Advisory Council Guiding Principles:

- **1.** Ensure consumer protection and safety.
- 2. Base recommendations on data and science.
- **3.** Develop clear recommendations and guidance that considers alignment with other state, federal, and/or international standards when possible and appropriate.
- **4.** Avoid adverse effects on the existing legal marijuana program.
- **5.** Support education and research opportunities.

Terms & Definitions Discussed:

General discussion notes.

- Discussed realigning the nomenclature in HB948 and potential downstream administrative rule to better match that used on the national landscape. For example, amending the term "Synthetic Marijuana Product" to "Synthetic Cannabinoid Product".
- 2. Discussed the difference between statutory definitions and administrative rule definitions.
- 3. Definitions may include language explaining what the term includes and excludes.
- 4. Discussed the utility of defining "semi-synthetic cannabinoid" and "synthetic cannabinoid".
- **5.** Discussed the utility of defining "synthetic cannabinoid" versus "synthetically derived cannabinoid" and "natural cannabinoid" versus "naturally derived cannabinoid".

The following terms were discussed:

- 1. "Synthetic Cannabinoids" or "Synthetically Derived Cannabinoids"
 - i. Discussed the utility of using the word derived.
- 2. "Semi-Synthetic Cannabinoids"
 - i. Discussed the utility of differentiating semi-synthetic and synthetic.
- 3. "Synthetic Marijuana Products" versus "Synthetic Cannabinoid Product"
 - **i.** Discussed updating the current MT statutory nomenclature to something that better aligns with the national landscape.
- 4. "Natural Cannabinoids" or "Naturally Derived Cannabinoids"
 - i. Discussed the utility of using the word derived.
- 5. "Natural Cannabinoid Product"
- 6. "Cannabinoid Product"
- 7. "Decarboxylation"
 - i. Discussed the utility of listing specific allowed/prohibited cannabinoids.
 - **ii.** Include the decarboxylation of acidic natural cannabinoids into neutral natural cannabinoids.
 - **iii.** Exclude the decarboxylation of acidic synthetic cannabinoids into neutral synthetic cannabinoids.
 - iv. Decarboxylation is a natural process and can also be done with human agency.
- 8. "Impairing"
 - i. Discussed the difficulties to reliably define this term.
 - ii. No standardized testing to utilize for the definition like there is for blood alcohol.
 - iii. Concerns that this may not be the time or bill to attempt to define this term.
 - iv. Has implications far beyond cannabinoids.

- v. The council could instead provide the latest psychoactivity literature on synthetic cannabinoids with available data.
- vi. Impairing may mean something different with other novel cannabinoids.
- 9. "Manufacturing"
 - i. Means "the <u>production</u>, preparation, propagation, compounding, or processing of a substance, either directly or indirectly or by extraction from substances of natural origin, or independently by means of chemical synthesis or by a combination of extraction and chemical synthesis, and includes any packaging or repackaging of such substance or labeling or relabeling of its container; except that such term does not include the preparation, compounding, packaging, or labeling of a substance in conformity with applicable <u>State</u> or local law by a <u>practitioner</u> as an incident to their administration or dispensing of such substance in the course of their professional practice."
 - ii. Jon Speare Does this same reference define "chemical Synthesis"? Please investigate.
- 10. "Chemical Synthesis"
 - i. Discussed human agency and the AFDO definition of synthetic.
 - ii. Discussed language about what the term may include and exclude.
 - iii. Multiple times the discussion rounded back to adequately defining this term.
 - iv. The term "synthetic cannabinoid" hinges on the definition of "chemical synthesis".

Tasks for the Next Advisory Council Meeting:

- 1. Council members draft definitions for the terms listed above for a more in-depth group discussion and eventual consensus.
- 2. Review resources posted on the CCD website <u>here</u>.
- **3.** Investigate the "Dangerous Drug Analogs" language in the Controlled Substances Act. Do synthetic cannabinoids fall under the CSA definition of "Dangerous Drug Analog"? If so, does this have implications on the council putting forth guidelines for safe methods of synthesizing cannabinoids? Tony King offered to bring this topic to the Board of Pharmacy's legal department.

See the pertinent MT CSA language below:

50-32-222(10) Dangerous drug analogues. Unless specifically excepted or listed in another schedule, this designation includes any material, compound, mixture, or preparation defined in **50-32-101** as a dangerous drug analogue.

50-32-101(7)(a) "Dangerous drug analogue" means any material, compound, mixture, or preparation that is structurally related to or chemically derived from any dangerous drug in Schedules I through V set forth in Title 50, chapter 32, part 2, or that is expressly or impliedly represented to produce or does produce a physiological effect similar to or greater than the effect of a dangerous drug in Schedules I through V.

(b) The term does not include any material, compound, mixture, or preparation that is currently listed as a dangerous drug in Schedules I through V set forth in Title 50, chapter 32, part 2, or in an administrative rule, that is approved for use by the United States food and drug administration, or that is otherwise specifically excepted from Title 50, chapter 32, part 2.

50-32-222(4)(kk) synthetic cannabinoids, including:

(i) unless specifically excepted or listed in another schedule, any chemical compound chemically synthesized from or structurally similar to any material, compound, mixture, or preparation that contains any quantity of a synthetic cannabinoid found in any of the following chemical groups, or any of those groups that contain synthetic cannabinoid salts, isomers, or salts of isomers, whenever the existence of those salts, isomers, or salts of isomers is possible within the specific chemical designation, including all synthetic cannabinoid chemical analogs in the following groups:

(A) naphthoylindoles, whether or not substituted in the indole ring to any extent or the naphthyl ring to any extent;

(B) naphthylmethylindoles, whether or not substituted in the indole ring to any extent or the naphthyl ring to any extent;

(C) naphthoylpyrroles, whether or not substituted in the pyrrole ring to any extent or the naphthyl ring to any extent;

(D) naphthylmethylindenes, whether or not substituted in the indene ring to any extent or the naphthyl ring to any extent;

(E) acetylindoles, whether or not substituted in the indole ring to any extent or the acetyl group to any extent;

(F) cyclohexylphenols, whether or not substituted in the cyclohexyl ring to any extent or the phenyl ring to any extent;

(G) dibenzopyrans, whether or not substituted in the cyclohexyl ring to any extent or the phenyl ring to any extent; and

(H) benzoylindoles, whether or not substituted in the indole ring to any extent or the phenyl ring to any extent;

(ii) any compound that has been demonstrated to have agonist binding activity at one or more cannabinoid receptors or is a chemical analog or isomer of a compound that has been demonstrated to have agonist binding activity at one or more cannabinoid receptors;

(iii) 1-pentyl-3-(1-naphthoyl)indole (also known as JWH-018);

(iv)(6aR,10aR)-9-(hydroxymethyl)-6,6-dimethyl-3-(2-methyloctan-2-yl)-6a,7,10,10a-

tetrahydrobenzo[c]chromen-1-ol (also known as HU-210 or 1,1-dimethylheptyl-11-hydroxy-delta8-tetrahydrocannabinol);

(v) 2-(3-hydroxycyclohexyl)-5-(2-methyloctan-2-yl)phenol (also known as CP-47,497) and the dimethylhexyl, dimethyloctyl, and dimethylnonyl homologues of CP-47,497;

(vi) 1-butyl-3-(1-naphthoyl)indole (also known as JWH-073);

(vii) 1-(2-(4-(morpholinyl)ethyl))-3-(1-naphthoyl) indole (also known as JWH-200); (viii) 1-pentyl-3-(2-methoxyphenylacetyl)indole (also known as JWH-250);

(ix) 1-hexyl-3-(1-naphthoyl)indole (also known as JWH-019);

(x) 1-pentyl-3-(4-chloro-1-naphthoyl)indole (also known as JWH-398);

(xi) JWH-081: 1-pentyl-3-(4-methoxy-1-naphthoyl)indole, also known as 4-methoxynaphthalen-1yl-(1-pentylindol-3-yl)methanone;

(xii) the following substances, except where contained in cannabis or cannabis resin, namely tetrahydro derivatives of cannabinol and 3-alkyl homologues of cannabinol or of its tetrahydro derivatives:

(A)[2,3-Dihydro-5-methyl-3-(4-morpholinylmethyl)pyrrolo[1,2,3-de]-1,4-benzoxazin-6-yl]-1napthalenylmethanone (also known as WIN-55,212-2);

(B) 3-dimethylheptyl-11-hydroxyhexahydrocannabinol (also known as HU-243); or

(C)[9-hydroxy-6-methyl-3-[5-phenylpentan-2-yl]oxy-5,6,6a,7,8,9,10,10a-

octahydrophenanthridin-1-yl]acetate;

- **4.** Webinars to watch prior to the next meeting:
 - <u>Changing Potency Landscapes: Emergences of Synthetic Cannabinoids</u> Discusses the chemistry and isomerization of cannabinoids and why isomerization is important. Draws a parallel to the drug Thalidomide once used to treat morning sickness in pregnant women.
 - **ii.** <u>Intoxicating Hemp and Synthetic Cannabinoids: Insights into lab Testing</u> Discusses the chemistry of synthetic cannabinoids, contaminants, hemp, marijuana, the farm bill, testing, and paths forward.
- 5. FDA Adverse Events Reporting System (FAERS)
 - i. <u>https://open.fda.gov/data/faers/</u>
 - **ii.** Synthetic cannabinoid adverse events reporting data is available here.