The PR Campaign Against ICER, FDA's AdComm, and Psymposia: Visual Timeline of Events

Click images to expand.

May 30, 2024

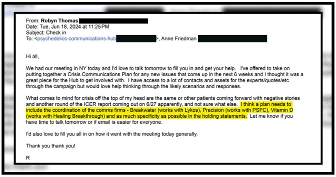
ICER hosts meeting to review Lykos' MDMA application and recommends **against** approval.

ICER
INSTITUTE FOR CLINICAL AND ECONOMIC REVIEW

June 4, 2024

FDA Advisory Committee convenes and recommends **against** approval of Lykos' MDMA-Assisted Therapy application.

June 18, 2024



From: **Robyn Thomas** [redacted]
Date: Tue, Jun 18, 2024 at 11:25 PM
Subject: Check in
To: <psychedelics-communications-hub[redacted]>, Anne Friedman [redacted]

Hi all,

We had our meeting in NY today and I'd love to talk tomorrow to fill you in and get your help. I've offered to take on putting together a Crisis Communications Plan for any new issues that come up in the next 6 weeks and I thought it was a great piece for the Hub to get involved with. I have access to a lot of contacts and assets for the experts/quotes/etc through the campaign but would love help thinking through the likely scenarios and responses.

What comes to mind for crisis off the top of my head are the same or other patients coming forward with negative stories and another round of the ICER report coming out on 6/27 apparently, and not sure what else. I think a plan needs to include the coordination of the comms firms - Breakwater (works with Lykos), Precision (works with PSFC), Vitamin D (works with Healing Breakthrough) and as much specificity as possible in the holding statements. Let me know if you have time to talk tomorrow or if email is easier for everyone.

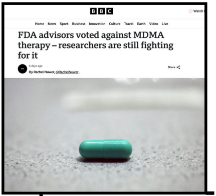
I'd also love to fill you all in on how it went with the meeting today generally.

Thank you thank you!

R

Robyn Thomas emails plans for a **coordinated PR campaign** involving Lykos, PSFC, Healing Breakthrough, and the Psychedelic Communications Hub.

June 20, 2024



BBC

Home News Sport Business Innovation Culture Travel Earth Video Live

FDA advisors voted against MDMA therapy – researchers are still fighting for it

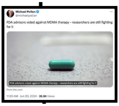
6 days ago

By Rachel Nuwer, @RachelNuwer.

Share

Journalist Rachel Nuwer publishes article on BBC focusing on researchers and activists in **support** of Lykos' drug application.

Retweeted by Tim Ferriss and Michael Pollan.



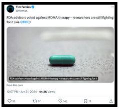
Michael Pollan
@michaelpollan

FDA advisors voted against MDMA therapy – researchers are still fighting for it

FDA advisors voted against MDMA therapy – researchers are still fighting for it

From bbc.com

11:26 AM · Jun 20, 2024 · 26.9K Views



Tim Ferriss
@tferriss

FDA advisors voted against MDMA therapy – researchers are still fighting for it (via @BBC)

FDA advisors voted against MDMA therapy – researchers are still fighting for it

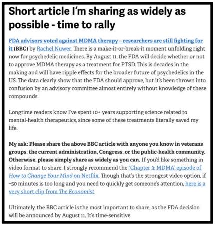
From bbc.com

12:07 PM · Jun 21, 2024 · 44.2K Views

23 37 143 12

June 21, 2024

Tim Ferriss — funder of UC Berkley psychedelic journalism scholarship — sends email asking followers to share Nuwer's article.



Short article I'm sharing as widely as possible - time to rally

FDA advisors voted against MDMA therapy – researchers are still fighting for it **(BBC)** by Rachel Nuwer. There is a make-it-or-break-it moment unfolding right now for psychedelic medicines. By August 11, the FDA will decide whether or not to approve MDMA therapy as a treatment for PTSD. This is decades in the making and will have ripple effects for the broader future of psychedelics in the US. The data clearly show that the FDA should approve, but it's been thrown into confusion by an advisory committee almost entirely without knowledge of these compounds.

Longtime readers know I've spent 10+ years supporting science related to mental-health therapeutics, since some of these treatments literally saved my life.

My ask: Please share the above BBC article with anyone you know in veterans groups, the current administration, Congress, or the public-health community. Otherwise, please simply share as widely as you can. If you'd like something in video format to share, I strongly recommend the "Chapter 3: MDMA" episode of *How to Change Your Mind* on Netflix. Though that's the strongest video option, if ~50 minutes is too long and you need to quickly get someone's attention, here is a very short clip from *The Economist*.

Ultimately, the BBC article is the most important to share, as the FDA decision will be announced by August 11. It's time-sensitive.

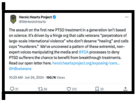
HEROIC
HEARTS
PROJECT

EXPOSING ICER'S ANTI-VETERAN CAMPAIGN AGAINST MDMA-ASSISTED THERAPY

June 23, 2024

Heroic Hearts Project publishes press release misrepresenting Psymposia, claiming ICER is funded by "Big Pharma," and pinning FDA and ICER decisions largely on Dr. Neşe Devenot.

Heroic Hearts tweets press release.



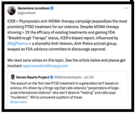
Heroic Hearts Project @WeHeroicHearts

The assault on the first new PTSD treatment in a generation isn't based on science. It's driven by a fringe org that calls veterans "perpetrators of large-scale international violence" who don't deserve "healing" and calls cops "murderers." We've uncovered a pattern of these extremist, non-expert voices manipulating the media and @FDA processes to deny PTSD sufferers the chance to benefit from breakthrough treatments. Read our open letter here. heroicheartsproject.org/exposing-icers... @HBveterans

10:29 AM · Jun 24, 2024 · **190.7K** Views

21 56 210 22

*Quote tweeted by Genevieve Jurvetson — Board Member of PSFC (**PSFC donated $250,000 to Heroic Hearts in 2022**).*



Genevieve Jurvetson @gjurvetson

ICER + Psymposia's anti-MDMA-therapy campaign jeopardizes the most promising PTSD treatment for our veterans. Despite MDMA therapy showing > 2X the efficacy of existing treatments and gaining FDA "Breakthrough Therapy" status, ICER's biased report, influenced by #BigPharma + a shameful Anti-Veteran, Anti-Police activist group, swayed an FDA advisory committee to discourage approval.

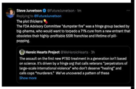
We need sane voices on this topic. See the article below and please get involved: approvemdmatherapy.com

Heroic Hearts Project @WeHeroicHearts · Jun 24

The assault on the first new PTSD treatment in a generation isn't based on science. It's driven by a fringe org that calls veterans "perpetrators of large-scale international violence" who don't deserve "healing" and calls cops "murderers." We've uncovered a pattern of these

Show more

*Quote tweeted by SpaceX Board Member Steve Jurvetson (**donated $479,447 to Heroic Hearts in 2022**).*



Steve Jurvetson @FutureJurvetson · 1m

Replying to @FutureJurvetson

The plot thickens 💊

The FDA Advisory Committee "dumpster fire" was a fringe group backed by big-pharma, who would want to torpedo a 71% cure from a new entrant that obsoletes their highly-profitable SSRI franchise and lifetime of pill-popping.

Heroic Hearts Project @WeHeroicHearts · 3h

The assault on the first new PTSD treatment in a generation isn't based on science. It's driven by a fringe org that calls veterans "perpetrators of large-scale international violence" who don't deserve "healing" and calls cops "murderers." We've uncovered a pattern of these

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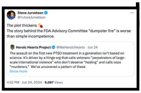
Jurvetson deletes, edits and reposts tweet.



Steve Jurvetson @FutureJurvetson

The plot thickens 💊

The story behind the FDA Advisory Committee "dumpster fire" is worse than simple incompetence:

Heroic Hearts Project @WeHeroicHearts · Jun 24

The assault on the first new PTSD treatment in a generation isn't based on science. It's driven by a fringe org that calls veterans "perpetrators of large-scale international violence" who don't deserve "healing" and calls cops "murderers." We've uncovered a pattern of these

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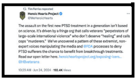
4:52 PM · Jun 24, 2024 · **6,087** Views

Tim Ferris retweets Heroic Hearts' post.



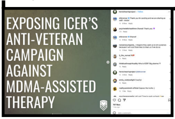
Tim Ferriss reposted

Heroic Hearts Project @WeHeroicHearts

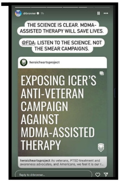
The assault on the first new PTSD treatment in a generation isn't based on science. It's driven by a fringe org that calls veterans "perpetrators of large-scale international violence" who don't deserve "healing" and calls cops "murderers." We've uncovered a pattern of these extremist, non-expert voices manipulating the media and @FDA processes to deny PTSD sufferers the chance to benefit from breakthrough treatments. Read our open letter here. heroicheartsproject.org/exposing-icers... @HBveterans

10:29 AM · Jun 24, 2024 · **192.4K** Views

Heroic Hearts posts press release on Instagram.



*Dr. Bronner's Instagram account boosts Heroic Hearts' post (**Dr. Bronner's has donated over $200,000 to Heroic Hearts**).*



drbronner · 1h

THE SCIENCE IS CLEAR. MDMA-ASSISTED THERAPY WILL SAVE LIVES.

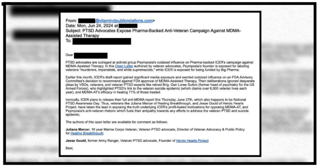
@FDA: LISTEN TO THE SCIENCE, NOT THE SMEAR CAMPAIGNS.

heroicheartsproject

heroicheartsproject As veterans, PTSD treatment and awareness advocates, and Americans, we feel it is our r...

Reply to drbronner...

June 24, 2024



From: [redacted]@vitamindpublicrelations.com>
Date: Mon, Jun 24, 2024 at [redacted]
Subject: PTSD Advocates Expose Pharma-Backed Anti-Veteran Campaign Against MDMA-Assisted Therapy
To: [redacted]

Dear [redacted]

PTSD advocates are outraged at activist group Psymposia's outsized influence on Pharma-backed ICER's campaign against MDMA-Assisted Therapy. In this Open Letter authored by veteran advocates, Psymposia's founder is exposed for labeling veterans "murderers, imperialists, and white supremacists," while ICER is exposed for being funded by Big Pharma.

Earlier this month, ICER's draft report gained significant media exposure and exerted outsized influence on an FDA Advisory Committee's decision to recommend against FDA approval of MDMA-Assisted Therapy. Their deliberations ignored desperate pleas by VSOs, veterans, and veteran PTSD experts like retired Brig. Gen Loree Sutton (former head of psychiatry for the US Armed Forces), who highlighted PTSD's link to the veteran suicide epidemic (which claims over 6,000 veteran lives each year), and MDMA-AT's efficacy in healing 71% of those treated.

Ironically, ICER plans to release their full anti-MDMA report this Thursday, June 27th, which also happens to be National PTSD Awareness Day. Thus, veterans like Juliana Mercer of Healing Breakthrough, and Jesse Gould of Heroic Hearts Project, have taken the lead in exposing the truth underlying ICER's profit-fueled motivations for opposing MDMA-AT, and Psymposia's anti-veteran rhetoric which fuels their antipathy towards any efforts to address the veteran PTSD and suicide epidemic.

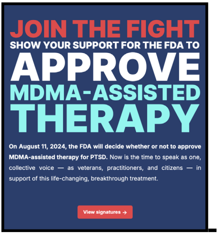
The authors of this open letter are available for comment as follows:

Juliana Mercer, 16 year Marine Corps Veteran, Veteran PTSD advocate, Director of Veteran Advocacy & Public Policy for Healing Breakthrough

Jesse Gould, former Army Ranger, Veteran PTSD advocate, Founder of Heroic Hearts Project

Best,

Vitamin D Public Relations sends email to media on behalf of Healing Breakthrough and Heroic Hearts Project promoting Heroic Hearts' Open Letter.



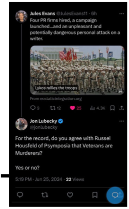
JOIN THE FIGHT
SHOW YOUR SUPPORT FOR THE FDA TO
APPROVE
MDMA-ASSISTED
THERAPY

On August 11, 2024, the FDA will decide whether or not to approve MDMA-assisted therapy for PTSD. Now is the time to speak as one, collective voice — as veterans, practitioners, and citizens — in support of this life-changing, breakthrough treatment.

Heroic Hearts, Healing Breakthrough, and Mission Within launch "Approve MDMA Therapy" website. Website form asks people if they would be willing to sign letters, speak on Zoom, or appear at press interviews.

June 25, 2024

In response to Evans' tweet about this article, former MAPS Veteran Affairs Liason Jon Lubecky responds with unfounded claims about members of Psymposia.



Jules Evans @JulesEvans11 · 6h
Four PR firms hired, a campaign launched...and an unpleasant and potentially dangerous personal attack on a writer.

Jon Lubecky @jonlubecky

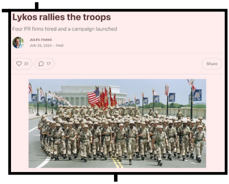
For the record, do you agree with Russel Housfeld of Psymposia that Veterans are Murderers?

Yes or no?

5:19 PM · Jun 25, 2024 · **22** Views

June 25, 2024

Jules Evans publishes article noting that **four PR firms** have been hired by Lykos and veteran organizations to combat FDA advisory committee/ICER recommendations.



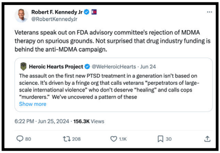
Lykos rallies the troops

Four PR firms hired and a campaign launched

JULES EVANS
JUN 25, 2024 · PAID

"The troops being sent into this PR battle are any researchers, journalists or veteran groups which have received funding from the Psychedelic Science Funders Collaborative (PSFC)..."

June 25, 2024



Robert F. Kennedy Jr
@RobertKennedyJr

Veterans speak out on FDA advisory committee's rejection of MDMA therapy on spurious grounds. Not surprised that drug industry funding is behind the anti-MDMA campaign.

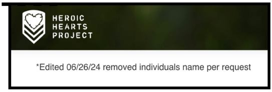
Heroic Hearts Project @WeHeroicHearts · Jun 24
The assault on the first new PTSD treatment in a generation isn't based on science. It's driven by a fringe org that calls veterans "perpetrators of large-scale international violence" who don't deserve "healing" and calls cops "murderers." We've uncovered a pattern of these
Show more

6:22 PM · Jun 25, 2024 · **156.3K** Views

Presidential candidate **Robert F. Kennedy Jr.** quote tweets Heroic Hearts press release, receiving over 1,000 Likes.

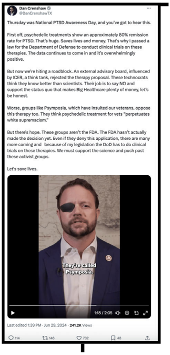
June 26, 2024

Heroic Hearts removes Dr. Neşe Devenot from its press release.



*Edited 06/26/24 removed individuals name per request

June 29, 2024


Dan Crenshaw @DanCrenshawTX

Thursday was National PTSD Awareness Day, and you've got to hear this.

First off, psychedelic treatments show an approximately 80% remission rate for PTSD. That's huge. Saves lives and money. That's why I passed a law for the Department of Defense to conduct clinical trials on these therapies. The data continues to come in and it's overwhelmingly positive.

But now we're hiting a roadblock. An external advisory board, influenced by ICER, a think tank, rejected the therapy proposal. These technocrats think they know better than scientists. Their job is to say NO and support the status quo that makes Big Healthcare plenty of money, let's be honest.

Worse, groups like Psymposia, which have insulted our veterans, oppose this therapy too. They think psychedelic treatment for vets "perpetuates white supremacism."

But there's hope. These groups aren't the FDA. The FDA hasn't actually made the decision yet. Even if they deny this application, there are many more coming and because of my legislation the DoD has to do clinical trials on these therapies. We must support the science and push past these activist groups.

Let's save lives.

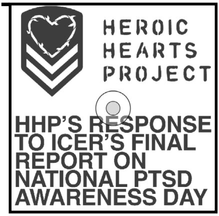
Last edited 1:39 PM · Jun 29, 2024 · **241.2K** Views

Congressman **Dan Crenshaw** tweets Heroic Hearts' talking points and publishes a video mischaracterizing ICER and Psymposia. This was reshared by Heroic Hearts with the quote:

"Thank you, [Dan Crenshaw]! The success of MDMA-AT to treat PTSD should not be undermined by activists. We need all the support we can get, especially from the [FDA]. This country's veterans deserve effective PTS treatments immediately."

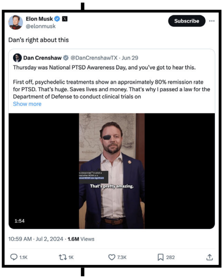
June 29, 2024

Heroic Hearts releases a **second** press release characterizing ICER's report as "anti-MDMA."



HHP'S RESPONSE TO ICER'S FINAL REPORT ON NATIONAL PTSD AWARENESS DAY

July 2, 2024


Elon Musk @elonmusk

Dan's right about this

Dan Crenshaw @DanCrenshawTX · Jun 29

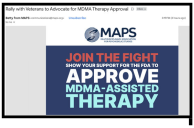
Thursday was National PTSD Awareness Day, and you've got to hear this.

First off, psychedelic treatments show an approximately 80% remission rate for PTSD. That's huge. Saves lives and money. That's why I passed a law for the Department of Defense to conduct clinical trials on

Show more

10:59 AM · Jul 2, 2024 · **1.6M** Views

Elon Musk shares Dan Crenshaw's tweet and video stating "Dan's right about this."

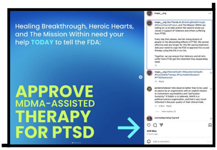

Rally with Veterans to Advocate for MDMA Therapy Approval

Betty from MAPS <communications@maps.org> Unsubscribe 3:19 PM (3 hours ago)

to me

MAPS
MULTIDISCIPLINARY ASSOCIATION FOR PSYCHEDELIC STUDIES
JOIN THE FIGHT
SHOW YOUR SUPPORT FOR THE FDA TO
APPROVE
MDMA-ASSISTED
THERAPY

Lykos Therapeutics' parent organization, the **Multidisciplinary Association for Psychedelic Studies** (MAPS) promotes Heroic Hearts and Healing Breakthrough on Instagram and in emailer.


Healing Breakthrough, Heroic Hearts, and The Mission Within need your help TODAY to tell the FDA:
APPROVE
MDMA-ASSISTED
THERAPY
FOR PTSD

maps__org

maps__org Our friends at @HealingBreakthrough, @HeroicHeartsProject, and The Mission Within are calling on us to take action! We need to share our voices in support of Veterans and others suffering from PTSD.

Every day that passes, we risk losing dozens of people to the devastating effects of PTSD. We cannot afford to wait any longer for this life-saving treatment. Add your name to urge the FDA to approve this crucial therapy using the link in our bio.

Together, we can ensure that Veterans and all who suffer from PTSD get the treatment they desperately need.

2h

maps__org #MentalHealth #MassMentalHealth #PsychedelicTherapy #PsychedelicResearch #PTSDAwareness

2h Reply

jordonwhatever Vets deserve better than to be used as pawns by an organization with an explicit mission to mainstream psychedelics and "spiritualize humanity." If Doblin is to believed, MAPS is a political science organization, and that's very much reflected in the poor quality of their clinical trials.

1h 4 likes Reply

View replies (1)

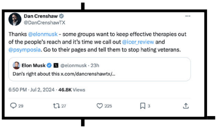
erickadayrising Signed!

409 likes

2 hours ago

Add a comment...

July 2, 2024



Dan Crenshaw
@DanCrenshawTX

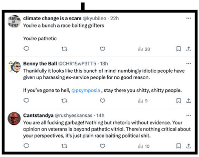
Thanks @elonmusk - some groups want to keep effective therapies out of the people's reach and it's time we call out @icer_review and @psymposia. Go to their pages and tell them to stop hating veterans.

> **Elon Musk** @elonmusk · 23h
> Dan's right about this x.com/dancrenshawtx/...

6:50 PM · Jul 2, 2024 · **46.8K** Views

Dan Crenshaw encourages his followers to collectively harass Psymposia and ICER.

July 2, 2024



climate change is a scam @kyubileo · 22h
You're a bunch a race baiting grifters

You're pathetic

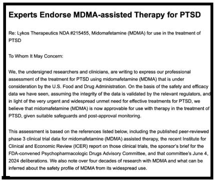
Benny the Ball @CHR15wP3TT5 · 13h
Thankfully it looks like this bunch of mind-numbingly idiotic people have given up harassing ex-service people for no good reason.

If you've gone to hell, @psymposia , stay there you shitty, shitty people.

Cantstandya @rushyeskansas · 14h
You are all fucking garbage! Nothing but rhetoric without evidence. Your opinion on veterans is beyond pathetic vitriol. There's nothing critical about your perspectives, it's just plain race baiting political shit.

Pinned tweet on Psymposia's Twitter page receives vitriolic harassment within hours our Crenshaw tweet.

Open letter coordinated by **Bob Jesse** is published endorsing Lykos' MDMA NDA. It was signed by 20 individuals. Shared by **Steve Jurvetson** and **Elon Musk**.



Experts Endorse MDMA-assisted Therapy for PTSD

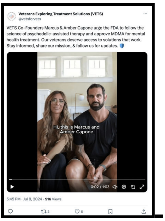
Re: Lykos Therapeutics NDA #215455, Midomafetamine (MDMA) for use in the treatment of PTSD

To Whom It May Concern:

We, the undersigned researchers and clinicians, are writing to express our professional assessment of the treatment for PTSD using midomafetamine (MDMA) that is under consideration by the U.S. Food and Drug Administration. On the basis of the safety and efficacy data we have seen, assuming the integrity of the data is validated by the relevant regulators, and in light of the very urgent and widespread unmet need for effective treatments for PTSD, we believe that midomafetamine (MDMA) is now approvable for use with therapy in the treatment of PTSD, given suitable safeguards and post-approval monitoring.

This assessment is based on the references listed below, including the published peer-reviewed phase 3 clinical trial data for midomafetamine (MDMA) assisted therapy, the recent Institute for Clinical and Economic Review (ICER) report on those clinical trials, the sponsor's brief for the FDA-convened Psychopharmacologic Drugs Advisory Committee, and that committee's June 4, 2024 deliberations. We also note over four decades of research with MDMA and what can be inferred about the safety profile of MDMA from its widespread use.

July 8, 2024



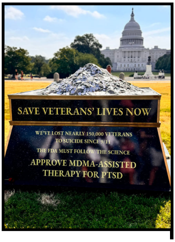
Veterans Exploring Treatment Solutions (VETS)
@vetsforvets

VETS Co-Founders Marcus & Amber Capone urge the FDA to follow the science of psychedelic-assisted therapy and approve MDMA for mental health treatment. Our veterans deserve access to solutions that work. Stay informed, share our mission, & follow us for updates. 🛡

5:45 PM · Jul 8, 2024 · **916** Views

Nonprofit **VETS** releases statement urging FDA to approve Lykos' MDMA application. VETS was founded in 2019 on a *$100,000* donation from PSFC and received *$71,000* from Lykos' parent company MAPS in 2020.

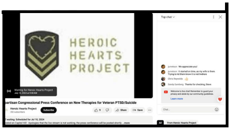
July 8, 2024



SAVE VETERANS' LIVES NOW
WE'VE LOST NEARLY 150,000 VETERANS TO SUICIDE SINCE 9/11
THE FDA MUST FOLLOW THE SCIENCE
APPROVE MDMA-ASSISTED THERAPY FOR PTSD

July 10, 2024

Heroic Hearts announces press conference in Washington D.C., unveils memorial art project. Livestream never starts. Video posted later.



partisan Congressional Press Conference on New Therapies for Veteran PTSD/Suicide

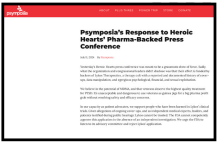
Heroic Hearts Project

Scheduled for Jul 10, 2024
…sted on Capitol Hill - Apologies that the live stream is not working, the press conference will be posted shortly ...more

jurvetson We appreciate you!
jurvetson It started on time, as my wife is there. Trying to let them know it is not livehere
Chris Reynolds 👍
Sandy Samberg Thanks for checking, Steve

Welcome to live chat! Remember to guard your privacy and abide by our community guidelines.

July 11, 2024



Psymposia's Response to Heroic Hearts' Pharma-Backed Press Conference

July 11, 2024 By Psymposia

Yesterday's Heroic Hearts press conference was meant to be a grassroots show of force. Sadly, what the organization and congressional leaders didn't disclose was that their effort is funded by backers of Lykos Therapeutics, a therapy cult with a reported and documented history of cover-ups, data manipulation, and egregious psychological, financial, and sexual exploitation.

We believe in the potential of MDMA, and that veterans deserve the highest quality treatment for PTSD. It's unacceptable and dangerous to use veterans as guinea pigs for a big pharma profit grab without resolving safety and efficacy concerns.

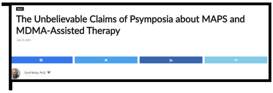
In our capacity as patient advocates, we support people who have been harmed in Lykos' clinical trials. Given allegations of ongoing cover-ups, and as independent medical experts, leaders, and patients testified during public hearings: Lykos cannot be trusted. The FDA cannot competently approve this application in the absence of an independent investigation. We urge the FDA to listen to its advisory committee and reject Lykos' application.

Psymposia releases rapid response statement on Heroic Hearts' Washington, D.C. press conference.

July 19, 2024

Chacruna (*whose Executive Director Bia Labate is a MAPS staff member*) publishes critical article about Psymposia's criticism of MAPS/Lykos.

This article was published days after Dr. Devenot blocked article author Geoff Bathje — a MAPS-endorsed psychedelic clinic co-founder —from their Facebook for bullying.

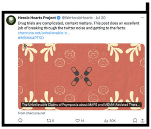

News

The Unbelievable Claims of Psymposia about MAPS and MDMA-Assisted Therapy

July 19, 2024

Geoff Bathje, Ph.D.

This article is shared by Genevieve Jurvetson of PSFC, her husband Steve Jurvetson, Michael Pollan, and Heroic Hearts Project.

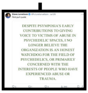

Heroic Hearts Project @WeHeroicHearts · Jul 20

Drug trials are complicated, context matters. This post does an excellent job of breaking through the twitter noise and getting to the facts:
chacruna.net/unbelievable-c...
#MDMA4PTSD

The Unbelievable Claims of Psymposia about MAPS and MDMA-Assisted Thera...

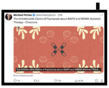
From chacruna.net

5 14 30K


Steve Jurvetson · Jul 20

First pull quote

DESPITE PSYMPOSIA'S EARLY CONTRIBUTIONS TO GIVING VOICE TO VICTIMS OF ABUSE IN PSYCHEDELIC SPACES, I NO LONGER BELIEVE THE ORGANIZATION IS AN HONEST WATCHDOG FOR THE FIELD OF PSYCHEDELICS, OR PRIMARILY CONCERNED WITH THE INTERESTS OF PEOPLE WHO HAVE EXPERIENCED ABUSE OR TRAUMA.

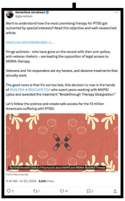

Michael Pollan @michaelpollan · 22h

The Unbelievable Claims of Psymposia about MAPS and MDMA-Assisted Therapy - Chacruna

The Unbelievable Claims of Psymposia about MAPS and MDMA-Assisted Thera...

From chacruna.net

13 2 29 8.2K


Genevieve Jurvetson @gjurvetson

Want to understand how the most promising therapy for PTSD got subverted by special interests? Read this objective and well-researched article.

chacruna.net/unbelievable-c...

Fringe activists - who have gone on the record with their anti-police, anti-veteran rhetoric - are leading the opposition of legal access to MDMA-therapy.

Veterans and 1st responders are my heroes, and deserve treatments that actually work.

The good news is that it's not too late, this decision is now in the hands of @US_FDA + @DrCaliff_FDA who spent years working with MAPS/ Lykos and awarded the treatment "Breakthrough Therapy Designation."

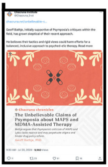
Let's follow the science and create safe access for the 13 million Americans suffering with PTSD.

The Unbelievable Claims of Psymposia about MAPS and MDMA-Assisted Therapy

From chacruna.net

11:41 AM · Jul 20, 2024 · 2,106 Views

3 7 19 2


Chacruna Institute @Chacruna_Inst

chacruna.net/unbelievable-c...

Geoff Bathje, initially supportive of Psymposia's critiques within the field, has grown skeptical of their recent approach.

He believes their tactics and rigid views could harm efforts for a balanced, inclusive approach to psyched-elic therapy. Read more

Chacruna chronicles

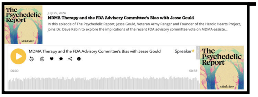
The Unbelievable Claims of Psymposia about MAPS and MDMA-Assisted Therapy

Bathje argues that Psymposia's criticism of MAPS and Lykos lacks nuance and may perpetuate stigma and hinder drug policy reform.

Geoff Bathje, PhD

9:30 AM · Jul 20, 2024 · 9,960 Views

July 25, 2024


July 25, 2024

MDMA Therapy and the FDA Advisory Committee's Bias with Jesse Gould

In this episode of The Psychedelic Report, Jesse Gould, Veteran Army Ranger and Founder of the Heroic Hearts Project, joins Dr. Dave Rabin to explore the implications of the recent FDA advisory committee vote on MDMA-assiste...

MDMA Therapy and the FDA Advisory Committee's Bias with Jesse Gould

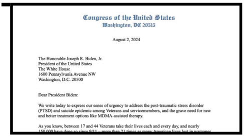
Spreaker

00:00 50:38

Jesse Gould (Heroic Hearts) is interviewed on "The Psychedelic Report."

August 2, 2024

61 House and 19 Senate members sign letter asking Joe Biden to approve MDMA-assisted therapy.


Congress of the United States
Washington, DC 20515

August 2, 2024

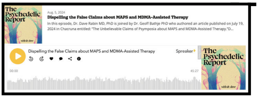
The Honorable Joseph R. Biden, Jr.
President of the United States
The White House
1600 Pennsylvania Avenue NW
Washington, D.C. 20500

Dear President Biden:

We write today to express our sense of urgency to address the post-traumatic stress disorder (PTSD) and suicide epidemic among Veterans and servicemembers, and the grave need for new and better treatment options like MDMA-assisted therapy.

As you know, between 17 and 44 Veterans take their lives each and every day, and nearly 150,000 have done so since 9/11 – more than 21 times as many American lives lost in warzones

August 5, 2024


Aug. 5, 2024

Dispelling the False Claims about MAPS and MDMA-Assisted Therapy

In this episode, Dr. Dave Rabin MD, PhD is joined by Dr. Geoff Bathje PhD who authored an article published on July 19, 2024 in Chacruna entitled: "The Unbelievable Claims of Psymposia about MAPS and MDMA-Assisted Therapy."D...

Dispelling the False Claims about MAPS and MDMA-Assisted Therapy

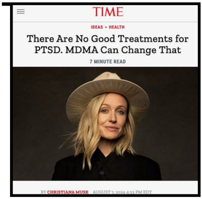
Spreaker

00:00 45:27

Geoff Bathje (author of Chacruna article) interviewed on "The Psychedelic Report."

August 7, 2024

Christiana Musk publishes pro-MDMA piece in *Time*. Musk does not disclose that Satori Capital — where she is an Operating Partner — is an investor in Lykos Therapeutics.



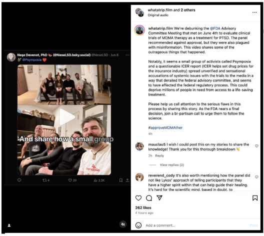
IDEAS • HEALTH

There Are No Good Treatments for PTSD. MDMA Can Change That

7 MINUTE READ

BY CHRISTIANA MUSK AUGUST 7, 2024 4:53 PM EDT

August 9, 2024


Neşe Devenot, PhD (@NeseLSD.bsky.social) @NeseLSD · Jun 8
@Psymposia

whatatrip.film and 2 others
Original audio

whatatrip.film We're debunking the @FDA Advisory Committee Meeting that met on June 4th to evaluate clinical trials of MDMA therapy as a treatment for PTSD. The panel recommended against approval, but they were also plagued with misinformation. This video shares some of the outrageous things that happened.

Notably, it seems a small group of activists called Psymposia and a questionable ICER report (ICER helps set drug prices for the insurance industry) spread unverified and sensational accusations of systemic issues with the trials to the media in a way that derailed the federal advisory committee, and seems to have effected the federal regulatory process. This could deprive millions of people in need from access to a life-saving treatment.

Please help us call attention to the serious flaws in this process by sharing this story. As the FDA nears a final decision, join a bi-partisan call to urge them to follow the science.

#approveMDMAther

4h

mauclau5 I wish I could post this on my stories to share the knowledge! Thank you for this thorough breakdown 👏

2h Reply

View replies (2)

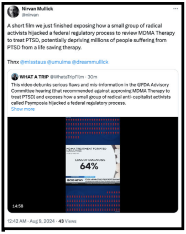
reverend_cody It's also worth mentioning how the panel did not like Lykos' approach of telling participants that they have a higher spirit within that can help guide their healing. It's hard for the scientific mind. based in doubt. to

262 likes
4 hours ago

WHAT A TRIP film releases a video claiming Psymposia and ICER "derailed the federal advisory committee."

Film maker Nirvan Mullick writes that "a small group of radical activists hijacked a federal regulatory process."

Film erroneously labels many public commenters at FDA's advisory committee as "Undisclosed Psymposia Activists."

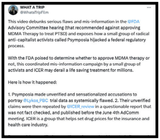

Nirvan Mullick
@nirvan

A short film we just finished exposing how a small group of radical activists hijacked a federal regulatory process to review MDMA Therapy to treat PTSD, potentially depriving millions of people suffering from PTSD from a life saving therapy.

Thnx @misstaus @umuima @dreammullick

WHAT A TRIP @WhataTripFilm · 30m
This video debunks serious flaws and mis-information in the @FDA Advisory Committee hearing (that recommended against approving MDMA Therapy to treat PTSD) and exposes how a small group of radical anti-capitalist activists called Psymposia hijacked a federal regulatory process.
Show more

12:42 AM · Aug 9, 2024 · **43** Views

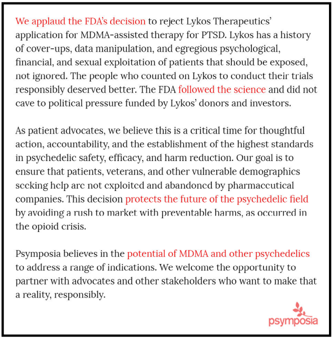

WHAT A TRIP
@WhataTripFilm

This video debunks serious flaws and mis-information in the @FDA Advisory Committee hearing (that recommended against approving MDMA Therapy to treat PTSD) and exposes how a small group of radical anti-capitalist activists called Psymposia hijacked a federal regulatory process.

With the FDA poised to determine whether to approve MDMA therapy or not, this coordinated mis-information campaign by a small group of activists and ICER may derail a life saving treatment for millions.

Here is how it happened:

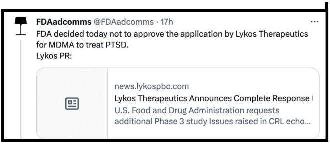
1. Psymposia made unverified and sensationalized accusations to portray @Lykos_PBC trial data as systemically flawed. 2. Their unverified claims were then repeated by @ICER_review in a questionable report that was not fact checked, and published before the June 4th AdComm meeting. ICER is a group that helps set drug prices for the insurance and health care industry.


We applaud the FDA's decision to reject Lykos Therapeutics' application for MDMA-assisted therapy for PTSD. Lykos has a history of cover-ups, data manipulation, and egregious psychological, financial, and sexual exploitation of patients that should be exposed, not ignored. The people who counted on Lykos to conduct their trials responsibly deserved better. The FDA followed the science and did not cave to political pressure funded by Lykos' donors and investors.

As patient advocates, we believe this is a critical time for thoughtful action, accountability, and the establishment of the highest standards in psychedelic safety, efficacy, and harm reduction. Our goal is to ensure that patients, veterans, and other vulnerable demographics seeking help are not exploited and abandoned by pharmaceutical companies. This decision protects the future of the psychedelic field by avoiding a rush to market with preventable harms, as occurred in the opioid crisis.

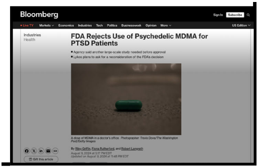
Psymposia believes in the potential of MDMA and other psychedelics to address a range of indications. We welcome the opportunity to partner with advocates and other stakeholders who want to make that a reality, responsibly.

psymposia


FDAadcomms @FDAadcomms · 17h
FDA decided today not to approve the application by Lykos Therapeutics for MDMA to treat PTSD.
Lykos PR:

news.lykospbc.com
Lykos Therapeutics Announces Complete Response |
U.S. Food and Drug Administration requests additional Phase 3 study Issues raised in CRL echo...

FDA rejects Lykos' Application. The agency requests a new Phase 3 study.



Industries
Health

FDA Rejects Use of Psychedelic MDMA for PTSD Patients

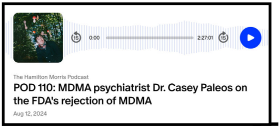
- Agency said another large-scale study needed before approval
- Lykos plans to ask for a reconsideration of the FDA's decision

A dose of MDMA in a doctor's office. *Photographer: Travis Dove/The Washington Post/Getty Images*

By Riley Griffin, Fiona Rutherford, and Robert Langreth
August 9, 2024 at 5:17 PM EDT
Updated on August 9, 2024 at 11:48 PM EDT

August 10, 2024

Psychedelic podcaster Hamilton Morris publishes podcast with Dr. Casey Paleos, a principal investigator and study therapist for Lykos-sponsored phase 3 clinical. In the episode description, Morris baselessly speculates if Psymposia was “responsible for a type of manipulation or coercion [of MAPS’s clinical trial participants] analogous to the coercion that yielded false accounts of satanic ritual abuse during the Satanic Panic of the 80s and 90s[.]”



The Hamilton Morris Podcast

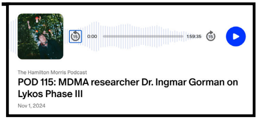
POD 110: MDMA psychiatrist Dr. Casey Paleos on the FDA's rejection of MDMA

Aug 12, 2024

August 12, 2024

November 1, 2024

Hamilton Morris publishes another podcast accusing Psymposia members of crimes and being responsible for the FDA’s rejection of MDMA.

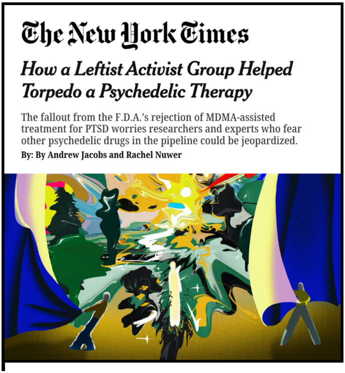


The Hamilton Morris Podcast

POD 115: MDMA researcher Dr. Ingmar Gorman on Lykos Phase III

Nov 1, 2024

February 4, 2025



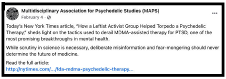
The New York Times

How a Leftist Activist Group Helped Torpedo a Psychedelic Therapy

The fallout from the F.D.A.’s rejection of MDMA-assisted treatment for PTSD worries researchers and experts who fear other psychedelic drugs in the pipeline could be jeopardized.

By: By Andrew Jacobs and Rachel Nuwer

Andrew Jacobs and Rachel Nuwer (who wrote the June 20, 2024 BBC article above) publish a New York Times article laying blame on Psymposia for the FDA’s rejection of Lykos’ application. This article contains numerous incorrect claims about Psymposia and was widely shared, including by MAPS.



Multidisciplinary Association for Psychedelic Studies (MAPS)

February 4 ·

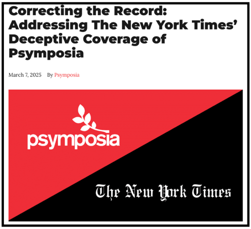
Today’s New York Times article, “How a Leftist Activist Group Helped Torpedo a Psychedelic Therapy,” sheds light on the tactics used to derail MDMA-assisted therapy for PTSD, one of the most promising breakthroughs in mental health.

While scrutiny in science is necessary, deliberate misinformation and fear-mongering should never determine the future of medicine.

Read the full article:
http://nytimes.com/.../fda-mdma-psychedelic-therapy...

March 7, 2025

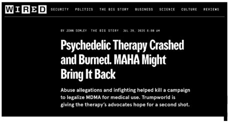
Psymposia publishes article pointing out numerous errors in the NYT’s reporting.



Correcting the Record: Addressing The New York Times’ Deceptive Coverage of Psymposia

March 7, 2025 By Psymposia

July 29, 2025



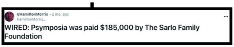
BY JOHN SEMLEY THE BIG STORY JUL 29, 2025 6:00 AM

Psychedelic Therapy Crashed and Burned. MAHA Might Bring It Back

Abuse allegations and infighting helped kill a campaign to legalize MDMA for medical use. Trumpworld is giving the therapy's advocates hope for a second shot.

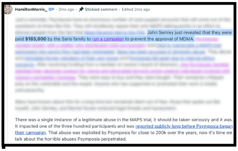
John Semley publishes an article in *Wired* that reports Psymposia received a 2024 donation from the Sarlo Foundation.

WIRED article is shared by popular commentators like Hamilton Morris, who incorrectly claim that this reporting proved Psymposia was paid to "run a campaign to prevent the approval of MDMA." This is stated nowhere in Semely's reporting.



r/HamiltonMorris · 2 mo. ago
HamiltonMorris_

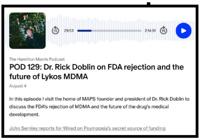
WIRED: Psymposia was paid $185,000 by The Sarlo Family Foundation



HamiltonMorris_ OP · 2mo ago · Stickied comment · Edited 2mo ago

John Semley just revealed that they were paid **$185,000** by the Sarlo family to run a campaign to prevent the approval of MDMA.

There was a single instance of a legitimate abuse in the MAPS trial, it should be taken seriously and it was. It impacted one of the three hundred participants and was reported publicly long before Psymposia began their campaign. That abuse was exploited by Psymposia for close to 200k over the years, now it's time we talk about the horrible abuses Psymposia perpetrated.



The Hamilton Morris Podcast

POD 129: Dr. Rick Doblin on FDA rejection and the future of Lykos MDMA

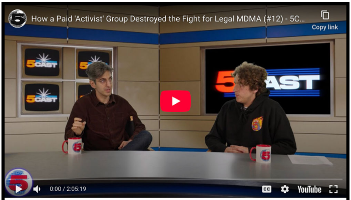
August 4

In this episode I visit the home of MAPS founder and president of Dr. Rick Doblin to discuss the FDA's rejection of MDMA and the future of the drug's medical development.

John Semley reports for Wired on Psymposia's secret source of funding

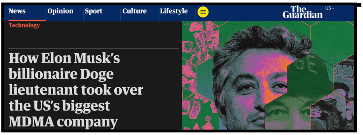
August 24, 2025

A popular content creator, Andrew Callaghan of Channel 5 (4M social followers, 400M views), broadcast a video interview with Hamilton Morris to millions of his followers, making a number of false and hostile claims about Psymposia. Callaghan and Morris erroneously claim that the nonprofit Usona secretly funded Psymposia to attack Compass Pathways and interfere with MDMA legalization efforts. They continue to spread the lie that Psymposia was paid to "run a campaign" to prevent MDMA approval, and that Psymposia lied to the FDA. They refer to Psymposia as "terrorists," and Callaghan ends the video asking Morris how his followers can help "destroy these bastards."


How a Paid 'Activist' Group Destroyed the Fight for Legal MDMA (#12) - 5C...
Copy link
5CAST
5CAST
5CAST
0:00 / 2:05:19
YouTube

How a Paid 'Activist' Group Destroyed the Fight for Legal MDMA (#12) - 5CAST w/ Andrew Callaghan ft. Hamilton Morris

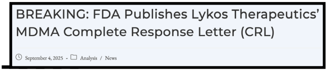
August 29, 2025



How Elon Musk's billionaire Doge lieutenant took over the US's biggest MDMA company

The Guardian reports that psychedelic advocates including MAPS founder "[Rick] Doblin…blamed the anti-corporate psychedelics group Psymposia" for MDMA's rejection.

September 4, 2025



BREAKING: FDA Publishes Lykos Therapeutics' MDMA Complete Response Letter (CRL)

September 4, 2025 - Analysis / News

The FDA releases its Complete Response Letter to Lykos detailing its 2024 rejection of MDMA-assisted therapy. The letter revealed that the FDA had discovered "several unreported adverse events" at two trial sites. This corroborates what Psymposia had been saying consistently: adverse events were not reported, and this pattern of non-reporting represents a threat to public health. The letter specifies numerous other specific reasons for rejection unrelated to Psymposia's concerns, including failure to collect 'positive' adverse events; lack of durability data; and high rates of prior MDMA use among participants, and high rates of prescreening failures.