

LEGAL REVIEW NOTE

LC#: 0652, To Legal Review Copy, as of Nov. 17, 2014

Short Title: Revise laws related to health care options for patients with terminal illnesses

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CONFORMITY WITH STATE AND FEDERAL CONSTITUTIONS

*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).*

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.

Legal Reviewer Comments:

LC0652 may raise potential federal constitutional issues related to the Supremacy Clause under the United States Constitution, Art. VI, cl. 2, which provides that federal law is the "supreme law of the land". Under the Supremacy Clause, if a conflict between state law and federal law exists, federal law prevails. *Gonzales v. Raich*, 545 U.S. 1, 29, 125 S. Ct. 2195, 2212 (2005).

The Federal Food, Drug, and Cosmetic Act prohibits general access to experimental drugs.¹ However, under the expanded access provision of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 360bbb, patients with serious or immediately life-threatening diseases may access experimental drugs after receiving FDA approval. As drafted, LC0652 bypasses the FDA expanded access program and allows patients to obtain experimental drugs from manufacturers without obtaining FDA approval. This procedure directly conflicts with the federal expanded access program and may raise potential Supremacy Clause constitutional issues.

Requester Comments:

Here is my response to the legal review note on LC 652.

Q: By what authority can Montana pass the Right to Try Act?

A: It is well-established that the U.S. Constitution was designed to provide a floor of protection for individual rights, not a ceiling. State constitutions may provide additional and greater protections to individuals---and all of them do. For instance many states protect speech to a greater extent than the U.S. Constitution, others provide greater privacy rights. The Right to Try Act is designed to provide the expanded individual right to life by ensuring a right to medical self-preservation.

Q: Could the Right to Try Act be challenged by the federal government as preempted by federal law enforced through FDA regulations?

A: Yes. A federal challenge to the Right to Try Act would pit the concepts of federalism and individual rights against the expansive power of the federal government. Often the federal government prevails in federalism clashes with state, however the current Supreme Court is the most pro-federalism Court in decades, particularly relating to individual rights revolving around medical treatments. In *Gonzales v. Oregon* (2006), the Court upheld the state's "right-to-die" law, which was enacted by Oregon voters, over the objections of the U.S. Attorney General, who argued that federal law preempted the state law. Applying "the structure and limitations of federalism," the Court observed that states have great latitude in regulating health and safety, including medical standards, which are primarily and historically a matter of local concern. To hold otherwise would mark "a radical shift of authority from the states to the Federal Government to define general standards of medical practice in every locality." Considering the Supreme Court unquestionably recognized a person's right-to-die based on traditional state powers, it can be presumed that the Court would closely examine an individual's right-to-try under the same principles. A federal challenge to a state's protection of a patient's highly personal right to medical self-preservation would be closely scrutinized by the Court.

Further support for the Right to Try Act can be derived from substantive due process clauses of

¹See *Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach*, 495 F.3d 695, 708 (D.C. Cir. 2007); 21 U.S.C. 355a.

the 5th and 14th Amendments to the U.S. Constitution. Based on the continuously evolving precedent relating to “fundamental rights” recognized by the Constitution, it is possible that if challenged by the federal government, courts could find the right to medical self-preservation is so “deeply rooted in the Nation’s history and tradition” and “implicit in the concept of ordered liberty,” that its regulation by the FDA violates fundamental rights. In other words, the right to medical self-preservation is a liberty so inherent and vital that no government can place limitation on it through regulation or otherwise.

The Supreme Court has held, a party seeking to establish that an activity is protected under the Fourteenth Amendment’s substantive due process clause must show two things: that the activity is 1) deeply rooted in the Nation’s history and tradition and implicit in the concept of ordered liberty and 2) that the fundamental liberty interest is “carefully described.” *Washington v. Glucksberg*, 521 U.S. 702, 720-21 (quoted in *Raich v. Gonzales*, 500 F.3d 850, 862 (9th Cir. 2007)).

Q: Is Right to Try preempted by federal law?

A: It remains an open question. The Supreme Court has never addressed the issue of experimental medication in the context presented by Right to Try. In *United States v. Rutherford*, 442 U.S. 544 (1979) the Supreme Court held that the government has an interest in regulating **unsafe** drugs. It also found that a drug is unsafe if the risk of death or physical injury is not outweighed by the drug’s potential benefit. (The drug Laetrile had not yet been proven safe by the FDA.) Right to Try presents a different scenario, one that has not reached the Supreme Court. Under Right to Try terminally ill patients will be able to access drugs already proven safe (by passing Phase I of FDA testing) but not yet approved for use. Therefore the concerns for safety expressed by the Court in *Rutherford* are not present.

Only one federal case has directly addressed the situation like that presented by Right to Try. In *Abigail Alliance v. Von Eschenbach*, 445 F.3d 470 (D.C. Cir. 2006), a three judge panel found that the due process clause of the 5th Amendment guaranteed terminally ill patients access to experimental drugs that had already passed FDA Phase I safety testing. Upon a request by the FDA for rehearing the Court, sitting *en banc* reversed its decision finding there is no fundamental right to access unapproved experimental drugs, even for the terminally ill. *Abigail Alliance v. Von Eschenbach*, 495 F.3d 695 (D.C. Cir. 2007). However, *Abigail Alliance* is not binding on any other federal court outside the D.C. Circuit and the Supreme Court has not decided the issue. Therefore the question of whether terminally ill patients have a fundamental right to experimental medicine as outlined by Right to Try has not yet been settled.

Senator Cary Smith
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