GENERAL QUESTION TO CONSIDER: How do we ensure cultural and health equity across product manufacturing and innovation to meet the variable needs of diverse clientele?

EQUITY SC RECOMMENDATIONS

Equity SC Recommendations: Passed and Pending Board Approval (10/15/21)

- OAR should maintain a list of foods, food ingredients, and additives that will be *prohibited* in the manufacture of psilocybin products, as opposed to creating a list of foods, food ingredients, and additives that will be *allowed* in the manufacture of psilocybin products.
- OAR should make permissible, and carefully regulate and ethically examine, psilocybin product innovation, such as but not limited to innovations in formulation and routes of delivery, that improves accessibility to clients with disabilities, gastrointestinal intolerances, or other physical or mental barriers to ingestion.
- OAR should direct OHA and the Psilocybin Services Program to maintain a list, with scientific citations, of allowable and prohibited food, food ingredients, and additives that may potentiate, attenuate, or affect the onset of action or duration of action of psilocybin.

Equity SC Recommendations Under Discussion (as of 10/15/21)

- Include/exclude cannabinoids derived from hemp on the list of foods, food ingredients, and additives that are prohibited in the manufacture of psilocybin products.
- Make permissible, and carefully regulate and ethically examine, additives or technologies, such as but not limited to inactive fillers or preservatives (i.e. excipients) or nanoemulsion, that may be necessary in formulating products across variable routes of administration for bioavailability, predictability, safety, shelf stability, and tolerability.
- Avoid prohibiting foods, food ingredients, or additives solely on the basis of being liable to potentiate, attenuate, or affect onset of action or duration of effect, as these effects are not inherently adverse.
 - Prohibition should be based on adverse effect and/or toxicity profiles, and/or known negative interactions.

- Require the accurate labeling of all foods, food ingredients, and additives in a psilocybin product, which should be accompanied by appropriate disclaimers such as potential potentiation or attenuation, acceleration or delay in onset, or shortened or extended duration of action of psilocybin.
- Allow the mixing of psilocybin products with pre-manufactured foods and beverages at service centers at point of care and in the presence of the client.
- Direct the Products SC and Psilocybin Advisory Board to examine considerations or concerns for products or substances clients may consume prior to or after administration sessions.
- Direct OHA and the Psilocybin Services Program to evaluate psilocybin products every twelve months beginning in 2024, and report
 - 1. its findings regarding the economic, safety, and social impacts of allowable psilocybin products;
 - 2. the announcement of newly allowed or excluded psilocybin product categories, foods, or other additives;
 - 3. a review of ongoing and pending clinical trials and FDA approval status for natural or synthetic psilocybin products;
 - 4. the implications of such a status on the Oregon Psilocybin Services Program; and
 - the opportunities and limitations of allowing or excluding chemical synthesis in the manufacture of psilocybin products in the Oregon Psilocybin Services Program, and the economic, safety, and social impacts of those opportunities and limitations.

PRODUCT SC RECOMMENDATIONS

Approved by Psilocybin Services Advisory Board (9/22/21)

- Cultivation should be limited to the species *P. Cubensis*.
 - Direct OHA to review allowable species for cultivation every twelve months, beginning January 2024.
- Limit psilocybin production to cultivation of fruiting bodies and mycelium
 - Direct OHA to review allowable production methods every twelve months, beginning January 2024.
- Prohibit use of dung and wood chips as substrates for cultivation.
- Permit extracts as an allowable psilocybin product.

Product SC Recommendations: Passed and Pending Board Approval (10/14/21)

- Prohibit chemical synthesis of psilocybin.
- Allow psilocybin products to be combined with food products.
- Prohibit psilocybin products that contain cannabis or beverage alcohol.
- Direct OHA to revisit all Products SC recommendations every twelve months beginning January 2024.

Product SC Recommendations Under Discussion (as of 10/14/21)

- Create a short list of foods and additives that will be prohibited in the manufacture of psilocybin products.
 - Motion made and failed with a 2:1 vote in favor, the majority of members abstaining until a list is considered.
- Prohibit the addition of MAOIs, whether naturally occurring in foods or as an isolate, in the manufacture of psilocybin products.
 - Motion made but not seconded, leaving it tabled.

Equity SC Assessment Rubric

- Does this recommendation consider cultural equity?
- Does this recommendation consider health equity?
 - Economic equity?
 - Environmental equity?
 - Human equity?
 - Social equity?
- Is this recommendation decolonizing?

Definitions

"Cultural Equity" means the respectful acknowledgement, representation, consideration, and preservation of the values, policies, and practices of all people, especially those who have been historically marginalized based on race, ethnicity, language, disability, age, gender, gender identity, sexual orientation, social class, intersections among these communities or identities, or other socially determined circumstances, in the development of social pathways to health equity.

"Health Equity" means the assuredness of access to full health and wellbeing for all people despite differences and disadvantages created by designations of race, ethnicity, language,

disability, age, gender, gender identity, sexual orientation, social class, intersections among these communities or identities, or other socially determined circumstances. (See <u>OHA's</u> <u>definition of Health Equity</u>. See <u>CHEM Pillars of Health Equity</u>, whereby health equity is achieved by investing in and optimizing the pillars of health equity: economic equity¹, environmental equity², human equity³, and social equity⁴.)

"Decolonization" means unlearning the thinking, practices, and societal systems that assert western superiority over traditional and Indigenous governance, knowledge and practices. Decolonization requires dismantling systems and structures that assert power and control, and cause harm by the dominant culture, making repairs for the damages done, and returning to a culture which honors and centers Indigenous sovereignty and justice.

Colonization means 1) The action or process of settling among and establishing control over the Indigenous people of an area. 2) The action of appropriating a place or domain–including another's intellectual property or cultural characteristics, contribution(s), or identity–for one's own use and/or economic gain without the owner's permission and/or economic reciprocity.

¹ Economic equity means 1) The assurance of economic reciprocity and access to economic resources such as income, savings, assets, and capital. 2) Possessing personal and collective agency over the flow of economic resources through a household or community.

² Environmental equity means the assurance of access to and maintenance of 1) clean air, water, land, and soil, 2) clean, natural, and safe outdoor spaces, 3) clean and safe indoor spaces, and 4) clean, safe, and consistent housing options.

³ Human equity means 1) The optimization of an individual's knowledge, skills, ability, capability, adaptability, introspection, empathy, enlightenment, gratitude, and self-actualization. 2) The optimization of an individual's physical, mental, and spiritual fitness.

⁴ Social equity means fairness in policy, regulation, and in the distribution of social resources and services to ensure that policy and societal infrastructures facilitate 1) impartial and continual access to economic, environmental, and human equity, and 2) the social participation, cooperation, confidence, trust, cohesion, cultural respect and preservation, protection, and productivity of all people.