

LEGAL REVIEW NOTE

Bill No.: SB 422

LC#: LC0635, To Legal Review Copy, as
of February 10, 2023

Short Title: Expand eligibility for the Right
to Try Act

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Date: February 21, 2023

CONFORMITY WITH STATE AND FEDERAL CONSTITUTIONS

As required pursuant to section 5-11-112(1)(c), MCA, it is the Legislative Services Division's statutory responsibility to conduct "legal review of draft bills". The comments noted below regarding conformity with state and federal constitutions are provided to assist the Legislature in making its own determination as to the constitutionality of the bill. The comments are based on an analysis of jurisdictionally relevant state and federal constitutional law as applied to the bill. The comments are not written for the purpose of influencing whether the bill should become law but are written to provide information relevant to the Legislature's consideration of this bill. The comments are not a formal legal opinion and are not a substitute for the judgment of the judiciary, which has the authority to determine the constitutionality of a law in the context of a specific case.

*This review is intended to inform the bill draft requestor of potential constitutional conformity issues that may be raised by the bill as drafted. This review IS NOT dispositive of the issue of constitutional conformity and the general rule as repeatedly stated by the Montana Supreme Court is that an enactment of the Legislature is presumed to be constitutional unless it is proven beyond a reasonable doubt that the enactment is unconstitutional. See *Alexander v. Bozeman Motors, Inc.*, 356 Mont. 439, 234 P.3d 880 (2010); *Eklund v. Wheatland County*, 351 Mont. 370, 212 P.3d 297 (2009); *St. v. Pyette*, 337 Mont. 265, 159 P.3d 232 (2007); and *Elliott v. Dept. of Revenue*, 334 Mont. 195, 146 P.3d 741 (2006).*

Legal Reviewer Comments:

As drafted, SB 422 may raise potential federal constitutional issues related to the Supremacy Clause under the United States Constitution. Article VI, clause 2, of the United States Constitution provides that federal law is the "supreme Law of the Land".

The federal Right to Try Act, Pub. L. 115-176, restricts the right to try investigational or unapproved drugs to those who are suffering from a "life-threatening disease" as defined in 21 CFR § 312.81.

As the Ninth Circuit Court of Appeals recently confirmed in Advanced Integrative Med. Sci. Inst., PLLC v. Garland, 24 F.4th 1249 (9th Cir. 2022), an "eligible patient" is someone who has been diagnosed with a "life-threatening disease or condition," and has "exhausted approved treatment options and is unable to participate in a clinical trial involving the eligible investigational drug" (as certified by a physician) and has provided written informed consent regarding the drug. 21 U.S.C. § 360bbb-0a(a)(1)." Advanced Integrative Med. Sci. Inst., PLLC v. Garland, 24 F.4th at 1253 (emphasis added).

SB 422 expands the federal Right to Try Act, by amending 50-12-104 to allow a person who does not have a terminal illness the right to try investigational drugs, biological products or devices.

As drafted, SB 422 may raise potential federal constitutional issues related to the Supremacy Clause in that it proposes to supersede federal law allowing a person who does not have a life-threatening disease or condition the right to try investigational drugs.

Requester Comments: