(Photo: Getty Images)

TAKEPART FEATURES

The Incredible True Story of How Cannabis Could Be Coming to Rite-Aid

The first medicine developed straight from pot plants is poised for FDA approval. What would that mean for medical cannabis, legalization, and patients in need?

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Bio

The Mayflower in Washington, D.C., is one the capital's grand old hotels, presenting to Connecticut Avenue a broad, brick facade and an awning festooned with the flags of many nations, as if the king of one of them might drop in at any moment. It regularly hosts meetings and conventions of staid and proper groups like the Georgia Trust for Historic Preservation, and concurrent with a meeting of that organization at the hotel last winter was the first National Medical Cannabis Unity Conference. It was organized to bring together patients, activists, doctors, researchers, business owners in the pot and hemp industries, and others, and included lectures, symposia, and other elements typical of scientific and medical conferences.

Attendees at this one were significantly less perky, though, and less present, for an address at 9 a.m. on the conference's second day than were, say, the folks at the early-morning sessions of 2011's big triennial conference on multiple sclerosis (and it was in Amsterdam). The speaker was Steph Sherer, founder and executive director of Americans for Safe Access, a medical marijuana lobbying group. Like many in the movement, Sherer says she has personally experienced benefits from ingesting cannabis for a medical condition—in her case, a neck problem that caused pain and inflammation for which she was prescribed pharmaceuticals she says led to kidney damage. Standing at the ballroom's lectern, Sherer wound up by noting there had been some complaints about the smell in the hotel's upstairs hallways the night before, where attendees had been "taking their medicine." (A member of the Georgia group had mentioned the same thing to me when we were chatting in the hotel bar.) Medical marijuana has been legal in Washington, D.C., since 2010, though it's not clear whether out-of-towners can use in the city since they aren't allowed to obtain the required registration card; in any case, the Mayflower is entirely nonsmoking. But that didn't bother the advocates at the

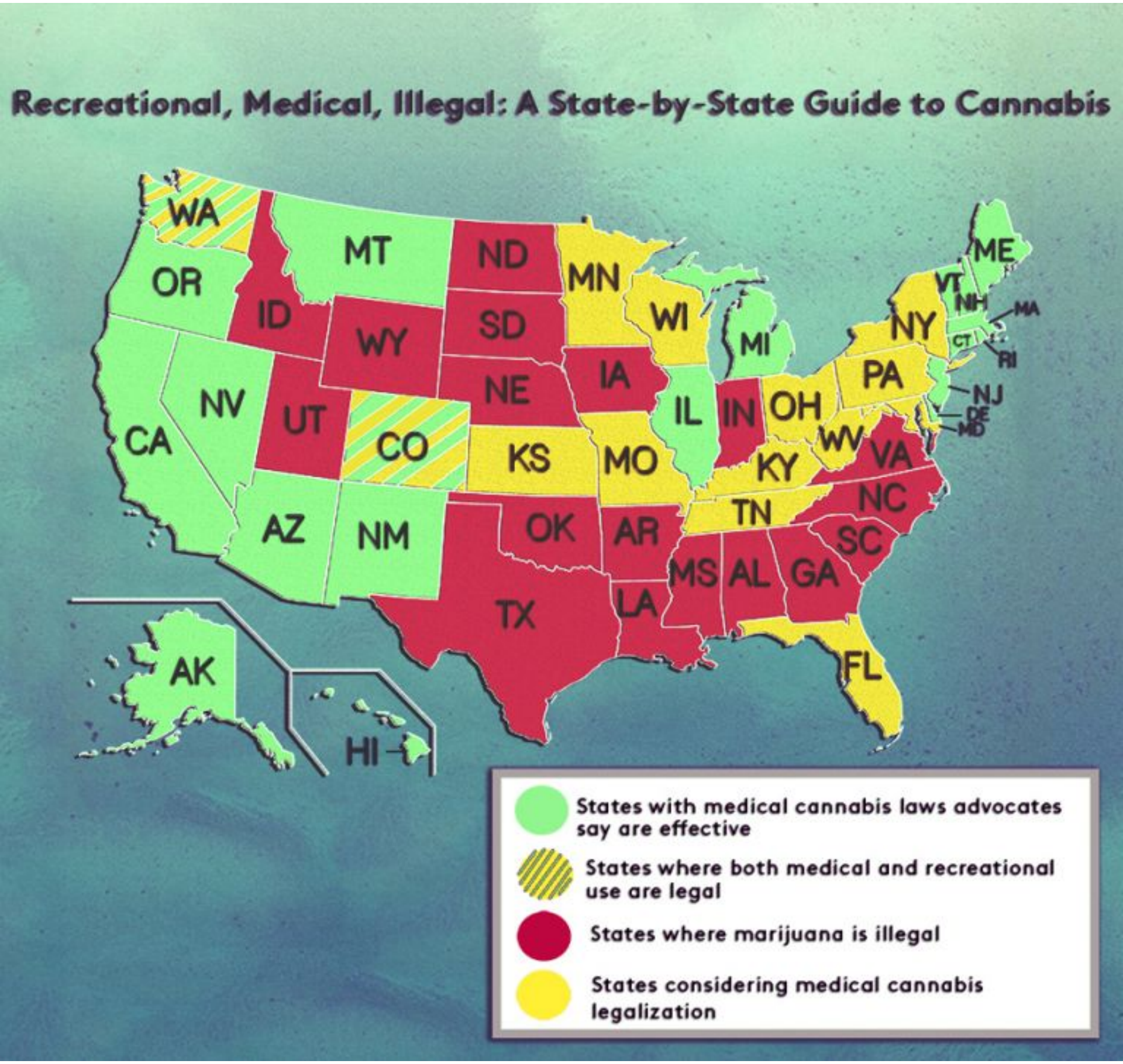
conference; they took their medicine late on a Friday night right in their hotel rooms, just as surely as they'd have done had they been diabetics injecting insulin or schizophrenics swallowing clozapine. So, referring to one of the items included in the goody bag attendees had received upon registering at the conference—a spray bottle of an "air freshener"—Sherer said, "Everybody, don't forget to use your Febreze tonight."

> The cannabinoid system is incredible.... We have tremendous potential for medication development from cannabis.
>
> **NORA VOLKOW, DIRECTOR, NATIONAL INSTITUTE ON DRUG ABUSE**

This is pot's big moment. Colorado just became the first jurisdiction in the world to tax and regulate marijuana similarly as it does alcohol. That followed Colorado and Washington voters' approval of ballot initiatives in November 2012 that provided for the legal use and sale of marijuana in those states. The Gallup organization announced in October that for the first time since it began asking the question in 1969, a majority of Americans favored legalizing the plant. The 58 percent in favor is a huge leap from the 41 percent who felt the same way only in 2010, and the 17 percent in 1991. CNN, *60 Minutes*, and *Dan Rather Reports* have all broadcast lengthy segments exploring the legal, medical, and commercial aspects of the new pot regime with a tone and balance that would have been unimaginable in broadcast media a decade ago. Twenty states allow marijuana use for ostensibly medical purposes, and more ballot initiatives legalizing medical and recreational use are expected this year, and in 2016.

Though it would be easy to caricature activists like Sherer—forgetting to use their air freshener when lighting fatties in a hotel room—considering what the war on drugs told us about how lazy and slovenly weed would make a person, the real irony is perhaps that people who smoke pot every day have proved so successful. For these legal changes are in large part attributable to the work the medical marijuana movement has been doing since it began in the 1980s in San Francisco,

and as it's spread, it's touched off a flurry of medical research into cannabis.



(Illustrated by Lauren Wade)

Medical marijuana is no longer just about relieving nausea from chemotherapy or giving AIDS patients the munchies. In recent decades it was discovered that humans (and many animals) possess a system of cannabinoid receptors throughout the brain and body, which is involved in regulating a broad swath of human physiology. Many believe the endocannabinoid system to be on a par

with the central nervous system or the immune system in terms of its significance to human health. (Decades later, few, if any, medical or nursing schools teach anything about this system.) The research has demonstrated cannabis' remarkable potential to reduce the frequency of seizures, shrink tumors, and more.

"The cannabinoid system is incredible, and much more diverse than we thought. We have tremendous potential for medication development" from cannabis. So says a medical cannabis advocate? No, that's what the head of the National Institute on Drug Abuse, a pioneering research psychiatrist named Nora Volkow, told me.

Capitalizing on these developments is a small British company called GW Pharmaceuticals. GW has been quietly moving forward with a mouth spray called Sativex that's derived from cannabis and poised for an FDA thumbs-up or -down this year or next. The drug is in Phase 3 trials—that is, testing the drug on humans in a randomized, double-blind, placebo-controlled trial, the gold standard for medical evidence—for the treatment of cancer pain. It's already approved in the U.K., Canada, Italy, Germany, France, Switzerland, and 18 other countries to treat spasticity associated with multiple sclerosis, which affects most of the 2.3 million people worldwide who have MS. (GW, along with all the big pharma companies, had an impressive electronic display at the MS conference in Amsterdam.) GW is also pursuing cannabis-derived drugs to treat epilepsy, type 2 diabetes, and brain tumors. Last year GW was awarded a patent for Sativex and listed on Nasdaq.

(Photo: Courtesy GW Pharmaceuticals)

A drug containing synthetic THC, a psychoactive compound in marijuana, has been around for a while, and at least one batch of the generic version of the drug, dronabinol, has been made from the plant. (Patients hate dronabinol because it doesn't take effect for hours and completely floors them when it does.) Sativex is the only medicine to reach pharmacy shelves that was developed from the beginning directly from the plant material; its delivery mechanism is intended to lead to a steadier and more reliable absorption than pill form, without the detrimental health effects of smoking. If approved for cancer pain, it's likely to be prescribed for "off-label" uses as well–the FDA allows doctors to "use a product for an indication not in the approved labeling" as long as they follow certain guidelines–meaning that many people with MS and other diseases and conditions should be able to get Sativex if it passes FDA muster.

Advocates for medical marijuana, and proponents of its current criminalization, are each using the Sativex story as evidence in support of opposing policies. As such, it's a window into many of the complexities, contradictions, and capricious oddities of the regulation of cannabis use in the United States (whether medical, recreational, or scientific), and into the many government restrictions involving

research into medical cannabis that critics say are scientifically invalid at best, and costing lives at worst. GW's experience, though, also shows that much of what the medical cannabis movement says about these restrictions isn't wholly true.

Last year I spoke by phone with the father of a young girl who told me his daughter had been experiencing hundreds of seizures a day as a result of a rare form of epilepsy. (He was extremely wary of being identified, as he said he lived in a state with no approved use of marijuana, so I won't name him, his home state, or the person who put us in touch.) The condition had slowed the girl's development and was threatening her life. Drugs she'd been prescribed weren't working. Desperate, the parents tried sneaking a drop of hash oil, a potent, viscous cannabis extract, into her food. The change was almost immediate, and dramatic: Her seizures fell overnight by a third, then by half, and within a week of taking the concoction regularly were down more than 90 percent. He said her professional caregivers, who he couldn't tell about her new medication for fear of getting busted (neither is the girl herself aware of it), were amazed as the girl's physical and cognitive development suddenly leaped forward.

A few months later, I was changing planes in Denver during research for another story when I looked up to a TV and saw Sanjay Gupta telling the same story on CNN, about a different girl who, from the sound of it, had the same condition. Shortly afterward, the FDA approved GW to treat 125 American children with Dravet syndrome using a cannabis-derived medication different from Sativex.

If cannabis can shrink tumors in mice and reduce the number of seizures a child suffers from hundreds a day to several, it may be that the wonder drug of the century has been in the bong behind a jillion college dorm couches all along. If Sativex wins FDA approval—its success rate in other countries is 100 percent—it's going to be difficult for the government to keep arguing that pot has no medical value and is impossible to use safely. But if cannabis legalization goes badly, as many experts fear, there could be a reaction that ends both experiments.

"We're opening the gate on this," says GW's vice president, U.S. professional relations, Alice Mead, "and I hope other manufacturers will follow after us with

other cannabis-derived medicines. There needs to be a trailblazer, and we're it."

The story of Sativex begins, perhaps unsurprisingly, in Amsterdam. An expat Californian named David Paul Watson, after years of wandering the globe compiling a library of cannabis types, had settled there. In 1997, the company he cofounded, HortaPharm, received the Dutch Ministry of Health, Welfare and Sport's first license to cultivate cannabis for medical research.

HortaPharm developed the first homozygote cannabis (a plant with two identical sets of chromosomes), enabling the company to produce strains overwhelmingly high in a single cannabinoid. It's long been known that THC is the "active ingredient" in pot—it's what gets a person stoned. But more recent research has found numerous other cannabinoids in the plant, which have different effects on the body. One that's shown early promise for antiseizure and antianxiety properties is cannabidiol, or CBD. Watson could grow plants that were 98 percent THC, or 98 percent CBD, or whatever. (The hash oil treatments given to the girl on CNN are from high-CBD strains, and GW's antiseizure medication is high-CBD.)

HortaPharm soon crossed paths with Dr. Geoffrey Guy, who in 1998 received a license from the British government to grow pot for medical R&D for his company: GW Pharmaceuticals. Guy was searching for a legal source of plant materials with

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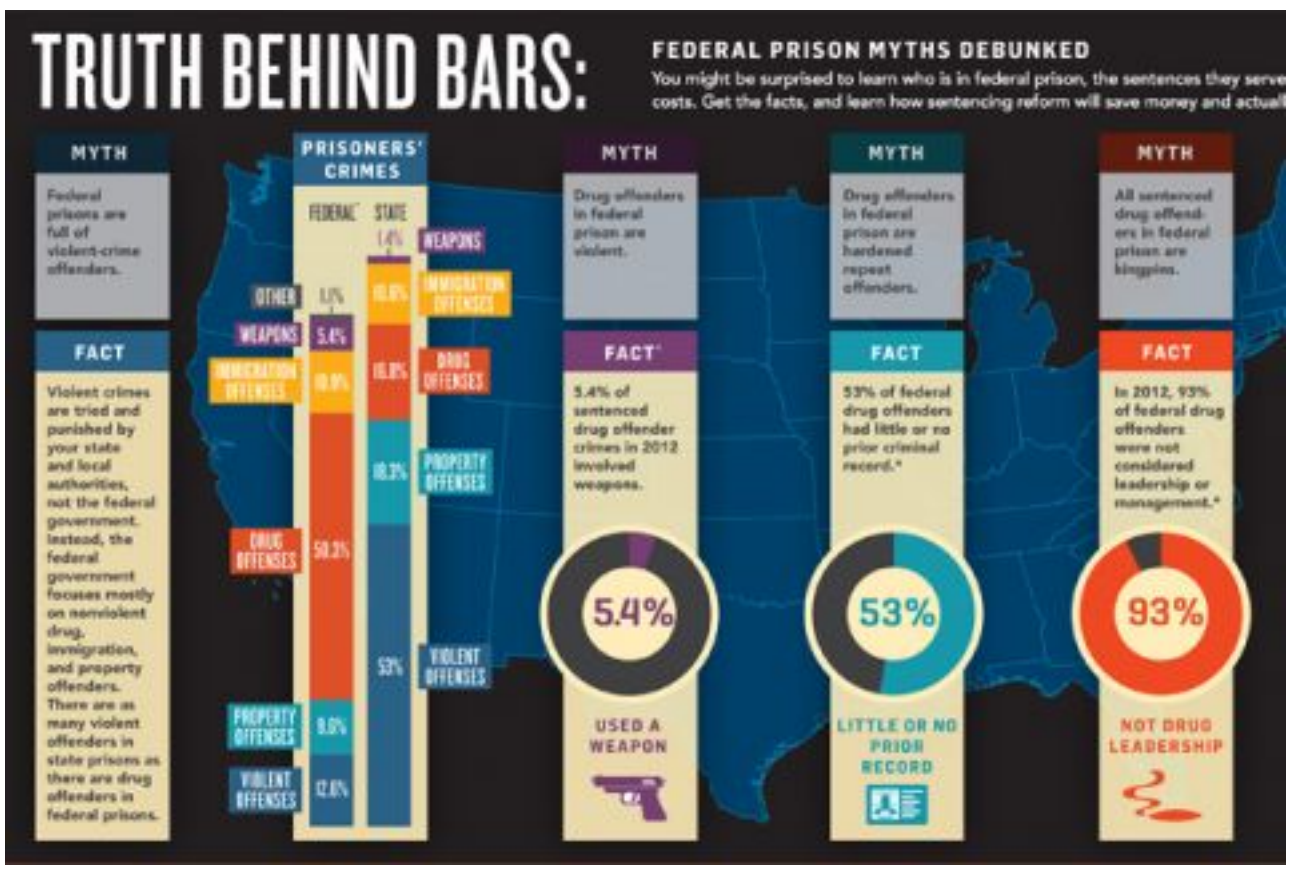

varying compositions of cannabinoids. He wanted to hybridize different plant strains so he could test the effects of various combinations of cannabinoids on various maladies.

And that's the first way in which GW's development of its medicine ran up against American law.

Marijuana is classified under the Controlled Substances Act as a Schedule I drug, a category reserved for drugs with "no currently accepted medical use in treatment in the United States" and "a lack of accepted safety for use under medical supervision." Just before Congress passed the act in 1970, a Department of Health and Human Services assistant secretary wrote to Congress, "Our recommendation is that marihuana [*sic*] be retained within Schedule I at least until the completion of certain studies now underway," including a study by the National Commission on Marihuana and Drug Abuse.

Two years later, the commission recommended that pot be taken off Schedule I. No U.S. attorney general has been willing to take up that mantle, though, so cannabis' status has remained unchanged ever since.

The federal government allows only one entity to produce marijuana: the pharmacology department at the University of Mississippi. Anyone who wants to conduct research in the U.S. on pot applies to HHS and the DEA to acquire some of this Mississippi cannabis.

Perhaps because the Mississippi lab operates under a contract with the National Institute on Drug Abuse, its cannabis is high in THC compared with other cannabinoids. (Which is not to say it's high in THC; a published cannabis researcher described to me the stuff he'd been sent from Ole Miss as "low potency.")

"We always knew there's much more to cannabinoid science than THC," says GW's CEO, Justin Gover. "Our interest is in looking at materials that take us well

beyond THC."

That might be possible in the U.S. today, if the DEA were to take the advice of its own administrative law judge; Mary Ellen Bittner ruled in 2007 that the government's monopoly on pot for research was not in the public interest and recommended that another avenue be opened. The recommendation has been ignored, so GW's work with plants all happened in Britain.

Guy's company looked at hospitals around the U.K. that focused principally on multiple sclerosis, cancer, or neuropathic pain to identify the most promising conditions to treat and which cannabis strains were most effective against them. Would an extract from a high-THC strain do well against pain? If it were mixed with a high-CBD strain, would that mitigate the psychoactive effect?

"Although it's a single plant species, what's important is which of the cannabinoids has the desired medical effect," Gover says. "We would take different plant types—some high in THC, some high in CBD—combine the two, and do small-scale patient studies. There was enough data to give us the signal of which direction to go in."

Key to that development, of course, was Britain's allowing GW to grow the plants in the first place. The company's founders had capitalized on sudden interest in cannabis' medical potential that arose out of the community of U.K. multiple sclerosis patients. MS is incurable; the available medications don't work for everyone and often come with debilitating side effects. Some patients in 1990s England were finding relief in the cannabis plant. Complaints that they'd been forced to become criminals to get help for their illness culminated in the Science and Technology Committee of the House of Lords looking into the matter: In November 1998 it issued a report acknowledging recent research that demonstrated the plant's potential for drug development, but also pointed to a lack of meaningful, controlled data.

Guy and his associates discussed with British

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authorities the prospect of developing medicine derived from cannabis that would meet the standards of prescription drugs. Eventually they got their permit to grow the plants from seeds legally acquired from HortaPharm and manufactured a solution that could deliver identical chemical compositions at controllable doses, which critics of smoked cannabis as medicine, such as Volkow, say can't be done consistently by smoking even if you know exactly what's in the plant. That made the small-scale studies reliable enough to proceed with the substantial investment of time and money in studies required for a government's approval process for medication.

Rocky Mountain High: Colo. Has a Billion-Dollar Pot Industry

Though the MS patients' crusade in Britain lacked any real association with recreational users—other than the drug's having been recommended by them—the U.S. medical marijuana movement has never been able to shed its affinity with the legalization movement. When the Cannabis Cultivators Club, the birthplace of (quasi-)legal, medical marijuana, began operating in San Francisco in 1992, although it provided for some cancer and AIDS patients, the operation was clearly a joke: "Prescriptions" were sometimes written on cocktail napkins, and children were allowed on the premises, where a rogues' gallery of San Francisco stereotypes of another era filled the room with smoke, ostensibly because they suffered from backaches, menstrual cramps, anxiety, or any of a host of other conditions. There was little hard data on smoked marijuana's ability to help with these at the time, and though subsequent research indicates the non-

terminal patients may have been onto something, advocates didn't proceed first, as GW did, with seeking that research. They just went ahead and had a drug that gets you stoned declared legal in San Francisco, and proceeded to get stoned.

To pass California's Proposition 215, which would legalize medical marijuana statewide in 1996, advocates hired a political professional to run the campaign; he cast it as a mercy mission for AIDS and cancer patients, and that's been the strategy ever since (adding veterans with PTSD, which gave the cause bipartisan cred, along the way). State Senate Bill 420 (get it?), passed in 2003, was meant to officialize and control what Prop. 215 had wrought, but as far as acquiring medical marijuana in California 22 years into the experiment, the situation hasn't changed hugely since the go-go days of the San Francisco Cannabis Cultivators Club. When I acquired, during the course of researching this article, a card permitting me to buy pot legally, I was asked to fill out a form listing schizophrenia as both a condition for which pot could be prescribed and a contra-indication against such a prescription. I went around the corner to buy my medicine, and the place had more Bob Marley posters on the wall than did all the pharmacies in all the towns in all the world I've been in, combined. (I was affronted to learn that my employer refused to reimburse me for these expenses.)

"There are about 15 different ways to analyze the involvement of the medical marijuana movement and the legalization movement" in the U.S., said Steve Fox, a lobbyist for the National Cannabis Industry Association, which represents business operators in the legal commercial realm, when we met for coffee in Washington, D.C.'s Union Station last fall. Fox himself had recently moved over from the Marijuana Policy Project, a leading medical marijuana lobby.

"The simple, plain truth is that marijuana does provide medical benefits, and while we don't believe anyone should be arrested for possession of marijuana, we should at least start with the people who need it," Fox said. "We've never been shy about working on [medical marijuana] while pursuing the larger goal" of legalization. That doesn't come close to describing the efforts of MS patients in the U.K., which led directly to the development of a prescription medicine derived from cannabis now available to thousands of patients around the world.

"There are scientifically proven antiviral and anticarcinogenic effects of cannabis," said Dr. David Miller, a veteran of the HIV-AIDS advocacy group ACT UP who's now involved in medical cannabis development. "The problem is, everybody's talking about patients' rights to grow pot plants in their backyard for pain management or depression." Miller was among those who pushed the FDA to fast-track AIDS drugs in the 1980s and '90s so patients like those depicted in *Dallas Buyers Club* might lengthen their lives—he knows something about raising the right kind of stink to change public opinion of experimental medicines and move an entrenched bureaucracy to allow their prescription. He's got no love for the DEA or NIDA and the delays and hindrances placed on researchers like UCSF's Donald Abrams, who waited nine months for NIDA to reject his application to get cannabis under an FDA-approved protocol. "Scientists and biotech companies should not be forced to fight with the federal government to get marijuana to do research," he said.

But Miller sees much of Sherer's movement—we spoke for an hour on the sidelines of the conference at the Mayflower—as an impediment. "I think filling up the fourth floor with pot smoke was completely inappropriate and disrespectful of other guests, and I think with any movement there's a responsible approach that should be applied, and there are people here who won't do that," he told me. "Come on—professionalize. Do this appropriately. And that's what GW took a lot of great steps with. The movement's hopefully going to mature further. But people are talking about rights, people are talking about pot, and *then* people are talking about cannabinoids. Meanwhile, we're missing a cornucopia of pharmacology out there. There's got to be a biotech company that emerges that uses these like GW is."

To navigate the regulatory apparatus in Washington, D.C., GW hired a U.S.-based lawyer with experience dealing with the FDA—Alice Mead—in 1999. "We brought her on really to start exploring how this program would be perceived by the relevant agencies," CEO Gover says. It took several years of explaining that the company was trying to go through the FDA process, not shortcut or circumvent it, all while collecting data in its trials in Britain. "I'm not saying she spent five

years banging on closed doors to try and open them," Gover explains, "but we realized this was very sensitive and wanted to make sure people understood what we were trying to do. When we approached FDA with the data, they gave us permission."

To conduct FDA trials on Sativex in the U.S., GW would need an export license from the U.K. as well as an import license from the DEA, which enforces the Controlled Substances Act. "Because it has THC and CBD in it, which are from cannabis, and the Controlled Substances Act has cannabis as Schedule I, for it to be studied we have to ascertain that the security requirements of the act are met," says DEA spokesperson Barbara Carreno.

There's not a mechanism to move the medicinal cannabis research from these smaller-scale studies to the next step. Rescheduling would promote research because scientists would be less reluctant to try if it weren't so difficult.

DR. IGOR GRANT, PROFESSOR AND EXECUTIVE VICE-CHAIR, DEPARTMENT OF PSYCHIATRY, UNIVERSITY OF CALIFORNIA, SAN DIEGO, SCHOOL OF MEDICINE

Sativex is manufactured using a refined, more technologically sophisticated version of a process people have been using for centuries to make hash oil. (It's described in company FDA filings, and Gover confirmed the following description.) Cannabis buds are dried, and a liquid CO_2 technology borrowed from the perfume industry dissolves everything but their essence. The essence is then washed with cold alcohol, and glycol is added. GW mixes the essences from the high-THC and high-CBD strains in a 25:27 ratio, and adds some peppermint flavor.

"The CBD makes it more tolerable for people who don't want to get high," says Sunil Aggarwal, MD, Ph.D., a board member at the Americans for Safe Access

Foundation and senior resident at New York University Langone Medical Center. Still, he says, THC is THC. Sativex won't be the first prescription drug with euphoric or other psychoactive side effects, and Canada's national public health department warns, in its Fact Sheet on the drug, "Patients may also experience symptoms of cannabinoid intoxication."

The contraband that's classified as prescription medicine in 24 countries is therefore kept at a secure distribution site, from which it's sent to about 40 hospitals and pain-treatment centers around the U.S. where the research is conducted. "The material has to be secured so it won't be diverted from its approved use to an illegal use," spokesperson Carreno says. "If it comes from a cannabis plant, it's Schedule I."

Rep. Earl Blumenauer, D-Ore., speaks outside the Capitol in 2013 about a bill he's proposed to change DEA policy on cannabis. To his left, with dark hair, is Americans for Safe Access executive director Steph Sherer.

Until, that is, it isn't. When I asked if the company foresees a change in Sativex's legal status should it win FDA approval, spokesperson Simona Kormanikova

emailed back, "If approved by the FDA, we expect...Sativex to be listed by the DEA as a Schedule II or III controlled substance." Geoffrey Guy has boasted to the press that Sativex contains the same 420 compounds as the plant itself, and Sativex will, of course, still contain THC and CBD. Now it will be medicine, though, not contraband, because the scientific process will have proved its efficacy. This paradox is what the House of Lords was talking about when it wrote in 1998, "While cannabis itself is banned as a psychoactive drug, THC, the principal substance which makes it psychoactive, is in legitimate medical use."

Other government entities, too, can put the kibosh on advancing medical science on cannabis. Marijuana is the only widely used drug that requires its own process of review before scientists can research it, and the only one whose supply is controlled entirely by the government. Apart from the DEA's refusal to open up another avenue of access to cannabis for research, the U.S. Court of Appeals, D.C. Circuit, ruled last year that it was A-OK for the DEA to have denied a petition ASA had filed asking it to remove marijuana from Schedule I because HHS had found in 2006 that there were "no adequate and well-controlled studies" on the plant's effectiveness as medicine. The court agreed with the DEA that the several smallish, randomized, double-blind, placebo-controlled studies of inhaled marijuana that had been published by researchers like Donald Abrams didn't carry enough weight. Neither did the many thousands of preclinical studies (meaning done in petri dishes or on animals) that have been published in the peer-reviewed literature. What the government wants to see are large trials of the kind GW is now doing with Sativex.

Here's where it gets Kafkaesque: Those studies have been done—on Sativex.

The DEA says Sativex is marijuana. Studies show Sativex is effective medicine. But according to the D.C. Circuit there are no studies showing marijuana is effective medicine.

"We're always gonna be in this catch-22," says Paul Armentano, deputy director of the National Organization for the Repeal of Marijuana Laws. "That's not gonna change until there's a legal status change under federal law. Sativex never would've been developed in the U.S., because no private entity could've received"

the license to grow that the U.K. granted to GW. “There are preclinical studies showing the potential of marijuana, but the government says they’re not persuasive, and then they don’t allow the research that would be persuasive. Politics is clearly trumping science,” he said.

It’s not just the pot activists who feel this way; Dr. Igor Grant, professor and executive vice-chair of the Department of Psychiatry at the University of California, San Diego, School of Medicine and head of the state-funded Center for Medicinal Cannabis Research, told me, “There's not a mechanism to move the medicinal cannabis research from these smaller-scale studies to the next step. It’s absolutely not true that cannabis is a useless drug that’s dangerous. Rescheduling would promote research because scientists would be less reluctant to try if it weren’t so difficult. It can be done—we did it—but we were very well funded.”

GW agrees—sort of. “The logistical process” of demonstrating Sativex’s effectiveness to the U.S. government has been “more difficult because of the DEA licensing requirements,” Gover says. “But proving it works is no different. Our experience is if a cannabis formulation meets the requirements you’d expect for any other product, the FDA does not treat it any differently.”

GW’s Alice Mead says, “The system seems to be working for us. I know the belief is that the federal government is preventing the unlocking of cannabis, but our experience is that it can be done.” Still, she allows, “if we could cultivate in the U.S., it would make it more convenient.”

In the current regulatory environment, Grant says, “the federal government is the only entity with the resources to support [large-scale human trials], unless pharma got involved. I don’t see how they can make that profitable with the actual plant product.”

This seems to be GW’s stroke of genius: It’s not testing the actual plant product, but a patented extract.

That’s a point of grief for the medical marijuana activists, who say that private industry has created a false distinction between the weed that grows by the side

of the road all over Kansas and the liquid in a bottle with a brand name on the label.

“You can't pretend this stuff isn’t marijuana," ASA’s Aggarwal says of Sativex. “That’s like saying to a judge when you get caught with pot brownies that this is something different. Marijuana shouldn’t be cordoned off for the sake of FDA drug applications or patents.”

GW draws a clear distinction between cannabis the plant and Sativex. “We have a reproducible dose and a safe delivery system,” says Mead. “That's hard to do with the raw plant material. As medicine, it needs to be standardized to a high level; FDA can't have a lot of deviation.”

Gover says, “We are required by regulators to prove exactly what's in each batch and prove that the concentration of chemicals is the same every time, which is a fundamental requirement of any prescription medicine. There’s a difference between products that go through those quality-control measures and those that don’t. It’s meant to safeguard the safety of patients and guarantee consistent efficacy. The process of manufacturing standardization ensures that can be achieved.”

Nonetheless, according to a neurologist at Barts and The London School of Medicine, Prof. Gavin Giovannoni, there are patients who’ve tried both and choose pot. “Some MSers prefer” smoking cannabis to Sativex because they find it more effective, even if it comes with greater “euphoria/dysphoria” side effects, Giovannoni emailed me in February. Moreover, he wrote, “Sativex has not been proven to be cost-effective” under Britain's National Health Service, and as a result, “a large number of MSers” have continued to use cannabis. The price should go down if the U.S. market is opened to the product.

Correction: A previously published version of this article stated that Sunil Aggarwal is an NIH clinical fellow. His fellowship does not begin until July 1, 2014.

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