

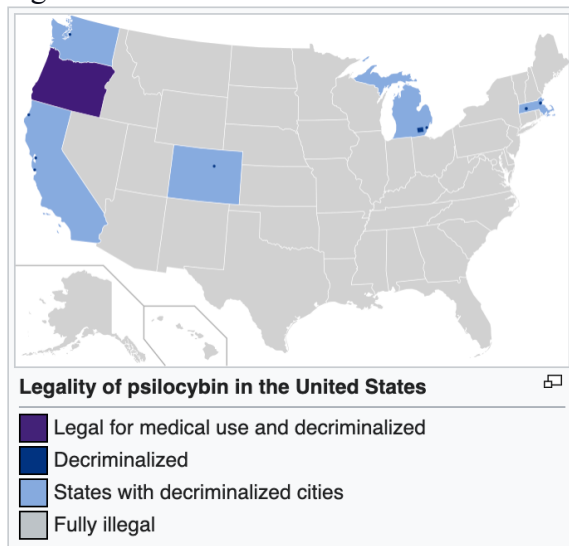
Right To Try Laws and Psychedelics

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The recent Supreme Court decisions regarding the Second Amendment ^[1] and the overturning of *Roe v. Wade* ^[2] have generated significant and vigorous debate. Undoubtedly gun rights and abortion access are at the forefront of the cultural zeitgeist. Within the Psychedelic legal sphere, one piece of legislation may offer an expedited way forward.

Currently, many different approaches are being taken regarding the legal status of psychedelics. In a small number of cities across the country, steps toward decriminalization are underway. Conversely, the work of MAPS and other Psychedelic Research groups has, for the first time in nearly five decades, the potential for re-medicalization of these substances squarely within the realm of the possible. Aside from decriminalization and medicalization, efforts at full drug legalization are being pursued but seem to be the most inchoate, with only the state of Oregon passing legislation to legalize psychedelics.

Figure 1 ^[3]



All three options of decriminalization, medicalization, and legalization carry inherent trade-offs. The quickest option to implement is decriminalization. However, city decriminalization laws directly conflict with the federal and some state drug laws already on the books. Decriminalization relies on the federal or state government deciding not to investigate or prosecute individuals for those specific drug-related offenses—this disposition to prosecute or not can radically change from election cycle to election cycle and administration to administration ^[4]. Additionally, in a decriminalized environment, there are issues of economics and quality control. Selling a federally illegal substance creates numerous issues regarding economic transactions and banking. In states where cannabis is legal, several small business owners have documented the difficulty of getting bank accounts, and this will be even more difficult, if not impossible, concerning psychedelics ^[5]. If a substance is only decriminalized, one cannot reasonably set up a small business from which to distribute a substance. The federal government has also taken steps to cut off State Medicaid funding to states that have legalized federally illegal substances like cannabis ^[4]. Likewise, safely manufacturing a psychedelic substance and ensuring that no cross-contamination occurs is of the utmost importance. Quality control is essential in light of the increasing number of opioid overdoses and the number of individuals obtaining what they believe is a non-opioid-based substance only to tragically discover later that it is contaminated with an opioid such as fentanyl ^[6]. The lack of quality control can also feed into previously held stereotypes surrounding the safety of psychedelics. If an individual were to take a psychedelic substance laced with an alternative drug like a

stimulant or opioid and have an adverse event, the psychedelic substance would likely receive at least some of the blame. If frequent enough, these adverse events and accompanying negative press attention would significantly undermine all the work that organizations like MAPS have done to rehabilitate and legitimize the image of psychedelics.

Medicalization efforts, primarily led by MAPS, have been the most consistent and fruitful legal interventions employed by psychedelic groups. However, while it appears that drugs like psilocybin and MDMA are within two to five years of being approved by the FDA for specific indications, the specific prescribing requirements and ability to use the psychedelic substances off-label remains undefined ^[7]. Suppose the medical bureaucracy imposes severely burdensome regulations regarding psychedelic use. In that case, these substances may be restricted to only those with a significant enough symptom burden and the economic means to afford these treatments.

Lastly, complete or partial psychedelic legalization could address the economic and quality control issues encountered in decriminalization while simultaneously providing more affordable and widespread access to a large population. However, the legalization of psychedelics faces numerous cultural and legal challenges, unlike cannabis which has been successfully legalized in several states ^[8]. The stench of the 1960s and 1970s still lingers with psychedelics. Even considering that most of the concerns raised about psychedelics were unsubstantiated, broaching the topic of national legalization would be perilous. While the opinion of psychedelics has steadily been changing, the sentiments across the country have varied widely based on location ^[9, 10]. These regional differences would likely result in a patchwork of legalized states and potentially even further stratification into specific cities and counties within those states that elect to pursue

legalization. These legalization efforts would produce a cultural map similar to alcohol, where there are dry and wet counties across many states.

Even if the legal barriers are removed, the cultural sentiment will still dictate the wide-scale adoption or prohibition of psychedelic substances. Efforts to highlight the benefits of psychedelic-assisted psychotherapy are currently underway, but one avenue of significant underutilization is right to try laws. Right to try laws allow individuals "with life-threatening diseases or conditions who have tried all approved treatment options and who are unable to participate in a clinical trial to access certain unapproved treatments ^[11]." A federal right to try bill was passed and signed into law in 2018, and currently, 41 states have passed some version of a right to try law ^[12]. Patients eligible for the right to try must meet the following criteria ^[11]:

- Been diagnosed with a life-threatening disease or condition.
- Exhausted approved treatment options and is unable to participate in a clinical trial involving the eligible investigational drug (this must be certified by a physician who is in good standing with their licensing organization or board and who will not be compensated directly by the manufacturer for certifying).
- And has provided, or their legally authorized representative has provided, written informed consent regarding the eligible investigational drug to the treating physician.

The selected drug must also meet specific criteria including ^[11]:

- A Phase 1 clinical trial has been completed.
- Has not been approved or licensed by the FDA for any use.
- An application has been filed with the FDA or is under investigation in a clinical trial that is intended to form the primary

Right To Try Laws and Psychedelics

basis of a claim of effectiveness in support of FDA approval and is the subject of an active investigational new drug application submitted to the FDA.

- Has active development or production is ongoing, and that has not been discontinued by the manufacturer or placed on clinical hold by the FDA.

Psychedelic substances have already shown significant promise in treating anxiety and depression in individuals with a life-threatening illness or terminal cancer. The positive benefits have been repeatedly demonstrated across different locations, patient populations, and psychedelic substances [13-15]. Depressive and anxiety spectrum disorders are common among patients with life-threatening or terminal conditions [16]. Still, these diagnoses would often not meet the inclusion criteria for most psychedelic clinical trials. Expanding the use of psychedelic substances to a broader population would provide additional clinical information outside those commonly reported in efficacy-based clinical trials. Outside of the medical benefits that psychedelics would provide to patients suffering from these end-of-life disorders, positive results in this population could also help persuade psychedelic skeptics and opponents toward supporting further psychedelic research or at least not taking active steps to prevent research or FDA approval. Engendering goodwill toward psychedelics or at least reducing the apprehension around them will be particularly important as these substances begin to be reintroduced to popular culture, especially for psychedelic advocates and supporters who wish to avoid a negative backlash like the one seen in the 1970s.

Right to try laws represent an underutilized legal pathway to expand access to psychedelic substances while efforts toward medicalization are ongoing. Right to try laws present a safer alternative to decriminalization by ensuring that patients receive

pharmaceutical-grade compounds under reasonable quality control, thereby reducing the likelihood of harmful adverse reactions. Furthermore, if used appropriately, right to try laws provide the opportunity to improve and enhance the perception of psychedelics culturally, which could pay long-term dividends in future legalization efforts.

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