



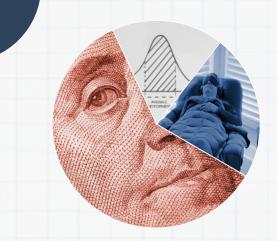
University of California San Francisco





# HOPE

Health Outcomes and Psychedelic Economics









a project of **Psychedelic Medicine** Coalition 501(c)(3)

## The Price of Despair

#### The Economic and Human Burden of Mental Illness and Addiction

#### Healthcare Costs

People with mental health disorders require approximately three times more spending on medical care per capita.

#### Economic Costs

Estimated to reach \$1 trillion in direct healthcare expenses, lost productivity, and criminal justice costs.



#### Lives Lost

Over 100,000 lives are lost to overdose each year. Nearly ½ of adults in the US has a substance use disorder or mental illness.

#### Efficacy Gap

Current treatment paradigms have been around for half a century and aren't providing relief for 30-50% of patients.



## **Psychedelic-Assisted Therapies (PAT)**

Offering Hope with Breakthrough Therapies

The FDA has assigned breakthrough therapy designation to five drug developers (Lykos, Compass, Usona, Mindmed, Cybin), signaling strong support from the regulatory agency.



MDMA-assisted therapy shows a 67% remission rate for patients with treatment-resistant PTSD in Phase 3 clinical trials.



Psilocybin-assisted therapy has shown a 42% sustained depressive symptom response rate in patients with 'treatment-resistant' depression.

## 80% Smoking Cessation

A small trial of psilocybin therapy finds that six months after the study, 80% of participants were smoking free (67% at the 30-month follow-up).



## Validating Breakthrough Therapy Value

Five Targeted Studies for Cost-Effective Mental Health Care

#### **Cost-Effectiveness**

We are undertaking five focused projects to analyze the cost-effectiveness of cutting-edge psychedelic therapies for major mental health and addiction challenges.

#### Psychedelic Therapies

Our work covers MDMA-assisted therapy for PTSD, Psilocybin for depression, smoking cessation, and alcohol use disorder, plus Ibogaine for opioid withdrawal.

#### **Demonstrating Impact**

By demonstrating clear health and economic benefits, we'll equip decision-makers with the evidence for coverage, reimbursement, and integration, driving sustainable innovation in mental healthcare.



## The Cost of Delay vs. Unlocking Federal Action

Independent Economic Proof is the Catalyst for Bold Policy & Investment

## *without* Hesitation, Delays & HOPE Incrementalism

- Delayed Policy: Lawmakers lack economic data for "safe cover" to champion major reforms/budgets.
- Limited Federal Funding: Without proven ROI, agencies hesitate on large PAT trials, infrastructure, and data.
- Slower Payer Adoption: Lack of strong federal signals slows state Medicaid & private payer coverage.
- Timeline: 5-10+ years for federal action.

## withAccelerated Action &HOPETransformation

- Empowered Policy: HOPE's credible economics support stronger legislation, CBO scores, and broader policymaker backing.
- Catalyzed Federal Investment: Proven ROI unlocks significant new federal funding for research and implementation.
- Accelerated Payer Coverage: Clear economic benefits drive faster, favorable coverage by CMS, VA, and insurers.
- Timeline: 2-4 years for federal action.



## Igniting Capital for Care Innovation

Driving Economic Growth for Psychedelics Industry

#### Potential Policy & Payer Impact

- Enable CMS & public payers to justify coverage and optimize ROI for innovative therapies.
- Empower law- and policy makers to make legislative and budgetary priorities.
- Provide evidence akin to ICER analyses, influencing formulary and reimbursement decisions.

#### Economic Transformation

- May help unlock a significant influx of capital into the sector, fueling rapid growth and innovation.
- De-risks investment through comprehensive economic analysis that attracts substantial new funding.
- Lays the foundation for transformative financial support, positioning mental healthcare for swift, scalable change.



## Voices of Support

#### Pharma Industry & Payers

"As a long-term database researcher, I recognize the strong value of the HOPE proposal to provide both quantitative and qualitative evidence of the value of psychedelic therapies.

In the US and globally, payers are reluctant to support therapeutic interventions without a clear value statement that includes both economic and scientific data."



James E. Smeeding RPh, MBA President and Founder, *Indication BioScience* President, *TPG National Payor Roundtable* 

#### Commercial Payers & Healthcare Policy

"I fully support the HOPE Initiative. This proposal offers a timely and much-needed economic analysis to evaluate the cost-effectiveness of psychedelic therapies. It's exactly the kind of data payers and policymakers need to make responsible, informed decisions in this emerging space."



James Roosevelt, Jr., J.D. Former CEO, *Tufts Health Plan* Former Associate Commissioner for retirement policy of the Social Security Administration

"Throughout my career, I have been an active consumer and advocate for high-quality research in behavioral health policy. I strongly support this project because a careful, methodologically sound assessment conducted by credible researchers will provide essential evidence to educate policymakers and encourage the adoption and dissemination of psilocybin and MDMA therapies. Such research is vital for advancing evidence-based policy decisions in this emerging field."



Henry Harbin Former CEO, *Magellan Health Services* 



## Voices of Support

#### Federal Legislation Advocates

"The HOPE initiative will create powerful information that can help move federal legislation and funding for psychedelics forward quickly. Psychedelic Medicine Coalition immediately recognized the value of this research.

This value has been affirmed to us by legislators and their staff, who have expressed enthusiasm to have this information as soon as possible. We are excited for it to move forward as quickly as possible."



Melissa Lavasani, MPP, MS Founder & CEO, *Psychedelic Medicine Coalition* 

#### **Government Payers**

"As plant-based therapies have shown impressive clinical benefit in early studies, more evidence suggests that their effects are durable for many mental health conditions.

As they make decisions on coverage, public and private payers will want to know what this means for total costs of care. We must gain these insights as soon as possible, and this research will be crucial"



Shereef Elnahal, MD, MBA, Former Under Secretary for Health at the U.S. Department of Veterans Affairs



The Costs and Health Benefits of Expanded Access to MDMA-assisted Therapy for Chronic and Severe PTSD in the USA: A Modeling Study

## Is Improving Lives also Cost Effective?

MDMA-AT can be as impactful as, or better than, other major public health interventions. MDMA-AT is cost-saving under all scenarios compared to Standard of Care (SoC).

Expanding access to MDMA-Assisted Therapy (MDMA-AT) to 25–75% of eligible patients with chronic and severe PTSD over 10 years:

- Saves Lives: Prevents 43,000–106,000 deaths.
- Improves Health: Gains 3.3–8.2 million QALYs (Quality-Adjusted Life Years).
- Reduces Costs: Achieves \$109–\$266 billion in healthcare savings.

Deaths prevented by MDMA-AT exceed those prevented by fluoxetine (Prozac) for depression (~33,600).

QALYs gained by MDMA-AT (8.2 million) surpass:

- Antiretroviral therapy in the early HIV/AIDS epidemic (2.95 million).
- National HIV testing/treatment targets over 20 years (2.14 million).

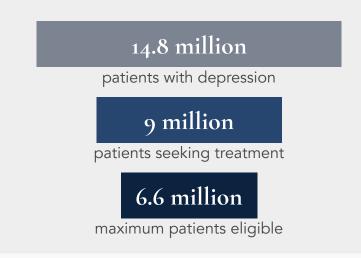


Published Research

An Estimate Of The Number Of People With Clinical Depression Eligible For Psilocybin-assisted Therapy In The United States

## Is Improving Lives also Cost Effective?

Significant demand exists for Psilocybin-Assisted Therapy for Major Depressive Disorder (MDD) and Treatment-Resistant Depression (TRD).



24–62% of treated patients could be eligible based on real-world clinical settings.

Eligibility translates to 2.2M–5.6 million patients with MDD and 0.6M–1.7 million patients with TRD.



## Our Research Approach

#### **Rigorous Analysis for Policy Impact**

By comparing PATs to current standard-of-care (efficacy, safety, cost) and documenting its baseline failures, HOPE provides independent, unbiased evidence of PAT's cost-effectiveness and potential to significantly reduce healthcare expenditures.

Yale

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#### A Data-Driven Approach

In contrast to earlier academic studies, HOPE uses real-world healthcare data from multiple sources and compares directly with current SoC via claims data.

JOHNS HOPKINS

- Medicare & Medicaid
- Private Insurance (Optum-United)
- Veterans Affairs

Berkeley

#### Modeling Techniques

HOPE employes sophisticated health economic modeling techniques to project the long-term costs and benefits of PAT.

DELPHI

- Clinical trial data
- Healthcare utilization patterns
- Quality of life improvements









## **Project Timeline and Deliverables**

#### 12 Publications, Policy Briefs, & Implementation Guides

1	Foundation & Initial Analysis (Months 1-6)*	Multi-Dataset Analysis & Model Expansion (Months 7-12)*	Analysis Across Interventions (Months 13-18)*	Synthesis and Integration (Months 19-24)*
•	& Data Acquisition	Analysis	<ul><li>Tracks</li><li>Publications in Top-Tier</li></ul>	<ul> <li>Cross-Intervention Synthesis</li> <li>Final Products</li> <li>Dissemination and Engagement</li> </ul>

\*Iterative feedback from targeted strategic consultations with expert advisors at key milestones



## Meet the Team

#### Core Research Team ↓

#### Dr. Elliot Marseille Director, CEP at UCSF/Berkeley Project Research Lead

Dr. James 'Jim' G. Kahn Emeritus Professor, UCSF Health Policy & Economics

#### Academic Partners $\downarrow$

Dr. Julian Urrutia Ripoll Yale University Health Economics Specialist

Dr. Anton Avanceña University of Texas at Austin Health Policy Research

Dr. Michael Darden Johns Hopkins University Substance Use Disorder

#### Data Implementation $\downarrow$

Desislava Prodanova, M.A. President, MSIDE Healthcare Systems Engineer

Dr. Sylvestre Quevedo Vice-President, MSIDE Healthcare Data Analyst

#### Project Management $\downarrow$

Lia Mix, LMFT, CPTR CEO, Delphi Strategic Guidance & Project Management

Floris Wolswijk, MSc Senior Project Manager, Delphi Project Coordination

Lauren Tannhauser Fundraising, Delphi Fundraising & Support



## Breakdown of Project Expenditures

This 24-month project will cost \$1.85 million and produce 12 academic papers and presentations for policymakers. The research will help government officials, insurance companies, and healthcare systems decide if and how to include these treatments in standard medical care.

Economic Analysis & M	odeling↓	Data Access & Analysis↓	Project Management ↓
MDMA / PTSD \$193,000	Psilocybin / AUD \$339,250	Data Access \$95,000	Project Coordination \$114,400
Psilocybin / MDD \$240,450	lbogaine / OUD \$339,250	Data Analysis <i>\$160,000</i>	PR & Stakeholder Engagement <i>\$125,600</i>
Psilocybin / TUD \$240,450			



## Who needs this information?\*

#### Data-driven Decisions Lead to Better Outcomes



Government Decision-Makers



Pharmaceutical Industry



Financial Institutions and Decision-makers



Centers for Medicare and Medicaid



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Commercial Health Plan Payers



Our comprehensive data empowers stakeholders to support critical budget decisions, coverage policies, budget decisions, and strategic investments in research and care delivery.

\*Outputs co-shaped by targeted strategic consultation with these stakeholders



## Be a Champion for Mental Health Innovation

#### The cost of inaction is too high. Join us to drive urgent change.

Your support for HOPE accelerates vital research on psychedelic therapies, delivering evidence-based, cost-effective solutions to millions in need—*sooner*.

- Accelerate access to transformative mental health & addiction solutions
- Ensure breakthrough treatments reach underserved communities, faster
- Ready to make a profound impact?

• Drive systemic, data-informed change in mental healthcare

• Reduce the immense human and economic burden of delayed action

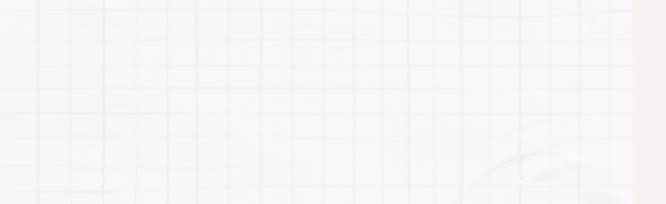
Contact <u>lia.mix@delphi-circle.com</u> to champion this vital research.

The HOPE initiative is made possible through the Psychedelic Medicine Coalition 501(c)(3). All funds are managed by PMC.



## APPENDICES

Health Outcomes and Psychedelic Economics



### Intervention Protocols and Analytical Frameworks 1/2

#### Overview of Analyzed Interventions

- MDMA for PTSD: Treating post-traumatic stress disorder with MDMA-assisted therapy, focusing on cost-effectiveness and long-term savings.
- Psilocybin for Major Depression: Examining cost utility in general and treatment-resistant depression.
- Psilocybin for Smoking Cessation: Highlighting high abstinence rates and healthcare cost offsets.
- Psilocybin for Alcohol Use Disorder: Reducing heavy drinking days and societal costs.
- **Ibogaine for Opioid Use Disorder:** Addressing opioid withdrawal with potential emergency care reductions.

#### Methodology Highlights

• Cost-Effectiveness Models:

Using Markov and decision-analytic models to simulate chronic conditions and estimate quality-adjusted life years (QALYs).

- Perspectives: Societal (healthcare and productivity) and Payer-specific (public/private insurance).
- Sensitivity Analysis: Evaluating treatment efficacy, costs, and scale-up scenarios, including scenarios for real-world effectiveness vs. trial efficacy.
- Real-World Data Sources:
  - CMS (Medicaid/Medicare): Costs and utilization in public insurance populations.
  - Optum-United: Commercial claims analysis for broader demographic insights.
  - VA Data: Targeted analysis for veteran-specific PTSD outcomes.



### Intervention Protocols and Analytical Frameworks 2/2

#### Key Supporting Findings and Impact

- MDMA for PTSD:
  - Potential \$132.9M savings for 1,000 patients over 30 years.
  - Scaled implementation (10%, 25%, 50% eligible patients) shows significant QALY gains and cost offsets.
- Psilocybin for Depression:
  - Improves long-term healthcare savings, particularly for treatment-resistant cases.
  - Projects reduced disability claims and increased productivity.
- Psilocybin for Smoking Cessation:
  - 60% abstinence rates at 12 months, vastly outperforming standard treatments (10–20%).
  - Reduces costs from smoking-related illnesses.
- Psilocybin for Alcohol Use Disorder:
  - Early data suggests decreased emergency visits and societal harm from alcohol-related incidents.
  - Increased abstinence rates lead to improved societal and familial outcomes.

- Ibogaine for OUD:
  - Models predict substantial reductions in overdose deaths and emergency care costs.
  - Addresses critical gaps in withdrawal management protocols.

#### **Research Products**

- Planned Deliverables:
  - 12 peer-reviewed manuscripts.
  - Comparative and cross-database analyses for broad implementation insights.
  - Implementation guidance tailored for policymakers and insurers.
- Stakeholder Communication:
  - Policy briefs for Medicaid and VA systems.
  - Presentation at healthcare and addiction conferences.
  - Accessible materials for broader public engagement.



## Technical Details of Models & Data Sources 1/2

#### Economic Modeling Framework

- Model Types:
  - Markov Cost-Effectiveness Models: Simulate chronic conditions (e.g., PTSD, addiction) with transitions between health states over time (remission, relapse, severity stages).
  - Decision-Analytic Models: Evaluate treatment pathways, resource use, and outcomes.
  - Agent-Based Modeling (ABM): Simulate individual trajectories, capturing variability in treatment adherence and response rates.
- Model Perspectives:
  - Societal Perspective: Includes direct medical costs, productivity losses, and caregiver burden.
  - Healthcare Payer Perspective: Focuses on costs relevant to public (Medicaid/Medicare) and private insurance.
- Sensitivity Analyses:
  - One-Way Sensitivity: Key cost-effectiveness drivers.
  - Probabilistic Analysis: Cost-effectiveness acceptability curves.
  - Scenario & Break-Even Analysis: Impact of varying assumptions on treatment costs and uptake.
  - Threshold Analysis: Impact of varying real-world effectiveness vs. trial efficacy.

#### Data Sources

- Claims Data (Key Datasets):
  - CMS (Medicare & Medicaid): Public insurance costs, focusing on PTSD, depression, addiction.
  - Optum-United Healthcare: Commercial claims database for diverse populations.
  - Veterans Administration (VA): Veteran-specific PTSD care and costs.
- Clinical Efficacy Data:
  - Published trial results from leading institutions (e.g., Johns Hopkins, NYU).
  - Real-world evidence updates (as therapies gain FDA approval).
- Supplementary Inputs:
  - Epidemiological data (e.g., incidence/mortality rates).
  - Published literature for baseline healthcare costs and quantifying burden & costs of current standard of care.





## Technical Details of Models & Data Sources 2/2

#### Key Data Management Strategies

- Cleaning and Harmonization:
  - Standardizing ICD-10, CPT codes, and payer-specific data fields.
  - Imputation for missing data.
- Stratification:
  - By demographics (age, gender), condition severity, and comorbidities.
- Security & Compliance:
  - HIPAA-compliant environments.
  - De-identified data to ensure patient privacy.

#### Innovations in Modeling

- Transition to advanced software platforms (e.g., TreeAge, R) to:
  - Simulate long-term treatment impacts.
  - Incorporate stochastic effects for probabilistic outcomes.
  - Enable cross-database comparisons for robustness.

#### **Practical Applications**

- Cost-Effectiveness Metrics:
  - Incremental cost-effectiveness ratio (ICER) per QALY gained.
- Implementation Scenarios:
  - Scale-up models for 10%, 25%, and 50% patient adoption rates.
- Policy Guidance:
  - Projected cost savings by payer (e.g., Medicaid, VA) and societal benefits.



## Expanded Team Introduction 1/5

#### Core Research Team



Dr. Elliot Marseille

- Director, CEP at UCSF/Berkeley | Project Research Lead
- Dr. Marseille leads the economic modeling and analysis for the project, leveraging decades of experience in health policy and cost-effectiveness research. As the Director of the Center for the Economics of Psychedelics (CEP), he has pioneered groundbreaking studies on healthcare interventions and is recognized for his work on economic evaluations that influence policy and healthcare strategies globally.

#### Dr. James 'Jim' G. Kahn

- Emeritus Professor, UCSF | Health Policy & Economics Expert
- Dr. Kahn is a highly respected figure in health economics and policy, with a career spanning decades of research on cost-effectiveness and resource allocation in healthcare. His expertise is critical to developing robust analytical frameworks for assessing the societal and economic impacts of psychedelic therapies.



- Dr. Stefano Bertozzi (supporting contributor)
  - Professor, Health Policy & Management, UC Berkeley | Healthcare Systems Expert
  - Dr. Bertozzi brings significant expertise in healthcare systems and implementation science. His work focuses on developing sustainable healthcare strategies, making him a key contributor to the integration of psychedelic therapies into existing systems. He is a renowned leader in both academia and healthcare implementation.





## Expanded Team Introduction 2/5

#### Academic Partnerships



- Dr. Julian Urrutia Ripoll
  - Yale University | Health Economics Specialist
  - Dr. Urrutia Ripoll provides critical expertise in health economics, focusing on the cost-effectiveness of psychedelic therapies. His collaboration ensures the integration of cutting-edge economic analysis methods into the project.

#### Dr. Michael Darden

- Johns Hopkins University | Substance Use Disorder Researcher
- Dr. Darden contributes his deep understanding of substance use disorders, particularly their economic implications. His research informs the models used to evaluate the cost savings and health impacts of psychedelic treatments for addiction.

#### Dr. Anton Avanceña

- University of Texas at Austin | Health Policy Researcher
- Dr. Avanceña is a decision scientist and health policy researcher who aims to improve value and equity in health globally. He has worked on several papers on the costs and health benefits of psychedelic therapies.
- Dr. Michael Bogenschutz (supporting contributor)
  - New York University | Alcohol Use Disorder Researcher
  - Dr. Bogenschutz specializes in clinical research on alcohol use disorder (AUD). His insights into patient outcomes and treatment efficacy ensure the project's economic models are grounded in real-world clinical realities.
- Dr. Matthew Johnson (supporting contributor)
  - Johns Hopkins University | Smoking Cessation Researcher
  - Dr. Johnson is a leader in clinical research on smoking cessation using psychedelics. His groundbreaking work on psilocybin-assisted therapies forms a cornerstone of the project's analysis of smoking-related health impacts and economic benefits.



## Expanded Team Introduction 3/5

#### Technical Implementation



Desislava Prodanova, M.A.

- President, MSIDE | Healthcare Systems Engineer
- Desislava brings expertise in healthcare software solutions and data analytics, playing a critical role in managing complex healthcare data. Her work ensures the integrity and precision of the data underlying the economic models.



- Vice-President, MSIDE | Healthcare Data Analyst
- Dr. Quevedo is a highly respected figure in psychedelic clinical research and health economics and policy, with a career spanning decades of research on cost-effectiveness and resource allocation in healthcare. His expertise is critical to developing robust analytical frameworks for assessing the societal and economic impacts of psychedelic therapies.





## Expanded Team Introduction 4/5

#### Advisors and External Collaborators



#### Dr. Bob Jesse

- Advisor | Psychedelic Research and Policy Expert
- Dr. Jesse is a respected figure in psychedelic research, offering strategic advice on navigating regulatory landscapes and fostering impactful collaborations. His expertise bridges the gap between research findings and policy implementation.

#### Melissa Lavasani

- Founder and CEO, Psychedelic Medicine Coalition | Chairwoman, Decriminalize Nature DC | Policy Advocate
- Melissa is a pioneering leader in the psychedelic policy landscape, known for her instrumental role in advancing legislative change. As the founder and CEO of the Psychedelic Medicine Coalition and President of the Psychedelic Medicine PAC, she drives advocacy efforts at the national level. Melissa also led the historic Initiative 81, a groundbreaking ballot measure that decriminalized entheogenic plants and fungi in Washington, D.C., setting a precedent for policy reform nationwide. Her leadership and strategic vision ensure the project aligns with the evolving regulatory environment for psychedelic therapies.



#### Dr. Cameron Wolf

- Senior Advisor for the Department of Health & Human Services / SAMHSA Office for Prevention Innovation
- Cameron brings extensive expertise in designing, managing, and scaling innovative public health programs, with a focus on vulnerable and marginalized populations. A leader in HIV/AIDS prevention and care, Cameron has shaped impactful interventions through data-driven strategies, behavioral science, and cross-sector collaboration. With a Ph.D. in Health Policy & Management from Johns Hopkins and a track record of driving resiliency and equity in healthcare, Cameron's consultative leadership bridges global health priorities and emerging solutions, including the expanding role of psychedelics in public health innovation.



## Expanded Team Introduction 5/5

#### Project Management



Lia Mix, LMFT, CPTR

- CEO, Delphi | Strategic Guidance & Project Management
- Lia oversees strategic direction and ensures seamless coordination across all aspects of the project. With extensive experience in managing complex healthcare initiatives, she specializes in psychedelic healthcare implementation and engagement with federal agencies. Her leadership ensures alignment between research objectives and stakeholder needs.



Floris Wolswijk, MSc

- Senior Project Manager, Delphi | Project Coordination
- Floris manages day-to-day operations and ensures timely delivery of research milestones. With a strong background in project management and psychedelic research, he plays a pivotal role in coordinating diverse teams and fostering collaboration among research and implementation partners.





## **Published Research**

The Center for the Economics of Psychedelics (CEP) and its collaborators have established themselves as pioneers in the economic analysis of psychedelic-assisted therapies.

Led by Dr. Elliot Marseille, the team has published several groundbreaking papers examining the cost-effectiveness and broader economic implications of these novel treatments. Their 2022 paper in PLOS ONE provided a comprehensive cost-effectiveness analysis of MDMA-assisted therapy for PTSD, demonstrating potential healthcare cost savings of \$132.9 million over 30 years per 1,000 patients treated. This work has since become a cornerstone reference for healthcare systems considering the implementation of psychedelic therapies.

Building on this foundation, Dr. Marseille and colleagues have published additional analyses examining various aspects of psychedelic therapy economics. Their work spans both healthcare system and societal perspectives, incorporating sophisticated modeling of long-term outcomes and broader economic impacts. These publications demonstrate the team's expertise in handling complex economic evaluations of novel therapeutic approaches, particularly in mental health and substance use disorders.

- Marseille, E., Kahn, J. G., Yazar-Klosinski, B., & Doblin, R. (2020). The cost-effectiveness of MDMA-assisted psychotherapy for the treatment of chronic, treatment-resistant PTSD. PLOS ONE, 15(10), e0239997. https://doi.org/10.1371/journal.pone.0239997
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