Establishment of a Domestic Hemp Production Program

Presentation to The Office of Information and Regulatory Affairs Kelly D. Fair, US General Counsel, Canopy Growth USA September 9, 2019





COMPANY SNAPSHOT

Canopy Growth (TSX:WEED) (NYSE: CGC) is a world-leading diversified cannabis and hemp company, offering distinct brands and curated cannabis varieties in dried, oil and soft gel capsule forms.



\$16.8B¹ Market Cap. 9.3M² \$4.0B Avg. Daily Vol. (3 Day) by NYSE: STZ

S&P/TSX Composite Index and S&P/TSX 60 Index member



Capital: \$4B investment + future warrants (NYSE: STZ)

Scale: 5.0M+ sq. ft. licensed globally / commercial scale GMP manufacturing

Vision: "First" mentality

Medical Market Leader - Spectrum Therapeutics: Spectrum color classification system Certified education programs/learning modules Operations in over 14 countries on 5 continents **R&D Leader:** Ebbu, Inc., acquisition



Driving Future Growth

Expanding global footprint

Cannabinoid as an ingredient

Potential cannabinoid based medical therapies

IP protection program









@ June 24 2019

Combined volume of TSX:WEED and NYSE:CGC

Excludes Ontario supply (125 SKUs secured). Ontario represents 40% of national population

Company Snapshot

- Canopy Growth is a leader in hemp research and development
- Supporter of high standards for testing and safety; competitive advantage in compliance
- Currently working with Canadian agricultural regulators
- Dedicated to growing the US hemp and CBD industry
 - 4,500 acres growing across seven states (CA, CO, KY, OR, PA, NC, NY)
 - \$150 million investment in Hemp Industrial Park in Broome County, NY
- Vertically integrated: Canopy will be a presence in field, laboratory, factory, and store shelf





State of Play

- Massive public interest in hemp cultivation, processing, and retail
- Nearly 4500 comments at FDA hearing on CBD (before proposed rules even released)
- Stakeholders are now meeting around the country to discuss standards and proposed regulations, e.g. CHAMP initiative in Colorado
- States are rolling out commercial hemp programs but looking to USDA for guidance
 - Interim regulations do not have to address everything; a "Nudge" in the right direction
 - E.g. Texas Dept of Agriculture: "TDA is required to wait for guidance from USDA on implementation procedures related to 2018 Farm Bill hemp provisions."
- For interim regulations, follow states where regulations are converging, e.g. California and Texas; guide states proposing divergent regulations, e.g. Nevada





Overview of Recommendations

- Consistent Sampling Methods:
 - Timing of collection and how the plant is collected
- Third Party Sampling and Testing: Standardizing Process and Creating Efficiency
- **Consistent Testing Methodology**: accounting for decarboxylation and consistent testing methods
 - Need to specify standard type of testing (HPLC vs. GC)
 - Need to specify analyte ("Total THC" vs. delta-9 THC)
- Hemp Re-Testing
- Hemp Seed Certification: Currently Impractical and Unnecessary
 - Genetics research incomplete / existing protections in place
 - Too late for current growing season

Interstate Transport





Consistent Sampling Methods

- Pre-Harvest THC testing should be consistently timed due to the following:
 - States use different sampling times for collection of hemp which leads to inconsistent testing results across states
 - Variation in a hemp plant's THC content increases nearer the time of harvest, sometimes resulting in a "hot" plant
 - Variation can be very dependent on growing conditions during the last week
 - These conditions are largely beyond the control of the grower
 - THC levels in the hemp crop more uniform 30 days prior to the harvest





оке Spectrum Therapeutic

Consistent Sampling Methods (continued)

- Current Collection Practices Include:
 - Nevada: Takes samples less than 15 days before harvest
 - Michigan: Requires testing (and sampling) more than 15 days before harvest
 - California: Takes samples at some point less than 30 days before harvest
 - Texas: Takes samples at some point less than 28 days before harvest

<u>Canopy Growth US Recommendation:</u> THC levels can vary significantly in the week before harvest due to weather and sun conditions beyond the farmer's control. Setting sampling for 30 days prior to harvest yields consistent testing results.





Third Party Sampling and Testing: Standardizing Process and Creating Efficiency

- Growers should have the option to use certified third parties to sample crops:
 - Relieve staffing burdens on state/federal agency and allow quicker turnaround and a tighter window for crop sampling
 - Sampling could be done by representatives of the testing laboratory, or other certified third parties
 - Certification requirements for sample collectors should be standard across states and not be onerous
 - Most states allow third parties to collect hemp samples on behalf of the agency, including California and Texas
 - The interim rules should specify a system for approved transport of samples from the field to local or out-of-state labs





Third Party Sampling and Testing: Standardizing Process and Creating Efficiency (continued)

- Growers should also have the option to use certified third parties to test crops:
 - Same as with crop sampling: allowing labs would save agencies time, drive competitive pricing, and allow quicker turnaround on testing
 - Certification for laboratories that meet ISO/IEC 17025 standards or the relevant state requirements for licensed cannabis testing facilities
 - Most states allow certified laboratories to conduct THC testing on behalf of the agency





Third Party Sampling and Testing: Standardizing Process and Creating Efficiency

- Hemp collection and sampling should be standardized across every state as THC varies
- Hemp plant THC content is concentrated in the hemp flower
 - Hemp flower is often, but not always, at the top of the plant
 - In windblown fields, growth patterns can lead to leaves at the top of the plant
 - Entire plant is used for extraction
- States use different sampling rules for which part of the hemp plant
 - Some states collect only top 2 in of the plant, other states collect only the top 18 in of plant.
 - Some states use a composite of different sections of the entire plant, including California.

<u>Canopy Growth US Recommendation</u>: Because hemp is based on dry-weight of the harvested plant and not just the flower, third party testing across states should use a composite of different sections when sampling for THC content thus narrowing the margin for inconsistency and error while creating an efficient and standardized process.





- 2018 Farm Bill requires procedures for testing delta9-THC concentrations "using post-decarboxylation or other similarly reliable methods" but does not give guidance on how to account for decarboxylation or what constitutes "other similarly reliable methods."
- Decarboxylation is defined as the heating or aging process in which THCA is converted to THC
- In raw hemp, THCA is much more abundant than naturally occurring THC (10 to 1). THCA doesn't fit into the brain's cannabinoid receptors, and does not have the same effect as THC





- "Total THC" (post decarboxylation) vs. "delta-9 THC" (pre conversion testing)--Testing Should Focus on delta-9 THC
 - 2014 and 2018 Farm Bills define "hemp" in terms of delta-9 THC content
 - California, Oregon, Kentucky, Colorado, North Carolina, North Dakota, Minnesota test for delta-9-THC only
 - THCA will stay THCA, and only low levels of naturally occurring delta-9 THC





- "Total THC" (post decarboxylation) vs. "delta-9 THC" (pre conversion testing)
 - "Total THC" is a black box– states are estimating the effects of decarboxylation
 - Nevada = "Total THC" = (.877 x molecular weight of THCA) + molecular weight of THC. Not clear from where the .877 coefficient is derived.
 - These estimates and methodology are often not fully explained.





- Testing methodology:
 - If the lab uses gas chromatography (GC) (becoming more common), the THCA will be decarboxylated and will show up as THC, this may result in higher THC levels than in states using pre-conversion testng like high performance liquid chromatography (HPLC)
 - GC Ignores that relative concentration of CBD and CBDA (and other cannabinoids) will affect the readings of THC.
 - If the lab uses HPLC, the THCA is not decarboxylated and both THCA, delta-9 THC, delta-8 THC, CBD, CBDA, and other cannabinoids will show up in the test. This is a better type of test and each cannabinoid is listed separately

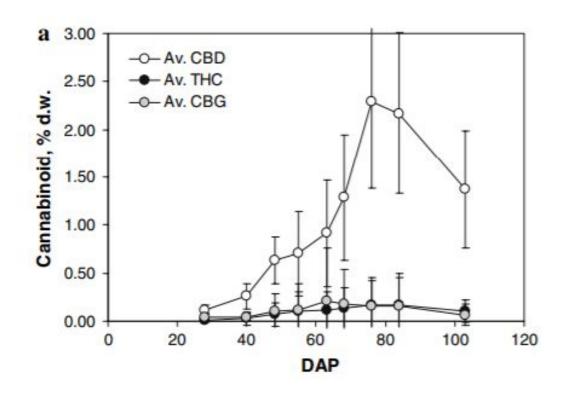




- Testing methodology continued:
 - The problem with GC is that it ignores the effect of other analytes and cannabinoids:
 - 0.2% THCA + 0.02% THC + 2% CBDA + 0.2% CBD = measures 0.02% THC
 - 0.2% THCA + 0.02% THC + 10% CBDA + 1% CBD = measures 0.1% THC
 - In GC, increased levels of CBD or other cannabinoids can skew readings on THC levels
 - HPLC and GC are not identical tests and will result in different readings. If they are both allowed, states must be clear on how they make them equivalent







Spectrum

This is the cannabinoid profile for a hemp plant (Carmagnola, an Italian fiber variety). Harvest is usually at 80 DAP (days after planting). You can see where the CBD and THC levels start diverging, starting at around 30 days prior to harvest. HPLC will show you both the high-CBD and low-THC profiles, which should be a clear giveaway that it's hemp. THC-only GC testing will not.





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<u>Canopy Growth US Recommendation</u>: Testing should target delta-9 THC in the plant, and not other cannabinoids. High performance liquid chromatography should be the standard lab method, since it specifically measures delta-9 THC separately from other cannabinoids and is at least as reliable as post-decarboxylation testing.





Hemp Re-Testing

- Re-testing of hemp should be allowed if the results are close to the legal threshold
 - California: If first pre-harvest test results show 0.30-1.00% delta-9 THC, additional samples for testing "shall be collected"
 - Nevada: If first pre-harvest test results show 0.40-1.00% delta-9 THC, grower can request a re-test
 - Recommend that duplicate set of samples can be collected for re-testing if THC levels are close to threshold, e.g. 1.00% THC or less, at grower's option and grower's expense
 - Collected with and at the same time as the first sample, and retained for re-testing

<u>Canopy Growth US Recommendation</u>: Re-testing of hemp should be allowed if the results are close to the legal threshold. Duplicate* set of samples can be collected for re-testing if THC levels are close to threshold, e.g. 1.00% THC or less, at grower's option and grower's expense *Collected with and at the same time as the first sample, and retained for re-sampling





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Hemp Seed Certification: Currently Impractical and Unnecessary

- Companies developing hemp genetics with manual (non-GMO) techniques
 - Developing breeds with different cannabinoid profiles
 - Developing weather resistant breeds that grow in different climates
 - Developing breeds more efficient for processing
- Seed certification is premature and would stifle R&D in early stage of industry
- Seed certification takes time to demonstrate genetic purity and germination rate; 2020 growing season seeds already acquired
- Growers/breeders needs for specialty strains are unknown at this time
- There is no way to guarantee a < 0.3% THC level seed strain at this time





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Hemp Seed Certification: Existing Protections in Place

- Federal and State Seed Acts
 - Protects farmers using commercial hemp seed
 - Requires accurate labeling and purity standards for seeds in commerce
 - Prohibits importation and movement of adulterated or misbranded seeds
- Truth in advertising federal and state laws
 - Prevents sales of seeds based on false claims or deceptive practices
 - Hemp is really just another farm crop, and should be treated the same as other crops except for THC
- THC testing of crop + testing of consumer products
 - Protects against harvest and processing of high-THC crop
 - Makes certification of low-THC seed redundant
- Seed certification stands as barrier to innovation not currently supported by R&D





Hemp Seed Certification: Open Questions Remain

- No accounting for certification of clone varieties
- No method to test for CBD and CBD content to accurately test seeds for THC and CBD content of plants - new certification protocol needed
- No accounting for pollination, seed-borne disease genetics
- All issues require further discussion and stakeholder input before certification

<u>Canopy Growth Recommendations:</u> Certification should not be part of interim regulation because genetics are not stable and seeds too varied; certification cannot guarantee low-THC hemp crops. Additionally, farmers are protected by existing federal seed law and states already require post-harvest THC testing.





Ensuring Smooth Interstate Transport

- 2018 Farm Bill prohibits states and Indian tribes from stopping transportation or shipments of hemp or hemp products that are "produced in accordance with subtitle G of the Agricultural Marketing Act of 1946." 7 U.S.C. 1639o
- 2019 USDA legal opinion applies the interstate commerce provision to hemp produced under the 2014 Farm Bill and to hemp produced under future state hemp plans
- States are unifying around documentation requirements for shipment:
 - Grower registration (place of origin)
 - Processor registration (destination)
 - Certificate of Analysis showing > 0.3% THC
 - Shipping manifest



Ensuring Smooth Interstate Transport (continued)

- U.S. Postal Service and UPS official policy: shippers self-certify for hemp and hemp products
- No state registration or licensing of transportation company should be allowed
 - Dormant Commerce Clause: "instrumentalities of commerce"
 - Not effective, e.g. Utah, and only creates red tape

<u>Canopy Growth US Recommendation</u>: All hemp should move freely in the U.S. regardless of any state restrictions on sale or processing as long as it is from a registered grower and not "marijuana" or another controlled substance. Hemp should also be allowed to exceed 0.3% THC if it is being transferred for additional processing at destination, e.g. distillate for use in manufacturing.





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THANK YOU







Spectrum Therapeutics