



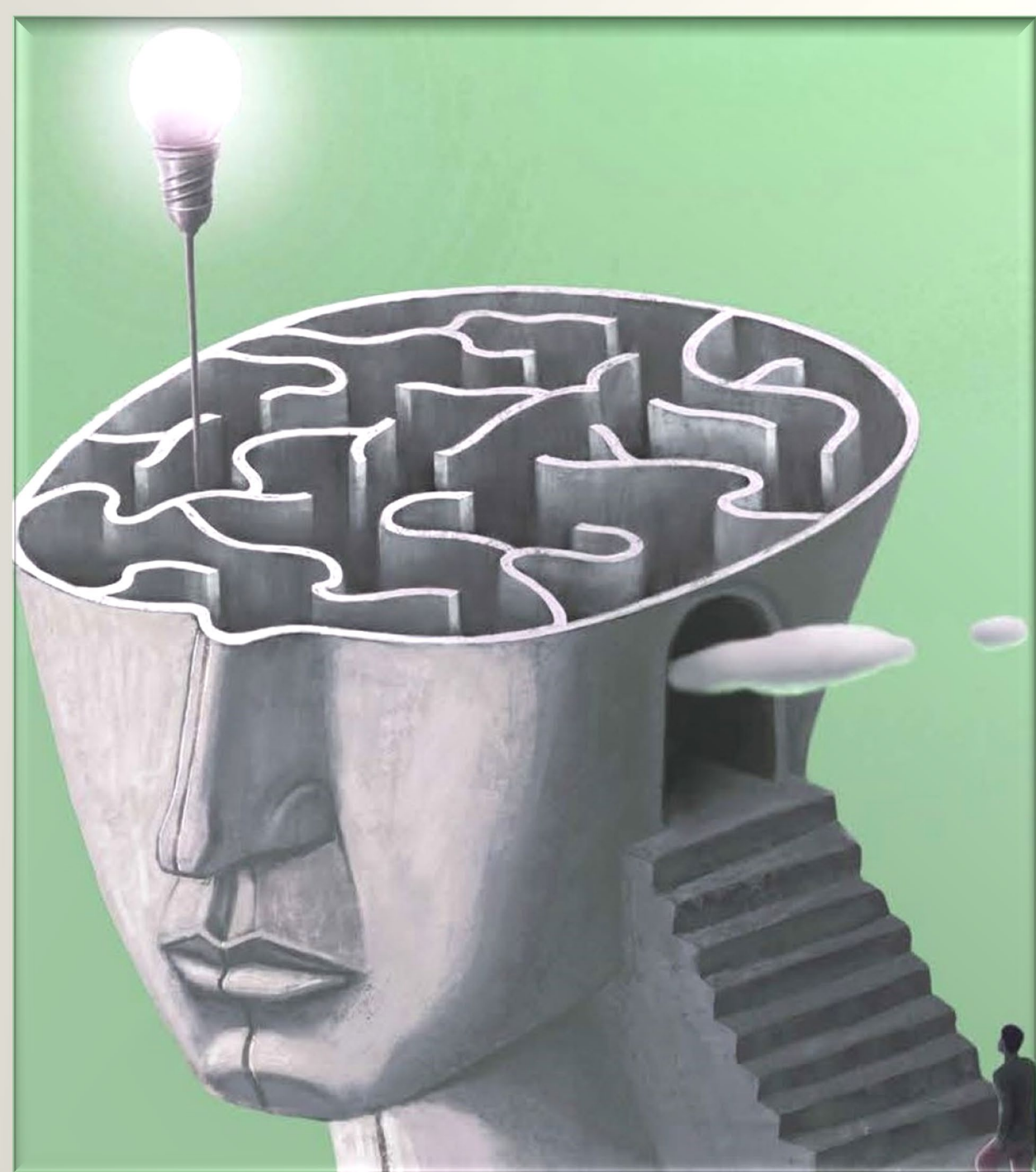
PAREA

PSYCHEDELIC ACCESS AND RESEARCH EUROPEAN ALLIANCE

The Time is Now

Preparing Europe for safe,
effective and accessible
psychedelic assisted therapies

Tadeusz Hawrot, Founder and Executive Director



Addressing unmet needs with psychedelic assisted therapies (PATs)

Massive unmet needs in mental, neurological and substance use disorders – over 100 m Europeans affected by mental health conditions, including alcohol use disorder

Slow pharmaceutical innovation

Groundbreaking scientific advances related to psychedelic drug development and PAT

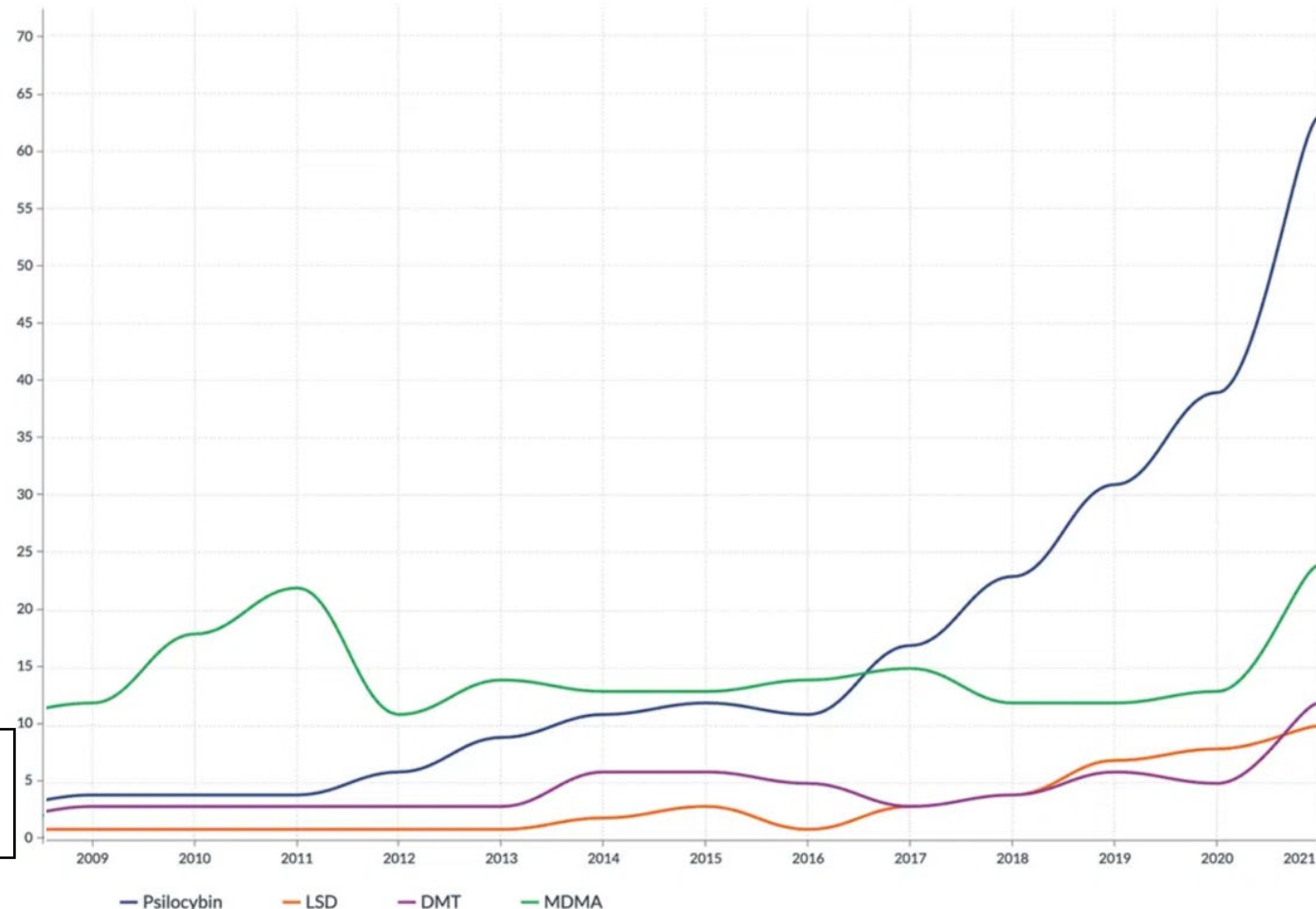
US FDA granted Breakthrough Therapy designation to PAT for 3 trials

A need for bigger sample sizes and more research – using rigorous methodologies – to further understand safety, the (long-term) effectiveness and treatment parameters

European health systems are not prepared for these treatments

Active Clinical Trials on Different Psychedelics 2009 - 2021

Data on Psilocybin, LSD, DMT, and MDMA sourced from Dimensions Analytics



The Greek word **παρέα (paréa)** means to **be in the company of friends** or to **do something together**.

In Greek culture, **parea** is a **venue for the growth of the human spirit** and the **exploration of ideas to enrich our quality of life**.



Those values guide our joint efforts to change perceptions, raise awareness on the scientific advances re. PAT, scale up and accelerate action and, ultimately, bring better health to European citizens.

COLLECTIVE VOICE AND ONE-STOP-SHOP IN EUROPE



FULL MEMBERS



Association of European Cancer Leagues



Beckley Foundation



Drug Science



European Brain Council



European College of Neuropsychopharmacology



European Federation of Neurological Associations



European Psychiatric Association



Global Alliance of Mental Illness Advocacy Networks - Europe



MIND Foundation



Open Foundation



Osmond Foundation



Pain Alliance Europe



PsyPAN

ASSOCIATE MEMBERS AND OBSERVERS



Law Enforcement Action Partnership (LEAP) - Europe



Awakn Life Sciences



International Center for Ethnobotanical Education, Research, and Service



MAPS Public Benefit Corporation

INDUSTRY PARTNERS



Beckley Psytech



Cybin

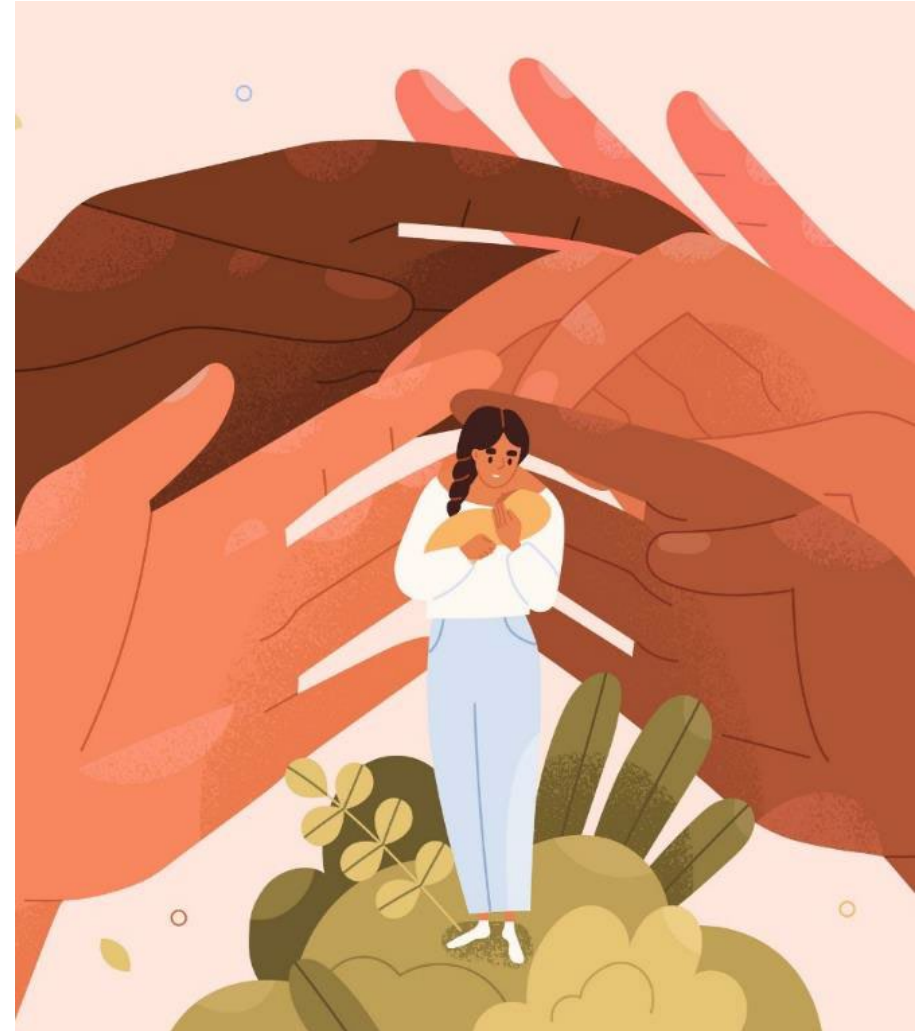


MindMed

AND SUPPORTERS...

Vision: help people heal

„A world in which brain health is valued, preventable suffering is avoided, and psychedelic novel treatments help people to heal and enhance their sense of wellbeing.“



Mission: getting PAT into mainstream services

„Safe, modern, and ethically responsible integration of PAT into European mainstream health services, where those novel treatments are an additional therapeutic option, accessible and affordable for all, as registered and reimbursed medical treatments.“

"I want it to be available at a reasonable cost for all those people that don't have tie-dye t-shirts, and can't spell psychedelics and are never going to grow mushrooms in their own closets. I want it integrated into medical care."

Dr. Bill Richards

How to Change Your Mind (E02) | Netflix

8 OBJECTIVES TO DRIVE PROGRESS



Foster research



Support drug reform



Decrease stigma



Build capacity in healthcare systems



Increase collaboration



Ensure equitable, timely, affordable, safe, and legal access



Promote meaningful engagement and safeguard optimal care and safety for patients



Contribute to a diverse and equitable psychedelic ecosystem

Global players moving at full speed: US&UK examples in 2022

NIH/FDA letter - details on current NIH funding of psychedelic research: \$35 m. in 2021



3 US Federal agencies: the National Institutes of Mental Health, Drug Abuse, and Alcohol Abuse and Alcoholism co-hosted a 2 day workshop "Psychedelics as Therapeutics"



US National Academies for Sciences, Engineering and Medicine co-hosted a 2 day workshop "Exploring Psychedelics and Entactogens as Treatments for Psychiatric Disorders"



US congressional bipartisan caucus formed to explore P. research, steer the congressional conversation around the therapeutic potential of P. and serve as an educational resource



Innovative Licensing and Access Pathway Innovation Passport granted by UK regulators to MDMA as an adjunct to therapy for PTSD



UK National Institute for Health and Care Research approved grant funding for Phase III clinical trial exploring the use of ketamine-assisted therapy for the treatment of AUD



USA



EU



PAT are coming: what's your plan, Europe?



US President Administration letter (2022)
Federal Task Force and PPP

It “anticipates” that regulators will **approve MDMA and psilocybin within the next 2 years** for designated breakthrough therapies for PTSD and depression

Establishing a **Federal Task Force** to address the numerous complex issues associated with PAT

- Establish a **PPP to address risks to public health** which may require harm reduction, risk mitigation, and safety monitoring

Collaboration across federal agencies with outside stakeholders
- the most effective way

Within the next few years, millions of Europeans may be eligible for a prescription of PAT



Unparalleled opportunity which also calls for bold but thoughtful measures

A need to formulate a similar initiative in the EU to address numerous safety, policy and regulatory considerations related to the future roll-out of PAT

Within the next few years, millions of Europeans may be eligible for a prescription of PAT



Phased roll out – this tree will take a while to grow

Unparalleled opportunity which also calls for bold but thoughtful measures

A need to develop infrastructure for the highest quality safe, affordable, and equitable access to PATs, good standards of practice, training of specialised therapists, credentialing and licencing, safe and ethical use monitoring, support for people with challenging experiences, engagement of communities and peer-support networks, and data standards.

Establish European guidelines for MS

Given the foreseeable bottleneck of qualified, trained providers based on a likely high demand, a phased roll out will need to be considered, balancing a need for widespread access with safety, monitoring and supervision.



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