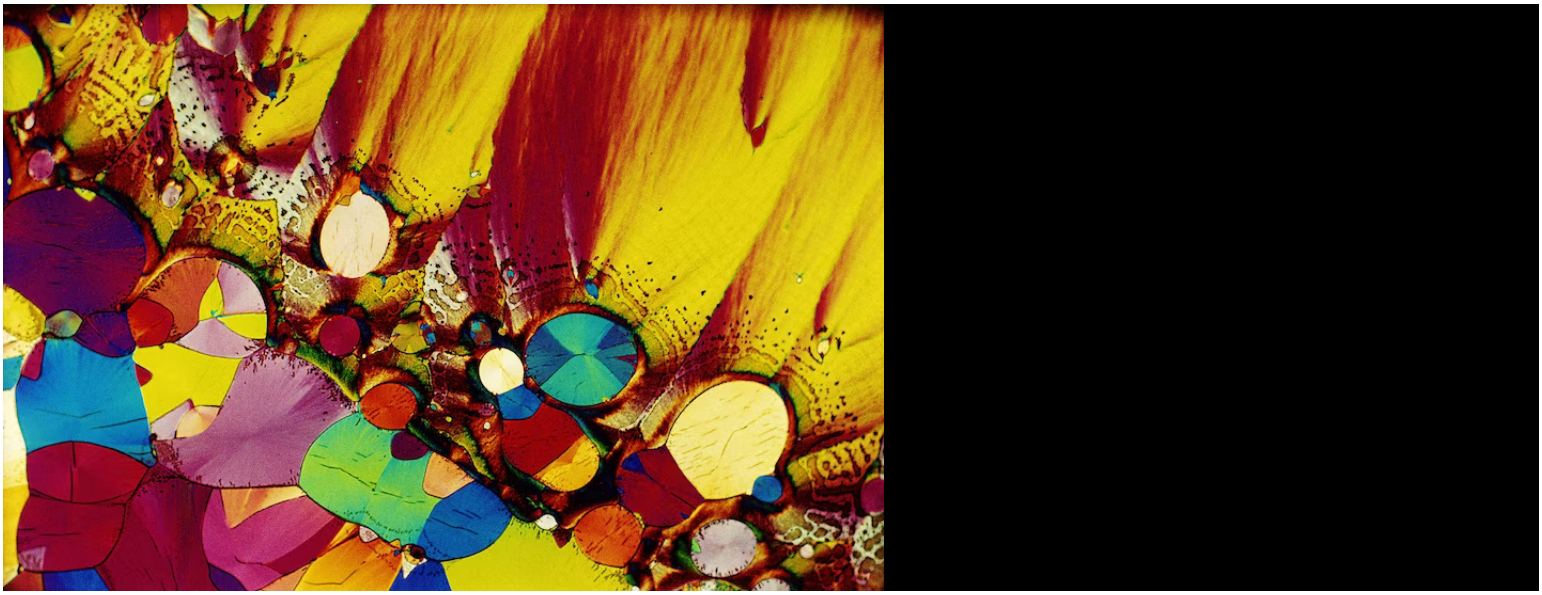


A polarized light micrograph of serotonin—a neurotransmitter produced in the brain—which plays a role in depression, memory, and sleep. Ma...
Show more
PHOTOGRAPH BY MICHAEL W. DAVIDSON, SCIENCE SOURCE

SCIENCE | MIND, BODY, WONDER

When will psychedelics be legal?

With the FDA reviewing psychedelic treatments, approval of such drugs would lead to DEA reclassification and open a world of new mental health care.

BY **MERYL DAVIDS LANDAU**

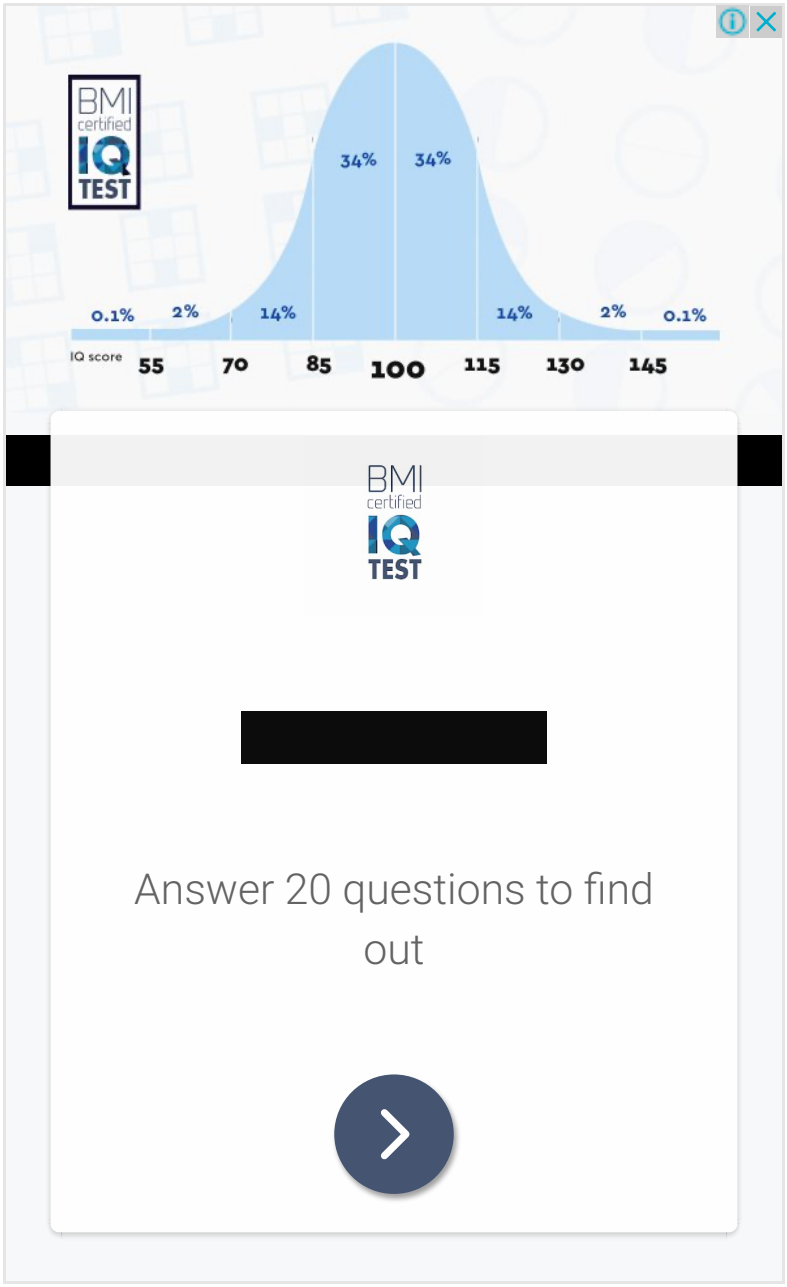
PUBLISHED JANUARY 31, 2024

For more than a decade after her mother died suddenly, Sehrish Sayani suffered from post-traumatic stress disorder. Over the years the most intense panic attacks receded, but symptoms including a constant state of

hypervigilance, hairpin triggers, and fitful sleep became normal parts of her life.

Three years ago, a friend told Sayani, a 35-year-old marketing executive in Los Angeles, about psychedelic therapy with methylenedioxy-methamphetamine, or MDMA. Sayani searched online and discovered she qualified for a clinical trial that was testing the drug against an inert placebo. As part of the clinical trial, Sayani was given a pill during three in-office sessions, along with intensive psychotherapy.

Such a trial would have been hard to fathom a decade ago, since anyone possessing a psychedelic drug, including MDMA (known on the streets as ecstasy or molly), is subject to severe criminal penalties under the U.S. Drug Enforcement Administration's classification. The agency lists psychedelics as Schedule 1, the most restrictive category, defined as having "no currently accepted medical use and a high potential for abuse."



This remains the case, but in December Lykos Therapeutics (formerly MAPS Public Benefit Corporation) submitted the first psychedelic in decades to the U.S. Food and Drug Administration for evaluation as a treatment for PTSD. A similar submission for a synthetic form of psilocybin, the active ingredient in “magic mushrooms,” is expected to follow in a few years.

Approval of either drug would lead to DEA reclassification and open the possibility of doctors eventually prescribing psychedelic-assisted psychotherapy for their patients, in which the drug would be administered during one or more sessions and combined with talk therapy in the days or weeks before and after. (A limited number of people with PTSD have been able to access MDMA therapy under a compassionate access program started in 2022.)

During the clinical trial, Sayani felt marginally better but experienced no dramatic changes. Six months after the trial ended, Sayani was told she had been assigned the placebo but was now eligible for three more sessions with the actual drug.

This time, instead of chatting with the therapist in the room, Sayani was silent and introspective while under the drug's influence. By the time of her final post-drug therapy session, she felt transformed.

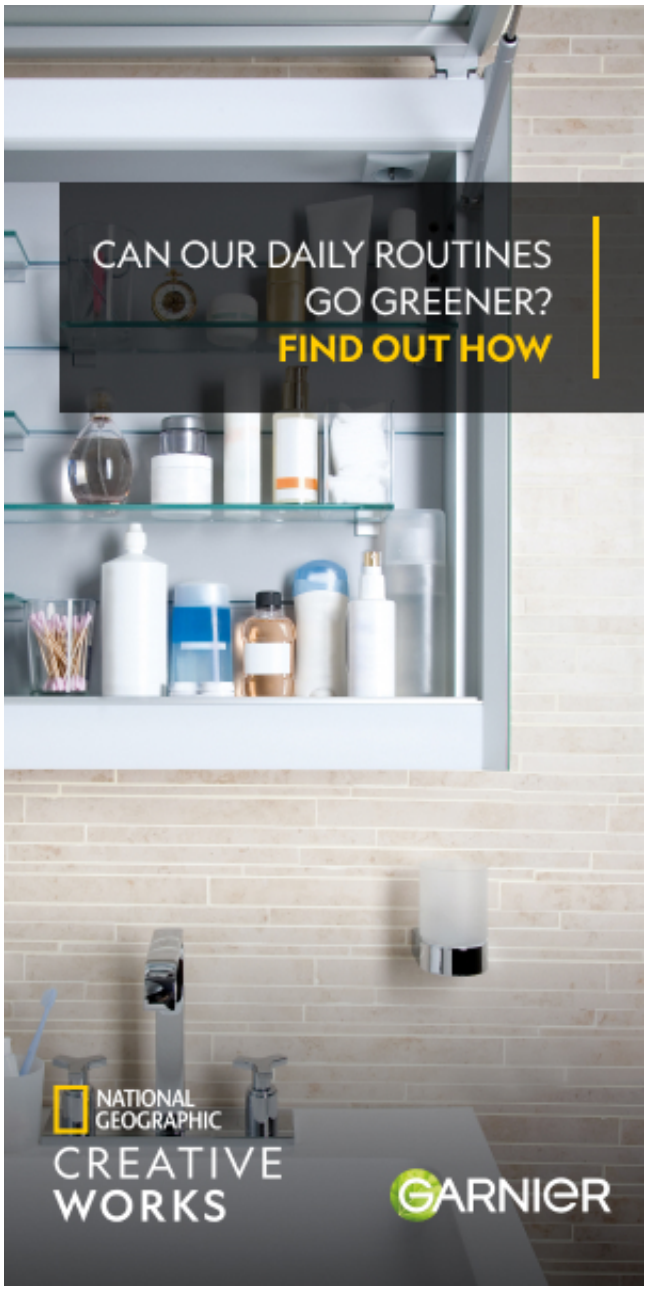
“It gave me an entirely different perspective,” Sayani says. “It brought down the curtains and let me see my [trauma] experience for what it was.” Being able to go back to the moment of her mother’s passing and sit with her emotions in a new way enabled Sayani to process the grief her PTSD had long held at bay. Now, nine months later she says she feels happy, sleeps well, and can stay calm, no longer prone to anxiety if a car drives too close as she walks her mini golden doodle, Bleecker. She’s convinced that

other people with PTSD could benefit from the drug.

Huge demand for mental health treatments

Given the millions of Americans with mental illnesses who have not found relief with traditional therapies, such a prospect is generating excitement among medical experts.

“We’re in a mental health crisis and the tools we have don’t seem to be sufficient,” says Tom Insel, a psychiatrist, neuroscientist, and former director of the National Institute of Mental Health. Even current medicines that do help some people must be taken continuously, while psychedelics require only one or a few applications, says Insel, author of the book *Healing: Our Path from Mental Illness to Mental Health*.



If the FDA believes Lykos's application is complete and ready for evaluation, it could rule on the medicine as soon as this summer. The FDA will base its assessment on two large-scale clinical trials published in *Nature Medicine* in 2023 and 2021 that found three sessions of MDMA-assisted therapy significantly improved PTSD, in many cases to the point where disease symptoms could no longer be detected. Side effects found in the study included nausea, chills, and other nuisances but also more

serious heart palpitations and blood-pressure rise.

The FDA submission from Lykos is the culmination of more than 30 years of advocacy and clinical research on MDMA, the company's CEO Amy Emerson said in a statement. Still, getting approval may not be easy. Even for conventional therapies, new drug applications are complex matters with additional data sometimes requested, and a psychedelic medicine is far from conventional.

"I would caution people to manage their expectations about how quick and easy this is," Insel says.

Top: Three varieties of the magic mushroom *Psilocybe* (or *Stropharia*) *cubensis* including, from left to right, Mexican, Colombian, and Thai. Th... **Read More**

PHOTOGRAPH BY TED KINSMAN, SCIENCE SOURCE

Bottom: Ecstasy is the name for the drug MDMA (3,4-methylenedioxymethamphetamine), which triggers feelings of joy and frenzied excitement... **Read More**

PHOTOGRAPH BY VICTOR DE SCHWANBERG, SCIENCE SOURCE

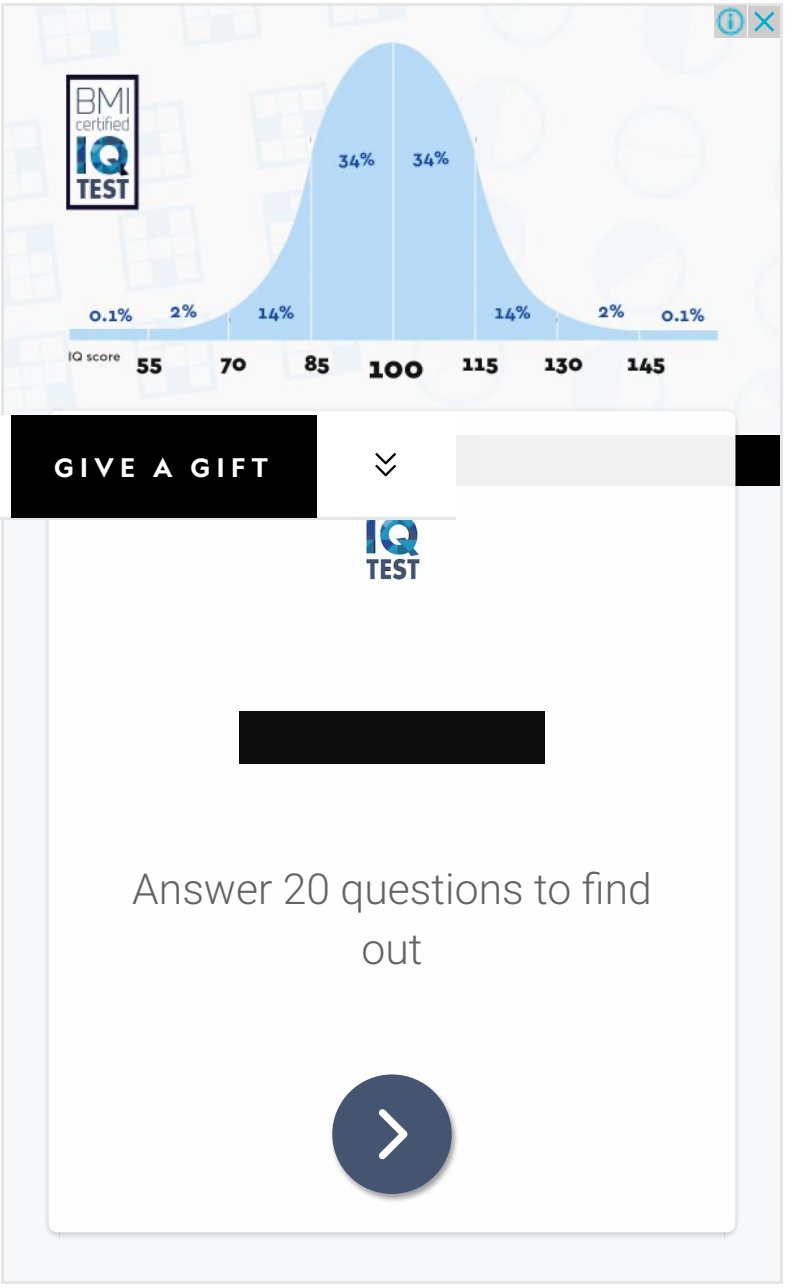
Fast tracking access

If the FDA approves MDMA therapy, healthcare professionals might be able to use it for other conditions in addition to PTSD. Small trials on the drug have found potential benefits for eating disorders, social anxiety in people with autism, and the distress of having a terminal diagnosis, among others.

Meanwhile, the company Compass Pathways has developed a proprietary, synthetic version of psilocybin and has shown in a small study that one session of the drug may help with treatment-resistant depression. The company is currently conducting a major trial in the U.S. and internationally in depressed patients. Results are expected by the end of 2025.

Other early studies show psilocybin may also work as treatments for anxiety and alcohol use disorder.

It's benefits like these that propelled Seattle integrative rehabilitative physician Sunil Aggarwal to provoke faster change by suing the DEA and demanding that they revise the scheduling of psilocybin. The agency's position that psychedelics have no currently accepted medical value flies in the face of the growing body of evidence, Aggarwal says.



Were the DEA to loosen restrictions even in advance of FDA approval it could allow physicians “to prescribe psilocybin-assisted therapy to patients who are seriously and terminally ill … improving the quality of life for such patients by helping alleviate depression, anxiety, and existential distress,” he says.

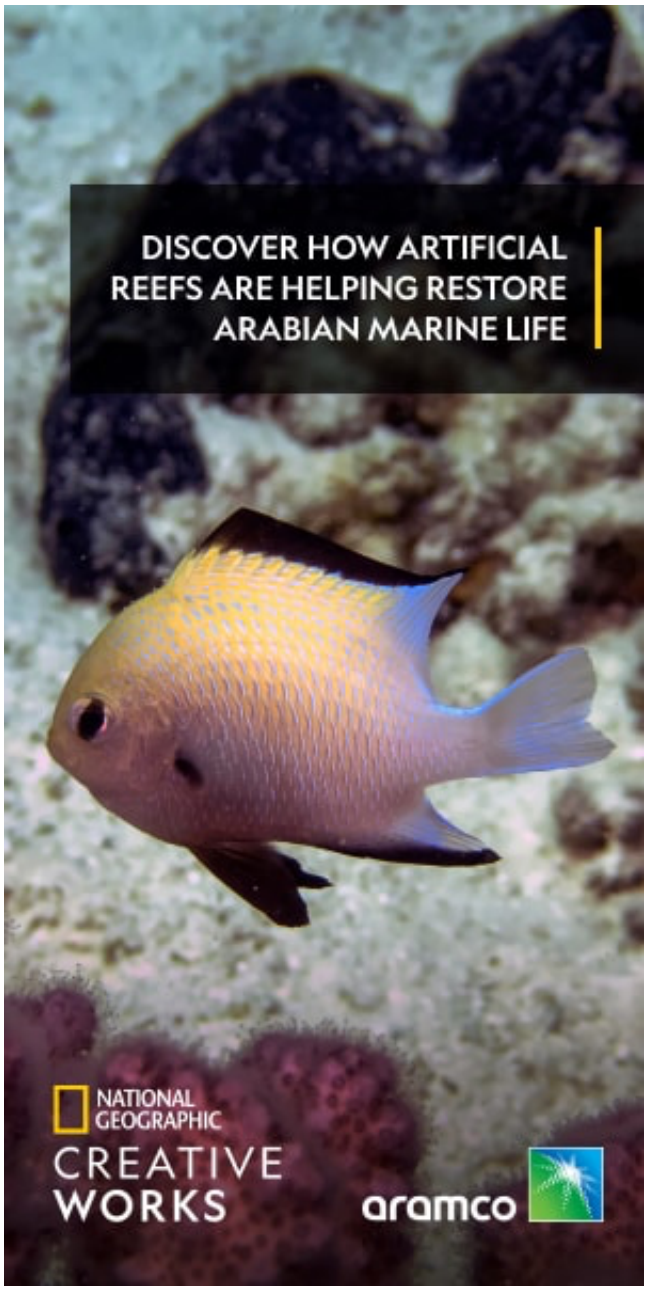
oval or the DEA to revise its

reclassification of these psychedelics.

In 2020, Oregon voters passed a ballot measure to legalize and regulate psilocybin-mushroom therapy in the state for people regardless of whether they have a mental-health diagnosis. After a long period when rules were set and licenses were granted to growers, manufacturers, testing laboratories, service centers, and individual facilitators, people in Oregon have been able to access this psychedelic therapy since the summer of 2023. Although the state currently doesn't collect data on users, advocacy groups estimate that several hundred have received psychedelic therapy there, with thousands more on waiting lists.

(*Psychedelic medicine is coming—But who's going to guide your trip?*)

A similar program will eventually be offered in Colorado, after voters there passed the Natural Medicine Health Act ballot measure in 2022. Meanwhile, several cities across the country have decriminalized possession of psychedelics for personal use making them a low law-enforcement priority including Ann Arbor, Michigan, Washington, D.C., and Somerville, Massachusetts.



Since state and local laws don't override DEA prohibitions, however, people involved in the delivery or consumption of psilocybin could still be subject to federal prosecution.

Several countries have legalized or decriminalized psychedelics in some way. Canada began a special access program in 2022, allowing people with terminal diagnoses to request psilocybin therapy. In June, Australia

became the first country to let doctors prescribe psilocybin and MDMA for mental-health conditions, while Spain, Italy, Argentina, and others have decriminalized the drugs.

Cost of therapy is a concern

Psychedelic therapy sessions consume a great deal of time for healthcare providers, including the five or more hours of a monitored drug experience and the numerous psychotherapy appointments before and after.

(*Can microdosing psychedelics boost mental health?*)

Many worry time-intensive therapy will translate to high prices for consumers if the drugs receive FDA approval—unless insurance covers the cost. Prices for treatments in Oregon have ranged from hundreds to many thousands of dollars, says Angie Allbee, manager of the psilocybin program at the Oregon Health Authority that administers the law.

Allbee says the state recognizes the inequities involved and is examining ways to ensure low-income individuals are not priced out.

The need for intensive psychotherapy along with the drug, while adding to the cost, may prove to be one of psychedelic therapy's most valuable contributions, Insel says. Currently, the field treats medications and psychotherapy as separate entities, with psychiatrists prescribing drugs and therapists offering psychological support.

“What’s fascinating and completely paradoxical is these new compounds have come with this idea that the only way to use them is within the context of psychotherapy,” Insel says. “That’s what the field needs—that reintegration of medical and psychological care in a way that hasn’t happened before.”

Editor’s Note: This article originally misstated the mental health condition being treated in the Compass Pathways trial. It is treatment-resistant depression.

READ THIS NEXT

SCIENCE MIND, BODY, WONDER

We finally know the cause of severe morning sickness

The debilitating, sometimes fatal condition called hyperemesis gravidarum has received scant funding and little acknowledgment, but new r...

SCIENCE

Psychedelic medicine is coming—but who will guide your trip?

SCIENCE MIND, BODY, WONDER

Experts warn against OTC sleep aids for kids

SCIENCE

The science behind seasonal depression

GO FURTHER

ANIMALS

ANIMALS

Like a moth to a flame? A new study debunks an age-old theory

ANIMALS

This might be the first newborn great white shark ever recorded

ANIMALS

Why are raven world's smalle

ENVIRONMENT

ENVIRONMENT

Can energy harnessed from Earth's interior help power the world?

ENVIRONMENT

What it's like to live through 'polar night'

ENVIRONMEN

Deadly wildfir way east

HISTORY & CULTURE

HISTORY & CULTURE

The real-life rise and fall of Griselda Blanco

HISTORY & CULTURE

The details 'Masters of the Air' gets right about WWII

HISTORY & CU

See how 5 fam and comfort ir

SCIENCE

SCIENCE

MIND, BODY, WONDER

Experts warn against OTC sleep aids for kids

SCIENCE

There's a frozen labyrinth atop Mount Rainier

HISTORY & CU

See how 5 fam and comfort ir

TRAVEL

TRAVEL

What it's like to cross Antarctica's Weddell Sea

TRAVEL

Why you should head to Tuscany for a spiritual reboot

TRAVEL

Photo story: o cuisine in Miar

NATIONAL GEOGRAPHIC