Removing Bureaucratic Barriers to Care with the Freedom to Heal Act

Background

In 2018, President Trump signed the *Trickett Wendler, Frank Mongiello, Jordan McLinn, and Matthew Bellina Right to Try Act of 2017,* which passed by unanimous consent in the Senate and a bipartisan vote in the House of Representatives. The Right to Try (RTT) Act created a pathway for patients with immediately life-threatening conditions—who have exhausted approved treatments and are unable to participate in clinical trials—to access *eligible investigational drugs* that have completed Phase I safety trials. Under this law, patients may work directly with their physician and the manufacturer to pursue treatment without needing FDA authorization. At the state level, RTT policies have gained significant popularity and support across party lines, with 42 states enacting their own RTT laws, and 38 states passing them unanimously or nearly unanimously through their state legislatures.

Current Roadblock

While the 2018 RTT law modified the *Food, Drug, and Cosmetic Act* (FDCA) to create this pathway, the bill did not include any modifications to the *Controlled Substances Act* (CSA), and the DEA currently lacks a pathway to register & approve physicians to administer Schedule I eligible investigational drugs under Right to Try.

Why This is Urgent

Since 2017, multiple Schedule I substances, including MDMA, psilocybin, and ibogaine, have shown potential as lifesaving treatments for a variety of mental health and neurological conditions. MDMA and psilocybin already qualify as eligible investigational drugs (EID) with promising data from Phase 2 and 3 trials, including receiving FDA breakthrough therapy designations for PTSD and depression, respectively. Ibogaine will likely qualify as an EID soon, as it is just beginning Phase 1 trials after incredible results from observational studies treating Veterans with traumatic brain injury. Without a pathway to access these emerging therapies through a qualified physician under RTT, eligible patients will be left at increased risk of suicide or early mortality. Indeed, thousands of Americans, particularly Veterans, have already been forced to travel abroad or risk breaking the law at home to access these therapies after exhausting approved treatments in the United States.

Supporting Patients with the Freedom to Heal Act

Senators Cory Booker (D-NJ), Rand Paul (R-KY), and Reps. Madeleine Dean (D-PA) and Nancy Mace (R-SC) will soon introduce the *Freedom to Heal Act of 2025* (FTHA) to create a special Schedule I Right to Try physician registration process – without changing the original RTT law – while ensuring DEA oversight and regulation to prevent drug misuse & diversion. This registration would only allow for the direct administration of an eligible investigational drug to treat eligible patients in the clinic. To be approved by the DEA, physicians will be required to hold a Schedule II-V DEA license, meet all RTT requirements, provide information on their credentials, training, and treatment site, and follow treatment guidelines supplied by the manufacturer based on ongoing clinical trials. DEA will issue regulations on various components of security and oversight, and states would remain free to permit or prohibit the use of Schedule I substances according to their own Right to Try laws.

This narrowly tailored fix ensures that the Right to Try Act's policy to empower patients and physicians applies equally to promising Schedule I investigational therapies—while maintaining rigorous control, accountability, and patient safety.

Reason for Hope

VETERAN MENTAL HEALTH LEADERSHIP COALITION

State Right to Try Landscape

State	Year Passed	State Vote	State	Year Passed	State Vote
AL	2015	Unanimous	MT	2015	50-0/93-7
AK	2018	Unanimous	NE	2018	35-13
AZ*	2014	78.5% (Ballot Initiative)	NV*	2015	Unanimous
AR*	2015	Unanimous	NH*	2016	Unanimous
CA	2016	38-0/77-2	NJ	n/a	
CO*	2014	Unanimous	NM	2017	Unanimous
CT	n/a		NY	n/a	
DE	n/a		NC*	2015	Unanimous
FL	2015	39-1/113-0	ND	2015	42-5/91-0
GA*	2016	Unanimous	OH	2016	32-0/96-1
HI	n/a		OK	2015	Unanimous
ID	2016	34-1/66-1	OR	2015	Unanimous
IL	2015	55-0/114-1	PA	2017	Unanimous
IN*	2015	Unanimous	RI	n/a	
IA*	2017	Unanimous	SC	2016	42-0/78-17
KS	2025	40-0/119-3	SD*	2015	32-0/61-1
KY	2017	38-0/87-7	TN*	2015	Unanimous
LA*	2014	Unanimous	TX*	2015	Unanimous
ME	2016	20-11/114-28	UT	2015	26-0/69-3
MD*	2017	Unanimous	VT	n/a	
MA	n/a		VA	2015	Unanimous
MI	2014	35-1/109-0	WA	2017	Unanimous
MN	2015	60-4/123-0	WV	2016	Unanimous
MS*	2015	Unanimous	WI	2018	Unanimous
MO	2014	26-8/143-20	WY	2015	28-1/58-1

* = State has expanded RTT since initial passage.

Section 2: Special Registration Requirements Related to Right to Try

Subparagraph 1: Uses the same definitions for “eligible investigational drug” and “eligible patients” as the federal Right to Try Act.

Subparagraphs 2 & 3(a): Creates a special DEA registration process for physicians to directly administer eligible investigational drugs in Schedule I to eligible patients under the original Right to Try Act. Applications under this special registration will require physicians to submit:

- Evidence of a valid registration to dispense or administer Schedule II-V substances.
- Evidence of compliance with the federal Right to Try Act, including:
    - Documentation from the manufacturer or sponsor of record verifying that the investigational drug in Schedule I is an eligible investigational drug.
    - An agreement from the manufacturer or sponsor of record to supply the eligible investigational drug, along with guidance on its administration, to the requesting physician for the treatment of eligible patients.
    - An affirmation that the physician will only directly administer the eligible investigational drug to treat eligible patients in a manner consistent with the guidance provided by the manufacturer or sponsor.
- The quantity of the eligible investigational drug to be supplied by the manufacturer or sponsor to treat eligible patients.
- Demonstration that the physician may treat eligible patients with eligible investigational drugs under the laws of the State in which the treatment will take place.
- Evidence of training, credentials, or experience relevant to treating patients with the eligible investigational drug.
- A description of the site at which the physician intends to possess and administer the eligible investigational drug.
- Any additional information that the DEA determines necessary to prevent diversion.

Subparagraph 3(b): Requires the DEA to rule on applications within 45 days of receipt.

Subparagraph 4: Requires the DEA to create an online submission system for applications.

Subparagraph 5: Requires that physicians only possess the amount of a Schedule I eligible investigational drug identified in their application. If a physician requires additional quantities for the treatment of a patient, they can submit a supplemental notification to the DEA, which must include the physician's name, the quantity needed, and an attestation that the treatment is consistent with the original application. DEA has 30 days to rule on the supplemental notification.

Subparagraph 6: Allows physicians to treat eligible patients at multiple sites under a single registration, provided the sites are a) located within the same city or county and b) under the control of the same institution, organization, or agency.

Subparagraph 7: Requires the DEA to issue an interim final rule to implement the registration process within 240 days that will include:

- The manner in which an eligible investigational drug may be delivered to an approved registrant;
- The storage and security of an eligible investigational drug;
- The maintenance of records for an approved registrant;
- The process for renewal, suspension, or revocation of a registration; and
- Any other matters necessary to ensure effective controls against diversion.

Subparagraph 8: Requires the DEA to issue a final rule within 2 years of the interim final rule.