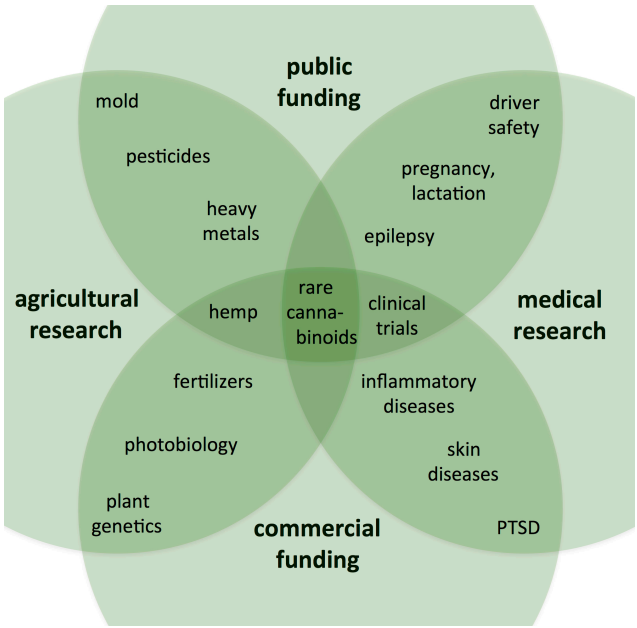
Cannabis research in Oregon under Measure 91
Mowgli Holmes, May 2015

The Cannabis industry is springing into existence essentially overnight. It is an unprecedented hybrid kind of industry - an agricultural product that is the source of a family of chemical compounds with many potential pharmaceutical uses. Because this plant is federally illegal, we do not have access to any of the basic medical and clinical research that would already exist for any other set of promising drug candidates. Nor do we do not have access to the basic agricultural research necessary for this new industry to run smoothly, efficiently, or safely.

Other agricultural and pharmaceutical industries today are highly modernized, because of years of research and development conducted both by public institutions and by companies. The recent wave of state-level Cannabis legalization has made a new industry possible, but it has not made possible the scientific research that supports and drives modern agriculture and medicine. This is largely because commerce can be done at a state level, but it is extremely hard to do *research* at a state level. In the United States, the vast majority of research is federally funded. This publicly-funded research infrastructure supports basic science that agriculture and medicine are dependent on, as well as public health and safety research that places critical limits on industry.

The intersections between public and private research are complex, and this is especially true for Cannabis. The legal issues that will determine which types of Cannabis research may be done in which kind of setting add another layer of complexity. This document was written in an attempt to clarify which public or private institutions might be able to carry out critical Cannabis research, in light of the



current conflict between state and federal law.

There are essentially three categories of public research institution, each with their own restrictions regarding approval and funding of research. These are: 1) universities, 2) federal agencies, and 3) state agencies. Private research can be carried out through either companies or non-profits. The sections below outline the types of Cannabis research that can be done in each of these settings.

Universities

In the United States, all research universities are dependent on this funding, and must remain in strict compliance with federal law. Federal laws are extremely restrictive with regard to Cannabis research. They do not *forbid* all such research; there is an established pathway to federal approval for certain kinds of Cannabis research. Nonetheless, it is because of the restrictiveness of this regulatory structure that we lack most basic clinical and agricultural knowledge about Cannabis.

The attached document is a legal memo issued by the University of Colorado regarding research on Cannabis. It explains why Universities will not participate in research that is not federally approved, and it outlines the path to such approval. This arduous approval process is not the only difficulty. There is also the restriction that any Cannabis used in studies must be produced by the federally licensed facility at the University of Mississippi. This Cannabis is notoriously low quality and low potency compared to the modern hybrid strains that are in actual circulation. There is an effort underway to improve this federal Cannabis supply, and it may eventually be suitable for clinical studies. By definition, it will *not* ever be suitable for agricultural studies relating to Cannabis production outside of the University of Mississippi. If any research relevant to the Cannabis agriculture industries in specific states is to be done, it will have to be done outside of the framework of federal approval, and outside of the university system.

Medical research.

Studies related to Cannabis that do not require an actual source of Cannabis can be done in the university setting, although they will likely need non-federal funding. These include observational human studies (for instance monitoring the progress of medical Cannabis patients with or without PTSD), retrospective studies (such as meta-analyses of published data aimed at determining the interactions between breastfeeding and Cannabis), and basic science work (such as receptor-interactions studies).

Clinical research involving human subjects can likely *never* be done completely outside of the university system. Such research is subject to complex federal restrictions, and invariably requires approval by an Institutional Review Board that is itself subject to federal approval. Attempting to do such research in a commercial or state-only structure would potentially violate federal laws in ways unrelated to Cannabis law. Colorado and California have each created state funding programs for Cannabis research, and used this money (about $10M in each case) to enable medical Cannabis research with full federal approval. These programs have had mixed success.

Agricultural Research.

Agricultural Cannabis research requires both access to Cannabis, and a waiver from the DEA allowing that Cannabis to be grown outside of the approved site at the University of Mississippi. Two or three labs in the US, in the last 40 years, have received limited approval to do such work. This is not a viable path for accomplishing meaningful research. There is a critical need right now for rapid advances in agricultural Cannabis research, especially on public health-related issues such as pesticides and *Aspergillus* infections. Such work will not happen within the federal regulatory structure, and will therefore not happen at universities unless they are willing to violate federal guidelines and put their overall funding at risk.

Federal agencies

The states that are currently developing legal Cannabis programs are being forced to do a great deal of work that would normally be done by the EPA, the FDA, or the USDA. These agencies have not been willing to be involved, and they will almost certainly not change course until Cannabis is re-scheduled.

State agencies

States that have already legalized recreational, or even medical, Cannabis, do not face much of an additional legal barrier to directing their state health or agriculture departments to perform Cannabis research. Nonetheless, many state agencies, particularly agriculture departments, have been extremely hesitant to involve themselves. Those that are already involved have done very little research of any kind. In Oregon, the Oregon Health Authority (OHA) has already formed a taskforce on Cannabis and public health, but it is mainly aimed at analyzing existing literature. State health and agriculture

departments are more than capable of undertaking small research studies on issues such as pesticides, food-safety microbiology, and environmental impact. To do so, they will need clear directions, and funding, from their legislatures.

Private companies

In the United States, it will not be possible for companies to engage in human subjects research aimed at developing cannabinoid-based therapeutics unless they follow the federal path toward approval. There are one or two large companies taking this difficult route.

Aside from human subjects research, privately-funded research is much less restricted than university-based studies are. Private companies can and should be doing the agricultural research that the Cannabis industry lacks and that would normally be done in public-private partnerships with land-grant universities. They should be doing basic science research with cannabinoids, and they should even be collaborating with state agencies on public-health research projects.

Nonetheless, very few companies with any genuine research capability have been willing to work with Cannabis, because of the risks involved with violating federal law even in Cannabis-legal states. This is problematic, because this research is critically important to the growing Cannabis industry, and companies are the only setting in which much of it can take place.

If companies could perform Cannabis research under a state license specifically directed at this purpose, it would provide an extra layer of protection from the risks associated with federal law. Although they would likely still be strictly in violation of federal law, such a license could allow companies to perform research without engaging directly in the commercial Cannabis supply chain. It would also allow them to perform research as necessary, without restriction by the limits that will be placed on growers and processors, as long as they do not contribute to the overall Cannabis production in the state.

Non-profit institutions would be effectively served by the same license type, and are a possible vehicle for enacting critical public health research with state funding.

Recommendations:

- The Oregon State Legislature should pass a bill aimed at enabling critical research projects into the agricultural and medical issues involving Cannabis. This bill should encourage three separate research pathways:

    1. *University-based research with federal approval.* This is the only path at present for clinical human subjects research, and will require state support. A Cannabis Research Board will need to be created and funded, and empowered to provide competitive grants to academic researchers for approved studies.
    2. *Research by state agencies.* The OHA and the ODA should be instructed to undertake critical research projects. They will need significant expansion of their funding to do so. A new agency or institute could also be created to house researchers with academic backgrounds.
    3. *Commercial research*. A Cannabis Research license should be created. Many of the pressing agricultural issues, and some of the medical ones, can be addressed by private research, whether commercial or non-profit. Companies capable of such work will not be likely to engage in Cannabis research without a specific state license for it.