISEASE	PARKINSON'S DISEASE	ADULT FEMALE, ADULT MALE	PENDING
CHI-921 (DELTA-9-TETRAHYDROCANNABINOL-CANNABIDIOL)	A DOUBLE-BLIND, RANDOMIZED, PLACEBO-CONTROLLED, MULTI-CENTER, DOSE-TITRATION STUDY ON THE EFFICACY AND SAFETY OF CHI-921 ON SLEEP INITIATION AND MAINTENANCE IN SUBJECTS WITH INSOMNIA	INSOMNIA	ADULT FEMALE, ADULT MALE	PENDING
DELTA-9-TETRAHYDROCANNABINOL-CANNABIDIOL	A DOUBLE-BLIND, RANDOMIZED, PLACEBO-CONTROLLED CROSSOVER PILOT TRIAL OF MEDICAL CANNABIS IN ADULTS WITH TOURETTE SYNDROME.	TOURETTE'S SYNDROME	ADULT FEMALE, ADULT MALE	ONGOING
DELTA-9-TETRAHYDROCANNABINOL-CANNABIDIOL	CANNABIDIOL IN CHILDREN WITH REFRACTORY EPILEPTIC ENCEPHALOPATHY: A PHASE 1 OPEN LABEL DOSE ESCALATION STUDY	DRAVET SYNDROME, REFRACTORY EPILEPTIC ENCEPHALOPATHY	PEDIATRIC	ONGOING
MRCP001(CANNABIDIOL-TETRAHYDROCANNABINNOL)	CANNABIS OIL FOR PAIN EFFECTIVENESS (COPE)	CANCER PAIN, PAIN	ADULT FEMALE, ADULT MALE	PENDING
PPP001 (DELTA-9-TETRAHYDROCANNABINOL-CANNABIDIOL)	INHALED PPP001 VERSUS FENTANYL BUCCAL TABLETS FOR THE MANAGEMENT OF BREAKTHROUGH PAIN IN CANCER PATIENTS: AN OPEN-LABEL, CROSSOVER, COMPARISON STUDY FOLLOWED BY A RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED TRIAL	CANCER PAIN	ADULT FEMALE, ADULT MALE	PENDING
PPP001 (DELTA-9-TETRAHYDROCANNABINOL-CANNABIDIOL)	SAFETY AND EFFICACY OF PPP001-KIT FOR IMPROVING HEALTH RELATED QUALITY OF LIFE IN ADVANCED CANCER PATIENTS WITH UNCONTROLLED PAIN: A RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED, PARALLEL GROUP STUDY.	ADVANCED CANCERS, PAIN	ADULT FEMALE, ADULT MALE	ONGOING
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PPP005 (DELTA-9-TETRAHYDROCANNABINOL-CANNABIDIOL)	SAFETY AND EFFICACY OF MEDICAL CANNABIS OIL IN THE TREATMENT OF PATIENTS WITH CHRONIC PAIN: A RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED PILOT STUDY, FOLLOWED BY AN OPEN-LABEL EXTENSION PHASE	PAIN	ADULT FEMALE, ADULT MALE	CLOSED
ZYN002 (CANNABIDIOL)	A RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED, MULTIPLE-CENTER, EFFICACY AND SAFETY STUDY OF ZYN002 ADMINISTERED AS A TRANSDERMAL GEL TO CHILDREN AND ADOLESCENTS WITH FRAGILE X SYNDROME - CONNECT-FX	FRAGILE X SYNDROME	PEDIATRIC	PENDING

16 study (10 listed in “THC” search, and 6 uniquely using CBD)

- 5 pain
- 3 substance use disorder
- 3 seizure disorder
- 1 HIV
- 1 Parkinson’s
- 1 insomnia
- 1 Tourette’s
- 1 Fragile X Syndrome

Opportunities & Challenges

Opportunities

- Significant increase in funding from federal government.
- Significant increase in regional academic research groups interested in studying cannabis (CRIS, DeGroote, CISUR, BCCSU, etc.).
- Some funding & support available through cannabis industry.

Challenges

- Significant delays in the processing of cannabis research licenses.
- Lack of research grade material and/or accompanying docs.
  - Quality Overall Summary (QOS) & Investigational Brochures (IBs).
- Perception of (and potential actual) bias in industry-supported research.

Tilray Clinical Trials

Clinical Trials

- Chemotherapy Induced Nausea & Vomiting (University of Sydney)
- Pediatric Epilepsy/Dravet Syndrome (SickKids)
- Post Traumatic Stress Disorder (UBC)
- Chronic Obstructive Pulmonary Disease (McGill)
- Essential Tremor (UCSD)
- HIV/AIDS (McGill)
- Children With Intellectual Disability (The Royal Children's Hospital, Melbourne)

Tilray Research Program - Observational

Current or Completed Observational Studies

Canadian Cannabis Patient Survey 2019 (University of Victoria, Canada; completed)

- This is the largest cross-sectional survey of Canadian cannabis patients to date (n=2102).
- Results being analyzed by UBCs CHEOS.

Tilray Observational Patient Study (University of Victoria, Canada; recruitment completed)

- This is the largest national prospective study of Canadian cannabis patients to date, with over 2100 participants at 21 medical clinics in 5 provinces.
- Results analyzed; publication in the works.

Medical Cannabis in Older Patients (Canada)

- Multi-site national study of medical cannabis use in patients over 50 years old.
- 7 sites now launched in ON & BC; NB to launch in Q2.

Tilray Research Program; Publications

Abdallah, S. J. et al. (2018). **Effect of Vaporized Cannabis on Exertional Breathlessness and Exercise Endurance in Advanced COPD:** A Randomized Controlled Trial. *Annals of the American Thoracic Society*, AnnalsATS.201803-198OC.

McCoy, B., Wang, L., Zak, M., Al-Mehmadi, S., Kabir, N., Alhadid, K., … Snead, O. C. (2018). **A prospective open-label trial of a CBD/THC cannabis oil in dravet syndrome**. *Annals of Clinical and Translational Neurology*, 5(9), 1077–1088.

Arkel et al, (2019). **Cannabidiol (CBD) content in vaporized cannabis does not prevent tetrahydrocannabinol (THC)-induced impairment of driving and cognition.** Psychopharmacology, https://doi.org/10.1007/s00213-019-05246-8

Lucas, P. (2017). **Rationale for cannabis-based interventions in the opioid overdose crisis**. *Harm Reduction Journal*, 14(1), 58.

Lucas, P. & Walsh, Z. (2017). **Medical cannabis access, use, and substitution for prescription opioids and other substances: A survey of authorized medical cannabis patients.** *International Journal of Drug Policy,* 42, 30–35.

Baron, E. P., Lucas, P., Eades, J., & Hogue, O. (2018). **Patterns of medicinal cannabis use, strain analysis, and substitution effect among patients with migraine, headache, arthritis, and chronic pain in a medicinal cannabis cohort.** *The Journal of Headache and Pain*, 19(1), 37.

Lucas, P., Baron, E. P., & Jikomes, N. (2019). **Medical cannabis patterns of use and substitution for opioids & other pharmaceutical drugs, alcohol, tobacco, and illicit substances; results from a cross-sectional survey of authorized patients.** *Harm Reduction Journal*, 16(1), 9.

Turna, J., Simpson, W., Patterson, B., Lucas, P., & Van Ameringen, M. (2019). **Cannabis use behaviors and prevalence of anxiety and depressive symptoms in a cohort of Canadian medicinal cannabis users**. *Journal of Psychiatric Research*, 111, 134–139.

TILRAY™

Tilray T2:C100 – New Product Launch

- Formulation matched to Pediatric Epilepsy clinical trial product (SickKids Hospital)
- Novel API manufacturing process
- IP Protection
  - Dosing
  - Cannabinoid ratios (composition)
  - Methods of treatment
- Highest strength CBD product from any CAN LP
- Precisely formulated for easy dosing and titration
- Onset of action: 60-90 minutes
- Duration of action: 8-12 hours

TILRAY

TILRAY OBSERVATIONAL PATIENT STUDY (TOPS)

Instruments:

1. **World Health Organization Quality of Life Short Form** (WHOQOL – BREF).
2. **Cannabis Use Survey.**
3. **Prescription Drug Questionnaire** (filled out by MD to minimize recall bias).

Study sites:

21 participating clinics, >2100 participants in BC, AB, ON, NB, NS.

Data for this preliminary analysis was gathered in January 2019.

- This data set is based on 1145 patients enrolled at/before Oct 15, 2018 that have completed at least one post baseline visit.
- Analysis was conducted by the Centre for Health Evaluation and Outcome Sciences (CHEOS) at UBC.

DEMOGRAPHICS

Age + Relationships

AGE, N (%)	
<25	19 (1.7%)
25-39	285 (24.9%)
40-55	384 (33.5%)
>55	457 (39.9%)

RELATIONSHIP STATUS, N (%)	
Single	274 (23.9%)
Married	537 (46.9%)
Divorced	109 (9.5%)
Widowed	64 (5.6%)
Separated	56 (4.9%)
Living as Married	105 (9.2%)

AGE	
Mean (SD)	51.2 (15.4)
Median (QR)	52 (38, 62)
Range	18-95

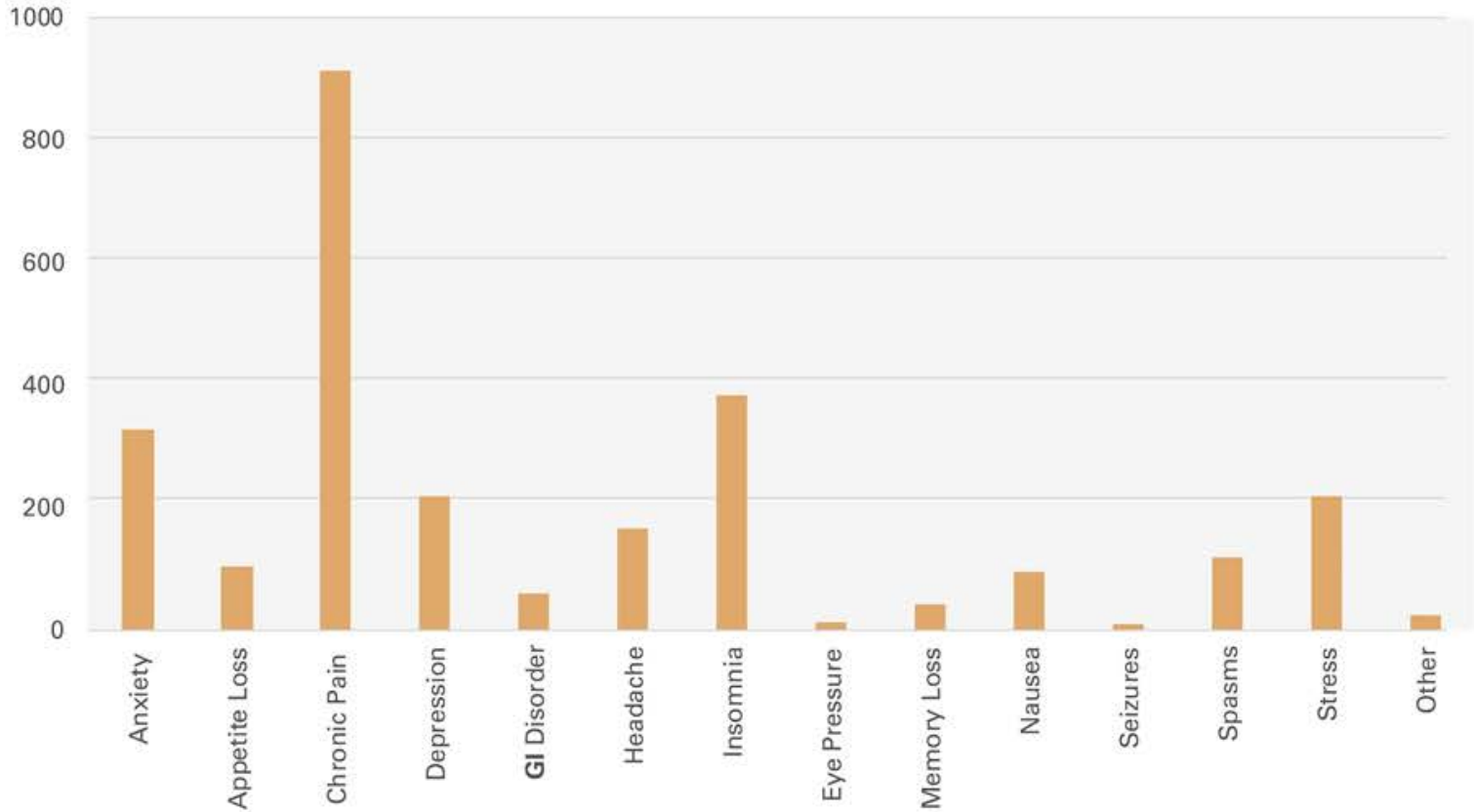
RELATIONSHIP STATUS, N (%)	
Single / Divorced	383 (33.4%)
Married / Living as Married	642 (56.1%)
Widowed / Separated	120 (10.5%)

Mean Age: 51.2

Married or Equivalent: 56.1%

PRIMARY SYMPTOMS

All patients



Symptoms	n (%)
Chronic Pain	915 (79.9%)
Insomnia	384 (33.5%)
Anxiety	327 (28.6%)
Depression	219 (19.1%)
Stress	219 (19.1%)
Headache	166 (14.5%)
Spasms	118 (10.3%)
Appetite Loss	105 (9.2%)
Nausea	95 (8.3%)
GI Issues	60 (5.2%)

Pain: 83.5% (n=956)

Mental Health Issues: 36.9% (n=422)

Insomnia: 33.5% (n=384)

CANNABIS PREFERENCES

Methods of use at 6 months

Preferred Type of Cannabis, n (%)	
High CBD	201 (51.8%)
Indica	35 (9%)
Sativa	34 (8.8%)
Hybrid	33 (8.5%)
No Preference	85 (21.9%)

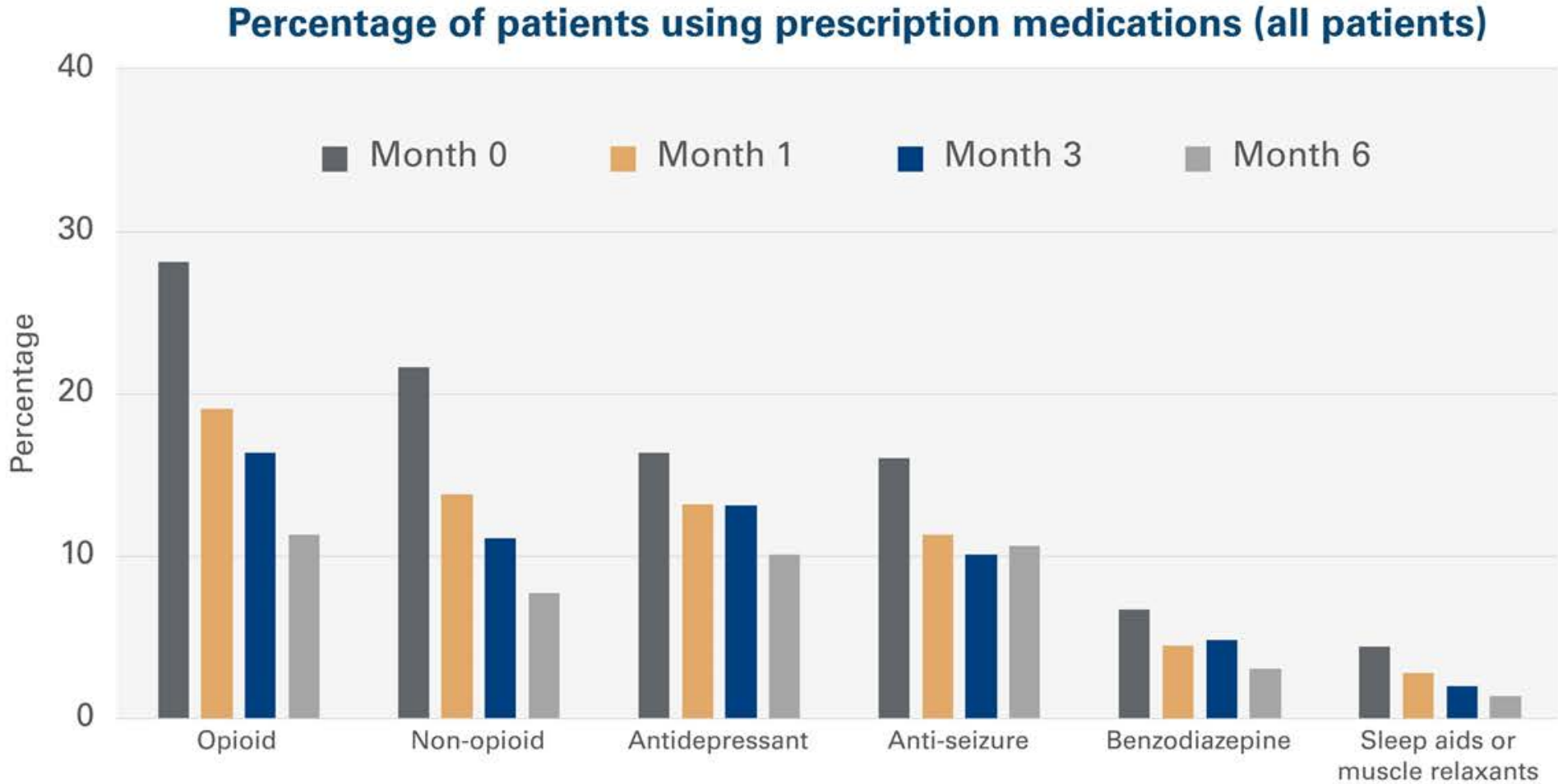
Primary Method of Use, n (%)	
Oral (Capsules/ Drops)	201 (51.3%)
Vaporizer (Flower/Bud)	86 (21.9%)
Joint	72 (18.4%)
Waterpipe/Bong	13 (3.3%)
Vaporizer/ Nail (Extracts)	7 (1%)
Topical	7 (0.9%)

- **High CBD is the preferred type of cannabis by a wide margin.**
- **Oral ingestion is the primary method of use.**
- **Non-smoked accounts for 75.1% of use.**

This data highlights a significant shift away from the smoked ingestion of high THC products.

% USING PRESCRIPTION DRUGS

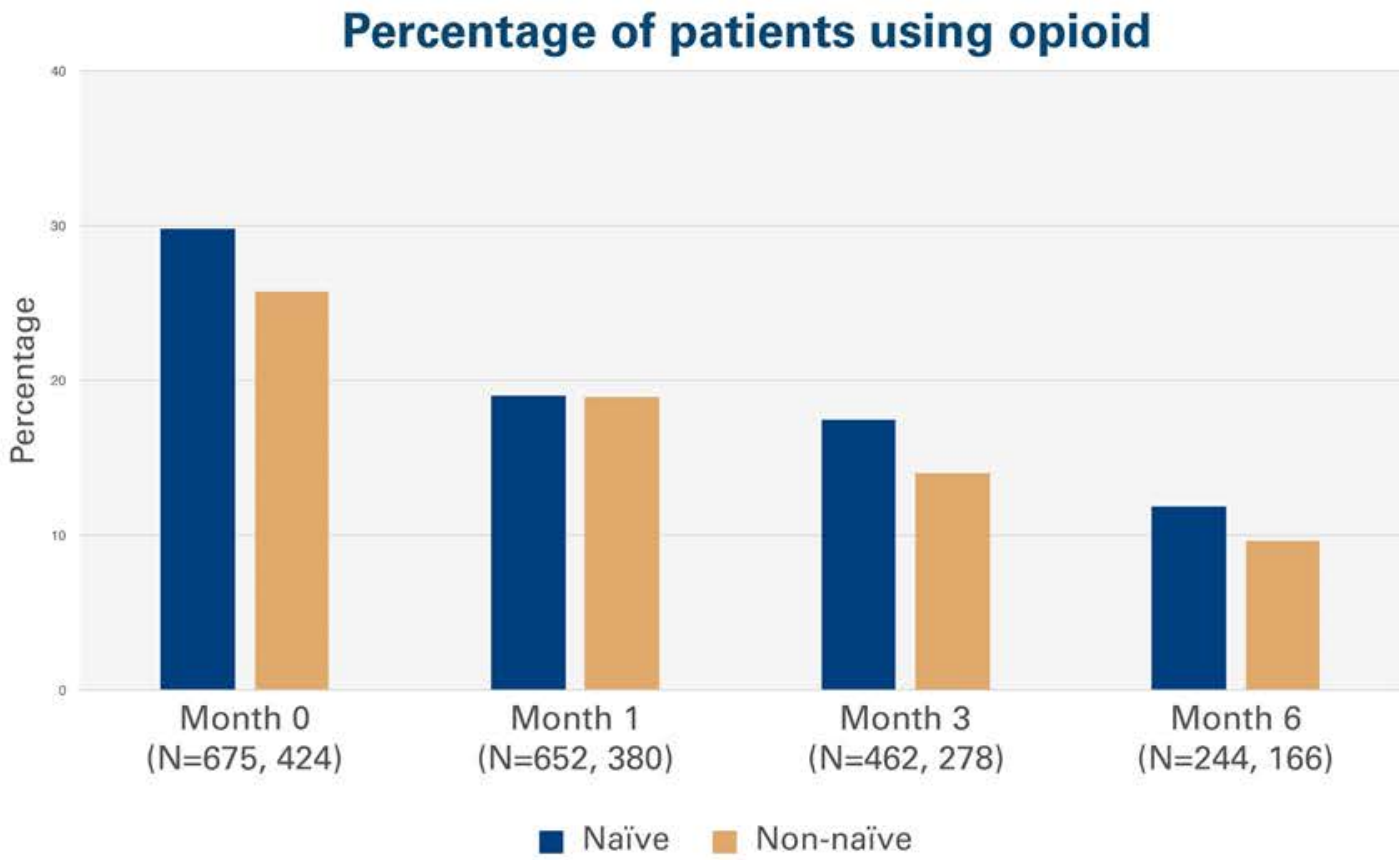
Baseline to 6 months



The % of patients using opioid/non-opioid pain medications, antidepressants, antiseizure medications, benzos, and sleep meds/muscle relaxants declined significantly from baseline to 6 months ($p<0.05$).

OPIOID USE

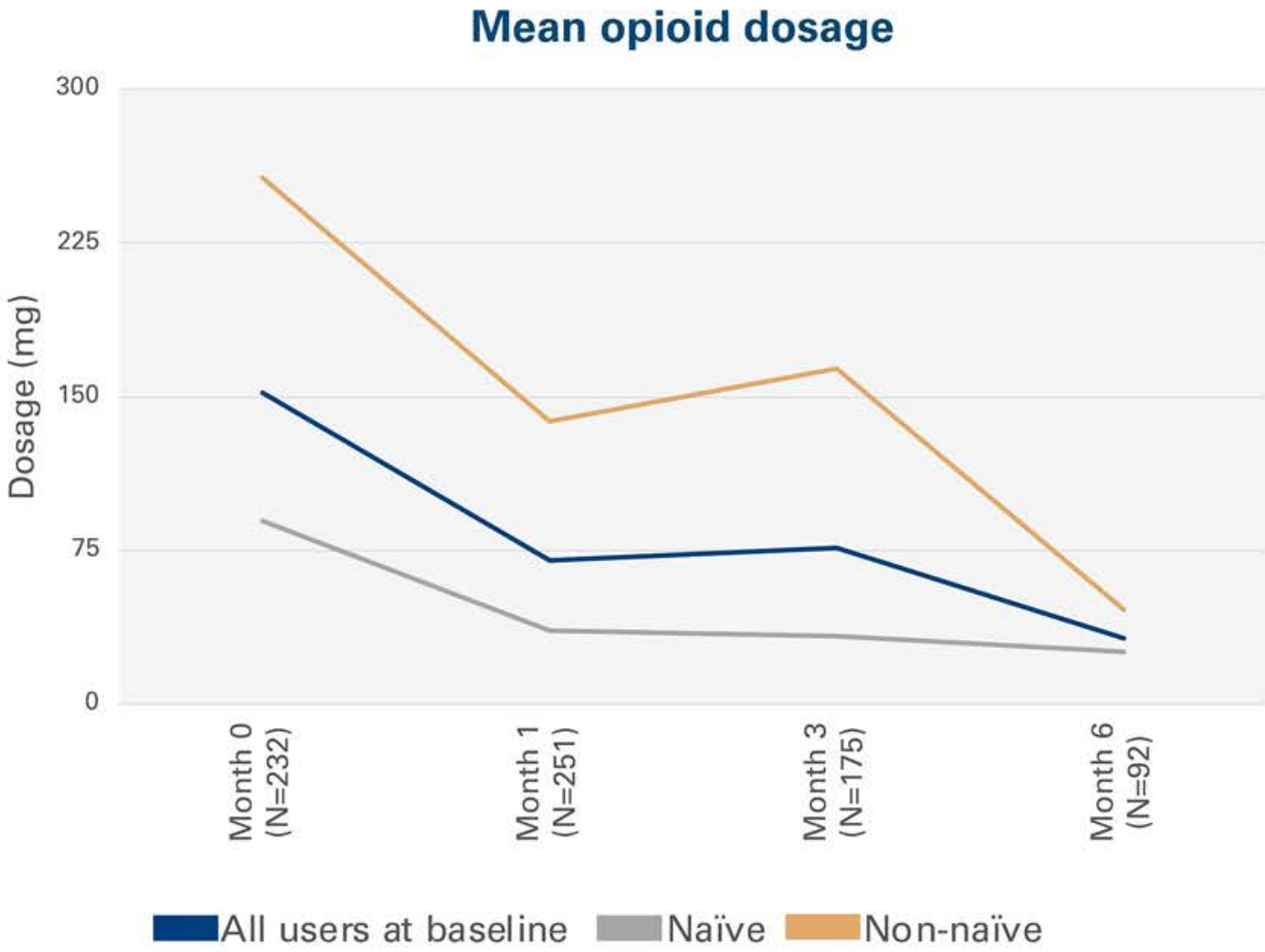
% of Patients Using Opioids by Baseline Cannabis Use



By opiod usage at baseline	Month 0 (N=675, 424)	Month 1 (N=652, 380)	Month 3 (N=462, 278)	Month 6 (N=244, 166)
Naïve	29.8	19	17.5	11.9
Non-naïve	25.7	18.9	14	9.6

Baseline opioid use was reported by 28.1% of patients (n=313), dropping to 11.3% (n=47) of total study participants at 6 months.

MEAN OPIOID DOSAGE (MME)

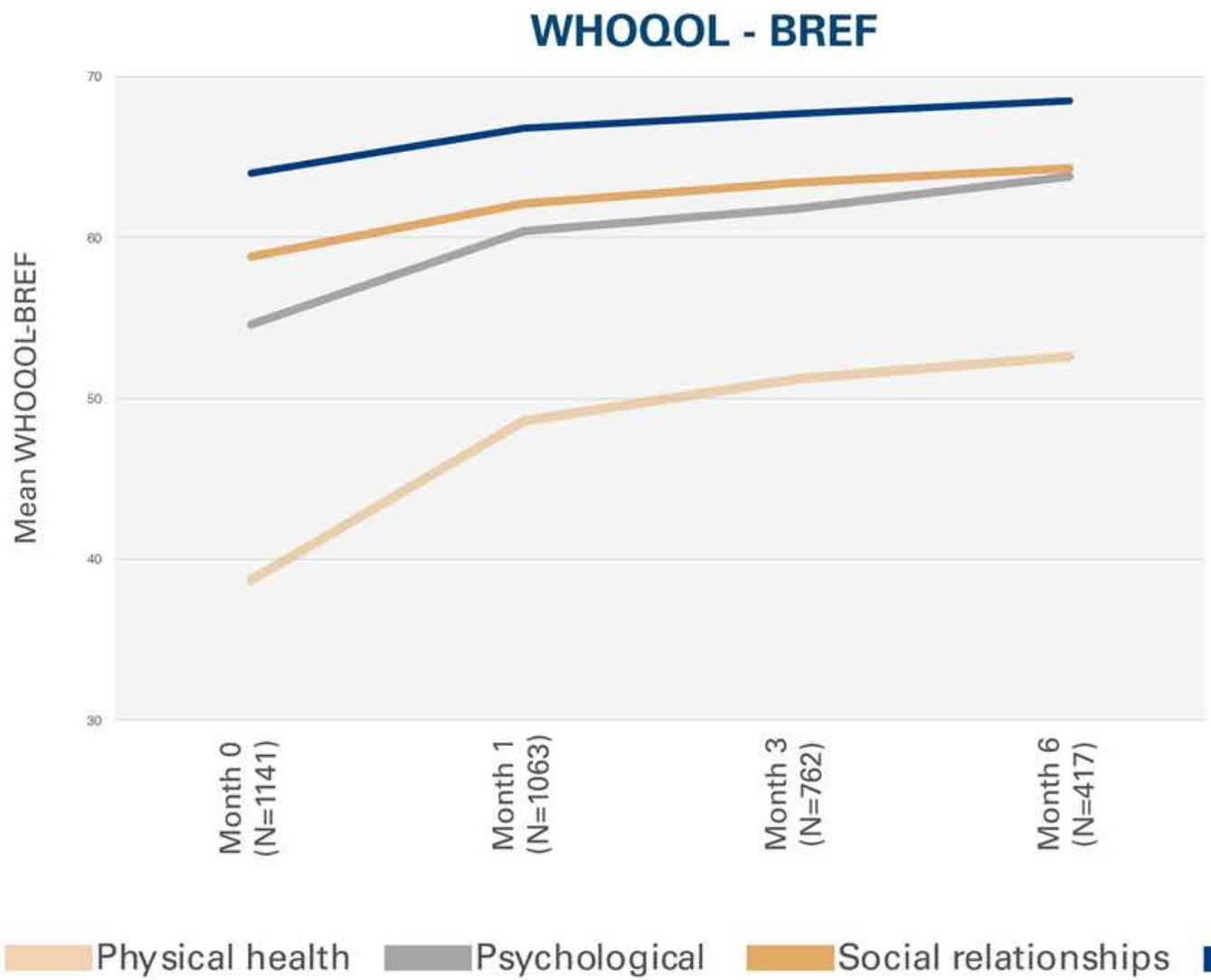


Mean	Month 0 (N=232)	Month 1 (N=251)	Month 3 (N=175)	Month 6 (N=92)
All users at baseline	152	70.2	76.3	32.2
Naïve	89.5	36	33.3	25.7
Non-naïve	256.9	138.1	163.8	46.2

Mean opioid use went from 152 mgs per day at baseline to 32.2 mgs at 6 months, a 78% reduction.*

*dosages determined using the Morphine Milligram Equivalent (MME) conversion factor.

IMPROVEMENTS IN QUALITY OF LIFE



Mean QOL over time				
	Month 0 (N=1141)	Month 1 (N=1063)	Month 3 (N=762)	Month 6 (N=417)
Physical health	38.7	48.6	51.2	52.6
Psychological	54.6	60.4	61.8	63.8
Social relationships	58.8	62.1	63.4	64.3
Environment	64	66.8	67.7	68.5

Significant improvements in all 4 domains of QOL ($p<0.05$).

Greatest changes seen in physical health (26.4% increase) and psychological health (14.4% increase).

Research *is the force that through the green fuse drives the flower...*

Research fills knowledge gaps, dispels myths, breaks down stigma, and informs policy.

- Medical cannabis used by young recreational users vs. middle aged adults.
  - Cannabis dangerous to those with mental health issues vs. common treatment for stress, anxiety & depression.
- Medical cannabis is largely about inhaled THC vs. oral CBD.
  - Cannabis is a gateway drug vs. harm reduction tool/exit drug.

"It is the responsibility of intellectuals to speak the truth and expose lies."
- Noam Chomsky

THANK YOU; QUESTIONS?

Philippe Lucas
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Five Days in May 2019: Cannabis Revelations through Research

From New Law to Clinical Practice: Considerations for Success

Richard Jones BSc, BSP, RPh, ACPR, FACHE
Director, Pharmacy Services, Island Health

Audience Question!

So you have your research license to begin study of clinical benefits of cannabis. Is that all there is before you can enroll your first patient?

1. Yes

2. No, but it is someone else's duty to finish the necessary steps

3. No, and I will be expected to engage with the clinical facility to ensure all requirements are complete

Disclosure

- I have no conflicts to disclose in this topic
- I own no stock or interest in any Cannabis organization
- I have previously been a youth volunteer in a Saskatchewan based national substance use educational organization known as Parent’s Resources Institute for Drug Education Canada

Agenda

Building Bridges from trial approvals and research licensing to patient enrollment:

Hospital factors for consideration for success.

Patient support beyond study

REB and Study Licensing: What Next?

- Host facility clinical trials group & study licensing under the Cannabis regulations
- Medical Use Cannabis does not have a Drug Identification Number (DIN) or Natural Product Number (NPN) from Health Canada: Not a “DRUG”, procurement and dispensing pharmacy license
- Possession is restricted to specific uses in the Cannabis Act and Regulation Different from narcotic regulations
- Hospital Pharmacy service licensing

Hospital Policy Factors

- Sourcing and product pedigree confirmation of product supplied with Study and pharmacy licenses
- Documentation requirements <Narcotic Product>
- Disposal and wastage policy
- Regulated Health Care workers: practice scope and obligations from Regulatory Colleges
- Routes of consumption/ administration: Smoking/Vaping Policy

Where Next

- Engage the pharmacy services early, before REB and Study licensing
- Be aware that distribution of study product will need to go through Pharmacy Services and not an ancillary service; Pharmacist must be directly involved
- Clinical trials in a hospital must use hospital pharmacy service
- Ensure hospital has established appropriate policy and procedure to ensure conformance with the Cannabis Act & Regulation as well as other relevant factors
- Build lots of lead time into your timeline
- Be prepared to have detailed discussions with Hospital leaders
- Anticipate cost recovery by the hospital for their costs.

Post Study Therapy Management

- Clinical trial product supply stops with the closure of a study
- Considerations for transitioning successful patients to medical use authorized supply
- Ongoing follow-up with primary care provider

Questions

Clinical Trials BC

BC AHSN

British Columbia Academic
Health Science Network

Canadian Regulatory Environment
Clinical Trials with Cannabis

Jean Smart, MGH, MDS, RAC
Regulatory Affairs and Quality Officer

May 30, 2019 - Victoria BC

Clinical Trials BC
British Columbia Academic Health Science Network

Disclaimer and Conflict of Interest

- The views and opinions expressed in this training are those of the individual presenter and should not be attributed to the BC Academic Health Science Network, its leadership, employees, volunteers, members or any other organization with which the presenter is affiliated.
- I have no conflicts of interest to declare

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Agenda

Canadian Regulatory Framework

- Acts that Apply to Cannabis Research
- Regulations that apply to Cannabis Research

New and in the Cue Guidance Documents

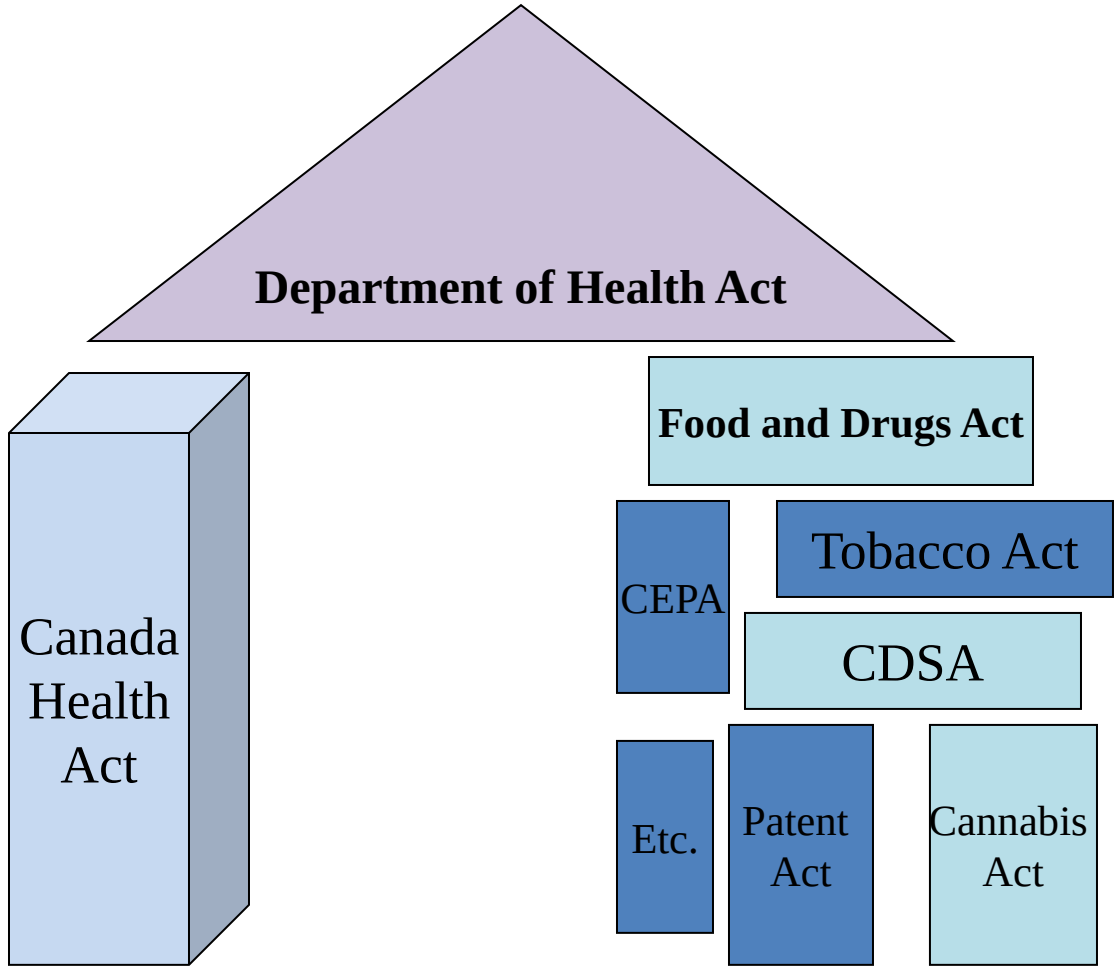
Applications

- Cannabis Research Licensing Process
- Clinical Trial Application Process

Issues and Hot Topics

Clinical Trial Resources

Canadian Regulatory Framework



Acts

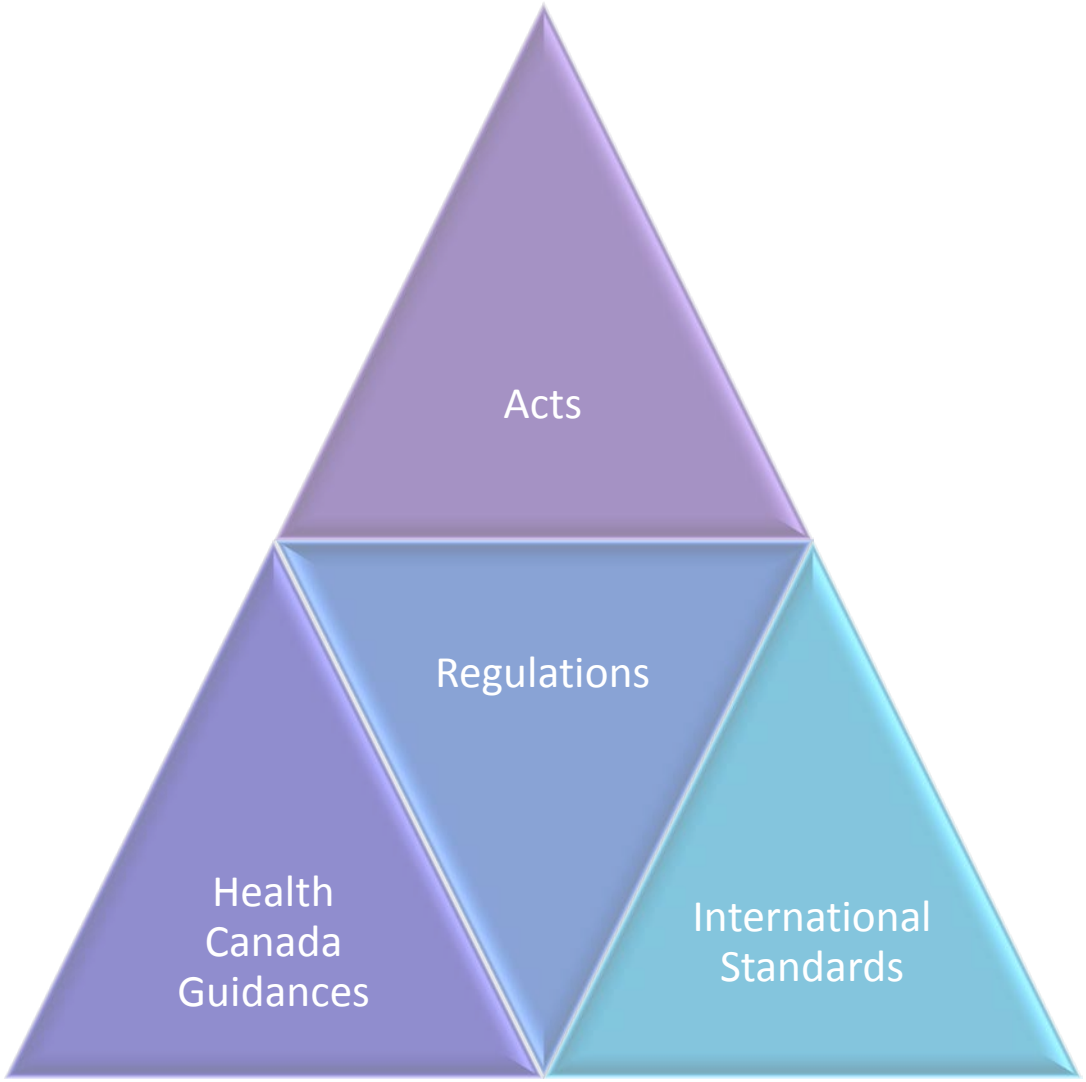
Food and Drugs Act (1953)
Hazardous Products Act (1969)
Pest Control Products Act (1969)
Radiation Emitting Devices Act (1970)
Quarantine Act (1872)
Controlled Drugs and Substances Act (1996)
Tobacco Act (1997)
Canadian Environmental Protection Act (1999)
Patent Act (relevant provisions passed in 1993)
Canadian Food Inspection Agency Act (1997)
The Cannabis Act (2018)

Applicable Acts by Use

*

Non Medical (Cannabis Act)	Medical (Cannabis Act)	Health Products with Cannabis (Cannabis Act and FDA)
• Limited classes initially • Additions after one year • Health care practitioner authorization **not required** • **No pre-market review** for safety or efficacy • Quality and security requirements under the Cannabis Act • **Cannot** make health claims	• Limited Classes • Additions after one year • Health Care Practitioner Authorization **Required** • **NO pre-market review** for safety, efficacy • Quality and security requirements under Cannabis Act • **Cannot** make health claims	• No restrictions on product classes that may be approved under the Food and Drug Act (dosage forms for prescription drugs) • Practitioner oversight required • **Pre-market review** for safety, efficacy and quality under the FDA • Manufacturing subject to quality and security requirements under both the FDA and Cannabis Act • **Can** make health claims if authorized

Regulatory Framework



Regulations

Cannabis Regulations
Food and Drug Regulations
Industrial Hemp Regulations
Controlled Substance Regulations
Good Manufacturing Practices Regulations
Patented Medicines (Notice of Compliance) Regulations
Medical Devices Regulations
Natural and Non-prescription Health Products Regulations
Cannabis Exemption (Food and Drugs Act) Regulations
National level privacy and provincial level privacy Regulations

New and In the Cue

Guidance Documents

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Where Guidance Documents, Standards Come from

Guidance Documents

- Assist in the interpretation of policies ,standards and regulations.
- They are usually written in layman terms with a definition index.
- Health Canada
  - adopts and makes effective All of the ICH legal international guidance documents
  - creates some of their own
  - selects and adopts guidance documents from other agencies

Examples:

- Guidance for the Cannabis Act, the Food and Drugs Act and Regulated Regulations (by Health Canada)
- All of the ICH Guidance documents (100+) E series, Q series, M series, S series
- HC Clinical Trials Manual (WHO)
- PICs Annex 11 on Electronic Records and Validation (PICs)

Health Canada - Guidance for the Cannabis Act, the Food and Drugs Act and Regulated Regulations

Health Canada Santé Canada

NEW

- Issued in **July 2018** before the Cannabis Act and Regulations was in effect
- Sets out the regulatory framework for health products containing cannabis or for use with cannabis It includes the requirements for licensed activities under the Cannabis Act and the Food and Drugs Act.
- **9 Sections - Introduction, 6 Topics and 2 Annexes**
  - Health research and clinical trials
  - Pre-market evaluation of Health Products under the FDA (Review)
  - Cannabis Drug Licence
  - Cannabis Act Restrictions and Authorizations that Apply to Health Products
  - Practitioner, Pharmacist and Hospitals
  - Import and Export
  - Annexes on Licence Application details and where to get more information

Clicker Question - E6R2 ?

Who or what is E6R2?

1. A Regulatory Sargent
2. The evil twin of R2D2
3. A regulated company on the stock exchange
4. A bad protein
5. A Good Clinical Practice

Clinical Trials BC

Answer: E6R2 is Good Clinical Practice

NEW

- Since 1996 E6 has stood as the unified standard for **Good Clinical Practice (GCP)** for trials in all international regions.
- The document principles have their origin in the Declaration of Helsinki.
- Recently been updated and came into effect in Canada on **May 3, 2019**
- Compliance provides public assurance that the rights, safety and well-being of trial participants are protected and that the clinical trial data are credible.
- ICH E6R2 is intended to be used in conjunction with other ICH guidelines relevant to the conduct of clinical trials E2A, E3, E5, E7, **E8**, E9, and E11, Q9, E17, etc.... and not in isolation

E6R2 Structural Overview

The Document is divided into a History, Introduction plus 8 Sections

1. Glossary
2. Principles
3. Institutional Review Board
4. Investigator
5. Sponsor
6. Clinical Trial Protocol and Protocol Amendments
7. Investigator’s Brochure
8. Essential Documents for the Conduct of a Clinical Trial

HC Guidance 0100

Health Canada Santé Canada

NEW or in the CUE?

Where is it?

Announced it would be out April 1, 2018 then April 1, 2019

Now Expected out in **June 15, 2019**

- December 2017 Draft Version 12 circulated for feedback suggested it would include the revised CTA process, E6R2 content and the records requirements
- Guidance 0068 Records for Clinical Trials is scheduled to be repealed.
- Multi-regional Clinical Trial (MRCT ICH E17) content **not** included
- **Big focus item for Canada in 2019**

Authorizations to conduct Cannabis based research

General Research

- Federal Cannabis Licence Application and Approval
- Ethics Application and Approval

Clinical Trial

- Federal Cannabis Licence Application and Approval
- Clinical Trial Application and Issued No objection Letter
- Ethics Application and Approval

Health Canada
Summary: Cannabis Licensing Application Guide

Health Canada Santé Canada

NEW or in the CUE?

- This document has been updated effective May 8, 2019
- Not posted as of May 24, 2019
- ‘Aligns with HC’s approach to cannabis licensing with other regulated sectors such as pharmaceuticals’
- The updated guide will be available ‘shortly’
- You can request electronic copies of the updated guide from cannabis@canada.ca

Research Licenses under the Cannabis Act

- The requirements to obtain a Research Licence under the Cannabis Regulations include the following:
  - Licence Holder and Key Individual
  - Site details
  - Type of research (in vitro, in vivo, clinical trial etc.)
  - Research Protocol
  - Physical security requirements
  - Information on record keeping and reporting.
- May also involve security clearance on individuals and key personnel, organizational security plan or increased physical security
- Reviewed on an individual basis
- Once approved any changes must be approved by HC before implementation of the change
- CDL holders are authorized to sell drugs containing cannabis to research institution/researchers with a cannabis research license

Clinical Trial Application Process

Guidance Document for Clinical Trial Sponsors: Clinical Trial Applications May 2013

- Pre-Clinical Trial Application (CTA) Consultation Meeting by request
- Complete application form in Common Technical Document (CTD) format
- Electronic or paper
- **Canada has a 30 Day default period for CTA's**
- CTA is required for Phase I,II and III trials
- May proceed after 30 days if not contacted.
- No objection letter (NOL) is sent by email
- Currently on schedule – no delays

Note: Need Ethics approval before proceeding with the trial

HC Guidance Medical Device ITA Consultation

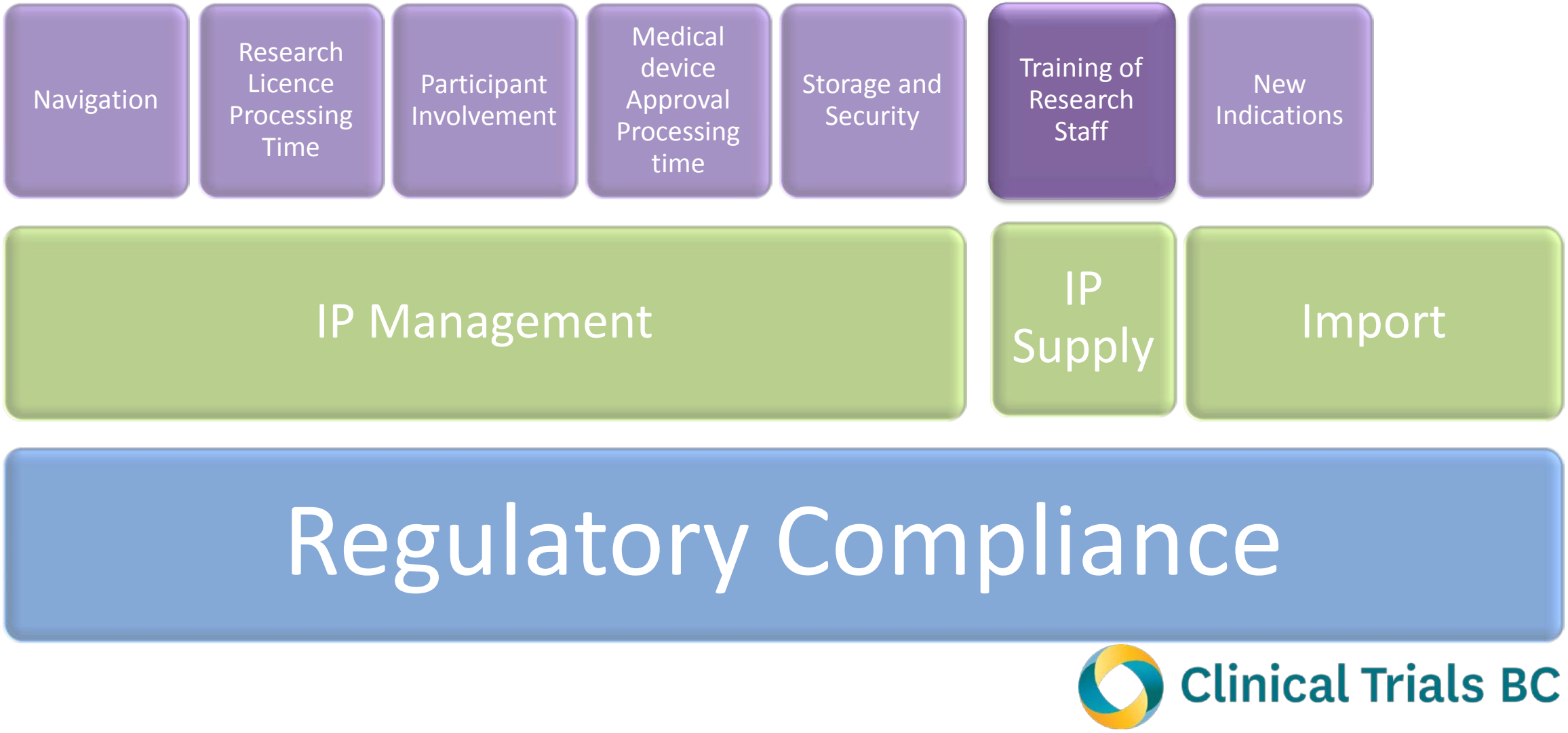
IN the CUE

- Health Canada Guidance - Applications for Medical Device Investigational Testing Authorizations Draft Oct 6 2017 closed for comment
- A Review and revision of Medical Device Investigational Testing Authorizations (ITAs) was prioritized in Health Canada's Action Plan - published in December 2018. The Review is to include longstanding issues identified by all stakeholders (including the IMDRF)

- Consultation is now **OPEN**
  - Question format
  - Comments to Health Canada Policy office by **June 21, 2019**
  - Comments should be from an organization and not an individual
  - Note that written feedback is public information

Current Status of Guidance – unknown (is slated for Fall 2019)

Hot Topics and Emerged Issues



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Navigating the Regulations

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Regulatory Programs and Resources for BC

- Audit and Inspection Preparedness Program (AIPP)
- Communities of Practice (ECOP)
- Compliance Education – Featured Lecture Series and Core Lecture Series
- Investigators Only Training
- Regulatory Guidance and Consultation
- Quality Management Systems (QMS)
- Inter-Provincial Regulatory Review
- Resource Bank

Summary Points

- It is important to be aware of the changing Canadian Regulatory Environment
- 2019 focus on interpretation and note updates – **Watch for the new Guidance documents**
- ICH, Health Canada, Clinical Trials BC, N2 and other agencies have resources for institutions and sites
- More revisions coming…

Thank You

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