Public Testimony

Enhancing the Cannabis Research Agenda for the Commonwealth of Massachusetts

Submitted to the

Cannabis Control Commission
Commonwealth of Massachusetts

by

Cannabis Community Care and Research Network (C3RN)

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About Cannabis Community Care and Research Network (C3RN)

Cannabis Community Care and Research Network (C3RN) is a Massachusetts-based research company that specializes in providing high-quality research and analytic services related to the impacts of medical and adult-use recreational Cannabis. As a social justice-oriented company, we specialize in designing, monitoring, and evaluating models of integrating adult-use and medical Cannabis to positively impact social, clinical, and public health outcomes. Our goal is to support the development of a Center of Excellence in Massachusetts that advances the scientific evidence-base for medical and legal Cannabis in the Commonwealth and beyond. For more information about our work and services, please visit: www.cannaresearchnetwork.com

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Acknowledgements
These recommendations related to advancing the research agenda for medical and adult-use Cannabis were prepared for the Cannabis Control Commission (CCC) to consider when designing the regulations for legal adult-use Cannabis in Massachusetts. Special acknowledgements go to Marion McNabb, DrPH, MPH; Margaret D'Elia, MPH candidate; and Randal MacCaffrie, for authoring this paper.

Opportunities for the Commonwealth of Massachusetts

- **Massachusetts is a global healthcare and education leader** and can leverage this expertise to advance medical, social, and economic research related to Cannabis to make it the leading State in the US.
- **The new adult use law in Massachusetts allows research licenses** if the Cannabis Control Commission (CCC) deems this a valuable addition.
- **A Center of Excellence for Cannabis in Massachusetts can be a financial and technical resource to support the CCC and its advisory board.** The advisory board is appointed for a two year term. A Center of Excellence and public fund for research can financially and technically back the State, driven by State and scientific priorities.
- **Expanding the research agenda to include medical, social, and economic outcome research** can make Massachusetts a global leader.

Recommendation One: Include Research Licenses as an Option

The following is recommended:

1. Design a research license program that follows the experiences of Pennsylvania and Washington provisions for research licenses
2. Allow accredited and independent institutional review boards (IRB) to serve as third-party ethical-reviewers of scientific research protocols
3. Ensure that medical Cannabis research funding is a supplement to the current access-based medical Cannabis program and should not replace or require dispensaries, clinicians, or medical patients to participate. All participation in any study should be voluntary and use standard ethical review and consenting procedures.
4. Patient identifying information should be kept confidential and according to HIPPA standards.

Recommendation Two: Add Medical Cannabis Research Topics

1. Expand the research topics to include, **but not limited to**:
    a. Clinical investigations of Cannabis-derived products
    b. Efficacy and safety of administering Cannabis as a part of medical treatment for any qualifying health condition
    c. Efficacy of Cannabis as a therapeutic alternative for opioid and other substance use and recovery
    d. Cannabis and related health indication genomic and other mapping research
    e. Cannabis, hemp, agricultural, horticultural, and related research
    f. Ancillary Cannabis products, consulting, or other related services
2. Follow other State lessons learned in issuing research licenses, allowing academic and private sector to conduct medically focused research studies.

Recommendation Three: Support the Development of a Public Fund for Cannabis Research

The following is recommended:

1. Consider contributing a percentage of the tax money to be allocated for an advanced medical, social, and economic research agenda that can be match by private and philanthropic contributions in the form of a public Cannabis research fund.
2. Consider incentive models such as tax exemption or other incentives for Cannabis industry professionals and other stakeholders to contribute to a public fund. To avoid conflict of interest, the public fund should be governed by a neutral, balanced, and scientifically-driven advisory board.

Recommendation Four: Support the Establishment a Virtual Center of Excellence for Cannabis Care and Research in Massachusetts

The following is recommended:

1. Support the establishment of a Virtual Center of Excellence for Cannabis Care and Research that can drive the scientific agenda for medical and adult-use Cannabis forward.
2. Design the Center of Excellence using lessons learned from national and international public-private partnership (PPP) models that drive innovation.

Letters of Support

The following individuals have submitted letters of support for establishing a Center of Excellence for Cannabis Care and Research in Massachusetts and are included in this submission to the Cannabis Control Commission.

1. **Dr. Alexandros Makriyannis, Northeastern University**
   George D. Behrakis Chair in Pharmaceutical Biotechnology; Director, Center for Drug Discovery, Northeastern University

2. **Dr. Staci Gruber, Harvard University**
   Director Cognitive and Clinical Neuroimaging Core (CCNC); Director, Marijuana Investigations for Neuroscientific Discovery (MIND), McLean Hospital, Associate Professor of Psychiatry, Harvard University

3. **Dr. Vaughan Rees, Harvard University**
   Director, Center for Global Tobacco Control, Harvard University

4. **Dr. James Wolff, Boston University School of Public Health**
   Associate Professor; Boston University School of Public Health and Physician, Vineyard Medical Care

5. **Dr. Jordan Tishler, InhaleMD**
   Board of Directors, Doctors for Cannabis Regulation (DFCR); Regional Director, Society for Cannabis Clinicians

6. **John Wilbanks, Science and Medical Commons Expert**

7. **Catherine (Rina) Cametti, CEO, Beacon Compassion Center, Inc.**

8. **Elizabeth Kinnard, Columbia University**
   Substance Abuse Research Expert

9. **Terry Buffalo, CEO, American Cannabis Company**

10. **Joseph Kreiger, President and CEO, Boston BioLife**

11. **Stacy Moore, Founder and Partner, Healing Harbors, Maine**

12. **Kirby Mastrangelo, Owner, Humble Bumble**

13. **Joe Gilmore, University of Massachusetts, Boston**
    President, Students for Sensible Drug Policy

14. **Sonia Espinosa**, Co-Founder, Massachusetts Recreational Consumer Council (MRCC)

Background

Nearly all of the States in the United States have adopted laws that permit the use of Cannabis, either medically or recreationally. Each State has its own jurisdiction, legal structure, and regulatory structure with regards to Cannabis, yet are still subject to Federal jurisdiction. The Federal government has not yet legalized Cannabis, and maintains strict policies and regulations on research regarding the health effects of Cannabis.

As a result, patients, healthcare providers, and policy makers are left with an absence of necessary information to make educated decisions. The classification of Cannabis as a Schedule I substance impedes the needed advances of Cannabis research. Federal regulations only allow researchers to study the health impacts associated with Cannabis flower cultivated by a facility approved by the DEA in Mississippi. Researchers are restricted in terms of quantity, quality, and type of Cannabis products compared to those widely available in the market.

However, in a legal adult-use State such as Massachusetts, the potential to explore the medical benefits using real world observation can further the field of Medical Cannabis. The lack of funding is critical barrier to Cannabis research. A strong and diverse network of funders is required to allow for the in-depth research required to allow interested Cannabis experts, researchers, clinicians, policy makers, patients, consumers, and advocates to advance the field.

In order to further the evidence related to the effects of short and long-term Cannabis use on health outcomes, improvements and standardization of protocols in controlled and observational trials are essential. Without a State-supported, diversely funded, and comprehensive research agenda, patients will be unaware of treatment options, providers will not be able to prescribe the most effective medications, policy makers will be unable to make evidence-based policies, and healthcare organizations and insurance providers will lack the knowledge they require to adapt to integrating effective preventative and curative therapies.

Opportunities for the Commonwealth of Massachusetts

- **Massachusetts is a global healthcare and education leader** and can leverage this expertise to advance medical, social, and economic research related to Cannabis to make it the leading State in the US.
- **The new adult use law in Massachusetts allows research licenses** if the Cannabis Control Commission (CCC) deems this a valuable addition.
- **A Center of Excellence for Cannabis in Massachusetts can be a financial and technical resource to support the CCC and its advisory board.** The advisory board is appointed for a two year term. A Center of Excellence and public fund for research can financially and technically back the State, driven by State and scientific priorities.
- **Expanding the research agenda to include medical, social, and economic outcome research** can make Massachusetts a global leader.

Barriers to Conducting Medical Cannabis Research

Cannabis was used as a medicine as many as 5,000 years ago. Until 1942, Cannabis was included in the American pharmacopoeia and between 1840-1900 more than 100 articles were published regarding the efficacy of Cannabis. The research on Cannabis was halted when the Marijuana Tax Act of 1937 was imposed, required tax stamps for the cultivation, possession, and consumption of Cannabis. However, none of these stamps were distributed, essentially making Cannabis illegal.[1]

The Federal government has historically only allowed one Cannabis cultivation facility in the United States, the University of Mississippi School of Pharmacy, to provide Cannabis for clinical trials related to the medicinal value of Cannabis in the United States.[2] The School of Pharmacy's Cannabis is far from representative of the types and potency of Cannabis currently available in the market. The lack of diversity of Cannabis options available for researchers coupled with significant Federal hurdles has left scientists with essentially two choices. They can spend years attempting to gain approval to administer Cannabis in a clinical trial only to be provided the federally grown Cannabis, or they can conduct an observational trial in which researchers monitor patients already using Cannabis on their own. The regulations for legal adult-use Cannabis are currently being designed by the Cannabis Control Commission (CCC) in Massachusetts. Within a new legal adult-use market, there is an opportunity to be innovative on the research methods, funding streams, and ways to increase participation in conducting observational and rigorous trials documenting the impact of Cannabis.

In response to long-term advocacy calling for more research, in 2016 the Drug Enforcement Agency (DEA) announced that it would begin accepting 25 applications for researchers to get licenses to cultivate Cannabis for research purposes.[3] As of October 31, 2017 only a few groups have been granted licenses. Other researchers, including Professor Lyle Cracker of the University of Massachusetts in Amherst, who has been applying for years to get a research license, still has failed to receive approval. While these hurdles obtaining licenses from the Federal level remain, there are options for States to consider adopting their own research agenda.[4]

The continued advocacy to expand the research agenda for medical Cannabis prompted the January 2017 National Academics of Science, Engineering, and Medicine release of the Health and Health Effects of Cannabis and Cannabinoids report.[5] The authors reviewed over 10,000 peer-reviewed publications and noted several barriers to conducting research for Cannabis:

- "There are specific regulatory barriers, including the classification of Cannabis as a Schedule I substance, that impede the advancement of Cannabis and Cannabinoid research (15-1)
- It is often difficult for researchers to gain access to the quantity, quality, and type of Cannabis product necessary to address specific research questions on the health effects of Cannabis use (15-2)

- A diverse network of funders is needed to support Cannabis and Cannabinoid research that explores the beneficial and harmful effects of Cannabis use (15-3)
- To develop conclusive evidence for the effects of Cannabis use for short- and long-term health outcomes, improvements and standardization in research methodology (including those used in controlled trials and observational studies) are needed (15-4)"[5]

Despite Federal regulatory and funding barriers to advancing the Medical Cannabis research agenda, experiences from other States designing local research agendas can be leveraged for Massachusetts. Adopting a State-wide strategy for Medical and Adult-use Cannabis research will make Massachusetts a global leader.

Massachusetts: A Global Healthcare and Innovation Leader

Massachusetts has been a global healthcare and innovation leader since the early 1900's when the inoculation for smallpox was first introduced.[6] Today, Boston boasts an impressive number of innovation centers with projects based both in Massachusetts alone as well as multiple inter-state projects.[7] There are over 130 universities of higher education in Massachusetts and over 50 in the Boston metro area alone. In total, there are eleven health care innovation projects involving Massachusetts, with an impressive four of those projects being geographically based in Massachusetts.[7]

Not only does Massachusetts' innovations set it apart in the rest of the world, but so does the caliber of medical education available in the Commonwealth. Boston is a mecca of medicine, with some of the most prestigious universities, scientists, and physicians in the world. Boston is home to more than twenty hospitals, and dozens more lie only miles outside of the city.[8] Each year, hospitals such as Mass General and Brigham and Women's Hospital rank among the best in the United States.[8] Additionally, Massachusetts Institute of Technology (MIT) and Harvard University were ranked first and second in the world in the QS World University Rankings in 2015/2016.[9] Boston houses another five universities which rank in the top 400, further solidifying Boston's status as an education capital of the world. The medical field in Boston not only provides a rigorous education, but is one of the most competitive places to work as a physician.[10]

The top-notch level of medicine offered in Massachusetts does not go unnoticed globally. Organizations such as the Dana-Farber Cancer Institute attracts patients seeking innovative new treatments from around the world.[11] Patients travel from across the world for a variety of reasons including cancer, orthopedics, cosmetic surgery, dentistry, and cardiovascular surgery.[12] The medical tourism market is estimated at $45.5-72 billion USD based on roughly 14 million cross-border patients worldwide who spend an average of $3,800-6,000 USD per visit.[12] The healthcare tourism market is growing at a rate of 15-25% due to the aging global population and the rising out-of-pocket medical costs of both essential and elective procedures.[12]

As of September 30th, 2017, the state of Massachusetts has 15 registered medical dispensaries (RMDs) operating, 41,077 active medical cannabis patients, 208 registered physicians, and 45,560 active physician certifications.[13] Through embracing the potential of Cannabis in healthcare, Massachusetts can even further itself as an innovator. To do so, further program innovations, coupled with scientifically sound research methods and standards is required.

Massachusetts has the opportunity during the design of the adult-use Cannabis regulations to include provisions for research licenses to develop an advanced research agenda in the Commonwealth.

Cannabis Research Recommendations for the CCC

The following sections outline the research related recommendations for the CCC, with supporting evidence and lessons learned from other legal adult-use and medical Cannabis States.

Recommendation One: Include Research Licenses as an Option

Currently, the Massachusetts legal Cannabis laws allow the CCC to consider including Research licenses as an option. There are several States that have moved towards advancing the medical research agenda, funded by the State and other private sector sources. According to the latest scientific findings published in the Health effects of Cannabis and Cannabinoids Report of 2017, “it is often difficult for researchers to gain access to the quantity, quality, and type of cannabis product necessary to address specific research questions on the health effects of cannabis use”.[5] Massachusetts can address this barrier by allowing local research licensing to examine the health effects of Cannabis.

The following is recommended:

5. Design a research license program that follows the experiences of Pennsylvania and Washington provisions for research licenses
6. Allow accredited and independent institutional review boards (IRB) to serve as third-party ethical-reviewers of scientific research protocols
7. Ensure that medical Cannabis research funding is a supplement to the current access-based medical Cannabis program and should not replace or require dispensaries, clinicians, or medical patients to participate. All participation in any study should be voluntary and use standard ethical review and consenting procedures.
8. Patient identifying information should be kept confidential and according to HIPPA standards.

The Massachusetts Policy Project has reviewed several States research agendas and suggests the following best practices:

- Research provisions should be supplemental to a state-based system for access, rather than seeking to serve as a substitute for such a program.

- Do not combine the Medical Cannabis program with any research program, and do not require anyone to participate. Rather, encourage voluntary participation only following State guidance
- Avoid cumbersome requirements on dispensaries and patients that can drive up costs and reduce participation.

Below is a review of each State that has made provisions for research licenses, including lessons learned.

STATE RESEARCH EXAMPLES AND LESSONS LEARNED

Colorado

In May 2017, Colorado legislators passed HB 1367, a bill that allows for state approved research and development licenses for clinical studies on potency, chemical composition, agriculture, and other areas regarding cannabis. The Marijuana Enforcement Division (MED) will issue these licenses for public and private studies by both nonprofit and government organizations and commercial businesses. Although there was general agreement regarding including retail cannabis in the bill, retail cannabis cannot be added to the program because, according to the Colorado Attorney General's Office, retail and medical products can't intermingle.[14]

Applicants will submit a project proposal to an institutional review board (IRB) and then the MED for approval before obtaining a license. As it currently stands, the length of the review time is recommended to be ninety days. Under the new law, the categories for research are:[14]

- Chemical potency and composition levels
- Clinical investigations of marijuana-derived products
- Efficacy and safety of administering marijuana as a part of medical treatment
- Genomic research
- Horticultural research
- Agricultural research
- Marijuana-affiliated products or systems

Lesson Learned[14]

- Researchers are generally frustrated with the long ethical review time
- Retail and medical Cannabis research was deemed to be separate per the Colorado State Attorney General due to the language used in the bill

Washington

In Washington, state research for Cannabis has been stalled for nearly three years due to administrative problems. Research license provisions are present however, and a law passed in 2016 for a new type of Cannabis license for firms intending to conduct Cannabis research. The new law requires a third party scientific reviewer explore the scientific merits for each applicant.

To date, there have not been any successful scientific reviewers who have applied to serve as the review board.[15]

The first version if the law dubs the state's Life Sciences Discovery Fund the scientific reviewer, but the organization was defunded last year. The hope was that either the University of Washington or Washington State University would step in as scientific reviewer, but neither school submitted an application. Cost was the main barrier in determining a scientific reviewer, as there is no indication of how many applications will be submitted and who would fund the work.[15] The Washington State Liquor and Cannabis Board had said it would begin accepting applications March 1, 2017, but that date has been continually pushed back.[16]

Washington's statute RCW.69.50.372 states that cannabis license holders may "produce, process, and possess marijuana for...limited research purposes". Research categories are restricted to:[16]

- Tests of chemical potency and composition
- Clinical investigation of cannabis-derived drugs
- Tests regarding the efficacy and safety of cannabis as a medical treatment
- Genomic or agricultural research

Lessons Learned

- There was no capital for Universities to do review and facilitate research applications, limiting interest at the academic level
- The application for research costs $250[17]

Pennsylvania

The Pennsylvania (PA) Medical Marijuana Act actively promotes Medical Cannabis research through a State-sponsored program to clinically study the medicinal impact of Cannabis therapies. This is a front runner state to permit the study for medical conditions. This Act provides protection for researchers to conduct human trials that are not allowed under Federal law, allowing freedom for academics.[18]

Quote: "The Act authorizes and directs the State's Department of Health (DOH) to petition the United States Food and Drug Administration (FDA) and the United States Drug Enforcement Administration (DEA) for approval to conduct medical marijuana research into serious medical conditions. DOH is also specifically tasked to seek participation from health systems and universities to conduct this research."[19] In PA law, as quoted: "the funding for research is derived from fees and taxes paid by medical marijuana organizations pursuant to the Act. The Act dedicates thirty-percent of the revenue from these fees and taxes to research: (1) medical marijuana treatment for serious medical conditions defined in the Act, and (2) the use of medical marijuana as a treatment for other medical conditions "for which medical marijuana may have legitimate medicinal value." Money in the fund can also be used to pay for the cost of the medical marijuana dispensed to patients in accordance with an approved research study."[19]

Maine

Maine established a Marijuana Research Fund that is supported by the Department of Health and Human Services.[20] The research fund is provided revenue through a 5% tax revenue designated for medical benefits research and also through voluntary donation.[20] The money within the fund is used to provide grants to allow for peer-reviewed research on cannabis' beneficial uses and safety.[20] The money is also used to cover administrative and management costs associated with the research.[20]

The government of Maine authorizes research with the following statement: "Notwithstanding the provisions of this chapter regulating the distribution of marijuana, a scientific or medical researcher who has previously published peer-reviewed research may purchase, possess and securely store marijuana for purposes of conducting research. A scientific or medical researcher may administer and distribute marijuana to a participant in research who is at least 21 years of age after receiving informed consent from that participant."[20]

A set of rules was adopted by the Department of Health and Human Services regarding the research on Cannabisd.[20] These rules include:[20]

- Application procedures, forms, deadlines and eligibility criteria for grants
- Selection criteria and composition of a grant review committee, which must include researchers with expertise in medical or scientific research
- Criteria for awarding grants, dates for decisions of grant awards and methods for disbursement of funds
- Minimum record-keeping, reporting and publication requirements for persons awarded grants
- Any other oversight requirements that the department determines necessary to administer the grants

Lessons Learned

- A tax revenue of 5%, placed into an interest gaining fund, provides adequate research funding
- The fund only provides grants to study medical cannabis, not recreational[20]

Connecticut

In Connecticut, licenses for research are provided after an application process.[21] Hospitals or health care facilities licensed under Chapter 368v, institutions of higher education as defined in Section 10a-55 of the General Statutes, licensed medical cannabis producers, and licensed medical cannabis dispensaries may apply.[21] Approval may be granted to programs seeking to increase knowledge or information regarding the growth, processing, medical attributes, dosage forms, and administration or use of cannabis to treat or alleviate symptoms of any medical conditions or the effects of those symptoms.[21]

The Department of Consumer Protection (DCP) will review applications as received.[21] If a program is approved, employees who will have access to Cannabis in connection with the research must apply for a license.[21] If the person is already licensed as an employee at a licensed medical cannabis business however, that person does not need to apply for such a license.[21]

Lessons Learned

- Studies need IRB approval, but don't need to be approved as an ethical body by the DCP. Meaning, any IRB can be used.
- Research licenses are $200
- Only applies to Medical Cannabis

Oregon

In Oregon, the Oregon Liquor Control Commission (OLCC) along with the Oregon Health Authority and Oregon Department of Agriculture will review the initial submissions of research proposals.[22] The proposal should contain the research question, detail the methodology of the study, and provide a research budget.[22] The information submitted is public record.[22]

Lessons Learned

- Studies require OLCC, Oregon Health Authority, and Oregon Department of Agriculture approval[22]
- Only applies to Medical Cannabis[22]

Florida

As of July 2017, Florida's Bill will be in effect that "Establishes the Coalition for Medicinal Cannabis Research and Education (Coalition), within the H. Lee Moffitt Cancer Center and Research Institute, Inc. (MCCRI) and specifies the Coalition's purpose, duties and administration; Creates the Medicinal Cannabis Research and Education Board to direct the Coalition's operations, annually adopt the Medicinal Cannabis Research and Education Plan, and annually report to the Governor and Legislature."[23]

Lessons Learned

- Only applied to Medical Cannabis research

California

The Center for Medicinal Cannabis Research was established at the University of California and has extensively studied the safety and efficacy of Medicinal Cannabis.[24] The Center was initially state funded and is a collaboration between UCSD and UCSF.[24] Cannabis research at the University of California is subject to federal rules and regulations despite the passage of Proposition 64, which permits the use, sale processing, and production of Cannabis for nonmedical purposes in addition to already permitted medical use.[25]

Lessons Learned

- Only applies to Medical Cannabis research

Utah

In 2017, Utah allowed state colleges and other institutions to study the medical impacts of Cannabis in an attempt to gather comprehensive data by 2018.[26] What was not conveyed to researchers was the laborious process involved with applying to conduct Cannabis research.[26] It typically takes two and a half months to get FDA approval and to complete the registration process with the DEA.[26]. Apply for research licenses and passing ethical review boards may take up to ten months if the researchers are requesting funding.[26] Utah currently only performs medical Cannabis research and the cost of applying for a research license is yet to be determined.[27]

Lessons Learned

- Only applies to Medical Cannabis research

New Mexico

The Medical Cannabis Research Fund (MCRF) was established at the University of New Mexico and consists of faculty and researchers at the University.[28] Direct costs of the MCRF are covered primarily by donations to the fund.[28] Researchers are studying the safety and efficacy of Cannabis as a pharmacological agent in scientifically valid and unbiased research.[28] Of the challenges encountered, the greatest barrier has been the federal regulations surrounding Cannabis and its classification as a Schedule I substance.[28]

Lessons Learned

- Only applies to Medical Cannabis research

Recommendation Two: Add Medical Cannabis Research Topics

Currently, the adult-use Cannabis law allows the research topics listed below. These topics listed below are important, however adding additional Medical Cannabis focused topics can make Massachusetts a leader and can leverage the scientific, academic, and local Cannabis community to generate global best practices and a robust evidence-base to quickly and positively impact the opioid epidemic.[29]

The following is recommended:

3. Expand the research topics to include, **but not limited to**:
    a. Clinical investigations of Cannabis-derived products
    b. Efficacy and safety of administering Cannabis as a part of medical treatment for any qualifying health condition

   c. Efficacy of Cannabis as a therapeutic alternative for opioid and other substance use and recovery
   d. Cannabis and related health indication genomic and other mapping research
   e. Cannabis, hemp, agricultural, horticultural, and related research
   f. Ancillary Cannabis products, consulting, or other related services
4. Follow other State lessons learned in issuing research licenses, allowing academic and private sector to conduct medically focused research studies.

According to the Massachusetts law, the following are the research topics included:[29]

- "patterns of use, methods of consumption, sources of purchase, and perceptions of cannabis among minors, college and university students, and adults
- incidents of impaired driving, hospitalization, and use of other health care services related to cannabis use
- economic impacts for state and local governments including the impact of legalization on the production and distribution of cannabis in the illicit market and the costs and benefits to state and local revenue
- ownership and employment trends in the cannabis industry examining participation by racial, ethnic, and socioeconomic subgroups, including identification of barriers to participation in the industry
- a market analysis examining the expansion or contraction of the illicit marketplace and the expansion or contraction of the legal marketplace including estimates and comparisons of pricing and product availability in both markets
- a compilation of data on the number of incidents of discipline in schools, including suspensions or expulsions, resulting from cannabis use or possession
- a compilation of data on the number of civil penalties, arrests, prosecutions, incarcerations, and sanctions imposed for violations of chapter 94C for possession, distribution or trafficking of cannabis or cannabis products"

There is room in the Cannabis research agenda to expand documentation related to social, economic, and health outcomes for Cannabis. At C3RN, we follow the recommendations of the Health Effects of Cannabis and Cannabinoids 2017 report.[30] Massachusetts can expand the network of funders and design an advanced research agenda. Key recommendations of interest:

- To develop conclusive evidence for the effects of cannabis use for short- and long-term health outcomes, improvements and standardization in research methodology (including those used in controlled trials and observational studies) are needed (15-4)

The State can work with several Universities, clinical providers and other relevant stakeholders to design standards that can guide both observational and controlled trials to further the evidence base for medical Cannabis. In addition to studying the medical benefits, other topics including social and economic impacts of medical and adult-use Cannabis can be considered.

Recommendation Three: Support the Development of a Public Fund for Cannabis Research

Currently, the tax revenue for adult-use Cannabis sales in Massachusetts is earmarked to support the Wellness fund and research on select topics. As per the latest scientific recommendations regarding Medical Cannabis research, one of the major barriers relates to the lack of funding to conduct Medically-focused studies. Specifically, one conclusion stated as per authors of the Health Effects of Cannabis and Cannabinoids Report 2017 was:

"A diverse network of funders is needed to support Cannabis and Cannabinoid research that explores the beneficial and harmful effects of Cannabis use (Health Effects of Cannabis and Cannabinoids Reccomendation15-3, 2017)"[31]

Expanding the pool of funders for researching Cannabis, in addition to State funds, can increase the pool of resources available for Cannabis Industry and Researchers alike.

The following is recommended:

3. Consider contributing a percentage of the tax money to be allocated for an advanced medical, social, and economic research agenda that can be match by private and philanthropic contributions in the form of a public Cannabis research fund.
4. Consider incentive models such as tax exemption or other incentives for Cannabis industry professionals and other stakeholders to contribute to a public fund. To avoid conflict of interest, the public fund should be governed by a neutral, balanced, and scientifically-driven advisory board.

Recommendation Four: Support the Establishment a Virtual Center of Excellence for Cannabis Care and Research in Massachusetts

There are over 130 academic institutions in Massachusetts, numerous innovation labs, and state up accelerators. Additionally, Massachusetts is a leader in healthcare innovations and many travel here to receive advanced and specialized healthcare. With a high concentration of clinical and academic experts from many disciplines, the Commonwealth can leverage these specialties to advance clinical research for a wide variety of health conditions where Cannabis is considered a therapeutic alternative. A network of clinicians, researchers, Cannabis Industry experts, housed within a virtual Center of Excellence model, is in line with industry and Federal government intentions to foster more public-private partnerships that advance innovation and best practices.

The following is recommended:

3. Support the establishment of a Virtual Center of Excellence for Cannabis Care and Research that can drive the scientific agenda for medical and adult-use Cannabis forward.
4. Design the Center of Excellence using lessons learned from national and international public-private partnership (PPP) models that drive innovation.

What is a Center of Excellence?

Per the Office of American Innovation (OAI), the center of excellence (CoE) model of government innovation focuses structure, attention, and resources around multiple CoEs that inspire research, best practices, and solution creation in key areas of interest[32]. Chris Liddell, White House Director of Strategic Innovations, has begun to make the case for such CoEs[32]. Within the government model, the combination of the Federal government and private sector capabilities might result in centralized entities with specific expertise[32].

Key areas of benefit have been identified as probable outcomes from moving to the CoE structure. These benefits include building upon existing government-industry collaborations, testing disruptive business models beyond shared services, and to identify where resources are being expended and work to expand capabilities and access[32].

The proposed Center of Excellence for Cannabis Care and Research would incorporate lessons from traditional Public-Private partnership (PPP) models. PPPs are a tool to deliver necessary public services and develop innovative infrastructure via the collaboration of governments, universities, institutions, and corporations interested in addressing the issues in a creative way[32]. PPPs develop innovative and conceptual frameworks for addressing a problem rather than using standardized conventional protocols. PPPs are supported by public, private, or non-profit partners who share risks, resources, and decisions regarding certain projects[32].

Biomedical PPPs have begun to generate tangible outcomes[33]. These outcomes are far reaching into the pharmaceutical industry, academia, health foundation's, patient organizations, and regulatory agencies[33]. It should be noted that there is a long timeline for the uptake of validated new developments in the biomedical and pharmaceutical fields, so continuation of the PPPs beyond the initially decided upon time span is necessary for their success[33].

Given the nature of the new Cannabis industry in Massachusetts, forming a partnership between private and public sectors can drive innovation and make the Commonwealth a Cannabis Industry leader globally.

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Annexes

Annex One: Research Language: Massachusetts Adult-Use Cannabis Law

Quote: The CCC will develop a comprehensive research agenda to evaluate the social and economic impacts of cannabis in the commonwealth, to provide evidence on which to base decisions regarding the closure of the black market, and to provide evidence of the public health impact of cannabis. The research agenda will include the following:

- patterns of use, methods of consumption, sources of purchase, and perceptions of cannabis among minors, college and university students, and adults
- incidents of impaired driving, hospitalization, and use of other health care services related to cannabis use
- economic impacts for state and local governments including the impact of legalization on the production and distribution of cannabis in the illicit market and the costs and benefits to state and local revenue
- ownership and employment trends in the cannabis industry examining participation by racial, ethnic, and socioeconomic subgroups, including identification of barriers to participation in the industry
- a market analysis examining the expansion or contraction of the illicit marketplace and the expansion or contraction of the legal marketplace including estimates and comparisons of pricing and product availability in both markets
- a compilation of data on the number of incidents of discipline in schools, including suspensions or expulsions, resulting from cannabis use or possession
- a compilation of data on the number of civil penalties, arrests, prosecutions, incarcerations, and sanctions imposed for violations of chapter 94C for possession, distribution or trafficking of cannabis or cannabis product

The research agenda will include current data and the results will be annually reported, with the first report being on or before July 1st, 2019.

Research Language in the Law in Massachusetts

Section 17. (a) The commission shall develop a research agenda in order to understand the social and economic trends of marijuana in the commonwealth, to inform future decisions that would aid in the closure of the illicit marketplace and to inform the commission on the public health impacts of marijuana. The research agenda shall include, but not be limited to: (i) patterns of use, methods of consumption, sources of purchase and general perceptions of marijuana among minors, among college and university students and among adults; (ii) incidents of impaired driving, hospitalization and use of other health care services related to marijuana use, including a report of the state of the science around identifying a quantifiable level of marijuana-induced impairment of motor vehicle operation and a report on the financial impacts on the state healthcare system of hospitalizations related to marijuana ; (iii) economic

and fiscal impacts for state and local governments including the impact of legalization on the production and distribution of marijuana in the illicit market and the costs and benefits to state and local revenue; (iv) ownership and employment trends in the marijuana industry examining participation by racial, ethnic and socioeconomic subgroups, including identification of barriers to participation in the industry; (v) a market analysis examining the expansion or contraction of the illicit marketplace and the expansion or contraction of the legal marketplace including estimates and comparisons of pricing and product availability in both markets; and; (vi) a compilation of data on the number of incidents of discipline in schools, including suspensions or expulsions, resulting from marijuana use or possession of marijuana or marijuana products; and (vii) a compilation of data on the number of civil penalties, arrests, prosecutions, incarcerations and sanctions imposed for violations of chapter 94C for possession, distribution or trafficking of marijuana or marijuana products, including the age, race, gender, country of origin, state geographic region and average sanctions of the persons charged.

(b) The commission shall incorporate available data into its research agenda, including the baseline study conducted pursuant to chapter 351 of the acts of 2016, and coordinate and form partnerships with the department of public health, the department of elementary and secondary education, the department of higher education, the executive office of public safety and security and the executive office of labor and workforce development. The commission shall annually report on the results of its research agenda and, when appropriate, make recommendations for further research or policy changes. The annual reports shall be posted online in a machine-readable format. The commission shall publish the first such report not later than July 1, 2019.

Research tax provisions in the Massachusetts law

(b) Money in the fund shall be subject to appropriation. Money in the fund shall be expended for the implementation, administration and enforcement of this chapter by the commission and by the department of agricultural resources for the implementation, administration and enforcement of sections 116-123, inclusive, of chapter 128 and the provision of pesticide control pursuant to chapter 132B. Thereafter, money in the fund shall be expended for: (i) public and behavioral health including but not limited to, evidence-based and evidence-informed substance use prevention and treatment and substance use early intervention services in a recurring grant for school districts or community coalitions who operate on the strategic prevention framework or similar structure for youth substance use education and prevention; (ii) public safety; (iii) municipal police training; (iv) the Prevention and Wellness Trust Fund established in section 2G of chapter 111; and (v) programming for restorative justice, jail diversion, workforce development, industry specific technical assistance, and mentoring services for economically-disadvantaged persons in communities disproportionately impacted by high rates of arrest and incarceration for marijuana offenses pursuant to chapter 94C.

Prevention and Wellness Fund Language

Section 2G of Chapter 111. (a) There shall be established and set upon the books of the commonwealth a separate fund to be known as the Prevention and Wellness Trust Fund to be expended, without further appropriation, by the department of public health. The fund shall consist of revenues collected by the commonwealth including: (1) any revenue from

appropriations or other monies authorized by the general court and specifically designated to be credited to the fund; (2) any fines and penalties allocated to the fund under the General Laws; (3) any funds from public and private sources such as gifts, grants and donations to further community-based prevention activities; (4) any interest earned on such revenues; and (5) any funds provided from other sources.

The commissioner of public health, as trustee, shall administer the fund. The commissioner, in consultation with the Prevention and Wellness Advisory Board established under section 2H, shall make expenditures from the fund consistent with subsections (d) and (e) ; provided, that not more than 15 per cent of the amounts held in the fund in any 1 year shall be used by the department for the combined cost of program administration, technical assistance to grantees or program evaluation.

(b) Revenues deposited in the fund that are unexpended at the end of the fiscal year shall not revert to the General Fund and shall be available for expenditure in the following fiscal year.

(c) All expenditures from the Prevention and Wellness Trust Fund shall support the state's efforts to meet the health care cost growth benchmark established in section 9 of chapter 6D and any activities funded by the Healthcare Payment Reform Fund and 1 or more of the following purposes: (1) reduce rates of the most prevalent and preventable health conditions, including substance abuse; (2) increase healthy behaviors; (3) increase the adoption of workplace-based wellness or health management programs that result in positive returns on investment for employees and employers; (4) address health disparities; or (5) develop a stronger evidence-base of effective prevention programming.

(d) The commissioner shall annually award not less than 75 per cent of the Prevention and Wellness Trust Fund through a competitive grant process to municipalities, community-based organizations, health care providers, regional-planning agencies, and health plans that apply for the implementation, evaluation and dissemination of evidence-based community preventive health activities. To be eligible to receive a grant under this subsection, a recipient shall be: (1) a municipality or group of municipalities working in collaboration; (2) a community-based organization working in collaboration with 1 or more municipalities; (3) a health care provider or a health plan working in collaboration with 1 or more municipalities and a community-based organization; or (4) a regional planning agency. Expenditures from the fund for such purposes shall supplement and not replace existing local, state, private or federal public health-related funding; or a community-based organization or group of community-based organizations working in collaboration.

(e) A grant proposal submitted under subsection (d) shall include, but not be limited to: (1) a plan that defines specific goals for the reduction in preventable health conditions and health care costs over a multi-year period; (2) the evidence-based programs the applicant shall use to meet the goals; (3) a budget necessary to implement the plan, including a detailed description of any funding or in-kind contributions the applicant or applicants will be providing in support of the proposal; (4) any other private funding or private sector participation the applicant anticipates in support of the proposal; (5) a commitment to include women, racial and ethnic minorities and low income individuals; and (6) the anticipated number of individuals that would be affected by implementation of the plan.

Priority may be given to proposals in a geographic region of the state with a higher than average prevalence of preventable health conditions, as determined by the commissioner of public

health, in consultation with the Prevention and Wellness Advisory Board. If no proposals were offered in areas of the state with particular need, the department shall ask for a specific request for proposal for that specific region. If the commissioner determines that no suitable proposals have been received, such that the specific needs remain unmet, the department may work directly with municipalities or community-based organizations to develop grant proposals.

The department of public health shall, in consultation with the Prevention and Wellness Advisory Board, develop guidelines for an annual review of the progress being made by each grantee. Each grantee shall participate in any evaluation or accountability process implemented or authorized by the department.

(f) The commissioner of public health may annually expend not more than 10 per cent of the Prevention and Wellness Trust Fund to support the increased adoption of workplace-based wellness or health management programming. The department of public health shall expend such funds for activities including, but not limited to: (1) developing and distributing informational tool-kits for employers, including a model wellness guide developed by the department; (2) providing technical assistance to employers implementing wellness programs; (3) hosting informational forums for employers; (4) promoting awareness of wellness tax credits provided through the state and federal government, including the wellness subsidy provided by the commonwealth health connector authority; (5) public information campaigns that quantify the importance of healthy lifestyles, disease prevention, care management and health promotion programs; and (6) providing stipends or grants to employers for the implementation and administration of workplace wellness programs in an amount up to 50 per cent of the costs associated with implementing the plan, subject to a cap as established by the commissioner based on available funds; provided, however, that any grants offered in connection with a workplace wellness program eligible for a tax credit under section 6N of chapter 62 and section 38FF of chapter 63 shall not, in combination with such tax credit, exceed 50 per cent of the costs associated with implementing the plan.

The department of public health shall develop guidelines to annually review progress toward increasing the adoption of workplace-based wellness or health management programming.

(g) The department of public health shall, annually on or before January 31, report on expenditures from the Prevention and Wellness Trust Fund. The report shall include, but not be limited to: (1) the revenue credited to the fund; (2) the amount of fund expenditures attributable to the administrative costs of the department of public health; (3) an itemized list of the funds expended through the competitive grant process and a description of the grantee activities; (4) the results of the evaluation of the effectiveness of the activities funded through grants; and (5) an itemized list of expenditures used to support workplace-based wellness or health management programs. The report shall be provided to the chairpersons of the house and senate committees on ways and means and the joint committee on public health and shall be posted on the department of public health's website.

(h) The department of public health shall, under the advice and guidance of the Prevention and Wellness Advisory Board, annually report on its strategy for administration and allocation of the fund, including relevant evaluation criteria. The report shall set forth the rationale for such strategy, including, but not limited to: (1) a list of the most prevalent preventable health conditions in the commonwealth, including health disparities experienced by populations based on race, ethnicity, gender, disability status, sexual orientation or socio-economic status; (2) a list

of the most costly preventable health conditions in the commonwealth; (3) a list of evidence-based or promising community-based programs related to the conditions identified in clauses (1) and (2); and (4) a list of evidence-based workplace wellness programs or health management programs related to the conditions in clauses (1) and (2). The report shall recommend specific areas of focus for allocation of funds. If appropriate, the report shall reference goals and best practices established by the National Prevention and Public Health Promotion Council and the Centers for Disease Control and Prevention, including, but not limited to the national prevention strategy, the healthy people report and the community prevention guide.

(i) The department of public health shall promulgate regulations necessary to carry out this section.

Annex Two: Letters of Recommendation for a Cannabis Center of Excellence

The following letters of support have been submitted to C3RN to initiate the establishment of a virtual Center of Excellence for Cannabis Care and Research in Massachusetts:

1. **Dr. Staci Gruber, Harvard University**
   Director Cognitive and Clinical Neuroimaging Core (CCNC); Director, Marijuana Investigations for Neuroscientific Discovery (MIND), McLean Hospital, Associate Professor of Psychiatry, Harvard University
2. **Dr. Alexandros Makriyannis, Northeastern University**
   George D. Behrakis Chair in Pharmaceutical Biotechnology; Director, Center for Drug Discovery, Northeastern University
3. **Dr. Vaughan Rees, Harvard University**
   Director, Center for Global Tobacco Control, Harvard University
4. **Dr. James Wolff, Boston University School of Public Health**
   Associate Professor; Boston University School of Public Health and Physician, Vineyard Medical Care
5. **Dr. Jordan Tishler, InhaleMD**
   Board of Directors, Doctors for Cannabis Regulation (DFCR); Regional Director, Society for Cannabis Clinicians
6. **Elizabeth Kinnard, Columbia University**
   Substance Abuse Research Expert
7. **John Wilbanks,** Science and Medical Commons Expert
8. **Stacy Moore,** Founder and Partner, Healing Harbors, Maine
9. **Kirby Mastrangelo,** Owner, Humble Bumble
10. **Catherine (Rina) Cametti,** CEO, Beacon Compassion Center, Inc.
11. **Joseph Kreiger,** President and CEO, Boston BioLife
12. **Terry Buffalo**, CEO, American Cannabis Company
13. **Joe Gilmore**, President, Students for Sensible Drug Policy, University of Massachusetts, Boston