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HOW THE U.S. IS FALLING BEHIND IN THE REGULATED GLOBAL CANNABIS MARKET



Shifting political dynamics, successful ballot initiative measures, and the entrepreneurial drive of American small businesses may have started the regulated global cannabis market, but we are quickly falling behind as that market expands internationally. Lack of federal regulation and the inability to expand beyond state borders means U.S. cannabis companies are constrained in their ability to grow and are at a competitive disadvantage to cannabis companies in other countries, with Canada and Israel being the most prominent examples. Growing a business to handle sophisticated cannabis product development or cross-border trade requires access to international financial markets. But federal prohibition effectively locks American cannabis companies out of legitimate financial markets and, in doing so, has provided a significant advantage to publicly traded Canadian firms. Changes to federal law are needed to enable American small businesses to compete on the emerging multi-billion-dollar global cannabis market. Without legislative action, U.S. cannabis entrepreneurs will miss out on opportunities to develop innovative new products, attract global investment funding, and expand their reach to capitalize on expanding international business opportunities.

ISRAEL'S RESEARCH AND DEVELOPMENT ADVANTAGE

Compared to nations like Israel and Canada, the United States is now at least a decade behind in cannabis research and the development of innovative cannabinoid medicines. Ever since Israeli scientists Raphael Mechoulam and Yechiel Gaoni isolated and synthesized the primary psychoactive component of cannabis, Delta-9-tetrahydrocannabinol, in the mid 1960's Israel has been at the forefront of cannabis technological innovation. Not only is medical marijuana federally legal in Israel, but the country is one of the few in the world where the Ministry of Health actively funds cannabis research and regulates medical cannabis product development. In 2017, there were more than 110 clinical trials involving cannabis in Israel, more than the United States or any other nation.¹ The competitive advantage Israel holds over the United States in facilitating research has caused many U.S. businesses to move overseas or partner with Israeli medical cannabis companies. American research firms looking to develop cannabinoid-based medicines sometimes conduct phase 1 and phase 2 clinical trials in Israel where scientific study using cannabis incurs far fewer bureaucratic hurdles. Once a safety profile has been established

abroad, the company brings the study back to the United States for phase 3 trials in an attempt to obtain FDA approval.² This process, caused by the unnecessary difficulties of performing cannabis research and product development in America, has caused millions of dollars in research funding to flow overseas. According to Saul Kaye, the founder of iCAN, an Israeli cannabis R&D firm, more than \$250 million was invested in Israeli cannabis companies in 2016, with half of this capital coming from North America. More than 50 American cannabis companies have established operations in Israel and the level of financial investment is expected to increase to \$1 billion over the next few years.³

MULTI-BILLION DOLLAR GLOBAL MEDICAL CANNABIS TRADE

This lucrative flow of investment has enabled Israeli business owners and entrepreneurs to capitalize on the growing international demand for legal medical cannabis products. Despite more than fifty years of global cannabis prohibition, the 1961 U.N. Single Convention, which established the worldwide drug control regime, actually permits cannabis for medical and scientific purposes. This exemption within the international drug control treaties has been utilized by federally-licensed companies in Canada to send billions of dollars' worth of cannabis across the globe. As of March 2017, seven different Canadian federally-licensed producers ("LPs") have been granted approval to export cannabis to almost a dozen countries internationally with shipments exceeding 1,164 pounds of dried flower and 911 liters of cannabis oil.⁴ Canadian producers have established major international business deals and are sending product to medical cannabis programs in almost every continent and countries including Germany, Australia, Brazil, and South Africa.⁵ Other developed nations are watching this new international opportunity and have removed legal barriers to capitalize on the ability for global medicinal products sales. Australia changed regulations to permit export in February 2018⁶ and the Israeli government will likely begin approving exports of medical cannabis in May 2018.⁷ Without a federally legal medical system, American cannabis entrepreneurs are unable to leverage this emerging market and export medical cannabis products produced at home. If prohibition continues, the U.S. economy will forgo the potential revenue derived from billions of dollars worth of exports (which would decrease our trade deficit) and our early advantage in

the development of a robust cannabis economy will be wasted, as we lose out to licensed and better capitalized players abroad.

DOMINANCE OF CANADA'S PUBLIC CANNABIS COMPANIES

The advantage of federal regulation not only allows American cannabis entrepreneurs' international competitors to reach global markets, it also allows them to attract investment capital faster and more efficiently. As of February 2018, approximately 39 of 89 federally-licensed Canadian cannabis producers were publicly traded.⁸ While U.S. companies continue to pay above-market interest rates to investors, Canadian LPs raised more than C\$1.2 billion on the public markets in January 2018 alone.⁹ And when it comes to rapid growth and the ability to capitalize on new opportunities across the world, access to cheap money matters. Despite the U.S. market containing nine times the number of cannabis consumers, five Canadian LPs are valued at more than \$1 billion, with the largest cannabis producer in the country, Canopy Growth Corporation, worth almost \$6 billion.¹⁰ There are no U.S.-based cannabis cultivators, manufacturers, or dispensaries anywhere close to that value. In January 2018, two dominant Canadian LP's continued the trend of multi-million-dollar consolidation deals. Aurora Cannabis Inc. announced the purchase of CanniMed Therapeutics Inc for \$852 million and Aphria bought Nuuvera for \$670 million.¹¹ **But the most high-profile investment of 2017 goes to Canadian company Canopy Growth, which sold a near-10% stake to the American alcohol company Constellation Brands, producer of brands such as Corona, Modelo, and SVEDKA vodka, for \$191 million.**¹² Without a federal legal framework to rest upon, American cannabis companies are unable to capitalize on these high-profile and lucrative deals. U.S. businesses will spend valuable time and money finding investors and paying expensive interest rates while Canadian companies continue to consolidate their international power. Major multi-billion-dollar international businesses like Constellation Brands will overlook U.S. cannabis companies as they seek out fully legal opportunities abroad.

INTERNATIONAL EXPANSION WITH THE UNITED STATES ON THE SIDELINES

With access to global financial markets, experience producing at pharmaceutical-grade standards, and an internationally legal medical cannabis market expanding, large Canadian public companies are opening up international subsidiaries and solidifying their first-mover position. If the United States continues to delay changes to federal cannabis laws, American firms will be unable to capitalize on legal medical markets abroad. The European Union is home to a population more than 50% larger than the United States, and Canadian firms like Canopy, Tilray, Cronos, Aphria, and Aurora have established supply contracts or subsidiaries in over a half dozen European nations. Cronos Group, currently the only Canadian licensed producer

traded on the Nasdaq stock exchange, recently inked an exclusive agreement to supply medical cannabis to more than 12,000 Germany pharmacies.¹³ Not only are U.S. companies locked within state borders and at a late-start disadvantage internationally, but they have not developed the manufacturing and extraction processes required to meet standards for medical sales in Western Europe. Although most medical cannabis markets internationally have just begun and contain fewer patients than individual American states, many countries will likely use their socialized healthcare systems to centrally control the imported supply of cannabis through traditional pharmaceutical channels. In such systems, establishing government contracts are paramount to the long-term success of a cannabis business globally. Without the legitimacy of a federally regulated system, and at a disadvantage in product development and capital access, American entrepreneurs will be forced to sit on the sidelines while international businesspeople monopolize on the impending worldwide cannabis boom.

POLICY CHANGE NEEDED

It is clear that American cannabis businesses have already missed out on the first wave of international cannabis expansion. In order to prevent the United States from falling further behind, serious federal policy change is needed. Approving additional federally-licensed manufacturers of research-grade medical marijuana, a policy change made by the Obama-era Department of Justice in August of 2016,¹⁴ would be a strong start. Despite bi-partisan support,¹⁵ the Justice Department, led by Attorney General Jeff Sessions, has failed to expand the research program. Still, this necessary policy fix would only put the United States where Israel was almost a decade ago. Catching up with our international competitors requires cannabis entrepreneurs to be permitted to unleash the unique drive of American innovation. This means descheduling cannabis and removing federal barriers that prevent effective banking, institutional investment, and clinical research, while burdening U.S. cannabis businesses with disproportionate taxation. With more than half of American states already regulating medical cannabis production and sales, a centrally-controlled federal program is unnecessary and would further hinder progress. Instead, Congress need only clear a legal runway so existing cannabis businesses operating in conformance with pharmaceutical-grade manufacturing practices can export products pursuant to international law. American providers and entrepreneurs took the first risks on medical cannabis more than 20 years ago and began to develop an industry that has already improved health outcomes for millions of patients. It is time for the U.S. government to acknowledge these major contributions and allow these entrepreneurs to capitalize on one of the most exciting new opportunities to export American products and innovation globally.

FOOTNOTES

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