



TRANSFORMING CARE FOR END OF LIFE AND CHRONIC CONDITIONS: **PSILOCYBIN AS MEDICINE**

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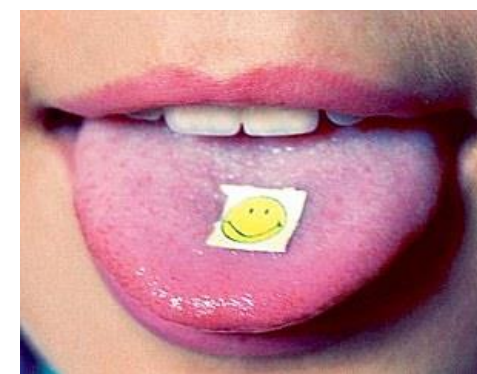
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The Nowak Society, A Colorado non-profit organization

www.nowaksociety.org



TRANSFORMING OUR RELATIONSHIPS WITH MEDICINES AND DRUGS OF ALL KINDS





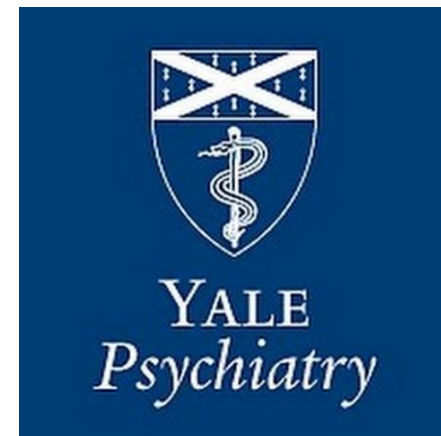
AGENDA

- Growing body of research evidence
- Personal experiences of patients
- Opportunities with the Right To Try Act
 - Other activism in Colorado
- Questions, sharing, discussion

* If you have a story you're willing to share, we would love to hear from you!



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Psyche – delic

“Mind revealing”

Rapid and sustained symptom reduction following psilocybin treatment for anxiety and depression in patients with life-threatening cancer: a randomized controlled trial

Stephen Ross^{1,2,3,4,5,6}, Anthony Bossis^{1,2,4}, Jeffrey Guss^{1,2,4}, Gabrielle Agin-Liebes¹⁰, Tara Malone¹, Barry Cohen⁷, Sarah E Mennenga¹, Alexander Belser⁸, Krystallia Kalliontzi², James Babb⁹, Zhe Su³, Patricia Corby² and Brian L Schmidt²



Journal of Psychopharmacology
2016, Vol. 30(12) 1165–1180
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DOI: 10.1177/0269881116675512
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- Single, moderate dose with psychotherapy, n=29
- Immediate reduction in depression and anxiety
- 60-80% reported sustained improvement at 6.5 month follow-up
- Improved spiritual well-being
- At follow-up, 70% rated it as the singular or top 5 most personally meaningful experience of their entire lives

Psilocybin produces substantial and sustained decreases in depression and anxiety in patients with life-threatening cancer: A randomized double-blind trial

**Roland R Griffiths^{1,2}, Matthew W Johnson¹, Michael A Carducci³,
Annie Umbricht¹, William A Richards¹, Brian D Richards¹,
Mary P Cosimano¹ and Margaret A Klinedinst¹**



Journal of Psychopharmacology
2016, Vol. 30(12) 1181–1197
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DOI: 10.1177/0269881116675513
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- Single, high dose under supported conditions, n=51
- Large and sustained (at 6 months) decreases in depression, anxiety
- Increased optimism, death acceptance, and life meaning
- Mystical-type experience mediates positive therapeutic outcomes



ADVERSE EFFECTS

- In general, well tolerated
- Most common adverse effects are:
 - headache,
 - nausea,
 - elevated BP and HR,
 - transient anxiety and/or psychological disturbance
- No serious adverse events
- No signs of addiction

PERSONAL EXPERIENCES

- Significant new understandings of death and dying
"There was a notion which almost immediately was clear, that there is nothing to fear after you stop being in your body"
- Sense of interconnectedness, felt sense of unity with all things
"it does help you accept death because you don't feel alone, you don't feel like you're going to, I don't know, go off into nothingness."
"cancer was part of the story, as opposed to something I had to separate out, divide my life into little pieces of the bad stuff and the good stuff . . . everything just felt unified."
- Spiritual or mystical experience
"universal subconscious," "pure love," "God"
- Reconnecting to a sense of aliveness and belongingness
"The percentage of my life that I am able to be present in just a moment has increased dramatically . . . just to lose yourself in the moment . . . it is unique and monumental in a way."

- **Right To Try Act:**
Supplements current *compassionate use/expanded access* mechanism via FDA
- Authorizes patient access to investigational substances via manufacturer
- **Colorado** had first RTA law (2014), but has been little used

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See NCSL Rx database and bill text for details

Federal (2018) Right To Try Act	Colorado (2014) Right To Try Act
“ life-threatening ”: likelihood of death is high unless course of condition is interrupted; the disease or condition has a fatal outcome	“ terminal illness ”: a disease that, without life-sustaining procedures, will soon result in death or a state of permanent unconsciousness from which recovery is unlikely
“ eligible investigational drug ” has passed Phase I testing and is currently being investigated in clinical trials	same
Patient has exhausted approved treatment options and is unable to participate in a clinical trial	same
Treatment is recommended by a doctor, with adequate informed consent	same
Limits liability of a sponsor, manufacturer, dispenser, or prescriber	similar
Not much about access	The State shall not block or attempt to block an eligible patient's access to an investigational drug

ADVOCACY EFFORTS

- Building a community network to understand how this is being applied and used
 - Tracking attempts, roadblocks, and outcomes
 - Video/audio documentation of patients' stories
 - Assessing community and hospice agency interest
- Amending CO legislation
 - Broadening patient eligibility (palliative care? serious and chronic conditions?)
 - Definition of a manufacturer?
 - Additional protections for suppliers and possessors
- Examining the issue of Access (interstate commerce?)
- Building a professional team to support medicine work with patients



Your Experiences? Stories?
Questions?