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Author
Hendy, Katherine M

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Affecting Chemicals: An Ethnography of Clinical Research, MDMA (Ecstasy), and the Experimental Structuring of Effects

By

Katherine Marie Hendy

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Committee in Charge

Professor Corinne P. Hayden, Chair
Professor Stefania Pandolfo
Professor Lawrence Cohen
Professor Abena D. Osseo-Asare

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Abstract

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This dissertation ethnographically follows the efforts of researchers to develop MDMA (Ecstasy) as a prescription pharmaceutical. In the 1970's MDMA became popular among psychedelic therapists as a legal alternative to banned substances like LSD and psilocybin. However, legal MDMA-assisted therapy came to a halt in 1985 when the Drug Enforcement Agency (DEA)—reacting to recreational use of MDMA in nightclubs—classified the drug as a Schedule 1 substance—which has no therapeutic application. In the decades following, activists, therapists and researchers have organized clinical trials with MDMA in order to contest the scheduling. The dissertation is based upon in depth ethnographic fieldwork with the Multidisciplinary Association for Psychedelic Studies (MAPS), which has sponsored an international clinical trial program on MDMA-assisted therapy. If successful, these studies will provide the basis for the organization to petition the Food and Drug Administration to approve a novel pharmaceutical treatment.

This dissertation examines the ways that various practices of experimentation grant robustness to the chemical, the body, and even experience. The shift to epistemological practice that characterizes this work as a whole is an effort to avoid the constructivist bind by focusing not on what MDMA is or is not, or what it does or does not do, or when it is or is not agentive, but rather *how it is apprehended*. At several junctures, I argue that the chemical cannot speak for its own identity, but rather requires documentary, regulatory and experimental structures to guarantee it. The focus on practice in my dissertation allows MDMA's status to remain fraught and allows central tensions to manifest—such as the distinction between MDMA and Ecstasy, which is central to MAPS clinical trial program. I argue that understanding the political work of these trials requires close attention to the minute practices of experimentation at work in clinical research.

To my parents,

Mary and Norman Hendy,

for always being there for me.

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Completing this work has been a deeply humbling experience. Every stage, from the preparation for my exams, to fieldwork, to writing, and even to the last minute collection of my signatures, has required the support and friendship of a great many people.

On Fieldwork

I didn't quite go away to the field—as the field was neither clearly defined, nor all that far away from either my university or the city I grew up in. However, I did make a new home for myself during those years in a house with a partial ocean view in San Francisco. The Outer Sunset has horrible public transportation, and very few restaurants or bars of note, but surprisingly the highest rate of prostitution outside of the Tenderloin. It was (at least then) an enticing mix of Chinese families, stoned surfers, working class Irish and Italians, and easy parking, dive bars and cheap rent. I miss it deeply.

Gerald Jon William Howe and Hayden Burton-Miller (and the associated puppies) were excellent friends and roommates to have during those years. I owe thanks to them and to the many others who lured me to barstools and cooked family dinners and watched bad television and generally kept me sane during those years: Seth and Deidre Miller, Jesse Gould, Sara Garcia, Lexie and Anthony Pretto, Jennifer Thom, all of the Unicorn Warhammers, and of course, the incomparable Bridget Klecker, who passed away recently, and will be deeply missed.

I owe a huge debt to the Multidisciplinary Association for Psychedelic Studies, who allowed an anthropologist who didn't quite know what she was looking for when she started to poke about till she found it. Rick Doblin, Michael and Annie Mithoefer, Valerie Mojeiko, Josh Sonstroem, Randolph Hencken, Brian Wallace, Brad Burge, Linnae Ponté and Kynthia Brunette all played parts big and small in this work.

Brian Axel lent an ear and gave advice during my years between the University of Chicago and Berkeley. Running into him time and time again during fieldwork was a delightful touchstone for remembering the winding path that led here.

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On Mentors

Geoffrey Hunt hired me many years ago as an ethnographic fieldworker and interviewer on a then nascent study of club drug use in the San Francisco Bay Area. That first job set in motion fourteen years and counting of my life, and I am thankful for the help (and coffee) he has given me over the years.

Many times during the formation of this project and the writing of this dissertation, I have had the uneasy sensation that my committee members had known long before I the direction of my work but had kindly given me the intellectual gift of letting me find my own way. Each in

their own way has inspired the kind of writing and engagement offered in this dissertation. One of the great pleasures of working with Lawrence Cohen has been taking small ethnographic tidbits to him and listening to him compose new conversational arcs which unfailingly help to rethink my questions. Stefania Pandolfo steered my thinking in foundational ways through writings on subjectivity. Her voice, inviting me to go further, was in my head throughout my writing. Abena Osseo-Asare struck the perfect balance between opening my eyes to new lines of thinking—in the rich historical literature of medicines and chemistry—while also remaining open to the tone and questions of this project.

Cori Hayden has proved a most excellent advisor over the past nine years. This work has been indelibly shaped by our many conversations. I thank her for both sharing my intellectual enthusiasm, and for deftly managing to direct it in productive ways.

And while more friend than mentor, it feels appropriate to thank Laura Hubbard here, as I often thought of the clicketyclacketing of her peep-toe pumps as I looked to find my own voice, my own rhythm, as an anthropologist, teacher and writer.

On Friendship

I had an excellent cohort with which to share in the joys of 240. I have but the best of memories of the vitality and intensity with which we all began our academic careers together. Learning with peers was one of the gifts of Kroeber Hall. During my years at Berkeley, I took the opportunity to engage in a wide array of extra-curricular curricular—from reading salons on Lacan, queer sexualities, drugs and post-socialism to various writing and study groups. Michael D'Arcy, Patricia Kubala, Xochitl Marsilli Vargas, Nick Bartlett, Larisa Kurtovic, Jordan Kraemer and William Benton were all welcome part of that blurry world between studying and socializing.

Ned Garrett was my lifeline to Berkeley while I wrote up remotely. It was a delight to have someone else in Kroeber Hall share in my love of the Giants (and their miraculous three World Series rings!!!).

The University of California wide Science and Technology Studies Summer retreat brought me together with more scholars than I can mention here, but the conversations engendered there provided the inspiration for several key arguments in this dissertation.

Gillian Feeley-Harnick and Damani Partridge opened the doors of the University of Michigan Anthropology Department's Ethnography Lab to me during my time in Ann Arbor. Those writing groups helped to structure several semesters of my writing, which might otherwise been sucked down the Internet. In particular, Geoffrey Hughes, Jane Lynch and Luciana Aenasoaie—by virtue of our extended summer writing group—have read and thoughtfully engaged with most of this work. I thank them all for their camaraderie.

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Writing dates with Beth Currans were a welcome way to get out of the house and into engaging conversation while writing my first hard fought pages. I was also lucky to have the insightful Eric Plemons here in Ann Arbor over the last couple of years. His comments and friendship helped push several of these chapters along. I am also incredibly grateful to have had

the support of Andrea Wright in these final months before filing. It was lovely to have a friend to share in the turbulent joys of writing up remotely while becoming a parent.

I would never have made it through the University of Chicago and therefore into Berkeley if it were not for the friendship and support of Matt and Beth Spurgeon. I am quite lucky to have them in my life.

On Family

My grandmother, Frances Baker, passed away long before I got it into my head to get a PhD, perhaps even before I knew what anthropology was. And my aunt, Margaret Flaharty, passed away just before I started the doctoral program at Berkeley. But the love and support both of those women gave me throughout the years is very much a part of this work.

Being with Kevin has brought Mary Karpiak into my life. She is unfailingly kind and generous and has supported Kevin and I in countless ways.

I think I am quite lucky to both love and *like* my family—most of the time. My brother Stephen's quick wit, humor and general zest for life, make our time together more enjoyable. My father, Norman, has passed his widely varying intellectual curiosity and love of used bookstores on to me—for which I am thankful. And I suspect that listening to my mother's stories of living on a beach in Morocco and learning to crochet on Parisian park benches is part of what drew me to the kind of engagement that Anthropology offers—prolonged and quotidian. Thank you to them all for their support.

Bennett Karpiak has been a constant source of joy and exhaustion throughout the writing of this dissertation. I wouldn't have it any other way.

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Introduction

Scheduled

In 1985 the United States Drug Enforcement Agency (DEA), used their enhanced Emergency Scheduling powers, granted as part of President Reagan's efforts in the War on Drugs to classify a new drug appearing in raids on Dallas night club[1] as a Schedule I substance. Schedule I exerts the tightest level of regulatory control over a drug. Substances in this category are deemed to have a high probability for abuse and no therapeutic application.

At that time the drug, MDMA, had not been a part of any formal clinical trials, however, it had been circulating among underground psychedelic therapists in the United States and Europe for over a decade. It had been patented, though never formally studied, at the beginning of the twentieth century by Merck pharmaceuticals, and had been included in the Edgewater experiments conducted by the US military looking for a truth serum—though never in human subjects. During the 1970's, MDMA seeped out into the psychedelic therapy community, which had just been driven underground by the federal criminalization of lysergic acid diethylamide (LSD). Psychedelics therapy dates back to the 1950's when LSD, then a novel pharmaceutical, was distributed by Sandoz pharmaceuticals to researchers throughout North America and Europe.

MDMA's rebirth is largely credited to the Northern California based psychedelic chemist Sasha Shulgin, who synthesized the drug in the late 1960's in his home laboratory and took the drug as part of his self-experiments with psychoactive substances. Shulgin, noting that the drug enhanced his capacity for personal reflection, passed the drug on to psychedelic therapist, Leo Zeff, who then introduced the drug to thousands of therapists and patients over the next decade or so (Shulgin 1991; Stolaroff 1997). It was the Earth Metabolite Design Laboratories—composed of a small group of these therapists in California—who sued in 1985 to stop the scheduling, claiming that the drug should be a Schedule III substance—thus allowing medical research to move forward. Various therapists testified to the therapeutic aspects of the drug. The lawsuit was successful, but the DEA chose to ignore the ruling of its own administrative court, and MDMA was criminalized.

While it is very difficult to conduct research with Schedule I drugs, difficult is not impossible. These substances can circulate if it is for Science. For all of the energy expended preventing the trafficking of drugs across boarders, or tracking the sales of precursors for methamphetamine on the shelves of pharmacies, Schedule I drugs can be synthesized by chemists and pharmaceutical companies and are allowed to circulate in clinical settings and laboratories. Of course, most of this research investigates issues like toxicology and damage to neurotransmitters; research that would directly contradict the very scheduling status of the drug is another matter entirely.

In spite of the DEA's criminalization of MDMA, during the 1990's and early 2000's the drug enjoyed a rapid expansion in popularity, became entangled with underground dance parties and a world wide rave and club scene, under the brand name: Ecstasy. Fears over links between

[1] During the early 1980's, Michael Clegg was openly selling MDMA in Dallas, Texas. Clegg was a former seminary student, who felt that MDMA brought him closer to God and considered it his personal mission to spread the drug. He went so far as to have a toll free hotline for placing orders and is credited with christening the drug with the name "Ecstasy." ("Drug History" 2015).

Ecstasy and Parkinson's disease, "holes in the brain" and other forms of neurological damage spread alongside media attention to several highly publicized deaths from hypothermia (over heating) at raves and night clubs (cite media articles). At the same time, Rick Doblin, who had been a part of the Earth Metabolite Design Laboratories, formed a new non-profit dedicated to promoting scientific research with psychedelics: Multidisciplinary Association for Psychedelic Studies (MAPS).

Over the next several decades, MAPS worked to develop a pilot study on the therapeutic use of MDMA—tacking back and forth between different legal and regulatory strategies. Should the first study be in the United States, and then expand to clinical trials abroad? Would first initiating a study abroad, say in Spain, or Russia, put pressure on the US government to approve a study? In 2000, MAPS was finally successful in obtaining approval from the Food and Drug Administration (FDA) to run a small, pilot study on treating treatment resistant posttraumatic stress disorder (PTSD) with MDMA. However, MAPS had difficulty finding a private Internal Review Board (IRB) to review their study until one of the major studies claiming to find dramatic neurotoxic effects from MDMA was retracted (Ricaurte and Yuan 2002). It turns out that the researchers had accidentally administered methamphetamine instead of MDMA to the lab animals. While MAPS is broadly dedicated to promoting research with psychedelic drugs as well as marijuana, MDMA was the impetus for the non-profit's founding and has remained the focus of its now international research program.

Despite the fact that MDMA has been used in the underground for a variety of psychotherapeutic purposes—couples therapy, end of life anxiety, depression, and existential malaise, to name a few—MAPS strategically chose to focus their first study on posttraumatic stress disorder (PTSD), which has several methodological advantages[2]. The first was the Clinician's Administered PTSD Scale (CAPS)—developed by the National Center for PTSD at the US Department of Veteran's Affairs, the CAPS is considered the gold standard for diagnosing PTSD. The existence of a widely accepted objective measurement of trauma is critical to the design of the MDMA-clinical trial. MAPS had considered other studies designed to treat problems like addiction, but the methodological issues were daunting. How do you *measure* improvement before and after treatment? Does staying sober or clean for three months count? Or three years? More importantly, how do you determine if the subject has actually abstained from drinking or using drugs? How often do you collect blood or hair samples? Do you interview family members? More important still were the paltry pharmaceutical competitors for treating PTSD. Currently, Zoloft and Paxil are the only drugs approved for treating PTSD by the FDA—though a number of other drugs are often prescribed off label (Jeffreys 2014). Neither is considered particularly effective. If MAPS can show that MDMA is more effective than either Paxil or Zoloft for treating PTSD, and safe, then it can provide a compelling argument for approval.

If MAPS is successful—and the constantly accelerating pace of its clinical trial program, as well as their highly successful mobilization of media attention make MDMA's approval look very possible—then these studies will go down as a landmark moment in the history of the regulation of pharmaceuticals in the United States. The movement for the medicalization and legalization of marijuana has been steadily chipping away at federal policy for the past several

[2] Since the completion of my fieldwork, MAPS has expanded the scope of the MDMA clinical trial program to include studies on treating social anxiety in adults with Autism and end of life anxiety.

decades—starting with California Proposition 215, which legalized medical marijuana within the state in 1996. Even so, the federal government has continued to seize property from marijuana farmers and raid dispensaries. An actual change in federal policy would be unprecedented in the United States.

MAPS as rhizome: Situating the organization, the drug and the paperwork

I don't think of MAPS as a place, but a rhizome, this network that spreads out around the globe.

-heard by the anthropologist on the first day of her fieldwork

The offices of the Multidisciplinary Association for Psychedelic Studies (MAPS) reside in a converted single-family house on a busy thoroughfare in Santa Cruz California. There is a small yard with a lovely picnic table where staff can take coffee and smoke breaks amidst the smells of the Mexican restaurant next door. A tiny parking lot fits five very strategically arranged cars, so I often parked illegally in the adjacent lot for the outpatient health services. Santa Cruz sits at the top of the Monterey Bay. Go north, and you are headed up the Pacific Coast on a small two-lane highway that runs through farmland and beaches and continues into San Francisco. Head northeast over Highway 17 through the Santa Cruz Mountains and you land in Silicon Valley. Head south and you are in Steinbeck territory—Salinas and Canary Row.

For years, MAPS withheld its location. A keen observer might have noted the Prop 19 Sign (a failed 2010 proposition on the California to legalized marijuana) in the front window, and wondered what business was conducted within. But otherwise, there was no plaque or sign declaring that "here sits the non-profit pharmaceutical company dedicated to developing drugs that most people know as illicit street drugs as pharmaceuticals." Printed materials featured a PO Box address in place of the one on Mission Street. An anonymous building deflected the unwanted attention of those who had mistaken a non-profit drug development company for a place that has actual drugs.[3]

Drugs do not pass through the Santa Cruz office. Neither do patients. Documents, documents, documents are what pass through the office. Clinical trials produce an incredible amount of paperwork: protocols, Informed Consents (ICFs), Standard Operating Procedures (SOPs), read and received for SOPs, drug master files. It isn't as sexy as patients or white powders, but that is clinical research for you: data and paperwork. The clinical department, which generally consisted of the Lead Clinical Research Associate supervising various interns like myself, worked out of a small room on the second floor, where we had a closet with fireproof cabinets for the study documents. While drug development might be the main mission of the organization, the majority of staff in Santa Cruz works on the running of a non-profit, and not on drug development. An immense amount of labor is needed to generate the funding to support clinical trials without venture capital, government funding or grants. Most of the funds for the clinical trials are provided by what non-profits refer to as "angels"—wealthy donors who make six and seven figure donations. Many of MAPS' angels come from Silicon Valley. MAPS supplements this money by crowd funding campaigns, as well as public events that combine fundraising with public education and entertainment, through conferences, art auctions, tribute dinners and music events.

I came to think of the Santa Cruz offices as the nodal point in the rhizome—a place where the connections are denser than others. But it is through the Clinical Department that the roots of MAPS shoot out and extend around the globe. To South Carolina, where Michael and

[3] Partway through my fieldwork, MAPS changed this policy and made its location public.

Annie Mithoefer have run several studies, including the MDMA-assisted therapy for Veterans with PTSD. To Switzerland, where MAPS has conducted two studies, one using MDMA to treat PTSD and another using LSD to treat end of life anxiety. To Canada, Israel and perhaps someday Jordan, where there are more study teams for MDMA and PTSD. To Mexico, where MAPS has helped run outcome studies on the use of ibogaine in treating addiction. To Colorado, where MAPS has both an MDMA-assisted therapy study and where MAPS received a two million dollar grant from the Public Health Department and Environment in 2014 to conduct an outpatient study on treating PTSD symptoms with different strains of marijuana. The list keeps going: Australia, Arizona and Spain are all possible sites for research. The clinical staff itself spreads out form the office as well to the San Francisco Bay Area, Michigan, Massachusetts and Italy. Connecting all these sites is a constant flow of electronic and hard-copied documents.

Drugs and patients pass through the doors of sites around the world. But their circulation is tightly controlled. An incredible amount of regulatory energy is put into ensuring that the drugs themselves don't circulate. But documents are another thing. In fact, it is the documents that materially connect the site and sponsor. Staff with the sponsor organization develop and edit all of the study materials, which provide the matrix for the data collection. It wasn't unusual for documents to be printed in the Santa Cruz office and then packed into suitcases and taken on planes to the study sites to save costs[4]. Those same documents would eventually leave the sites at the end of the study and make their way back to the Santa Cruz office, where they would then occupy space in the fireproof cabinets.

The distinction between a sponsor and site is not unique to MAPS. This is exactly parallel to the distribution of tasks used by pharmaceutical companies. While a drug development giant like Novartis, might be based in Emeryville, California, they run studies around the world. Novartis is then the sponsor of the studies, and like MAPS, is financially responsible for the cost and liability of the trials. Clinical trials need to go to where the subjects are in order to administer drugs and collect data. Study sites are like small offshoots of these large organizations. As Adriana Petryna describes in her ethnography *When Experiments Travel*, clinical trials are often run by Contract Research Organizations (CRO), who work out of small office-like spaces, where physicians meet with patients across bank teller like windows (Petryna 2009). Physicians pass drugs to the subjects, and the subjects provide the physicians with updates on side effects, as well as biological samples for testing. And in fact, MAPS has worked with a CRO to develop its Middle Eastern studies.

The 1962 Kefauver Harris Amendment, discussed further in Chapter 1, introduced the requirement that pharmaceutical companies provide data demonstrating the safety and efficacy of treatments before approval in the United States. The basic design of a clinical trial begins with taking baseline measurements during clinical trial enrollment (i.e. testing for levels of cholesterol in the blood stream, or administering psychometric tests to determine level and type of depression). There are basic criteria for both inclusion and exclusion (a history of high blood pressure might exclude a subject from a study using a drug that accelerates heart rate). Once enrolled, two kinds of measurements, tests or data are collected: safety and efficacy. For

[4] As the sponsor of the study, MAPS was responsible for the costs of providing all of the study documents to the site, and as a non-profit researchers were conscious of keeping costs down. Various calculations were done to compare the costs of printing documents in Santa Cruz (by salaried staff, using MAPS infrastructure), versus paying an hourly staff member at the site to print documents at a copy center.

example, in a study of cholesterol, blood draws will be taken at pre-specified intervals, to monitor the effectiveness of the treatment. At the same time, other kinds of tests or data will be collected to monitor the safety of the treatment. The FDA requires all clinical studies for a psychiatric indication to administer the Columbia Suicide Severity Rating Scale (C-SSRS) at intervals throughout the study. Moreover, the physicians themselves are blinded to the treatment condition (active or placebo) that the subjects are receiving. Physicians are primarily involved in administering the drug and collecting the data. In contrast to ethnographies of clinical trials that focus on the study sites, and the administration of experimental drugs, this ethnography focuses on the paperwork, and on the sponsor.

Study design, protocol development, regulatory approval, monitoring, data analysis are all tasks for clinical researchers. These little locations where the doctors hand the subjects drugs are just a blimp in the overall life of a clinical trial.

Another anthropologist might have focused on one of the sites, to be close to the drug or the patients. But in the case of the research done by MAPS, the pace of work at the sites is slow and sporadic. It can take years for a study to progress from the development of a protocol to enrolling the first subject. Four subjects a year might receive treatment at a particular site. And even then, the subjects interactions with the therapists would have been confidential and off limits. But at the nodal point of the network, one could watch as a dozen protocols were proposed, developed, revised. Some studies initiated. Some completed. One could listen as the finer points of study design, and data analysis were debated. One could work with the sites to make sure that they collected the data properly. One could in fact observe the administration of an entire clinical trial program.

I started my fieldwork in the winter of 2010, as MAPS was preparing to host its first international conference *Psychedelic Science in the 21st Century*. I didn't initially start out with the clinical trial team. I had been assigned to the Director of Communications, Randy, as an intern, and spent most of my early months of fieldwork getting an overview of the organization and helping to prepare for the conference. One of my tasks was to interview several of the members of the clinical team and collect short bios for the brochure. I was interviewing Amy, the head of the clinical team about the MDMA, when she made the offhand comment that MAPS didn't need to demonstrate *how* MDMA worked; just that it was safe and effective. The comment (discussed further in Chapter 1) piqued my interest, and after the conference was completed, I transferred to working with the clinical department. From the spring of 2010 through the winter of 2011, I conduced fieldwork. I sat in on weekly conference calls, reviewed protocols, and participated in the dozens of administrative tasks that constitute clinical trial research.

When I first started working with MAPS, they occupied the first floor of a small house turned office building—the West coast editors of High Times magazine occupied the second floor. However, during the years I worked with MAPS, the organization expanded and eventually took over the upstairs offices. The once quiet parking lot came to be full every morning as more and more staff, interns and other collaborators took to working in the office.

My fieldwork was centered in Santa Cruz, but it drew from a variety of settings around the United States. I worked out of the MAPS office, but also telecommuted, phoning-in for conference calls, and conducting work via email. That was the way of the clinical trial team, who were often scattered around the country, if not the globe. I flew to South Carolina to help initiate a new study and monitor an ongoing one. I attended conferences and fundraisers thrown by MAPS in New York City, Los Angeles and San Jose, as well as other organizations involved

in various capacities with drug policy. The larger Bay Area was a rich place to do fieldwork on drug activism in its many forms. Outside of going to potlucks with other MAPS interns, I went to documentary screenings on psychedelics and I stopped in at marijuana activist meetings in Oakland. I went to the famous Easter party thrown at the Shulgin Farm. I went to Burning Man, and listed to MAPS' president present to a dusty tent full of Burners on MAPS' research. And I gained the trust of a small number of underground psychedelic therapists, who allowed me to interview them about their work.

Chemical Worlding

For many years, Sasha Shulgin and his wife Anne, elders in the psychedelic community of California, hosted potlucks on Easter and the 4th of July, collecting together their friends, family and extended circle of psychedelic researchers and activists to their home in Lafayette, California—nicknamed The Farm. Sasha worked for many years out of laboratory that he himself put together on the outskirts of the property. On this particular Easter in 2011, I was invited to the potluck, along with the MAPS staff. Cars were packed tightly along the edges of the dirt road leading into The Farm. The party spilled out across the property with people mingling around tables of desserts outside—from which children grabbed cookies; and in the house where bottles of Shulgin Wine, coffee and other beverages had been set out; and down to the Lab where photographers were cataloging papers from Sasha's archive.

Standing in the kitchen, next to the bottles of opened wine and soda, one of the many guests summed it up to me with a gesture towards the hills: "Inside this hillbilly shack a whole new world was born." I held onto that comment, storing it away as I wandered down to take my own pilgrimage to the lab.

Inside the shack, nestled into the hill, amidst the dust and beakers, leather bound volumes of Merck chemicals, and chalkboards of chemical equations, another pilgrim, lanky and excited, greeted me with a smile and asked, "So what is your favorite Shulgin invention?" If synthesis is invention, then Sasha—who passed away in 2014—invented hundreds of new chemicals. But of all of these (world making) chemicals, I have only tried the one. So, I answered honestly and said, "I guess I would say a classic, MDMA. And you?" He grins, and turns to his companion, "I would have to say 2cI. We danced for ten hours. It was fantastic." We then took turns exchanging phones and photographing each other inside the lab.

But what or where are these new worlds born of chemicals? Is it the world that is here, at the Shulgin farm, the world that is knitted together from the intimate entanglements between scientists and activists and humans who take psychedelics and Burners and artists and friends and granddaughters? Or is it the world being made anew each time through the newly embodied experience of dance, as for my briefly held friend? Or is it just the one world that has been forever changed with these new chemicals floating around inside the various body-consciousness of these citizens of the world?

In its most concrete sense, this dissertation is about a set of clinical trials currently taking place on the treatment of posttraumatic stress disorder with MDMA (Ecstasy). It is about the non-profit organization that is organizing and running these trials and the various research practices, problems and logics that they have employed as the continue to develop MDMA as a prescription pharmaceutical. And it is also about the therapy itself—and the way that a (sensorial) subject—is constituted in relation to their experience of self, others, chemicals, cosmos, and the divine.

But it is also—as if those were not enough—about this question of worlding. Timothy Leary famously advocated "Tuning in, turning on and dropping out"—implicitly inciting a

generation to go out on journey and never come back. However, the psychedelic rhetoric in the 21st century is quite different. As MAPS' president, Rick Doblin, is fond of saying, "We don't want to be the counter-culture. We want to be part of the culture." Or, as I often heard the value of the psychedelic journey described: "The perfect trip is one you can bring back into your world." These clinical trials are very much premised on a politics of *worlding*—of both creating change by working within existing political structures and at the same time attempting to change the world from within. And of course, as Gayatri Chakravorty Spivak reminds us, the term *worlding* has its own imperialist and colonialist overtones[5] (Spivak 1985).

What is MDMA?

MDMA is the abbreviation of the chemical structure: 3,4 methyndioxidemethamphetamine. Its structure is part amphetamine ring and part mescaline ring. The amphetamine ring is responsible for the stimulant effects of the drug—and dancing all night for which in part it gained popularity in the rave scene. When sold on the street, it is called Ecstasy, X, E, Adam or Molly. On the street, it comes in a variety of forms ranging from encapsulated white powered, to colored and pressed pills with different branded logos (see Chapter 1).

MDMA isn't generally considered a psychedelic, even though, throughout this dissertation I say that it is used in psychedelic therapy. I was told on numerous occasions that MDMA was not a psychedelic because it was an emotional and not a cerebral drug—meaning, I suppose, that its chief characteristic is an enhancement of one's capacity for feeling and not of one's thinking. Even still, as discussed in Chapter 3, MDMA has been woven into a set of therapeutic techniques that were developed starting in the 1950's, integrating psychedelic experiences into talk therapy.

Some have proposed that MDMA is unique enough to deserve the generation of an entirely new category. The term "empathogen" was originally proposed to draw attention to the feelings of empathy that the drug elicits. This term was later replaced by "entactogen"—meaning to produce a touching within (Nichols 1986). Whatever the term: MDMA has still been incorporated within a set of therapeutic practices developed around the use of psychedelics. MDMA circulates alongside drugs like LSD and psilocybin within the psychedelic scene. And MDMA shares the same scheduling class as psychedelics. Psychedelic or not, MDMA is aligned socially, therapeutically and politically with this class of substances.

Conversations in Anthropology

This dissertation sits in relation to a number of different conversations within anthropology: pharmaceuticals generally, clinical trials in particular, and of course recent work on the hallucinogens.

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[5] Susan Zieger argues that American overtones of manifest destiny are deeply present in the narration of an intense journey into inner space presented in Fitz Hugh Ludlow's *The Hasheesh Eater* (Zieger 2007). These metaphors of psychedelic journey are also deeply overwritten by the Western trope of a Hero's Journey—not unfamiliar in anthropology. B. Malinowski begins his now canonical ethnography of the Trobriand Islands with the description of his ship touching down at the island, and himself, the intrepid anthropologist, arriving at the land of culture. In the process of spatializing culture, this image draws upon the powerful Western trope of the hero's journey. One must leave home and travel to exotic lands in order to find who one is.

The anthropology of pharmaceuticals emerged in the late eighties and early nineties through an engagement with the spread of Western pharmaceuticals in the Third World (Geest and Whyte 1991). Anthropologists have framed the pharmaceutical as the material instantiation of the intersection of capitalism and biomedicine, and focused on its status as a commodity. While anthropologists had previously attended to medicine as substances imbued with cultural and symbolic logics which produced them as efficacious in primitive societies, researchers had not dealt with the "synthesized, manufactured, and commercially distributed therapeutic substances that constitute the hard core of biomedicine" that are pharmaceuticals (Geest, Whyte, and Hardon 1996).

More recently, anthropologists have taken up pharmaceuticals in relationship to studies of globalization—tracking how the market and state align in various ways to produce different categories of disease, communities of patients and levels of access to different treatments (Kleinman and Petryna 2006). A number of anthropologists have glossed access to pharmaceuticals through the concept of citizenship (Nguyen 2005; Biehl 2004; Ecks 2005), as well as to issues of intellectual property (Peterson 2014; Hayden 2007), and the complex intersection of intellectual property and claims to citizenship (Ecks 2008).

Recently, anthropologists have shifted their attention away from consumption and towards the production of pharmaceuticals as medical-scientific objects within the framework of clinical trials. In particular, they have attended to the ethical issues surrounding the enrollment of vulnerable subjects (Petryna 2009; Abadie 2010; S. L. Jain 2013; Craddock 2004; Saethre and Stadler 2013). Collectively these scholars have brought to light how the ethical relationship between life, death and risk is being reconfigured within the framework of the globalized clinical trial, and how existing inequalities are exacerbated within a framework for producing new technologies of health. In these works, pharmaceutical companies are presented as a coherent industry with consistent obligations and interests—namely profit. Subjects on the other hand are asked to take on different forms of risk, in return for uncertain benefits.

The development of MDMA by a non-profit raises a different set of issues. What is a pharmaceutical? Is the pharmaceutical defined by its use in in biomedical practice? Is it defined by its production by a pharmaceutical company? Is it defined by regulatory structures? More importantly: what should be made of a non-profit pharmaceutical company? The absence of shareholders and profit margins does not mean that capital does not play a role in the MDMA-clinical trials. However, it does demand the new analytical questions. If there is an issue around MDMA and intellectual property, then it might manifest around the therapeutic technique itself. And at least for now, the donors cannot hope to see any return on their investment.

Moreover, most of the ethnographic literature on clinical trials makes an explicit link between the for-profit motives of a pharmaceutical company and the exploitation of research subjects. However, the subjects enrolled in these studies do not lack access to health care—many of the studies focused on treatment resistant PTSD, which meant that the subjects had already had treatment. In the recent study with Veterans, they have access to the Veterans Administration health system. These are not terminally ill subjects looking to extend or prolong their lives despite the risk of a clinical trial. These are chronically ill subjects looking to find a treatment that might work—having already tried ones that failed. This dissertation hopes to open a new space for ethnographic inquiry by closely following the practices of clinical research in order to think about how it is that pharmaceutical knowledge happens, and to extend from these practices to the realm of the ethical and political in new ways.

This dissertation follows closely on the heels of another ethnography of hallucinogen research: Nicolas Langlitz's *Neuropsychdedelia: The Revival of Hallucinogen Research since the decade of the Brain.* Based on fieldwork in two neuroscience laboratories conducting research with LSD and psilocybin—Mark Geyer's laboratory in San Diego, California and Franz Vollenweider's laboratory in Zurich, Switzerland—Langlitz's field site is deeply entangled, but distinct from the one described here. The laboratory in Switzerland used synthesized from the same lot of MDMA as the one used in MAPS Swiss study, and some of the same donors funded both field sites. More importantly, I tune in to a number of themes raised in Langlitz's work, namely the status of objectivity and mystical experiences. However, there are critical differences as well. Langlitz frames his work as fieldwork in perennial philosophy—a term from Aldous Huxley used to describe the universal core mystical experiences undergirding all religions. Langlitz's ethnography asks how mystical experiences are recast in light of new models of consciousness emerging from hallucinogen research. He frames the work a "meditation on the spiritual venues open to those living under the conditions of late modern materialism." Langlitz is engaged in a philosophical dialog with his interlocutors in the lab, and as such grants the individual scientists space for rich biographical detail. This dissertation takes a different tack. The scale of action in my ethnography of psychedelic research is much smaller. I focus on the small details and problems through which the effects of the MDMA manifest in clinical research. In part, this is because clinical research is highly pragmatic. To put it another way, I do not focus on existential quandaries of the informants, as much as I focus on how they do what they do. As such, the question of the human, which is central for Langlitz, is peripheral to the question of the chemical at stake in this ethnography. However, this ethnography is not performing an analysis of the vitality of matter—to borrow Jane Bennett's phrase (Bennett 2010). The experimental questions and practices of humans in this dissertation very much shape the effects and efficacy of the chemical.

Overview of the Chapters

This dissertation holds in tension the biochemical and the social—in broad terms. It works against narrative framings in which the meatiness of body, brain, and chemical are surrounded by the social ether bending and distorting their effects. It instead tries to think through the ways that various practices of experimentation grant robustness to the chemical, the body, the soul, and even experience. The shift to epistemological practices that characterize this work as a whole is an effort to avoid the constructivist bind by focusing not on what MDMA is or is not, or what it does or does not do, or when it is or is not agentive, but rather *how it is apprehended*. At several junctures, I argue that the chemical cannot speak for its own identity, but rather requires documentary, regulatory and experimental structures to guarantee it. The focus on practice in my dissertation allows MDMA's status to remain fraught and allows fault lines to manifest—such as the distinctions between MDMA and Ecstasy (Chapter 1) and GMP (Good Manufacturing Practice) and non-GMP MDMA (Chapter 4). Or between the neurobiological effects of MDMA on the fear response system versus its utility in accessing what MAPS' therapists term "staying in the experience".

Clinical research is characterized by its focus on effects—in contrast to other forms of research that see out mechanism of action or the etiology of disease. Yes substances like MDMA have a tense relationship to their own effects. This is a truism of pharmacokinetics writ large in the 21st century: the condition of the body—male, female, pregnant, hypertensive, anxious, ridden with SSRI's, dehydrated—allows vastly different effects to manifest. However, as a psychoactive substance tied to psychedelics, MDMA has another layer of disjuncture with

its effects. Throughout my fieldwork I encountered the claim that MDMA produces a non-ordinary state of consciousness of a kinship with an array of other substances and practices. Psilocybin mushrooms, LSD, mescaline, meditation, Holotropic Breathwork™, ecstatic dance, and Bodywork all lead to this same transformative state that is both particular to its impetus, and yet beyond it. This distinction is a hairline fracture in the relationship between MDMA-assisted therapy and biopsychiatry as it currently stands. To put it another way, psychedelic therapists and researchers maintain that the healing potential of the drug is at some level distinct from its neurobiological effects. In these narratives the chemical or psychedelic is but an opening—often described as a pathway—through which one approaches a non-discursive, embodied experience of expansion.

In the first chapter, *Effecting Substance*, I argue that an ethnography of pharmaceuticals and clinical trials should attend to the informational environments and research practices that structure pharmaceutical claims about therapeutic properties. I ethnographically follow how regulatory definitions, documentary procedures and study design combine in the clinical trial process to identify and isolate effects and then to relate them back to MDMA—producing it as a new political object.

In the second chapter, *Science, Politics and Substance*, I draw attention to the dual status of MDMA as both a Schedule I substance and an Investigational Product. I walk through the development of the Food and Drug Administration along side the Drug Enforcement Agency and argue that their overlapping jurisdictions produce MDMA as a *hyper legalized object*. While the two organizations have radically different mandates, I draw together how practices of surveillance are at work in both the DEA's monitoring of drugs and the FDA's monitoring of clinical subjects.

In the third chapter, *Chemical Consciousness*, I examine the fraught space between MAPS' competing theories of MDMA's therapeutic efficacy. On the one hand they argue that MDMA produces an optimal arousal zone, in which subjects can confront traumatic memory. This theory draws on the same neurobiological models being employed within exposure therapy for PTSD. I discuss how therapists encourage subjects to "stay in the experience" using eyeshades and silence—a state in which experience invokes an almost-impossible immediacy to the present. In this chapter, I begin to explore the language of *non-doing*, *presence* and *holding space* through which the work of the therapists is described.

In the fourth chapter, *Documenting Adherence*, I follow the significance of documents to the practice of clinical research and argue for documents as the instruments of clinical research. However, the chapter is also about the problem of replicating a therapeutic technique, of repeating the experiment, of surveillance and monitoring in research, and of the entangled role that documentation plays in all of these tasks. This chapter brings together insights anthropological conversations on the social significance of documents and on clinical research.

In the fifth chapter, *Experiential Politics*, I interrogate a contradiction at the heart of these clinical trials: a desire to produce a therapy that endows the chemical with therapeutic efficacy through cultivating the experiential knowledge of the therapist, and a set of research practices that actively seek to decouple the production of knowledge from the subjectivity of the therapist/researcher. I argue that clinical research, as an exercise in scientific objectivity, rests upon a set of anti-techniques of the self, in which the subject-as-researcher is actively curated as absent, blinded, objective (Daston & Galison, 2008). In the conclusion of the chapter, I extend that contention and argue that the objectivity-of-the-placebo points to a conflicted space from which MAPS is making political claims. Drawing upon interviews and fieldwork with the

organizers, I point to the latent notions of freedom, autonomy and cognitive liberty that undergird MAPS clinical trial project, and think about the conflicts between a therapy that depends upon knowledge generated from personal experience, claims to fundamental rights to cognitive liberty which extend from that position, and a mode of political action that depends upon negating that link between subject and knowledge.

The dissertation concludes by raising a set of questions on materiality, efficacy and experience drawn from the material in the chapter. At its best, this dissertation attempts to lay the groundwork for future inquiry, while also elucidating the rich and complex terrain of clinical research with psychedelics.

Chapter 1: Effecting Substance

Introduction

On the eve of hosting an international conference on scientific research with psychedelics in 2010, the Multidisciplinary Association for Psychedelic Studies (MAPS) overhauled their website. They redesigned the layout and removed the many images of fractal-overladen-expanding-cosmos and replaced them with photographs displaying men and women in white laboratory coats—ostensibly scientists—looking into microscopes.

For all of my year and a half working on the MDMA trials, I never donned a lab coat or looked into a microscope. There is no laboratory for the MDMA studies. The clinical research team is based out of the second floor of MAPS' Santa Cruz office, in a small room with slopping attic ceilings. Luckily, the researchers in the office were usually seated, either staring at their computers or gathered around a phone for a conference call. Berra is the lead clinical research associate, and the go-to-clinical-person in the MAPS office. Berra's dog was usually there with her, standing guard. The head of the clinical department, Amy, works remotely, so much of the day-to-day management of interns like myself falls to Berra. Berra has a lovely set up with an extra-large auxiliary screen hooked up to her Macbook Pro, so that she can easily scroll through large spreadsheets of data. I usually worked off of my own laptop, or sometimes at the one desktop computer in the clinical office—it was de-networked to protect confidential data. A file cabinet storing hard copies of clinical trial documents for active studies takes up most of the small closet. Much of our work involved quietly going through electronic and hard copies of documents—editing, reading, and signing off—while music played on the computers. If there was a form of observation taking place in the clinical office, then it was not the work of microscopes, but of protocols and psychometric tests and case report forms (CRF's).

This chapter examines the kind of observation methods that clinical trials bring to bear on the chemical. One of the primary problems of research with chemicals is that structures cannot predict effects. In other words, one cannot look at a chemical and be able to tell with certainty what it will do. The effects of a chemical emerge as it circulates in the world, interacting and entangling with other chemicals, environments, bodies, and—as I argue—experimental structures. In this chapter, I take up that basic chemical fact, and examine the ways that experiments structure the effects of the chemical. More particularly, I take up the clinical trial as a historically specific form of experimentation, which has been developed in concert with demands from contemporary regulatory institutions.

That chemicals do things, and by extension, that they take some form of being from the things they do, has become a commonplace way of referring to them in the 21st century. Acetaminophen is a pain reliever. The effect of ingesting this pharmaceutical is that pain is relieved. It *is* what it *does*. This is of course, somewhat of a simplification, as chemists and regulators have complex vocabularies through which they break down the chemical world—not all of which refer to effects. All the same, Selective serotonin reuptake inhibitors (SSRI), Monoamine oxidase inhibitor (MAOI), 5-HT2A-receptor antagonist, are all terms, which are based on establishing a link between a given effect and a chemical structure.

In this chapter, I try to slow down these statements, and hold back from claims of doing and being, in order to think carefully about the methods through which chemical knowledge is established. What is required to claim that a chemical has a particular effect—be it deleterious or palliative? Through what methods of observation is that claim established? In this chapter, I

draw upon ethnographic fieldwork with the Multidisciplinary Association for Psychedelic Studies clinical research team to illustrate how the effects of a given chemical are collected and managed. In short this chapter begins the project of the dissertation, which is to think through how knowledge about a chemical happens. Subsequent chapters will draw out the challenges that MDMA-assisted therapy poses to the form of the clinical trial, but in this chapter I look at how MDMA is a chemical like any other. If we can pause here to observe the ways that effects are linked back to chemical structures, and how these effects are then injected into the nature of the chemical, then we can begin to think about the ways that chemicals are shaped by the forms of experimentation and regulation that surround them.

One of the goals of this chapter is to extend a basic chemical fact to the social sciences' approach to the pharmaceutical: the structure of a chemical is not predictive of its effects. This is not to say that one cannot hazard a guess, or that similar chemical structures might produce similar effects. However, small variations in structures can have radically different effects, and there is no way to guarantee that a given chemical will behave in a particular way based on its structure. Thus chemical knowledge is built upon both the particularity of the case, and repeated experiments. The links between a given event, or effect have to be carefully observed. Effects are not given manifestations of structures. Rather, the effects and events are the matter at hand, and the very problem of clinical research is tracing them back to a given structure. Thus, thinking chemically requires attending first to the particularity of a case and then seeing where it might lead (Barry 2005). This means holding back from some of the structuring concepts and theories in the social sciences.

To make this argument, I turn to the work of social scientists and historians of science. Drawing upon the work of Isabel Stengers and Bernadette Bersaund-Vincent, Andrew Barry has developed the term "informed materials" to describe the ways chemical structures become richer and richer in information (Barry 2005; Vincent and Stengers 1996). I am purposefully invoking the chemical here—and not any number of other terms such as narcotic or pharmaceutical or drug—because I want to call attention to the historical links between pharmaceuticals and the industrialization of chemistry at the turn of the twentieth century (Vincent and Stengers 1996), as well as the entire set of disciplinary techniques, practices, machinery that produce the chemical as both a commodity and as an object of knowledge and regulation. Chemistry is a body of knowledge, a discipline, and a set of techniques for both producing and studying the object. In short, the term chemical imbeds the object in history, in a set of techniques and apparatuses, and knowledge practices. All of which at various points will be central to the drama of MDMA. What's more, the term pharmaceutical is not a given but is exactly what is in question for MDMA.

Synthetic psychedelics entered the world through the chemical industry. MDMA, LSD, psilocybin, mescaline were all first produced in the chemical laboratories that were rapidly expanding with the industrialization of chemistry at the turn of the century. All of these substances have ties to living organisms that can produce psychoactive effects without the intervention of the laboratory. For LSD that is ergot; psilocybin has mushrooms; mescaline has the peyote cactus; and MDMA is tied to nutmeg as well as sassafras. However, the intervention of the chemical laboratory made possible the circulation of these effects in new form—a form

that was not only conducive to measurement, calibration and regulation, but facilitated those acts in new forms[6].

MDMA's fate hinges on this question: which effects are linked back to its structure? Is it linked to neurotoxicity or alleviating symptoms of PTSD? It was the lack of knowledge about its effects that justified the DEA's classification of MDMA as a Schedule I substance[7], and as I will discuss in this chapter, the MDMA clinical trials were held back years because of fears of the chemical's possible neurotoxicity. But most importantly, if the regulatory status of MDMA is to change then these clinical trials must establish a clear link between the palliative effects and MDMA (In subsequent chapters, I will discuss the complexities in making these links given that MDMA is an *experiential* treatment which is shaped by the actions of a therapist).

In this chapter, I lay the groundwork for an approach to the chemical that highlights the way both its effects and its very structure are produced in the process of experimentation. I lay out both theoretically and ethnographically two intertwining arguments. The first is that the effects of a chemical are structured by the experiment. Thus new effects can emerge out of new experimental entanglements, which ask different questions of the chemical. Through these arguments, I try to trouble (but not reject) the idea that effects are inherent to the chemical—that they preexist observation or are in some way a part of the nature of a particular chemical. And through this I am trying to trouble the stability of identities given to particular chemicals. This is not to say that chemicals don't do things, or that outside of modes of observation and experimentation that they would not have effects. This is to say that in order to adequately contend with the contemporary knowledge claims made about chemicals, we must slow down and think through the ways that the practices of experimentation structure the possibilities for particular kinds of effects emerging. Secondly, I argue that the clinical trial is a historically specific form of observation, which is designed to contend with both the openness and indeterminacy of chemical effects, as well as a historically specific set of regulatory concerns.

My project follows historian of science Lorraine Daston's call to investigate the ontologies of scientific observation, and the ways that these forms of observation stabilize scientific objects (Daston 2000). Daston argues that twentieth century philosophy of science has too often assimilated scientific observation into the realm of brute perception. She argues instead that all forms of observation are informed by theory, and that they are creative of the objects that they observe. In other words, observation does not simply perceive a preexisting object, but is actually constitutive of that very object through the development of its practices of observation. In the following sections, I will map out ethnographically how this happens in the practice of clinical research.

Informed Materials

How does one go about discovering the action, the nature of the effects on the central nervous system, of a chemical which has just been synthesized, but not yet put into a living organism? I start by explaining that it must be understood, first of all, that the newborn chemical is as free of pharmacological activity as a newborn babe is free of prejudice... The properties cannot yet be

[6] See Cori Hayden's work on pharmaceuticals in Mexico, the concept of *similares*, and regulatory mandates for demonstrating bioequivalence for generic drugs (Hayden 2007).

[7] Schedule I is the most restrictive category for drugs in the United States. By definition Schedule I drugs have no therapeutic use and a high probability for abuse. When the DEA scheduled MDMA in 1985, there were no clinical studies on its effects.

known, for at this stage they do not yet exist... The process of establishing the nature of a compound's action is synonymous with the process of developing that action.
-Sasha Shulgin*, Pihkal*

Upon his passing in 2014, Sasha Shulgin was one of the world's preeminent psychedelic chemists. In the psychedelic community he holds prestige equal to Albert Hoffman, the chemist who first synthesized LSD. Trained as a biochemist after World War II, he spent his life synthesizing two families of psychoactive materials—tryptamines and phenethylamines—and then developing their actions through a careful method of auto-experimentation (Shulgin 1997; Shulgin 1991). While he is best known for his experimentations with MDMA in the 1970's, which led to the chemical being incorporated into the practice of underground psychedelic therapists[8], his experiments have given rise to an entire pharmacopeia of psychoactive materials (Stolaroff 1997). In the above quotation he articulates the very point I want to develop in this chapter: namely, that a chemical's effects are produced, or developed in the very process of inquiry. The premise that pharmacological activity emerges from experimentation is vital for understanding the informational quality of pharmaceuticals outlined by the following scholars.

In a parallel train of thought, sociologist Andrew Barry argues that contemporary pharmaceutical research practices have brought about new forms and levels of informational enrichment. Barry is wrestling with a contradictory moment in pharmaceutical research when chemical structures can be developed in the theoretical space of computer programs or *in silico*. Thus, even before a chemical is ever materially synthesized, a body of knowledge can exist based on computer models, which attempt to predict that chemical's effects. The relation between the chemical and the effect is not guaranteed, but the presence of this form of research troubles materialist conceptualizations of the chemical. Barry's argument draws on A.N. Whitehead's re-conceptualization of the materiality of chemicals. In the nineteenth century, Barry writes, many chemists viewed their discipline as a "science of atomic elements and molecules." Items like the periodic table displayed the molecular level as a combinatorial realm built up from invariant parts with stable identities. However, Barry points out, even though chemists write of individual molecules such as iron, in fact they never study those items in isolation. Rather what is of interest to the chemist is how the properties of particular molecules vary depending on the "form and circumstances of their association with others." In contrast to the commonplace view of chemistry, Whitehead argued that: "the identities of atoms and molecules were not distinct, nor were they invariant." A molecule for Whitehead was a historical rather than a physical entity. Whitehead argued that a molecule should be viewed as a 'historic route of associations.' It should be understood through is relations and associations, as something that comes to be in an event, rather than as a stable material entity. "The molecule that is isolated and purified in the laboratory will not have the same properties as it has in the field, the city street or the body" (Barry 2005). While the periodic table implies that atoms have given and invariant identities, combination is the source of complexity in the chemical world. Barry's reading of Whitehead calls attention to the complex relationship between chemicals structures and informational, or experimental environments.

In a similar vein, in her article "Methadone: Six Effects in Search of a Substance," Emilie Gomart argues that effects take precedence over substance in a clinical trial (Gomart 2002). She argues that only at the end of a clinical trial do experimenters find the substance in

[8] By the 1970's the use of psychedelics in therapy had became illegal. The "underground" is colloquially used to refer to the illicit and covert practice of psychedelic therapy.

the effects. Drawing upon the insight and language of actor-network theories, she compares two methadone substitution trials that have different results. Gomart asks: what is it that varies and what is it that stays the same? Rather than argue that it is the culture or context that varies (a social constructivist standpoint) or that there is a progressive telos of science at work, Gomart argues against a flow of action from a substance to an effect. In place of a stable entity that is the origin of a set of effects, for Gomart, there is a network from which action has multiple sources. This framework address not just the different methadones at work in different trials, but also the way that a difference between heroin and methadone-as-substitute is produced. According to Gomart, pharmacology has long struggled with the problem of predicting action from the structure of substance. While early pharmacologists began with the same classical *a priori* assumption that particular substances contained sets of effects that could be predicted on the basis of structure, there was, according to Gomart, a gradual drift to other techniques, namely substitution, which allowed them to speak of action without structure. Two substances were similar if they produced similar effects—if the heroin addict didn't go into withdrawal after taking methadone then the substances were similar, or substitutable. Observing similar effects becomes observing similar chemical structures.

If effects can become the identity of the substance, and if those effects emerge out of new experimental structures and entanglements with new bodies and environments, then chemical identities are not stable, but continually open and indeterminate. This chapter will push off from the combined insights of Gomart, Barry, Stengers and Bersaund-Vincent in order to think about the concrete practices through which these chemical effects, or events are produced. In the sections that follow, I will examine the different clinical trial techniques that were used to capture and document the effects of MDMA. Barry's analysis deals with chemicals that exist *in silico*, where computer models attempt to predict the complexity of effects that emerge through the exponential number of chemical associations. However, in this case, the chemicals are not *in silico*, but are in the degenerating brains of ravers, blinded envelopes, and padlocked safes (See Chapter 2). The issue is not the dematerialization of the chemical, but the very problem of tracing effects back to chemical materials. Thus, this chapter begins the process of examining the methods of observation through which this information is produced.

If, as Barry argues via Whitehead, chemicals exist as a historical route of associations, then this chapter begins the project of investigating how those associations are produced through clinical observation in the twenty first century. In the next section, I take up the work of series of historians who have followed the development of both the pharmaceutical industry and regulation in the twentieth century.

Industrial Invention

Most scholarly work on pharmaceutical regulation in the twentieth century at some point rehearses the thalidomide crisis of the 1960's, as it was a major turning point in the regulation of clinical research by the Food and Drug Administration (FDA). The story goes something like this: thalidomide was first patented in 1956 by the German pharmaceutical company Chemie Grünenthal (Tseng et al. 1996). The drug was initially marketed as a sedative and tranquilizer. (Though claims to its sedative properties were based entirely on a structural resemblance to diazepam and barbital, which have never been confirmed in clinical studies (Hoffman 1995)). Researchers later discovered that it was an effective antiemetic—meaning it could inhibit vomiting and nausea. The company then re-marketed the drug as a treatment for morning sickness in pregnant women. An increase in cases of phocomelia—a rare birth defect causing malformation of the limbs—in West Germany led to an investigation of the drugs effects. It was

eventually linked to thousands of birth defects, and pulled from the market. While the drug was never approved in the United States, in the wake of the crisis, the Kefauver Harris Amendment of 1962 was enacted which required that proof of efficacy be established through controlled clinical trials before a drug could be approved to market.

The thalidomide crisis came in the wake of a massive expansion of the pharmaceutical industry following World War II—bringing about the era of miracle drugs, or antibiotics. Historian of science, John Lesch has argued that the groundwork for the era of miracle drugs was laid in the decades leading up to the invention of the sulfa drugs—a treatment for bacterial infections based on a red dye—in the 1930's (Lesch 2007). Lesch argues that the success of the sulfa drugs led to a massive expansion of the pharmaceutical industry and that the invention of the sulfa drugs was the culmination of the rise of the fine chemicals industry at the turn of the century—a process that resulted in what he terms the industrialization of chemical invention. By industrialization he is calling to mind both the driving power of capital, and a particular organization of labor, wherein research by both chemists and medical doctors was integrated into a single project. Prior to the 1880's Lesch argues, most medicines were based on natural products—primarily through the isolation of naturally occurring alkaloids, like morphine, which is derived from opium. During the turn of the century, chemists shifted from isolating to being able to independently synthesize organic substances. What's more, Lesch points out, they were discovering new applications for these substances. The development of Aspirin is a case in point. Bayer was a fine chemicals company until the discovery that coal tar derivatives could have fever reducing powers, at which point the company opened a pharmaceutical laboratory and eventually launched acetylsalicylic acid, or Aspirin.

Part of what Lesch argues was so significant about the development of the sulfa drugs was the way that laboratories organized chemical inquiry into rational drug design. Lesch has followed the development of the research and development sectors at the nascent Bayer pharmaceuticals and has tracked how research was increasingly differentiated, specialized and decentralized. "Technical innovation at Bayer became a bureaucratically managed, routinized process carried out by teams of cooperating specialists." Lesch's argument calls attention to the importance of the development of research infrastructure and bureaucratic management in pushing the pharmaceutical industry forward.

The proliferation of new chemicals at the beginning of the twentieth century raised new questions for the relationship between market and government. Historian Harry Marks has argued that the efforts of a group he terms "therapeutic reformers" were critical to establishing regulatory oversight of the pharmaceutical industry in the twentieth century (Marks 2000). These reformers took up the problem of pitting market and science against each other: how to harvest new treatments from the laboratory and protect medicine from the market? Well before the era of miracle drugs, pharmaceutical companies were marketing a wide array of patent medicines and nostrums with no governmental oversight. In 1905 the American Medical Association founded the Council on Pharmacy and Chemistry, which set the first set of standards for drug manufacturing and advertising. The CPC's laboratory tested patent medicines and nostrums to ensure that a product contained the ingredients that it purported to and not just colored water. For these sorts of tests, the laboratory sufficed. (Marks, 1997).

While laboratory tests might filter out fraudulent medicines, claims to chemical doing, or efficacy, and safety, were not easily answered in the laboratory. Remember that thalidomide was initially marketed as a sedative with no evidence to back this claim. Initially, animal testing proved valuable for evaluating the safety of a given treatment. But, the real issue for therapeutic

reformers was establishing a properly controlled clinical trial in order to validate claims about therapeutic efficacy. Initially, academic medicine relied on the "cooperative studies" to produce the large amounts of data. Cooperative studies drew together the efforts of independent researchers through the controlled supply of a treatment. While the studies did rely on centralized planning and coordinated methodology, they didn't have an instrument for enforcing methodology. In the second half of the twentieth century, the Randomized Controlled Trial (RCT) was institutionalized as the gold standard of pharmaceutical research in concert with the rise of statistical thinking in medicine. Marks argues that the RCT shifted authority from institutions to methods—statisticians came play the role of enforcing the blinded randomization of subjects. RCT's utilize blinded controls and randomized assignment of subjects to different treatment conditions. All of which remove physician's judgment from the treatment regimen. Early coordinated studies did not have a mechanism preventing physicians from assigning the most promising cases to particular treatment conditions. (However, the rise of statistical thinking in pharmaceutical development has been extended from methods to the diagnosis of preventative disease through assessments of risk at the population level (Dumit 2012; Greene 2007).)

Thus, what emerged by the end of the twentieth century was a complex system in which methodology and statistics became central to the evaluation of a study's claims about the effects of a given pharmaceutical treatment, and a complicated system for oversight by the Food and Drug Administration. Mechanism of action is not necessary for establishing safety or efficacy—as Lesch points out, the sulfa drugs were in use for years before consensus emerged as to their mechanism of action. Thus, as I will argue in the next section, both research and regulation is focused on the observation of effects and the search for the chemical structures that underlie them.

Structuring Effects

"We don't need to show how MDMA works, just that it does." Amy, MAPS' clinical director, explains to me. I had just asked Amy the duplicitously simple question, "So how does MDMA work?" It is a question that I will circle back to again and again throughout my fieldwork. The answers I have been given range from the metaphorical to the neurobiological: *MDMA works by allowing the patient to access their inner healing intelligence. MDMA builds the therapeutic alliance with the therapists. MDMA works by releasing oxytocin and reducing the fear response in the brain*. However, these explanations are superfluous to the clinical trial, according to Amy. Mechanism of action is an unknown variable in the testing of a pharmaceutical, and it need not ever be solved for. The only thing that matters is that the chemical is shown to be effective and safe. Moreover, establishing safety and effectiveness requires different observational techniques.

Observation is a tricky word to use to describe clinical research, as clinical trials do not look through microscopes as much as they observe through documents—documents that are continually amended and refined. By documents, I am referring to a textual record—though there is debate about the parameters of the term (Buckland 1998). Much of my fieldwork was centered on producing, editing and reviewing documents in both electronic and hardcopy form (See Chapter 4 for further discussion). Let me clarify this point. The MDMA trials are psychotherapeutic, and their outcome measure thus depends on the results of a psychometric test, as I will discuss shortly. However, even when the outcome measure requires lab work—lets say as in a clinical trial where white blood cell counts are the outcome measure—it will be the documentation of that laboratory work that is at stake in the clinical trial. As the clinical trial saying goes, that which is not documented is not done.

A clinical trial begins with a protocol—the original document guiding the study. It lays out the basic study design so that regulators can evaluate the study. It also forms a blueprint from which all further study documents will be drafted. Any change in the study design or procedures has to be filed with the FDA as an amendment (The clinical team kept a running list of changes for future amendments). And finally, the protocol obligates the clinical trial team to provide certain kinds of data to the FDA. Thus the language used to describe the study design and procedures is critical[9]. Under Amy's direction, the study documents proliferated. Standard Operating Procedures (SOP's) were continually being developed. Read-and-receiveds were printed, signed, and filed for staff working with said SOP's. And the language of the protocol was refined and clarified.

In the early MDMA protocols, the section of the protocol that listed the study objectives was a laundry list of all the study measures and safety precautions being taken. As the trials expanded, so did the clinical trial staff. The new recruits, like Berra and Amy, had worked in the pharmaceutical industry. They had experience with running multi-sited clinical trials and gaining federal approval for new pharmaceutical treatments. Prioritizing or stratifying the study measures was a fundamental change that was made to the protocol after they arrived. Providing a primary outcome measure or primary end point is a convention of good clinical practice. The logic is that a primary end point not only narrows the range of effects that must be evaluated to determine the efficacy of a treatment, but that measure will also be used to guide statistical analysis of the data.

For all of the MDMA-PTSD studies, the primary outcome measure is the Clinician's Administered PTSD Scale (CAPS). The CAPS is considered the "gold-standard" for diagnosing PTSD. The CAPS was developed by the National Center for PTSD—a division of the US Department of Veterans Affairs. Of course, the CAPS is not the only psychometric test used during the study, or even the only psychometric test used to evaluate a subject's level of traumatic stress. Other outcome measures used in the MDMA-PTSD studies included:
The Posttraumatic Diagnostic Scale (PDS)
Posttraumatic Growth Inventory (PTGI)
The Global Assessment of Functioning (GAF)
Beck Depression Inventory-II (BDI-II)
Neuroticism-Extroversion-Openness Personality Inventory (NEO-PI)
Pittsburgh Sleep Quality Index (PSQI)
An improvement or positive change on any of those scales could be used to argue for a therapeutic or palliative effect of the treatment. The PDS is a self reported measure that can be used to correlate to a CAPS score. The NEO-PI and the PSQI were measures that were trying to look at other potential effects of the MDMA experience: changes in personality and quality of sleep. Both of these are potentially beneficial, and they might even play a role in the changes that are seen in the CAPS, but they are not the primary outcome measure. PTSD and depression have a high level of comorbidity, so improvement to symptoms of depression could be considered palliative to PTSD. However, the design of the clinical trial seeks to narrow the field of "effects." A change in CAPS score would be used to determine the effectiveness of the treatment. The clinical trial then becomes a test to see whether or not this effect manifests itself

[9] In Chapter 4, *Documenting Adherence*, I discuss the many kinds of work that documents perform in clinical research more particularly. In this chapter, I point to how documents like protocols shape the kinds of effects that a chemical can manifest.

in a predetermined method of observation. Thus, as long as the CAPS' score decreases, then MDMA works. The flow of effects emanating from the chemical must be specified. What's more, these effects manifest themselves through documents, which have already been subject to statistical evaluation. In some cases these psychometric tests can be downloaded from the Internet (Trained professionals can request copies of the CAPS online from the National Center for PTSD), in others they can be purchased from publishers who own the copyright. Before the statistical data can be compiled, they must be recorded on these documents in specified ways. And because the CAPS has to be administered in a specific way and scored in a particular manner, the raters administering the CAPS had to be trained—which was of course subject to its own set of documentary procedures (See Chapter 4).

"So I learned a new word today: mydriasis," I say to Brad, who is working next to me on the second floor of the MAPS offices in Santa Cruz, California. I am staring at a word document, reviewing a protocol in the common area. Interns, and sometimes full time staff, set up camp at one long desk that wraps around the wall in the open space of the second floor. I like chatting with Brad, who is the Director of Communications and is in charge of everything press and media related. Before Brad decided to focus on drug activism, he was a doctoral candidate in Science and Technology Studies. We first met as colleagues who were both interested in the research happening at MAPS.

"And what does that mean," he asks?

"It is the medical word for your pupils dilating. It is listed as one of the side effects of MDMA."

"Ah, yes side effect. Except for those times when your pupils dilating, and the sociality it cues, is in fact the desired effect of the drug," he replies.

I laugh, liking Brad's point and scribbling it down in my notebook: *the distribution of the main and the side effect of a drug are in fact contingent on the experimental context*. What is listed as to the side, as somehow secondary to the purpose of MDMA, is sometimes one of the effects that is sought out—or one of the primary effects. In a clinical study on PTSD, the dilation of the pupils is not a main effect of MDMA, but at a club or a rave or Burning Man, the visible effect MDMA and other psychedelics can have on the pupils allows for social cuing to others as to what the current state of consciousness is for that individual. And those cues can cultivate the sociality of the experience. For the MDMA-PTSD studies, the primary effect that is sought out is a change in the CAPS score.

The team worked on refining the language that was used, as well as creating a format that could easily be replicated and tailored to meet the needs of individual studies. In order to make MDMA into a treatment for PTSD, the myriad of possible effects—from sleep quality to personality to pupils—had to be put to the side. That work was done through the experimental structure of the protocol. The protocol clearly structured not just what effects would matter, but how those effects would be observed—always pointing down the line to another form of documentation through which the effects of MDMA would be manifested. Month by month, revision by revision, the protocols were morphing from a study protocol to a pharmaceutical grade clinical trial document.

Safety

While efficacy might require the stratification and prioritization of effects and their correlating observational techniques, determining if a given chemical is safe for the human body requires a different method of documentary observation. One can only specify adverse effects in advance to a certain degree. For example, in the wake of data indicating that patients taking anti-

depressants were at higher risk for suicide, the FDA has required that "suicidal ideation and behavior assessments should be carried out in all clinical trials involving any drug being developed for any psychiatric indication, as well as for all antiepileptic drugs and other neurologic drugs with central nervous system (CNS) activity, both inpatient and outpatient, including multiple-dose phase 1 trials involving healthy volunteers." (Center for Drug Evaluation and Research 2012) For this reason, the Columbia-Suicide Severity Rating Scale (C-SSRS) is administered to subjects in the MDMA studies at enrollment and through out the study—including at multiple points during the experimental sessions. In this case, the risk and the measure are specified in advance by the regulatory structures overseeing the study.

However, it is the unknown problems that are even more worrisome. To establish safety, one cannot simply rule out the harmful effects that one already knows are possible. One also needs to be able to capture the effects that may not yet be known. As in the case of the thalidomide crisis, the downstream effects of a chemical on a body or bodies can be wide ranging. Establishing a method or a technique to look for what can't be specified is part of the clinical experiment.

Looking for something that may or may not exist becomes tricky in the context of the clinical trial, which is subject to bureaucratic scrutiny and auditing. Clinical trial researchers need to design study procedures to not only look for adverse effects, but also to *verify that the researchers have looked for adverse effects*[10]. How does one document that one has looked for things, which can't be specified in advance?

Safety data collection begins with an umbrella term: adverse event, which the study protocol following the FDA defines as "any untoward or unfavorable medical occurrence in a clinical research study participant, including any abnormal sign (e.g. abnormal physical exam or laboratory finding), symptom, or disease, temporally associated with the participants' involvement in the research, whether or not considered related to participation in the research. This definition includes concurrent illnesses or injuries and exacerbation of pre-existing conditions." Meaning, any medical problem that a subject encounters while participating in the study is considered an adverse event. For example, a clinical trial subject gets in a car accident and breaks their wrist. Even if the subject was not driving the car, and if the accident was the fault of the other driver, even if the subject had not yet received the investigation product, that broken wrist would become part of the study record. It would even be labeled "severe" (as opposed to mild or moderate), since it impeded the subject's ability to perform normal daily activity. But it would also be labeled "probably not related." Because "The AE is not related if exposure to the investigational product has not occurred, or the occurrence of the AE is not reasonably related in time, or the AE is considered unlikely to be related to use of the investigational product, i.e. there are no facts (evidence) or arguments to suggest a causal relationship, or the AE is more likely related to the subject's pre-existing condition." MAPS did not create these definitions themselves. The definitions for adverse events (and their various ratings of severity) are set by the International Conference on Harmonization, which sets guidelines that have then been adopted by regulatory agencies like the FDA.

[10] To quote from a document on good clinical practice of documentation: "Any basic training in clinical research will definitely include these phrases: 'What is not documented is not done!' 'Document what is done as well as what is not done!'" (Bargaje 2011)

The collection of Adverse Events shaped debates around how to design a follow-up study. Some of the subjects from the very first MDMA-PTSD study were experiencing relapse in symptoms. A follow up study was proposed, so that these subjects could receive an additional MDMA session. The question was: would this be a new study or an extension of the original study? On the one hand, the private IRB board charged less to approve an extension than a new study. However, as an extension, everything that had happened to the subject in the intervening years would need to be recorded as potential adverse events—and for some subjects that had been over five years. The preference of the clinical staff was to submit it as a new study, at which point everything that happened during the time between the two studies would become medical history.

The Adverse Event then becomes defined in temporal relation to the study and not the drug. If a subject is enrolled in the study on a Monday and tries to commit suicide on Tuesday before receiving the investigational product, it is still considered an adverse event. More importantly, that suicide attempt, though not related to the drug, is considered a Serious Adverse Event (SAE), which is different from an adverse event that is severe. The language defining an SAE in MAPS protocol is taken directly from a the FDA's website:
defined as (Food and Drug Administration 2014):
An SAE is defined as any untoward medical occurrence that at any dose:
• Results in death
• Is life-threatening (i.e., the subject was, in the opinion of the investigator, at immediate risk of death from the event as it occurred); it does not refer to an event which hypothetically might have caused death if it were more severe
• Requires or prolongs inpatient hospitalization
• Results in persistent or significant disability/incapacity (i.e., the event causes a substantial disruption of a person's ability to conduct normal life functions)
• Results in a congenital anomaly/birth defect
• Requires intervention to prevent permanent impairment or damage
• Is an important and significant medical event that may not be immediately life-threatening or resulting in death or hospitalization, but based upon appropriate medical judgment, may jeopardize the patient/subject or may require intervention to prevent one of the other outcomes listed above
AEs which do not fall into these categories are defined as non-serious. It should be noted that a severe adverse event need not be serious in nature and that a SAE need not, by definition, be severe.
I have included the detailed list of events that can be considered serious as they are directly taken from FDA guidelines. Notice the inclusion of congenital anomaly/birth defect—the specter of the thalidomide crisis.

Towards the end of my fieldwork, the clinical team encountered an SAE. In this case, a subject had attempted suicide. On the one hand, it was two weeks after MDMA had been administrated, so it was unrelated to the drug itself. However, the possibility was raised that the suicide attempt was related to participation in the study, as the subject had only gone off of SSRI's as part of the protocol (SSRI's like Prozac prevent MDMA from effecting the release of serotonin). What's more, it was hypothesized that the therapy processes "things were being stirred up." While overall, most subjects CAPS scores declined from baseline to follow-up, it had been noted by researchers and therapist that they did sometimes go up during the course of treatment. This case illustrates the complexity involved in determining when an event is or is not

related to a chemical substance. Is the adverse event the absence of a treatment? A problem caused by a drug? Part of the overall therapeutic process? When is risk due to the investigational product and when is it due to the study of the investigational product? Very quickly, the chemical itself becomes difficult to pick out amid a range of effects.

Of course, neither of these categories, Adverse Events or Serious Adverse Events, captures the incredibly long list of possible bodily side effects that are now listed along side any pharmaceutical. What about the minute fluctuations, an upset stomach, a bad headache, blurring of vision, in the body of a clinical trial subject? How is this range of effects captured? How are they dealt with? These effects, MAPS termed "spontaneous reported reactions," are as follows: *Spontaneously reported reactions may include reduced appetite, dizziness, tight jaw or bruxism (tooth-grinding), difficulty concentrating, impaired gait or balance, dry mouth, and thirst. Other slightly less common reactions include drowsiness, impaired judgment, headache, restlessness, nausea, parasthesias (odd somatic feelings, such as tingling, feeling hot or cold), changes in thought, perspiration, drowsiness, nystagmus (eye-wiggling) and sensitivity to cold. These effects are transient and wane as drug effects wane. Sub-acute effects that may either continue for the next 24 hours or appear later include insomnia, fatigue, weakness, heavy legs, dry mouth, low mood or irritability. Sub-acute effects are reported less often than acute effects. Other spontaneously reported reactions include increased private worries (rumination) and needing more sleep. Sub-acute effects are reported less often than acute effects. Other common reactions in preliminary data from the initial study of MDMA-assisted psychotherapy in people with PTSD include muscle tension in approximately 20% and gastrointestinal discomfort or diarrhea in approximately 3.3% participants receiving MDMA. Spontaneously reported reactions will be collected during the experimental session and during the seven days of telephone contact beginning the day after each experimental session.*

Unlike Adverse Events, which are defined in relation to study participation, SRR's are defined in relation to the administration of the investigational product (IP). The administration of the drug is temporally bracketed with different strategies for collecting these effects. What's more, this laundry list of potential effects has a specific form that the clinical team designed for the collection of these effects. Even what is defined as spontaneous has been specified in advance.

MDMA is not Ecstasy

"So I am interested in the research that you are doing. How you are focusing on science to show that Ecstasy has therapeutic benefits."

"We aren't studying Ecstasy," Berra cuts me off right there. "We are studying MDMA."

"Sorry, MDMA."

"It is okay. I have to correct people all the time. We are studying MDMA which is not the same thing as Ecstasy."

I had just recently been given permission to join the clinical team as an intern in order to observe the clinical trial research process. My clumsy attempt to explain myself to the clinical team has raised one of the thorny issues involved in developing MDMA as a prescription pharmaceutical: its relation to the dangerous club drug, Ecstasy. It is no easy thing to disentangle these two substances. Any definition you find describes Ecstasy as the chemical substance, MDMA. And any reference to MDMA will describe it as being sold under the name Ecstasy (sometimes shortened to X or E). Scientific papers always use a dual set of referents "MDMA ('Ecstasy')" to describe the substance.

MAPS' website clarifies Berra's statement about the difference between the two substances:

Substances sold on the street under the name Ecstasy do often contain MDMA, but frequently also contain ketamine, caffeine, BZP, and other narcotics and stimulants. In laboratory studies, pure MDMA—but not Ecstasy—has been proven sufficiently safe for human consumption when taken a limited number of times in moderate doses.

In this section, I will unpack this claim that MDMA and Ecstasy are distinct substances in the world. The first half of the chapter examined the ways that effects are sought out through the process of experimentation, and structured via clinical documents and regulatory definitions. In this second half, I will push farther to argue that the very structure of MDMA is being solidified in these experiments. I argue that the MDMA clinical trials are in fact producing MDMA as a distinct substance from Ecstasy. I will argue that MAPS' claim to MDMA's difference from Ecstasy depends upon both testing and safety. In both cases, I argue, experimental procedures are introduced to enrich the structure of MDMA, producing it as a distinct chemical substance.

MAPS' claims that MDMA is a singularity, whose structure is certain, while Ecstasy pills are an uncertain, multiplicity. To clarify, MDMA looks like this:

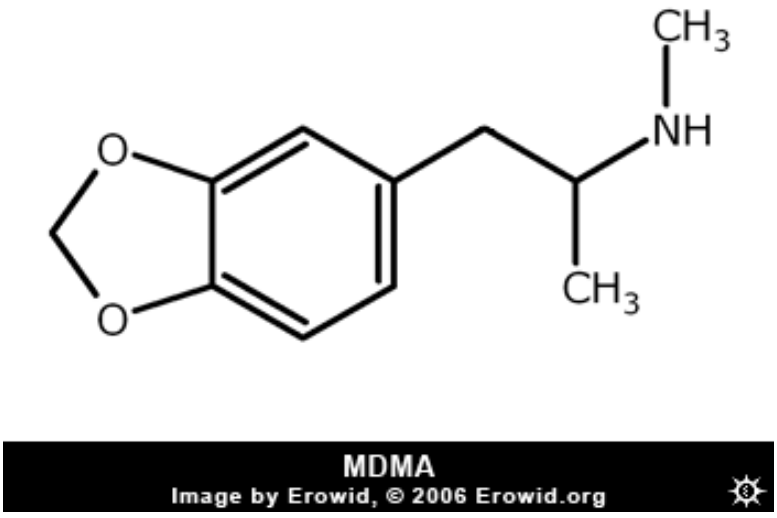

Figure 1 Chemical structure of MDMA from Erowid.com

While Ecstasy pills look like this:

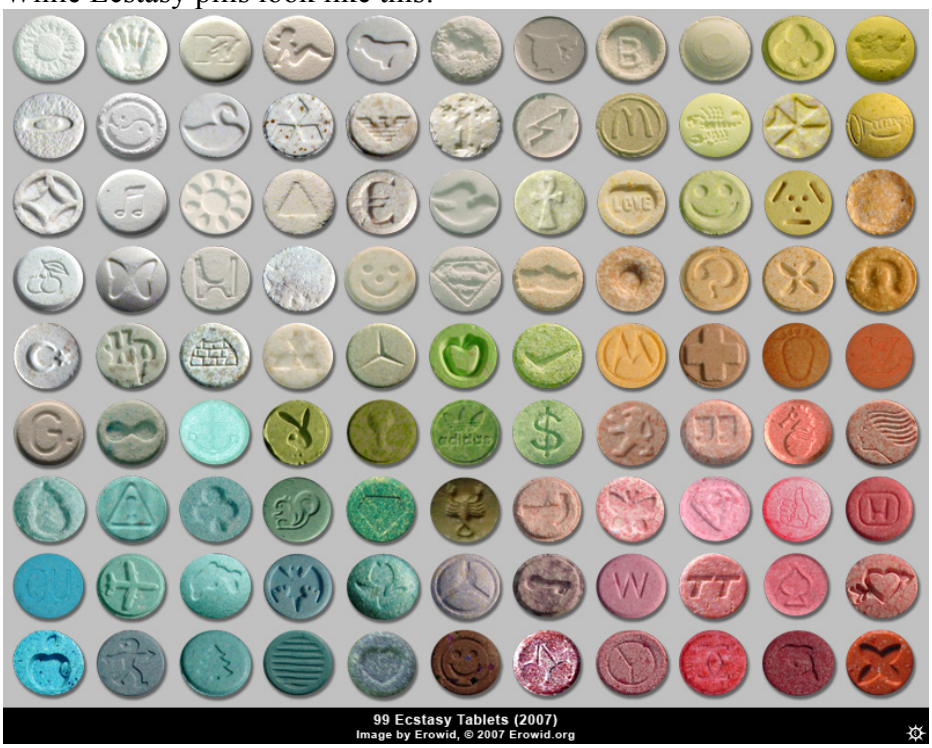

Figure 2 Pressed Ecstasy tablets from Erowid.com

Yes they are linked, MAPS concedes, in that Ecstasy may or may not contain MDMA, (and MDMA may be called Ecstasy), but they are distinct things in the world.

Of course, keeping them distinct requires testing. "We need to know everything that was done to our investigational product," Amy emphasizes. I am currently taking minutes for the weekly Clinical Teleconference meeting. Depending on the week, the calls ranged in length from one to three hours and consisted of updates on all of the studies both under development and in progress, as well as a dozen or so other administrative matters that were the responsibility of the clinical team. Currently at issue is the documentation of the MDMA being used in the US MDMA-PTSD studies. The clinical team knows that the drug was tested in 2001, but cannot find any documentation and has been emailing with the chemist who synthesized it to find it. When Amy emphasizes that we must know "everything" done to this product, she means this particular batch of MDMA: when it was synthesized, where it has been stored and when, where and by whom it has been tested.

Professor David Nichols, then at Purdue University, synthesized the MDMA that is used in MAPS's studies in the United States in Indiana in 1985. The product that Nichols synthesized twenty five years ago has been tested for purity several times. The most recent test found the greatest level of purity—the increasing purity of the drug is more likely due to improved testing. According to the study protocol:

The identity and purity of this MDMA was confirmed using High Performance Liquid Chromatography (HPLC) in 1997 as described in DMF # 6293 and was found to be 99.87% pure. On August 12, 2002, Chemic Laboratories reanalyzed the MDMA at the request of the sponsor prior to starting MAPS' first U.S. pilot study of MDMA-assisted psychotherapy in people with PTSD. The analysis found the MDMA to be more than 99.7% pure. A more recent analysis performed by Nichols at the request of researcher Dr. Carl Hart on February, 2006,

continued to find a high degree of purity. This analysis found the MDMA in question to be 99.9% pure.

While the "impurity" level of MDMA used in the clinical trials is incredibly small, it is still there. I am not nitpicking about the distinction between MAPS' MDMA and what might be bought on the street as Ecstasy. Some amount of the Ecstasy sold on the street is actually fairly pure—at least within range of MAPS' MDMA. The critical distinction between the two is not purity, but rather the piece of paper not only attesting to but quantifying that purity. That is the piece of paper that Amy and the clinical team care about. What allows MDMA to be MDMA (and "not Ecstasy") is the test *and* the corresponding documentation. My point here is that chemical structures cannot speak for themselves. In the scientific-regulatory context of a clinical trial, chemical substances require testing, and documentation of testing to guarantee and demonstrate that they are what researchers say they are.

"How did your presentation go?" I ask Berra, who has just returned from a conference in New York City. "Really well. I got some great feedback from the rest of the panel. They really liked that I was talking about safety." If MDMA is going to be held a distinct object in the world from Ecstasy, then this distinction turns on two different claims. The first is to purity, singularity. The second is safety. While MAPS argues that MDMA is safe because it is not Ecstasy, I argue that as it becomes "safe" it becomes not Ecstasy.

The issues around MDMA and safety date back to Ecstasy's rise in popularity as a club and rave drug. As the drug gained global popularity, there were several well-publicized deaths associated with Ecstasy use at raves and clubs. There were also a myriad of concerns about the potential long-term damage from the drug (Cloud et al. 2000). I went to college in the Bay Area during the late 1990's and early 2000's when Ecstasy was catching momentum. I remember quite clearly sitting in my friend Olivia's dorm room as she recounted how her friend now had a distinctive clicking sound in his neck after having taken too much Ecstasy—three hits, she said. While Oliva was a big fan of LSD, she flatly refused to try Ecstasy, both because of the supposed damage her friend had suffered and because she didn't want to develop Parkinson's. Just once, she said, and you could be damaged for life—a scary prospect to a young Berkeley student thinking of majoring in business.

Ecstasy (MDMA) use was increasing in the late 1990's among both college and high school students[11]. (Johnston et al. 2006) Ecstasy had been around just long enough to have a bit of mythology—"You know, it all got started in Ibiza or London or Goa," you would hear, or "It used to be used in couples therapy", but these background stories did little to assuage fears about the long term consequence of what was still considered an unknown drug. What exactly would happen to all of these young ravers in thirty years time? Ecstasy's dangers were framed in two alternating time scales: the immediate dangers of hospitalization from overheating at raves, and

[11] In 1996, the National Institute on Drug Abuse first began asking high school students about their own use of Ecstasy (MDMA) in the annual *Monitoring the Future* study. The Monitoring the Future study has been tracking trends in drug and alcohol use among high school students since 1975. It also conducts follow up questionnaires with participants during their college years. The 1995 study report had noted an increase the use of Ecstasy (MDMA) by college age-respondents, which was the reason that they began including questions to high school students. MTF study continued to find increasing use of Ecstasy throughout the late 1990's—with use leveling off around 2001.

the long ranging consequences of neurological damage which might not be felt for decades to come.

Olivia's Parkinson's fears stemmed from controversial evidence produced initially out of one case study. The first case was published in 1998 as a peer reviewed letter to the editor in the New England Journal of Medicine. The authors write: "Parkinsonism has not previously been associated with the use of MDMA. Although we have no firm evidence of a causal relation between this patient's drug use and his parkinsonism, there are no other tenable explanations." (Mintzer, Hickenbottom, and Gilman 1999) In other words, Ecstasy was the culprit simply because there was no other to be found—a tenuous strain of reasoning at best. However, the prestige of the journal, compensated for actual evidence. Moreover, the paucity of the subject's Ecstasy use (only eleven times in total over a two year period) fanned fears about the potent neurotoxicity of MDMA. In 2002, the Parkinson's fears got a boost when an article appeared in *Science* claiming to have found dopamergic damage in primates administered MDMA, and speculating that this damage could lead to Parkinson's disease (Ricaurte and Yuan 2002). The findings contradicted two previous human studies, which found no damage to the dopamine receptors in recreational uses of Ecstasy (Semple, Ebmeier, and Glabus 1999; Reneman, Booij, and Lavalaye 2002). However, in the wake of this article, two more case studies appeared linking Ecstasy use to Parkinson's. For a moment, the fears over Parkinson's disease seemed to have credible scientific evidence. However, they were short lived as the study was retracted amid controversy when it was discovered that methamphetamine and not MDMA had been accidentally administered to the animals in the lab. Methamphetamine's action on the dopmaine receptors is well established, and explains the unprecedented results. While MDMA might be part amphetamine ring, no studies have been able to repeat the results of dopaminergic damage with MDMA.

The other source of fear around Ecstasy stemmed from PET scan images that visually illustrated the potential "holes in the brain" caused by Ecstasy use. In response to the increasing rate of Ecstasy use among teenagers and college students, the National Institute on Drug Abuse commissioned a PET scan study to help in "educating" the public about the risks of Ecstasy use. The study compared the brains of 14 heavy MDMA users to 15 non-users and was published in Lancet (Mccann et al. 1998). Anthropologist Joseph Dumit discusses the production of these images of "holes in the brain" in his ethnography of the nascent neuroimaging technologies of MRI and PET Scans, as an example of how these images are subjected to visual manipulation in order to produce "evidence" of neurological damage (Dumit 2004). Dumit traces how controversial data from PET scans were presented in an escalating fashion: as correlational (dark areas on scans correlate to MDMA use), to causal (MDMA caused the dark areas), then as eventually diagnostic (it is clear that the damage in this brain was caused by MDMA). NIDA used the scans to produce a poster "Plain Brain/Brain after Ecstasy," in which two brain halves are shown side by side.

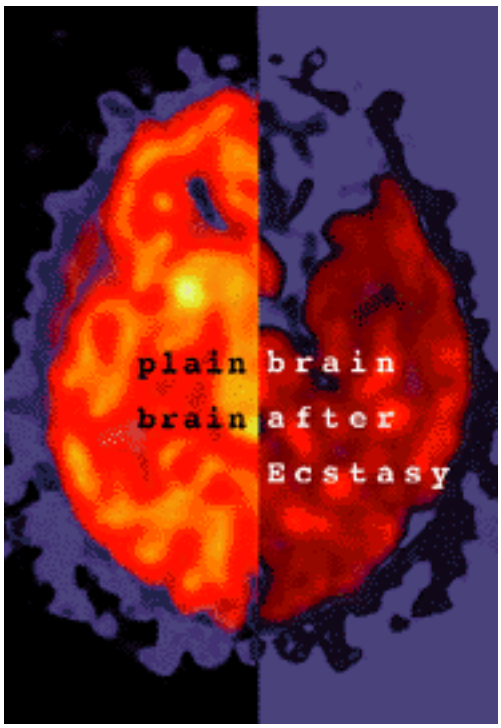

Figure 3 Image from NIDA's anti-Ecstasy campaign from Erowid.org

Dumit points out that not only did the designers choose the two most divergent brains from each sample for the poster, but also they manipulated the color ranges, and contrast in order to produce what he calls a "visual lie."

This visual lie came to animate understandings of the deleterious effects of ecstasy use. During the early 2000's, NIDA's poster sat above the desk of my supervisor at the Institute for Scientific Analysis. I was working as an ethnographic interviewer and fieldworker on another NIDA-sponsored study on club drug[12] use in the Bay Area. When I would ask participants if they had any fears about the long term consequences of their drug use, they would often respond with certainty that they had holes in the brain—no matter if they had used Ecstasy 3 or 300 times.

In the first MDMA-assisted therapy study, MAPS included several measurements that were meant to counter the accusations that MDMA impairs mental functioning. The protocol states: "Exposure to MDMA will not be associated with neurocognitive toxicity as assessed by the Repeatable Battery for Assessment of Neuropsychological Status (RBANS), the Paced Auditory Serial Addition Task (PASAT) and the Rey-Osterrieth Complex Figure Test." If these tests had demonstrated that MDMA was in fact associated with neurocognitive toxicity, then the distinction that MAPS is trying to make between MDMA and Ecstasy would begin to fall apart.

[12] For the purpose of the study, club drugs were defined by NIDA as Ecstasy, LSD, Methamphetamine, Ketamine, Rohypnol and GHB.

In short, the ability to call them distinct things in the world in fact rests on the demonstration of a different set of effects—particularly related to safety. In this way, one can begin to see how chemical structures and distinctions are themselves the product of experimentation. As each successive clinical trial is initiated and closed out without a drug-related SAE or sever AE, MAPS claim that MDMA can be administered safely grows stronger. In fact, each successive protocol and submission to the FDA cites the growing number of times that MDMA has been administered without problem. And the more that MDMA becomes attached to claims of safety, the more distinct it becomes from Ecstasy.

Conclusion

These clinical trials are currently in Phase 2—an interim stage in which safety is assessed in human populations before a large population is enrolled in order to determine efficacy[13]. Thus, each study only enrolls a dozen to two dozen subjects. However, if they continue to be successful, The FDA may approve a Phase 3 clinical investigation of the efficacy of MDMA-assisted therapy for PTSD, which would enroll hundreds of subjects. At this point, MAPS would draw closer to its long-standing political goal of challenging MDMA's scheduling. While many of the activists, supporters and researchers that I encountered with MAPS were hopeful for the success of the clinical trials, it was often remarked that whatever bureaucrat might sign off on MDMA as a prescription pharmaceutical would most likely lose his or her job.

Unless, of course, MAPS can convince the public that MDMA is in fact not Ecstasy. To this end, MAPS has a very savvy and active media department, whose goal is to raise public awareness about the therapeutic use of psychedelics and marijuana. Members of the MAPS organization regularly give interviews to media outlets and the organization has been participating in a documentary on MDMA, which will detail the clinical studies. MAPS is active on social media—not surprising given the organizations relationship to Silicon Valley and the fact that most of the staff is in their twenties and thirties. They have organized Question and Answer sessions on Reddit with participants from studies, and participated in online fundraising campaigns.

Even if, as I argue, the linking of therapeutic effects back to MDMA is a site of politics—it is not the limit of political action. I will return to this point in the conclusion of the dissertation when I discuss the latent notions of liberty and autonomy undergirding MAPS' project. For now I would like to point out, that whether or not MAPS ever gains approval for MDMA-assisted therapy, these studies have in fact produced a site for the legal practice of psychedelic therapy. Both the FDA and DEA tightly circumscribe the legal use of MDMA in these studies—as the next chapter will explore—but, just as chemicals are not easily described as this or that, neither can they easily be described as either legal or illegal. The next chapter will examine MDMA as a *hyper-legalized* object—subject to bureaucratic oversight by multiple regulatory organizations.

[13] A Phase 1 study is usually conducted with healthy volunteers, and is aimed at discovering side effects and how a drug is metabolized and excreted(Center for Drug Evaluation and Research 2015) .

Chapter 2: Science, Politics and Substance

The Fifth Visit

Subjects are enrolled in the MDMA-trials for weeks before MDMA ever enters their blood stream. The first "experimental session"[14] comes on the fifth visit, which occurs only after weeks of ridding the subject's body of all other psychotropic pharmaceuticals. While there are exceptions for pain maintence, the subjects enter the study as a clean system as possible. In particular, Selective Serotonin Reuptake Inhibitors (SSRI)— commonly prescribed to for the treatment of PTSD—impede the effects of MDMA. Thus, the protocol requires that the interval between the start of washout and the first experimental session is "at least five times the drug's half-life."

On the day of the experimental session, the subject arrives at the office of Dr. Michael Mithoefer early in the morning having consumed "nothing by mouth but non-caffeinated liquids"—a phrasing that was carefully chosen by the clinical researcher team so as to eliminate everything but the most innocuous liquids. No food. No coffee. No drugs. No herbal supplements. A drug test is performed to confirm that the subject has not taken any drugs.

If the drug test comes back negative, Dr. Mithoefer will open his safe and remove the labeled envelope with the encapsulated product for the subject's experimental session. A computerized randomization system has determined which envelope the subject will receive. The safe is hidden in a locked cabinet in Michael's office. The doors of the cabinet must remain locked unless Michael himself is present in the room. There is an alarm that must be set when he is out of the office. In addition to these protocols and lock and key forms of security, there are also forms and accounting procedures, which are periodically reviewed by a DEA agent to make sure that the MDMA is properly accounted for. How much MDMA has been encapsulated? How many capsules have been administered? How many capsules remain?

It is through Michael's hands that the drug will move from the safe, where it is ordered in "blinded" envelopes, and into the patient's hands and mouth. These two containers, the safe and the envelope, mark the two different statuses of MDMA. The safe secures a Schedule I substance, while the envelope secures an Investigational Product (IP). As a Schedule I substance, MDMA must be strictly accounted for, but as an IP in a double-blind placebo controlled trial, the location of the drug must be uncertain. While Michael must treat that envelope *as if* it contains MDMA, he also, as an investigator, can't know if it contains MDMA or a placebo. Just as the drug occupies two positions, so does the Michael, the researcher and DEA license holder. On the one hand, he is responsible for making sure that every gram of MDMA is properly handled and accounted for. On the other hand, he is the lead investigator in a placebo-controlled study, which means that to some degree he cannot know exactly where the MDMA is.

This scene illustrates MDMA, not as an illegal or illicit substance, but as a *hyper legalized*. It is controlled both as an Investigational Product and as a Schedule I substance. I use the term hyper legalized to call attention to the fact that federal regulation in the United States does not eliminate these substances from the polity, but rather places them under levels of hyper

[14] The protocol identifies three different kinds of visits by the subjects to the therapist's office: preparatory, experimental and integrative. The MDMA treatment (or placebo) is only administered on the days of the experimental session. The preparatory sessions precede the first experimental session, and the integrative sessions follow each experimental session.

security and surveillance. As legal medications, pharmaceuticals are overseen by the Food and Drug Administration, and as controlled substances, their non-medical use is policed by the Drug Enforcement Agency. The first part of the chapter asks: how did two different bureaucracies come to regulate the same substances? I begin with a short summary of the history of MDMA's legal status in the United States, and move on to discuss the rise of both the Food and Drug Administration and the Drug Enforcement Agency over the course of the twentieth century. In the second half of the chapter, I discuss how the dual interests of FDA and DEA shaped MAPS' efforts to initiate a clinical study using marijuana. This section highlights how both the FDA and DEA utilize forms of surveillance and monitoring over subjects and substances.

MAPS' president, Rick Doblin, is fond of saying that MAPS is promoting "science over politics," a framing which implies that it is the politically fueled, conservative "war on drugs" that has impeded research with psychedelics for the past several decades. However, two different regulatory agencies, both of which are products of a massive expansion in governance during the 20th century, have held sway over the fate of psychedelics. As an Investigational Product, MDMA is overseen by the FDA, which is housed with in the Department of Health and Human Services and is concerned with regulating the effects of medicines through the evaluation of empirical research—is a drug effective? Is it safe? As a Schedule I substance, it is overseen by the DEA, which is housed within the Department of Justice and is a branch of law enforcement primarily concerned with preventing crime by preventing the circulation of illicit drugs. In Doblin's narrative, only one of the two, the FDA, holds the possibility of using scientific reason to overturn political ideology.

This chapter traces the ways that the particular concerns of both the DEA and FDA have shaped the MDMA-trials. On the one hand, MAPS must utilize various tactics of surveillance to ensure against drug divergence—the term for drugs leaking out of controlled research settings and onto the black market. On the other hand, in order to meet the criteria for an objective pharmaceutical trial, the studies must be double-blinded. This chapter began by illustrating the juxtaposition between blinded-objectivity and surveillance in the studies, and will now shift to examining the historical logics shaping the control of narcotics, and the control of pharmaceuticals within twentieth century American governance.

Regulating MDMA: 1912 to Present

MDMA was first synthesized and then patented in 1912 by Merck pharmaceuticals. The pharmaceutical company was trying to find a chemical pathway leading to haemostatic substances, in order to evade a patent by a rival company (Freudenmann, Oxler, and Bernschneider-Reif 2006) Merck never administered the drug to humans. And while it had in fact been included in the US military's Edgewater experiments (MKUltra) during the 1950's, it was only administered to animals (Hardman, Haavik, and Seevers 1973)[15].

MDMA entered the psychedelic scene in California just after the 1970 Controlled Substances Act forced psychedelic therapy completely into the underground. In fact, there are no records of any human experimentation with the drug until the 1970's, when chemist Sasha Shulgin recorded his auto-experimentations with MDMA. In the 1970's MDMA sat in a regulatory loophole: it was neither classified as a narcotic nor approved as a pharmaceutical. The

[15] During the 1950's the US military carried out a series of secret experiments looking for a psychoactive substance that could be used as a "truth serum" during interrogations. MDMA was included in a study with lab animals at the University of Michigan that tested the effects of mescaline-related substances on the behavior of animals.

drug was out of patent, with no institutional history of medicinal use, and not yet classified by the DEA as a narcotic. And for the psychedelic therapists recently driven into the underground, alongside this promising legal ambiguity, it also offered a unique set of biochemical affects and effects, inviting feelings of empathy, trust, openness—all of which seemed ready made to be integrated into a psycho-therapeutic journey.

MDMA's days of semi-legality and chemical-promise came to an end in 1985 when the DEA put its emergency scheduling powers to use and classified the drug as a Schedule I substance. The scheduling was contested—the testimony of researchers, therapists and chemists filled ten volumes, and persuaded a DEA administrative court judge to recommend that MDMA be placed in Schedule III—a less restrictive category that would have allowed research on the therapeutic use of the drug to proceed. However, the DEA ignored its own judicial ruling and placed MDMA in Schedule I.

MDMA became caught in a bureaucratic catch-22: it was a Schedule I drug because it lacked a medical use. But it lacked a medical use because it had yet to be the subject of a controlled clinical trial. Being in Schedule I made it very, very difficult to establish a medical use through research since, well, the category itself assumes that the drug has already been studied.

Research takes place with Schedule I substances in laboratories throughout the United States. For all of the energy expended preventing the trafficking of drugs across borders, or tracking the sales of precursors for methamphetamine on the shelves of pharmacies, Schedule I drugs can be synthesized by pharmaceutical companies and are allowed to circulate in laboratories[16]. Of course, most of this research investigates issues like toxicology and damage to neurotransmitters or simulating mental illness. The idea of research that would directly contradict the very scheduling status of the drug is another matter entirely.

When I started my research in 2010, MAPS had just hosted the largest scientific conference on psychedelics to date, *Psychedelic Science in the 21st Century*, which gathered researchers from around the world. The conference sold out and garnered positive media from major outlets, including a spot on KQED—the San Francsico Bay Area's largest National Pubic Radio station—and Wired.com (Krasny 2010; Madrigal 2010). The first MDMA study treating PTSD had been closed out, a second study in Switzerland was nearing completion—both had safely treated all patients. Most promising of all, the FDA had swiftly approved a second US study: this time treating Veterans with PTSD. Long time skeptics were starting to feel cautiously optimistic that MDMA just might become a legal prescription pharmaceutical… one day. There was the palpable sense that a new, less repressive moment in the regulations of drugs was on the horizon.

But the years between the scheduling of MDMA in 1985 and the cautious optimism of 2010 had been difficult. It took fifteen years from the founding of MAPS in 1986 before the FDA would approve the first clinical trial with MDMA. And it would take another three years from the point of approval before the first subjects would be enrolled. During the early years, MAPS president Rick Doblin enrolled in the Kennedy School of Government's doctoral program, where he undertook a project specifically related to legalizing psychedelics in conjunction with clinical research. In 2000, he filed his dissertation entitled "The Regulation of the Medical Use of Psychedelics and Marijuana," which outlines a plan for undertaking clinical research with psychedelics and marijuana and for regulating their legal use as a policy exercise

[16] Particular Schedule I drugs are also allowed to legally circulate in religious ceremonies as sacraments. For further discussion of the use of psychedelics as sacraments see Chapter 5.

(Doblin 2000). The dissertation is dedicated to the "late Dr. John Harter whose vision resulted in the creation of the Food and Drug Administration's Pilot Drug Evaluation Staff, a short-lived but remarkable laboratory for bureaucratic innovation. Its legacy includes the renewal of FDA-approved psychedelic research and an enduring institutional framework emphasizing science over ideology." In his dissertation, Doblin argued against a higher standard of proof for approving psychedelics, and made an argument against using inert placebo controls when effective treatments already in existence can be used as a control. In outlining the regulatory plan for psychedelic therapy, he looked at the parallel cases of thalidomide, methadone and electroshock convulsive therapy. "The primary features of this proposal are the limitation of prescribing power to board-certified psychiatrists, the requirement that all prescribers participate in a specialized training and educational program, the licensing of facilities within which psychedelic psychotherapy can take place, mail-order distribution from a single source, and a national patient registry to record all treatment sessions." In short, Doblin outlined a plan for a highly regulated system in which the drug, therapists and administration are all heavily monitored.

I return to Doblin's plan for the legal regulation of psychedelic therapy in Chapter 5. However, the relevant point for this chapter, is that the horizon of possibility for the MDMA clinical trials is not less control by the federal government, but in fact would be an increased level of oversight and control.

Regulating Drugs: The development of the FDA and DEA during the Twentieth Century

Most scholarly work on the historical development of the two agencies examines them as mutually exclusive institutions. The irony is that while the two different agencies have radically different mandates, they are often concerned with regulating the same substances. In the next section, I follow how both the FDA and DEA emerged out of Progressive era reforms and, in different ways, were each formed to address the entangled problems of opium addiction and patent medicines.

Opiate Addiction and Progressive Era Reforms in the United States: 1895-1945

The regulation of drugs, as both medicine and as illicit substances emerged as a distinctly 20th century technique of governance. At the end of the 19th century in the United States, opiates circulated freely in unregulated medicinal and recreational markets. While the recreational market was primarily Chinese and lower class whites, there was also a large population of upper-middle class, white women who became addicted to opiates through their doctors. Iatrogenic addiction rose throughout the 19th century peaking in 1890 (Courtwright 1982). Between 1895 and 1910, physicians were able to slow down the rate iatrogenic morphine addiction. David Courtwright links this decline to both a wave of new drugs available to physicians which replaced morphine, as well as increasing conservatism among physicians over morphine prescription, and new legislation at the local level restricting the sale of narcotics.

Historian Harry Marks has tracked the Progressive era reform efforts of what he calls the "therapeutic reformers"—a political community that crossed professional boundaries with the common goal of uniting medical researchers and practitioners through science (Marks 2000). During the first half of the twentieth century, the therapeutic reformers focused their efforts on two fronts. The first was developing oversight for the sale of medication, including patent medicines. This meant not only doing laboratory testing on the contents of medicines, but also scientific evaluation of their claims. Their efforts brought about changes both through private

and federal channels. In addition to trying to reform the prescription patterns of physicians, these reformers worked to pass the Pure Food and Drug Act of 1906, which required patent medicines to state their ingredients on the label. They also were integral to the American Medical Association's founding of the Council on Pharmacy and Chemistry, which conducted early quality control tests on patent medicines and evaluated their therapeutic claims.

Even as the drugs themselves became subject to new standards for transparency and testing, therapeutic reformers still needed to reform the very process of drug approval and to convert physicians from artisans to scientists. Dovetailing with the first goal, therapeutic reformers wanted to direct physicians towards using scientific evidence to govern their clinical practice. The goal of the therapeutic reformers was to train physicians to base their prescriptions on objective scientific evidence rather than their own intuition or experience.

As iatrogenic addiction declined, a new addict became increasingly visible: the working class man who used heroin in the dance halls and pool halls of urban areas (Acker 2005; Courtwright 1982). Criminalization of non-medical use of opiates was one of the reforms enacted during the Progressive Era, "thus the American Junkie arose in an urban vice culture more harshly repressed than it had been just a generation earlier." (Acker, 2005) The 1909 Smoking Opium Exclusion Act and the 1914 Harrison Act, which required pharmacists and physicians to register with the Department of the Treasure and to keep records of their prescriptions, reflected rather than produced a shift in the figure of the opiate addict in the United States. In contrast to historical narratives that argue that as the anti-maintenance Harrison Act took effect and the legal supply of opiates dried up, addicts were forced into a criminal underworld; Courtwright argues that the decline in iatrogenic addiction led to emergence of a new working class addict, whom was being specifically targeted by these reforms.

Two key dynamics in the governance of medicine and drugs were developing during the first half of the twentieth century. First, non-medicinal or recreational drug use was framed as a supply problem (Acker, 2005), meaning that the government's response was to try and eliminate the supply of opiates from the general population, with the exception of medical use. Secondly, as the category of illicit narcotics emerged, and was criminalized at the federal level, drugs-as-medicines became increasingly subject to federal oversight. The therapeutic reformers advocated for government oversight of pharmaceutical products in order to protect consumers from the predatory practices of business. In short, two different government mandates came to characterize the regulation of medicines and drugs. One, the government's job was to reduce supply of illicit narcotics because drugs have been equated with crime. Two, government must act as a control on the predatory forces of the market.

The War on Drugs and the Advent of the Randomized Controlled Trial: 1960-1990

The discussions of drug policy that I encountered during my fieldwork rarely referenced the early twentieth century—if ever. The 1960's and the ensuing repressive crackdown on psychedelics were the major historical touchstone. By the mid twentieth century the basic infrastructure for the regulation of medicines and drugs were givens. However, during the second half of the twentieth century, the mandates of the US government to protect consumers from commerce and to regulate drug-use-as-criminal-activity were radically expanded.

President Richard Nixon coined the term "war on drugs" in a congressional address in 1971. It was both a culmination of a cultural shift around drug use, and the mark of a new moment in government regulation. Nixon's speech ushered in a radical expansion of the federal intervention into recreational drug use—which had previously been under the jurisdiction of

local and state government. During the 1960's and 1970's, drug use was used by politicians to explain a rise in crime in the 1960s—an argument that built upon associations between drugs and crime from the early part of the 20th century (David Musto and Korsmeyer 2002).

The War on Drugs was initiated by President Nixon to deflect attention from the failure of his "peace with honor" program in Vietnam. The policy built upon Nixon's disdain for the recreational use of drugs by American youth. The myth of the addicted army—an exaggeration of the abuse of marijuana and heroin by servicemen in Vietnam that can be traced back to media reports by John Steinbeck IV—deflected blame for the failure of US military interventions, and provided the rationale for continued international military interventions (Kuzmarov 2009).

President Lyndon B. Johnson originally developed Nixon's drug war program (David Musto and Korsmeyer 2002). It was based around three different policy initiatives. One, the US government would use diplomatic means to reduce foreign production of drugs—a supply side intervention. Two, rationalize drug policy through bureaucratic reorganization. This led to the consolidation of federal drug enforcement of drug policy through the creation of the DEA. Three, develop domestic policy that focuses on drugs as both criminal and public health problem. Under Nixon it was possible for addicts to receive special permission for maintenance narcotics. The rhetoric of the drug war was scaled back under the Ford and Carter Administration. In fact, for a brief period it seemed as if marijuana would be legalized in the late 1970's. Then the Reagan Administration took office, revitalizing the war on drugs. Starting in the 1980's there was an exponential increase in incarceration for drug offenses, stemming from "zero tolerance" minimum sentencing policies.

In parallel to the expansion of governance of illicit narcotics, during the second half of the twentieth century, the pharmaceutical industry expanded in new ways, developing treatments for depression (Healy 1997), chronic disease(Greene 2007), and contraception (Watkins 1998). Even as prescription medication played an increasing role in everyday life, there were also anxieties about the increasing use of pharmaceuticals. By the late 1970's, Valium was the single most prescribed drug in the United States—with women using at twice the rate of men. Highly publicized cases of addiction, led to a Valium panic and prescriptions of the drug declined—only to be taken over by Prozac and Xanax in the 1980's. The Valium panic was unusual in that the population of users was primarily middle-class and white, and in fact became a key feminist issue (Herzberg 2006).

The MDMA-trials are historically significant for several reasons. In addition to contesting the scheduling status of the drug, they are also designing double-blinded, placebo controlled trials with drugs that were once thought to resist the form of the RCT. Psychedelic research was shut down in the 1960's and 70's for scientific reasons as well as the eruption of the counter culture (Oram 2012). The institutionalization of the RCT—discussed in Chapter 1—by the FDA made research with psychedelics difficult since they didn't easily fit into the double-blinded model. How could investigators claim scientific objectivity when the robust effects of psychedelics meant that one could not hope to "hide" the drug or blind the researcher?

Controlled studies of clinical treatments date back to at least the 1740's when James Lind conducted a controlled study of the use of lemons to prevent scurvy. Lind took twelve men each with scurvy and assigned them to six different treatment conditions: "a quart of cider daily; to another two, elixir of vitriol; to another two, vinegar; to another two, half a pint of salt water; to another two, a concoction of garlic, mustard, radish and balsam; to another two, two oranges and a lemon daily. In six days the latter reported fit for duty. Most of the rest died." (Lloyd 1963) However, the idea that both the investigator and patient needed to be blinded to the treatment

condition is a much more recent invention. The randomized clinical trial was introduced to pharmaceutical research following World War II, and was part of what Marks argues is a general shift in scientific authority from institutions to methods. The RCT was intended to "provide a more reliable, less biased assessment of therapeutic value, and thereby moderate practitioners' uncritical use of novel therapies."(Marks 2000). In a RCT, subjects are randomly assigned to at least two different treatment conditions: those receiving the "active" treatment, and those receiving "control" or "placebo" treatment. Prior to WWII, clinicians might assign a patient to a particular treatment group, either the control/placebo or the active treatment. However, it was suspected that a physician's excitement over a new treatment might cause them to unconsciously bias the selection of subjects in favor of the treatment. The use of the RCT as the gold standard for pharmaceutical research was institutionalized in the 1960's when the FDA began requiring evidence of safety and efficacy from a "well controlled trial" for drug approval. Blinding the doctor administering a treatment was the subject of some controversy when it was first proposed in the 1950's. Earlier versions of the clinical trial had allowed for the doctor to select patients for a control group until it was decided that the physicians might unconsciously bias the selection. However, some doctors felt that binding was unethical as it was of the utmost importance for a doctor to know exactly what treatment a patient was receiving. I will return to these issues in Chapter 5, when I discuss the inherent conflict between the therapist as researcher and clinician.

Preventing Drug Divergence

The MDMA-trials are testing a regulatory boundary between medicine and narcotic that is precariously thin. A doctor can prescribe methamphetamine (Brand name Desoxyn), thus circumventing efforts by the Department of Justice to combat the use of a drug, which has become the blight of rural America over the past decade (Garriott 2011). Anthropologists have been attentive to the entanglement of addiction and pharmaceuticals—charting both the fluidity of the boundary between drugs of abuse and medicinal substances, as well as the way the development of pharmaceutical treatments for addiction.

The rise in the concern with the non-prescription use of pharmaceuticals in the United States has created new entanglements between the Drug Enforcement Agency and medical institutions[17](Paulozzi et al. 2012). The DEA has taken steps to increase the monitoring of the disposal of prescription medications. In 2010 the DEA's organized the first National Prescription Drug Take-Back event. "At that time the Controlled Substances Act made no legal provision for patients to rid themselves of unwanted controlled substance prescription drugs except to give them to law enforcement… The week after DEA's first Take Back Day, the Secure and Responsible Drug Disposal Act of 2010 was enacted. The Act authorized DEA to develop and implement regulations that outline methods the public and long-term care facilities can use to transfer pharmaceutical controlled substances and other prescription drugs to authorized collectors for the purpose of disposal." ("Headquarters News Releases, 09/23/14" 2014) The FDA may have jurisdiction over that drug when it is being manufactured and studied, but once its medical use expires, it becomes the concern of the DEA.

[17] The DEA is currently entangled in a battle with the American Civil Liberties Union and the State of Oregon over the right of the DEA to access the state's Prescription Drug Monitoring Database. The ACLU and state of Oregon maintain that this would violate the protection of private health information.

Despite the fact that the same substances are at stake, very different regulatory agencies have jurisdiction over them depending upon the circumstances. For the most part, the momentum has been for pharmaceuticals to shift from a medicinal-therapeutic context towards the black market. Abuse of prescription pain killers is a recent example, but others can easily be found dating back to cocaine, touted by Sigmund Freud as a treatment for opiate addiction (DF Musto 1987) The MDMA studies are the first to try and reverse that momentum at the federal level—and move a drug from the realm of the illicit-narcotic to the therapeutic.

The Office of Drug Diversion is a department within the Drug Enforcement Agency which is charged with the mission "to prevent, detect, and investigate the diversion of controlled pharmaceuticals and listed chemicals from legitimate sources while ensuring an adequate and uninterrupted supply for legitimate medical, commercial, and scientific needs." ("DEA Office of Diversion Control - About Us" 2015) Since the supply of narcotics is equated with crime, ensuring that MDMA does not leave the study site except through the metabolizing body of the subject has been a critical site of negotiation between MAPS and the various regulatory agencies overseeing the studies. MAPS has been asked to take a number of precautions to ensure that the drug is not "diverted" away from the study and into criminal hands. MAPS has been required to implement a number of safety procedures to ensure against the possibility that this controlled substance might escape, and somehow leak out into the black market. MDMA was kept in a bank vault for the study in Switzerland. The MDMA used in the Canadian PTSD study is secured in a hidden safe behind bullet proof glass in a pharmacy, and regulators asked if the investigator would be kind enough to take a different route each time she travels to pick up an envelope for an experimental session—ostensibly to prevent a possible heist by a thief who would have been tracking her movements in the hopes of stealing an envelope that has a one in three chance of being a placebo. Bulletproof glass, alarms, hidden safes are an intense amount of security for what, by street value, is a relatively small quantity of MDMA. With under twenty five subjects being enrolled in each of these studies, and only two thirds of them receiving the full dose of MDMA on only three occasions, there are somewhere around fifty doses of the MDMA at stake. However, bureaucratic logics often operate with their own internal logics of proportion.

This focus on the drugs themselves is one of the characteristics of what William Garriott has termed *narcopolitics*. From the point of DEA, this MDMA is more than an illicit commodity. Illicit drugs equal *the risk* of crime. The possession and use of an illicit drug is more than just a criminal act in and of itself: it is a predictor of future criminal acts as well (Garriott 2011). Narcopolitics refers to what Garriott calls the rationalization of the practice of governance via the concern with narcotics, and, he argues, has come to be one of the defining features of American statecraft in the 20th century. Narcopolitics is characterized in part by "The targeting of substances and their effects, rather than people and their actions, to structure the field of intervention." This field of intervention is much more broad than just the criminal justice system, but includes the forms of drug treatment and education to constitute what he terms a "illicit drug regulatory apparatus." Garriott's term calls attention to both the logic of governance through control over the circulation of drugs as well as the implicit equation between drugs and crime. As he argues, narcotics have come to structure set of interventions by the state, which seek to track and make visible the presence of narcotics within the social body. These interventions are drugs come to be a consolidation of both the criminal act itself and the threat of

future criminality[18]. It is against this backdrop that the hyper concern—safes, alarms, bulletproof glass—over the handling of MDMA in the clinical trials needs to be considered. Allowing the MDMA or any other Schedule I substance to leave the tightly controlled circuit of the clinical trial in any way but by consumption is equivalent to allowing a crime to happen.

MAPS decades long battle to buy marijuana for research and initiate a study illustrates some of Garriott's points. While the MDMA-PTSD studies have been the corner stone of MAPS' clinical trial program, MAPS has been engaged in a lawsuit with the DEA over setting up a facility to grow marijuana for research purposes. DEA licenses for synthesizing and handling Schedule I substances are routinely given out, which means that MAPS can obtain MDMA from multiple sources. However, marijuana is regulated differently. The only DEA licensed marijuana grow facility is run by the National Institute for Drug Abuse (NIDA) and medical grade marijuana is not yet available for import (Though MAPS has been hoping that facilities will be developed in either Canada or Israel).

Currently, the National Institute for Drug Abuse oversees the only licensed grow facility for marijuana in the United States, and as such they maintain it's right to review protocols requiring marijuana. Thus, when the FDA approved MAPS' study of marijuana for PTSD symptoms, NIDA also had to review the protocol. MAPS fought with NIDA over whether or not they had the right to review the scientific merit of the study, given that the FDA had already approved it. MAPS has been involved in a lawsuit that claims that the Federal government has an illegal monopoly on the supply of marijuana for research purposes. MAPS has maintained in the past that the NIDA facility is not equipped to grow the variety or potency of strains that they would like to study.

The proposed marijuana study[19] was designed around subjects self-administering marijuana to manage the symptoms of PTSD. Because the MDMA in the PTSD studies is directly administered by the therapist, drug diversion efforts focused solely on the storage and handling of the drug. However, the proposed marijuana study would have let the drug out into the world. The original study design called for enrolling approximately fifty subjects who would each self administer up to two joints every day—either by smoking or vaporizing. A variety of different strains of marijuana would be used, each with a different percentage of THC or CBD—two of the cannabinoids thought to have psychotherapeutic properties. The study was designed to examine the effectiveness of different strains of marijuana in managing the symptoms of PTSD. Thus, subjects needed to have independent access to the drug at all times. This meant entrusting a quantity of marijuana in their hands—a situation that was bound to produce concerns over drug diversion. Even trickier, the study protocol allowed for subjects to keep any leftover marijuana at the end of the study. The research rationale was that it would counter any inclination a subject might have to horde or hide marijuana. The idea was to create an incentive to only use the necessary amount of marijuana during the study. After having submitted the protocol to the FDA—the study and the drug handling procedures would ultimately need to be

[18] The rampant racial disparity in drug arrests and prosecutions indicates that drugs are only objects of intervention when they are in particular, racialized hands. In that the black male body is always already criminal, drug laws have been used to legitimize a whole set of searches and arrests.

[19] In 2014, NIDA approved MAPS application to purchase marijuana for the FDA approved study. However, the Principle Investigator, Sue Sisley, was subsequently let go from all three of her faculty appointments at the University of Arizona, where the study would have taken place. MAPS is currently seeking funding for a marijuana study in Colorado.

approved by the NIH, the DEA, and the private IRB board as well—MAPS was awaiting a possible call from the FDA to discuss concerns over the protocol. In preparation for the meeting, MAPS researchers convened on a conference call to discuss strategies for responding to concerns for the FDA.

"What is our greatest vulnerability?"

"They will probably want an inpatient study. There is no recent precedent that we can site. All the California State funded studies were all inpatient."

"The DEA will say that it is a major national security problem if people are sharing marijuana."

"I think that our protocol counters that concern because we are only giving a two week supply and we allow them to give it back at the end if they like."

"We could get slammed by the DEA with concerns over drug diversion. And the FDA may have concerns with this patient population [veterans with PTSD] *who is prone to violence and possibility suicide, or domestic violence."*

"So how do we respond if they ask for an inpatient study?"

"Inpatient would require people be in the hospital for three months, which isn't possible. And it wouldn't allow us to assess what we are trying to assess [daily life]*".*

"Okay, so how do address their anxiety? How are we monitoring the situation? With these subjects?"

The clinical team mapped out a set of responses that included introductory sessions with a therapist, establishing a 24-hour hotline, weekly assessment of risk of suicide, daily contact with therapist during the first week of study to monitor for any signs of mental distress, screening out people with suicide risk and substance abuse, and screening out people who have used marijuana in last month. This list combines both giving increased attention to subjects, and carefully crafting a low-risk treatment population. Monitoring subjects has become a constant in psychopharmacological research after studies indicated that people taking SSRI's have a higher risk of suicide.

"All those are great, but we shouldn't offer to add unless they ask!"

"With anti-depressants trials, they have a crisis line managed by the research coordinators. But the population is at high risk, which is of course why they are in the study. This is why the FDA allows that the study to move forward. There are black box warnings on the bottle. And we will argue for parallel with antidepressants."

"Should we offer this no matter what?"

"Crisis line" is more structured that "call doctor." All we have to do is change the phone number on the protocol for study emergency. And we should have an answering service or call diversion to IMPACT, which is a service in Arizona. Could we send them to the VA? The ER would be required to manage them if they are suicidal. So their benefits would be covered."

"Always review a crisis plan with patients because SSRI's have a black box warning."

"When they used to call me they had more administrative or research questions."

"There have been changes recently in VA policy. They won't exclude people using medical marijuana. Thus the VA agrees that the amount of risk is not that high.[20]*"*

[20] In 2010, the Veteran's Administration issued a directive allowing patients serviced through its hospitals and clinics to use marijuana in states where it is legal.

"How do we verify the upper limit of use? How do we keep them from using over 2 joints? What is to stop them from smoking part of a joint that they hadn't finished on another day?"

"Well, each day's supply is given in a single pack."

"We could shorten the length of time for distribution. Or give bottles that record the time of opening and closing. We wouldn't be able to stop them. We would just monitor and track."

"What do we do about people who receive the placebo? They may not want to keep using."

"That is okay. If they don't smoke it because they don't get any benefits that will tell us something."

"In telemedicine they use "MedSmart" which is a computerized medication dispensing system. Every time the bottle is opened or closed, it all gets sent to electronic records. And you just load it once a week. It is designed for pills, but we could talk with company to see if we would find something that would work. The only problem might be, I don't know if it would work if you are putting something back in [the unused joint]."

"What about having them pick it up everyday? We could model it on methadone distribution. We would need to only recruit locally in Phoenix, like only in the county. Could know what hospital we could send them to…"

"But then we have the problem of them transporting themselves after possibly having smoked marijuana."

" In other studies, patients are given bus passes. Or could we drive to them? Or could we Fed Ex it? The delivery service could pick up and drop off each day."

"Yes, but we would need someone with DEA license to do the delivery."

"That could get expensive."

"Yes, but since we don't really care about cost, then it is okay to tell the FDA we will do it[21]."

"Will they take issue with subjects taking home marijuana at the end of study?"

"If so we eliminate it."

"If it works for some people, then they can get medical marijuana in Arizona now. Though PTSD is not yet a qualifying diagnosis. We would need to petition stage legislature to add a seventh diagnosis. New Mexico has added it. And Colorado is possible petitioning to add it."

"Could we say that we will make sure that they are transitioned into a regimented program with the VA Hospital. Then they could get psych meds to contain symptoms."

"Or we could do an extended open label for people who benefit.[22]"

"Could we get a bill in now to add PTSD? Even if it gets voted down this year, then it would have more support in a year."

The meeting trailed off into a discussion about the feasibility that NIDA would be able to produce adequately strong strains of marijuana. The general assumption is that marijuana grown

[21] Since MAPS' president, Doblin, felt certain that NIDA would block the study, he was not concerned about the potential costs entailed in the protocol. Moreover, Doblin was confident that if the study were miraculously approved, he would be able to find donors to cover the costs.

[22] Open label refers to a period in a clinical trial in which no placebo is used and the subject receives the investigational product.

by the US government is relatively weak compared what is being grown in the medical marijuana industry.

"Even if NIDA says they can give us the marijuana, then the DEA could still have problems with it around diversion control. However, the DEA can't have any problems with the protocol itself."

"At least the FDA, even if they say no, will have to give reasons, and will have to allow us to dialog and respond."

"Since they haven't called then they should be getting something in writing to us soon. Rick will follow up with them."

I have included these notes at length—which move back and forth from the dialog of the meeting to my own jottings—because of the depth and nuance of the discussion of how to manage not only the risk of drug diversion, but also the risk of the patient population as well. It is at moments like these that the concerns of the DEA and FDA do not seem so far apart. Of note is the attention that the group gives to the possibility of violence and suicide. The risk of the drug is not absolute, but takes shape in relation to a very particular patient population. Moreover, the state takes on multiple forms each in the discussion, each of which requires a different form of response.

In the final solution to the drug diversion problem, several different forms of subject surveillance were instituted. First of all, each subject would have to name a person living with him or her who would monitor his or her use of marijuana. Secondly, it was decided that subjects would be issued a phone with video camera capabilities, which they would be required to use to video record themselves smoking or vaporizing the marijuana. Videos would then be reviewed on a weekly basis to ensure compliance. Lastly, researchers drew up a set of procedures to ensure the well being of the subjects.

Conclusion

According to MAPS' drug handling procedures, Michael must supervise the encapsulation of the MDMA at the beginning of the study because as the Schedule I license holder, it is his responsibility to ensure proper handling of the MDMA. However, as he is also the investigator in a double blind placebo controlled trial, he must watch the encapsulation without actually seeing. Thus, a masterful drug handling procedure was written up, in which Michael's presense and sight are carefully balanced so that he can see, but not too much. At critical moments the labels of envelopes are hidden from his line of sight so that he can see that the MDMA is properly handled without knowing where it is going. The word proper here does not refer to pharmaceutical technique. It is the pharmacist and not Michael-the-psychiatrist who is the expert in the weighing out the varying proportions of lactose and MDMA and then properly encapsulating them. Rather, proper handling refers to ensuring against drug diversion. This seems to me to be a wonderful illustration of the balance in these studies between policing drugs and producing scientific objectivity.

Michel Foucault's discussion of Jeremy Bentham's plan for the Panopticon in *Discipline and Punish* has spurred numerous discussions of the relationship between surveillance, power and subjection (Foucault 1977). Critical to the discussion is the status of sight and visibility. In fact, it is the dis-equilibrium in visibility that constitutes the clever trick of power. Knowing that he is always potentially being watched, and yet unable to verify the presence of an inspector in the tower, the prisoner internalizes the gaze and becomes his own guard. In Foucault's formulation, the productive work of the gaze is the subjection that it produces in the prisoners themselves.

However, I would like to conclude this chapter by raising a point made in a lesser cited discussion by Foucault—wherein he points out that the Panopticon was not only a technique of discipline and surveillance, it was also tightly aligned with experimental knowledge and the development of the human and social sciences. Watching without being seen is of course fundamental to the two-way mirrors used in both police interrogation rooms and experimental research. What should we make of the fact that contemporary research practices make use of forms of surveillance?

Chapter 3: Chemical Consciousness

Introduction

The interview had long since passed when I sat down to transcribe it.

I had a faded memory of a small studio, Oscar arriving late with plastic bags from the market, and piles of books stacked in the corners.

An underground psychedelic therapist is sometimes called a guide, a term which specifically draws upon the metaphorical language of a journey or trip to refer a psychedelic experience. What Oscar does is sit with people (in a very literal sense), clients, through non-ordinary, or to use his term, extra-ordinary states of consciousness induced by psychedelic substances. Ecstasy, LSD, psilocybin mushrooms are the most common. Clients are often referred to Oscar by psychotherapists, who see a therapeutic benefit in psychedelics but are unwilling to take the risk of administering themselves. The sessions are not cheap. A single session with Oscar costs $500.

The intertwining of psychedelics and psychotherapy dates back to the 1950's when LSD, then a novel pharmaceutical, was distributed by Sandoz pharmaceuticals to researchers throughout North America and Europe. By 1966 over two thousand articles had been published on psychedelics in medical journals. Researchers studied LSD and psilocybin, also a Sandoz product, as treatments for a range of psychiatric disorders, most notably, alcoholism and schizophrenia. Two forms of psychedelic therapy emerged during this period. Humphry Osmond and Abram Hoffer in Saskatchewan, Canada, developed psychedelic therapy, which involved a single large dose of LSD in conjunction with psychotherapy. Psycholytic therapy, which was developed in the United Kingdom by Ronald Sandison, used small does of LSD in conjunction with psychoanalysis (Sandison 1954). The large dose technique of psychedelic therapy was supposed to induce a new perspective on one's life, while the smaller doses of psycholytic therapy were supposed to induce a dream like experience during which material from the unconscious could surface. These emergent techniques seemed to bridge the gap between the rising interest in pharmaceuticals and psychodynamic psychology (Dyck 2010). All of this research, however, came to a halt in the 1960s due to changes in federal regulations (discussed in Chapters 1 and 2). When LSD and other psychedelics were criminalized in the 1960's, psychedelic therapy moved to the underground, where therapists continued the practice illegally and with great secrecy.

Oscar is one of these people.

The transcription program I am using lets the audio play forward then pauses, rewinds and begins to play back again. The play of repetition and pauses allows my gangly typing fingers to catch up to the flow of sounds. I have returned to my interview with Oscar, as part of attempt to think about the therapy itself—and not just the modes of surveillance or documentation that characterize clinical trials. But transcription is grunt work—slow and tedious. Interviews like this were intended to round out the time I was spending editing protocols and reviewing informed consents by taking me closer to the therapy itself. While I was logging hundreds of hours tracking how one studied the effects of MDMA-assisted therapy, I felt very absent from the therapy itself. But I can't help wondering how much closer narratives of the therapy will get me. This chapter departs from the previous ones, in that it moves away from how knowledge of the chemical comes to happen, and begins to think through upon how chemical doing is framed by psychedelic therapists and researchers.

Returning to the interview months later, as fieldwork was completing, I felt very far away from the world that Oscar inhabited.

I hear my voice on the recording: *So that is I guess that is the larger question. I mean, how is it," I hear myself hesitating in search of the right words, "how is it that non ordinary states of consciousness help people?*

Right there you have either a tragically blunt or brilliantly concise question. In an empiricist, positivist style it cuts straight to my desire to elicit from Oscar his narrative for how psychedelic therapy works.

Oscar begins his reply: *Aldous Huxley talked about the mind as a reducing valve. That in ordinary consciousness, in order to use our opposable thumb, to be able to* [I remember, vaguely, him waving his hand in the air in gesture of writing]*, right? We have to be able to eliminate a lot of what is our potential to understand. And this gives it back to us for a temporary period under some guidance.... You can travel to this place. I say that, but it is really within oneself. And understand that there is another order of existence to that with which one is familiar. And even actually the phrase non-ordinary state of consciousness... what does it mean?.... I personally think that the word extra ordinary is more descriptive really of that. Because it is extra to what we can understand. And I think why does it heal? I think because we just do get a bigger idea of ourselves. We understand who we are. We understand our being-ness. We potentially understand how we got to be who we are. With all of our fears and foibles. We can understand that the characters in our biography, family, friends upbringing everything that led us to that. We can understand the larger culture that has contributed to that. We can understand our place in historical time. You know... Born on the Fourth of July or born in 1945 at the end of the war. Whatever it is. And we are just getting more information about ourselves than we can in ordinary consciousness.*

Huxley's mind-as-a-reducing valve that Oscar refers to was influenced by the writings of Henri Bergson, William James and Charlie Dunbar Broad. (Langlitz 2013) However, contemporary neuroscience, as Langlitz points out, has challenged the idea of the brain as simply a filter, and has instead demonstrated the ways that the brain constructs perception.

But outside of that, what strikes me, as I type out Oscar's words, hearing his voice ebb and flow on the recording, is the paradox between the language (familiar to me after a year of spending time with a psychedelic non-profit) of a psychedelic journey and, as Oscar says, the fact that one is traveling to a location within the self. Yes, Oscar's explanation here invokes the familiar psychoanalytic language of a breakthrough—a deep and challenging personal insight that transforms the self. But alongside that is this spatial metaphor or travel. Oscar draws upon a well-trodden metaphor of mind expansion and journeying that has been used since the 60's to describe the psychedelic experience. This narrative of the psychedelic experience explodes boundaries of self, history, time, even as it happens within them. One can move past what ordinary consciousness presents to the individual. And it is exactly this located-ness, or as I will argue in this chapter, bounded-ness that is central to the way that both Oscar and MAPS conceptualize the healing power of psychedelics.

In this chapter, I am not so much interested in the ontological status of the brain or experience or the self. Rather, I am interested in the practices through which forms of interiority, expansion, and journeys take place. However, this chapter will move past these metaphors of tripping and journeying to describe the techniques used by therapists like Oscar; the narratives of self-expansion, I argue, paradoxically require the creation of boundaries.

The Neurobiology of MDMA-assisted Therapy

Guides like Oscar are quite secretive. After interviewing Oscar, I was only able to interview four more people working in the underground world of psychedelic therapy. A very kind interlocutor, who was herself documenting the stories of guides in the underground, warned me that unless someone could vouch for having known me for twenty years, then there were very few people who would be willing to talk with me about their work with psychedelics.

Oscar agreed to trust me only because of my involvement with MAPS, which has a complicated relationship to the underground. In various ways, MAPS' therapy is inflected by practices that have been developed in the underground[23]. However, MAPS has also been careful to chronicle the legal pathways through which they have developed their version of psychedelic therapy. While it would be irresponsible to project MAPS' version onto psychedelic therapy as a whole, as I delve into this interview, I find resonances between Oscar's narratives and the various articulations of MAPS' therapy from my fieldwork—the therapy manual, the protocols for the studies and numerous presentations that MAPS' therapists have given on MDMA-assisted therapy. The protocols, therapy manual, and presentations iterate the same language: MDMA-facilitates the therapeutic alliance between the therapist and patient. MDMA decreases the fear response and allows the subject with PTSD to enter into an optimal arousal zone. As discussed in Chapter 1, it is not necessary for FDA approval to demonstrate the mechanism of action. In order to approve a pharmaceutical treatment the FDA cares about two questions: is it safe and does it work. Of course, there are more nuances to the balance of safety and efficacy than that: safety, risk and efficacy are variously constructed in relation to particular populations, diseases and other available treatments (S. Jain 2010; Petryna 2009). But the point remains: how a drug works is not important for approval.

Over a year before I interviewed Oscar, I sat in the MAPS offices in Santa Cruz as Berra, the lead clinical research associate, explained the different theories about how MDMA works in the brain. In many ways, we were working on the same question: how do psychedelics heal? (Though our questions may have seemed similar, the kinds of answers or at least the terms through which one could evaluate answers were radically different.) Berra had just completed her PhD in Molecular, Cell and Developmental Biology at UC Santa Cruz, prior to which she had worked for several years in clinical research for a pharmaceutical company. Berra drew me a flow chart—much like one she would draw me a couple months down the road illustrating how the data moves, from source documents, to case report forms, to excel spreadsheets and back again. But this chart is showing the movement of neurons and receptors in the brain. Berra had just submitted a translational funding proposal to the National Institute of Mental Health for a project investigating the biological mechanism underlying MDMA-assisted therapy for PTSD. The proposal, which went unfunded, would have analyzed blood and urine samples taken before and after treatment for levels of the neurotransmitter oxytocin[24]. "Oxytocin," Berra explained to me, "is the hormone that is released in mother right after birth." It is also known as the "empathy hormone." The theory is that MDMA leads to the release of oxytocin, which in turn lowers the fear response in patients and facilitates their sense of trust and bonding with the therapist.

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[23] For example, the doses of MDMA used in MAPS-sponsored studies are based upon what is commonly used in the underground.

[24] MAPS has yet to complete biomarker research on MDMA and PTSD.

I ask Berra whether seeing a rise in oxytocin could be attributed to the MDMA. What if the oxytocin was released because of bonding with the therapist while on MDMA? How do you separate out what is happening in the interaction because of the chemical in the body, and what is happening in the body because of the interaction. Berra has, of course, already thought of this. Isolating the chemical's effects is really the research question at stake. This translational study would also involve a comparative study with mice, which have been traumatized. Most mice after receiving repeated shocks will become desensitized. But there is one genetic strain that demonstrates some of the behaviors associated with PTSD. They become "hyper-alert" and demonstrate fearful behaviors. These mice would then be given MDMA and have their oxytocin levels monitored. "The important part of the study is to correlate behavior with neurological effects, which we can do more easily with mice than humans."

In going through the details of Berra's research project, she tells me that one of the reasons for doing the research with the mice is that they don't know if the overstimulation of amygdala is cause or effect of PTSD. They know correlation, but not cause and effect. More importantly, part of the research design is to simultaneously test another model to see if that could also explain the effects of MDMA-assisted therapy. This theory is that lowered levels of norepinephrine, a neurotransmitter, could be responsible for the therapeutic effects. Its release is caused by an increase in adrenaline. If there is an "over active stress response" in the amygdale, then reversing the release of norepinephrine could reverse it. And if MDMA somehow helps to lower these levels, and enter an "optimal arousal zone" then that could explain the therapeutic effect of the drug.

While neurobiological models are often framed by social scientists as antithetical to deeply humanistic understandings of the self, in this case they seem to work in tandem. Throughout my fieldwork, I was struck not only by MAPS' ability to move nimbly back and forth between this neurobiological model of MDMA-assisted therapy and an experiential one that draws upon Oscar's language of expansion and journey, but also by the ways that the neurobiological and the mystical reinforce each other.

The fourth edition of the Diagnostic and Statistical Manual of Mental Disorders[25] describes three different symptom clusters for PTSD: re-experiencing, avoidance and arousal (American Psychiatric Association 2000). PTSD is described as pathology of memory, in which that which should be metabolized becomes stuck, and re-experienced (Leys 2000). Affective response is described within two polarized sets of symptoms: arousal and numbness. In increased arousal, the subject is constantly alert and on guard against the intrusive memories—delaying sleep, hyper vigilance, and difficulty concentrating. At the other end of the spectrum, subjects experience affectual deadening. Instead of being on constant guard for feeling, they experience a lack of emotion: joy, pleasure, sadness are all dulled. The traumatic brain is described as if it were stuck in feedback loop, unable to digest the memory, and the self shielding of the psyche from external stimuli becomes either a pathological state of numbness or arousal. MAPS therapy manual describes the technique as intervening between these two extreme states. According the manual, MDMA allows subjects to access an "optimal arousal zone"—a state somewhere between being overwhelmed and being numb. One can feel, but not too much. In

[25] The DSM-V was released in 2013 subsequent to the completion of my fieldwork. I cite the DSM-IV here as it was contemporaneous with the discussions of PTSD that were happening while I was in the field.

this state, the subject is able to bond with the therapist, confront the memories, and in the confrontation—metabolize the trauma.

While Berra's hypothesis works out what is happening in the brain because of PTSD and the ingestion of MDMA, what remains open, and even problematic, in Berra's hypothesis is what *the experience* of these different neurobiological effects are. An increase in oxytocin might simulate the bonding that a mother experiences with her baby and increase the trust a patient feels for the therapist, but the content of that experience—the sense that one's life and understanding are expanding—is not ruled out. A decrease in norepinephrine might allow the subject to enter into the optimal arousal zone, but that alone cannot explain the therapy, since it is the confrontation of the traumatic memories in which the therapy takes effect.

Later that week, a meme floats through my Facebook news feed: "Dopamine and Serotonin: technically, the only two things you enjoy," posted by a friend who has a PhD in Biology. What the scientist finds funny, the social scientist can't help but be slightly perturbed by. The humor of the meme depends upon a tautological argument. Dopamine and Serotonin have been defined as producing pleasure in the brain, therefore where there is pleasure there is also Dopamine and Serotonin. Competing definitions of pleasure, the phenomenological realm of its experience, various sources are all rendered inconsequential.

However, what is significant about MAPS' narrative is the ability of neurobiology not to reduce, but to work in tandem with humanistic discourses around mystical experience (Langlitz 2013). Numerous anthropologists and other critical social scientists have called attention to the biologization of psychiatry(Lakoff 2005; Luhrmann 2001; Rose 2007; Raikhel 2010). Nicholas Rose has argued for a shift from an early twentieth century self that was characterized by the deep interiority of Freudian psychotherapy to a flattened neurobiological self. What is provocative about MAPS' deployment of neurobiological is its ability to work in tandem, to integrate with what Rose might call, the deep interior space of psychiatry. Chemicals produce experiences; experiences that can profoundly change the self, even as they can be explained through neurochemical pathways.

The concept of neuroplasticity bridges experience and neurobiology. It shouldn't come as a surprise that Norman Doidge's *The Brain that Changes Itself* floated around the office. In the book, Doidge, a psychiatrist, argues that human brains do not become immutable machines after a certain age, but are instead capable of being rewired throughout lifetime (Doidge 2007). Neuroplasticity essentially blows open the door for temporary experiences to have lasting effects on the brain—a model that contradicts much of psychopharmacology, which has been premised on a continually augmenting and regulating neurochemical balance of a subject. But what if a chemical like MDMA can access the plasticity of the brain? Suddenly chemical experience can change the brain, rewire it, heal, and maybe even maximize it. Of course, once we enter the realm of chemical experience, and not just chemical therapy, a new set of variables shaping the therapeutic value of the chemical opens up.

Hyphenated Therapy

The study titles and protocols utilize a very particular phrase: MDMA-assisted therapy. The hyphen links the pharmaceutical to "traditional" talk therapy. This treatment exists neither in the realm of pharmaceutical, not completely in the realm of psychotherapy. In fact, what I find helpful about Oscar's narrative of interiority and travel is the way it destabilizes any attempt to locate the treatment in either the inter-subjective realm of language or in the neurobiological effects implied by the pharmaceutical. While MAPS and Oscar invoke the language of neurobiology and the brain, the very work of the therapy is always displaced from the brain to an

inner realm; an interiority which Oscar describes in the relation of absence from the biological functioning of the brain. In Chapter 1, I examined the complex way in which effects are written into the structure of the chemical, the ways in which MDMA's effects are structured in the process of experimentation. Here, I would like to examine the excess that cannot be contained either within the material structure of the chemical, or within neurochemical pathways. Put another way, within Berra's neurobiological model, the chemical can either produce an experience that is healing or it can produce an interaction that is healing. MDMA is integral, but so is the therapist[26].

Throughout this chapter, I dance around several paradoxes in psychedelic therapy. On the one hand, these non-ordinary states of consciousness are created through specific chemicals, but at the same time the psychedelic therapists sees their healing potential as located not in the specific effects of a drug on the brain, but in the more general state of the *non-ordinary*. Secondly, therapists emphasize the importance of "going inside" to the healing work of the psychedelic experience. The sensory world of the patient is manipulated in a number of ways in order to maintain this inner state. Going inside, as articulated by Oscar, or staying with the experience, as the Mithoefers call it, is achieved by closing off visual and linguistic processing, and at the same time positioning the body and using touch to ground the subject. While in this chapter, I push back on the structure of the chemical or the brain as being able to entirely contain therapeutic effects, I am also not arguing in favor of a disembodied consciousness. These experiences are deeply grounded not only in bodily practices, but also in the non-doing presence of the guide.

Non-Ordinary States of Consciousness

In a famous epistolary back and forth in 1956 the pioneering psychedelic therapist Humphry Osmond and author Aldous Huxley coined the term psychedelic to replace pathologically inflected term hallucinogen (Dyck 2010). Since then, other terms like entheogen—meaning God manifesting—have also been proposed to capture the mystical experiences engendered within the structures of particular chemicals. Of course, the problem that has been run into by those seeking to demarcate the space of the psychedelic state is that the chemical is not the only pathway to that particular state of consciousness[27].

Non-ordinary states is a general term used around psychedelics to gloss a number of pathways, chemical and otherwise, to reach a different state of consciousness. When LSD became illegal in the 1960's, Stanislav Grof, then a psychiatrist researching LSD, developed Holotropic Breathwork™. Breathwork is in essence a form of hyperventilation. Grof claims that Breathwork accesses the same regions in the brain as LSD, thus making it a legal substitute for LSD psychotherapy (Grof and Grof 2010). Similar to psychedelic therapy, Breathwork requires that the patient have a guide or a sitter. Oscar claimed Grof has said that future psychedelic therapists are all being trained through Breathwork.

"That is the other thing that I feel about Breathwork. I feel... Stan has a boilerplate lecture that he gives. I have heard it dozens of times. And it is called, 'The healing potential of

[26] There was speculation that perhaps a study with MDMA and no therapy should be conducted, so as to break apart the work of the drug and the work of the therapy.

[27] A universal model of mystical experience—quantified via a self-rating scale—underlies contemporary neurobiological research with hallucinogens, which examine the neurobiological correlates of particular brain states. Langlitz's research illustrates the differing ways that subjective experiences are not antithetical but critical to producing this research (Langlitz 2013).

non-ordinary states of consciousness.' It's not the healing potential of psychedelic drugs. It is not the healing potential of Holotropic Breathwork. It is the healing potential of non-ordinary states. Because he understands that the non-ordinary state is the goal. And quite often when people are gormandizing about psychedelics, I am saying to myself, 'This is like going to Cancun, and all you can discuss is how you got to Cancun.' You do nothing about how 'Oh how marvelous. It was so beautiful. We swam in the ocean.' It is all like 'I took freeway and then at the intersection I took a right... and then I got on.' It is like describing this process of getting there rather than the experience of being there."

What Oscar highlights here is the fundamental paradox at the heart of psychedelic therapy. While very specific chemicals are employed to enter into these non-ordinary states of consciousness, the state itself exceeds the particular effects of the chemical on the brain. MDMA, LSD, psilocybin, ibogaine, Breathwork all work through different biochemical pathways in the brain. But where they take you, Cancun if you will, is the same.

The expansiveness of 'where' starts to make more sense when one considers these as mystical states of consciousness instead of non-ordinary. Very early on in my research, I traveled to Zurich, Switzerland and interviewed a few of the neurobiologists who are conducing research on hallucinogens and the brain. Nicolas Langlitz had put me in touch with Felix, whom he met when he was doing is fieldwork in Franz Vollenweider's laboratory. Over coffee, one of these researchers, Felix, explained that chemicals were simply a more efficient, experimentally speaking, way of reaching these non-ordinary states of consciousness. "You might achieve the same state via meditation, but we can't very well sit around waiting for someone to have a mystical experience. We can induce a mystical state predictably with a dose of psilocybin." As Langlitz details in his ethnography, these studies are premised on the idea that there such a thing as a universal or core mystical experience.

There is even hope of leaving the chemicals behind all together within the psychedelic community. At a panel on the legalization and psychedelics at the biannual Drug Policy Alliance conference, a hand shot in the air, "You know the technology to induce these states directly in the brain with electrodes, we already have it. It is only a matter of time before we are going to be able to stimulate these brain centers directly. And how is the DEA going to regulate that?" This future vision of auto-brain-stimulation in which the chemical is no longer the vehicle to mystical enlightenment, dovetails with Oscar's account. What if one could just bypass the freeway altogether and go to straight to Cancun?

Bracketing for the moment the possibility of a single universal mystical experience, and questions around the way that the category of non-ordinary sates of consciousness has been stabilized and made measurable, in the next section, I want to instead ask how Oscar gets people there. I want to open up a space for questions around the materiality of the practices. The experience is not just made material through the drug and the brain. It is in fact grounded through a set of sensorial and bodily practices, ones that intimately tie the subject and the guide together.

Interiority

Returning to my interview with Oscar and "how" psychedelics heal. Expanded consciousness is only part of the "how" I am after. Or at the very least, there is another how underneath this one. "How" the chemical manages to do this sort of work, this journey into the self. The answer is that the chemical alone doesn't do this work alone. More precisely, I argue that the body and its sensorial capacities are critical for the creation of this interior space in which the therapy takes place.

A few minutes into the interview on the tape, I hear my voice asking a string of questions: *Talk me through a session. How do you prepare a patient? How do you prepare the setting? What do you actually do during a session? What happens afterwards?*

Oscar's voice replying: *Sometimes I do a little relaxation exercise, but mostly people just take the medicine and then we just sit and we talk and then at a certain point they say, "I think I am feeling something now?" "Okay... well lie down." So I have the bed with all the pillows. And they lie down and I don't insist on eye shades, but I highly, highly, highly recommend that experience because...*

I hear my voice interrupting: *What do the eyeshades do?*

Oscar: *Well what they do is... first of all... If I do that* (I remember his waving his hand in front of his eyes) *with my eyes shut I can see my hand, the shadow of my hand going across my eyes. With eyeshades I can't. So it is just an extra level of protection. But in the first instance, forty percent of our brain's activity is processing visual materials. So if we put on eyeshades that we have made a deliberate conscious choice to go inside and to stay inside. And we are actually giving that portion of the brain that could be occupied with visual stimulation over to the processing of whatever is coming up. It may be visual from inside. And it is also a very good indicator for me, on the outside, to know whether the person is really truly involved in the experience.*

To give you an idea of what Oscar is talking about, pictured below is a scene from one of MAPS clinical trials (Ferro 2015):

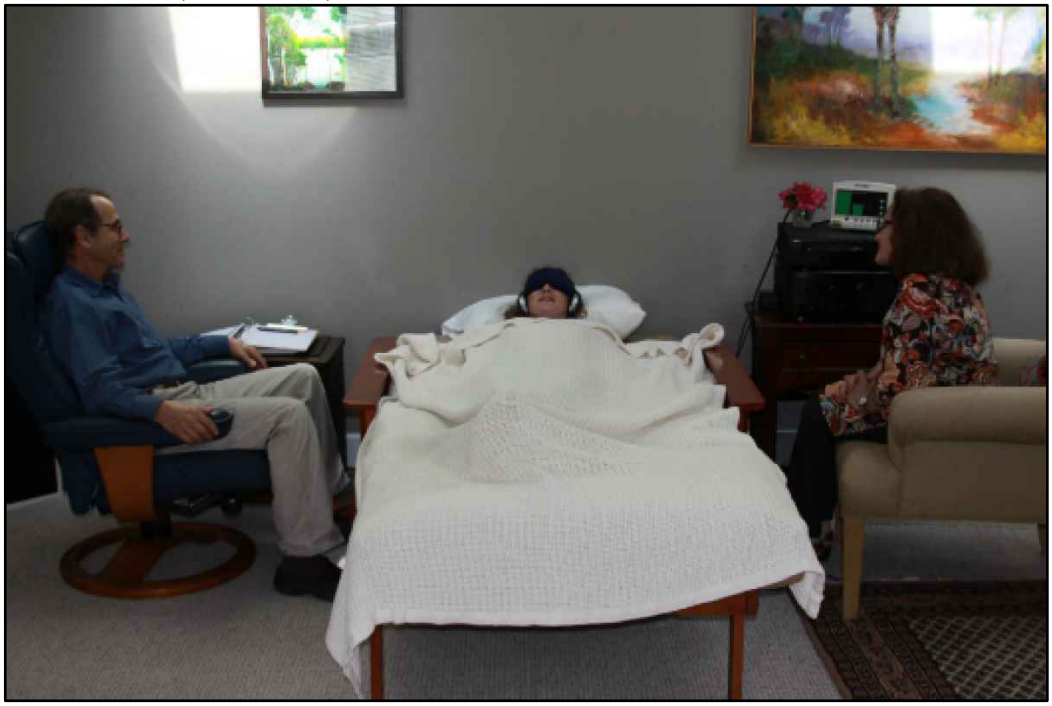

Figure 4 "Psychedelic Medicine" Michael and Annie Mithoefer guiding a subject through an MDMA session for MAPS' pilot study.

The closest I ever got to a therapy session was on video. I was given permission to watch the videotapes of one subject's sessions with Michael and Annie in order to edit a series of clips to be used in training materials. I sat alone in my office, watching, a virtual voyeur. The preparatory and integrative sessions were easily an hour long each. But the experimental sessions, so named for when the subject receives the MDMA (or placebo), were over eight hours.

I took notes. Sitting with a yellow legal pad, and cup of coffee, noting the different kinds of interactions and the times at which they took place. The experience vacillated between being emotionally draining and mind numbingly boring. In between listening to the subject recount the violence that he experienced in the military, and his struggles with PTSD, there were often silences—long periods in which the patient "went inside," eyes hidden behind eyeshades for sometimes fifty minutes while Michael and Annie just sat by.

You can see the subject lying there in Figure 4, bundled under blankets with the eyeshades on, as the therapists sit on either side, flanking her. Watching. Here, Oscar has told me how one takes a trip inside. It is not simply the drug itself, or its corresponding actions on the brain. If anything, the brain and its preoccupation with visual processing, is what must be worked against according to Oscar. The eyeshades intervene here, redirecting not just the work of the chemical, but also of the self.

As I move deeper into the interview, Oscar brings up this exact difference between the talking fundamental to psychotherapy and the kind of work that he does with clients.

Oscar: *So in the session I remember, actually, one fellow came in and he was recommended by a physician. And this guy was in serious trouble. He had a marriage. He had teenage children. He was having sexual relationships with men. He had a two million dollar lawsuit against his own father. He said that he had at one point half a billion dollars invested in the stock market on the margin. In other words, if things started going south, he has to pay it back and he had no money. And he had literally... he was Gordon Gekko on steroids. A one-man band. And so he came in and he needed some relief. So I'm talking with him.... about how the session would be and so on and I said, "It could be that we don't say anything throughout the whole session." And he said, "Can I talk?" "Yeah, of course you can talk, but you may not want to. It may be that the whole thing, four or five hours go by, and we haven't spoken a word. And that is fine. I am going to be here. I am totally present, available." He said afterward, "You know, when you said that, I almost walked out. Well if he's not going to talk to me what is the point?" Because he had been in talk therapy for years and years and years. He said there was a point in the session where I was feeling so good, he said, "All I could think was, 'I hope Oscar doesn't speak to me now.' [laughter] I said, "Whooohh... Gets the message!"*

MAPS' therapy manual calls for plenty of talking during the integrative sessions that follow the MDMA-assisted therapy. But when the drug is present, they highlight the need to direct the patient towards their "inner experience."

"To maintain the delicate balance between focusing on inner experience and providing a safe space for exploring this experience, the therapists must respect the natural healing mechanisms of the participant's own psyche and body. This involves skillfully interweaving interaction with the participant and periods of silent witnessing."

—MDMA-Assisted Therapy Manual

Like Oscar, the therapy manual emphasizes the role of silence during an MDMA-session. They make two kinds of arguments about the value of silence. One, talking may be a way of avoiding difficult feelings. And it is the role of the therapist to direct the patient towards the emotions and memories, which they have been avoiding. Two, talking and verbalizing is set up as the opposite of experiencing. When one is experiencing, one is not narrating.

While visual processing must be negated in order to facilitate this interior state, the aural capacities of music are strategically employed.

On the recording, I hear myself ask: *Do you let the patient decide what they are going to listen to?*

Oliver: *Yes. To some extent. I put something on and if they say, "Oh no. Can it be something else?" With Breathwork that is not the case. Breathwork needs the music to drive it. That is my little box over there. I sort of wheel that out and I put that at the end of the bed there. So the bed is there and their head is there and there are cushions against the table. And, yeah, I chat a bit and put the Ipod on and so on. And then different, sometimes different medicines require different music.*

I hear myself probing around chemical differences: *What does MDMA require?*

Oscar: *Very gentle. Sweet. There is one woman I worked with. She would only listen to Hildegard von Bingen. She wouldn't listen to anything else. She just wanted Hildegard von Bingen... from beginning to end and that was fine. I have found... especially with mushrooms, funny enough, that there is something about the mushrooms that demands simplicity. And that some people, and I have found this in my sessions, just wanted a single note. Anything where there was two or three instruments or voices or complex arrangements. It's like, "Too much! Too much! Too much!' So I use flute music. Lovely, lovely music. They can definitely request more or less. And some period of silence, too, depending.*

The specificity of the chemical returns in Oscar's rendering of the musical landscape for his sessions.

I encountered discussions of music used in therapy sessions throughout my research. It might be turned off to facilitate talking or to encourage reflection, but it was often a point of negotiation between voyagers and guides. Among researchers there were light discussions of whether the music was a variable that needed to be controlled from subject to subject, or if the music could vary. Some of the therapists with the psilocybin studies use the same soundtrack over and over again. Others, like the Mithoefers, customize the music to suit the subject's taste and mood.

In fact, as I return to MAPS' protocol for experimental sessions I find echoes of the kind of work that Oscar has told me about. For all of the work on the psyche, one cannot ignore the sensory capacities of the body in facilitating the experience of an inner realm.

"After the session begins, participants will recline in a comfortable position with eyes closed or wearing eyeshades if preferred. They will listen to a program of music designed to support their experience by initially aiding relaxation and later evoking and supporting deep emotions and the emergence of unconscious material (Bonny and Savary 1990; Grof 2000: 1980; Unkefer 1990). After the first hour, if the participant has not spoken spontaneously, the investigators will check in with him/her about the nature of the experience. For the rest of the experience, as appropriate, the investigators will support and encourage the participant in emotional processing and resolution of whatever psychological material is emerging. The investigators will also encourage periods of time in which the participant remains silent with eyes closed and with attention focused inward in order to allow for the further unfolding of their inner experience. Water and electrolyte containing fluids will be available throughout the session. Food will be available during the latter part of the session. All experimental sessions will be recorded to audio and video in their entirety."

The pull of the body in MAPS' protocol is unavoidable. Eyeshades, music, electrolytes, food, a body in recline. And yet, the thread that runs through all the discussions of psychedelic therapy that I encountered while doing my research was this inner realm. Where is this inside? How does one get there? What happens in this realm? While provisions are made for checking in with the patient, the sensory experience is designed to encourage a withdrawal from the therapists through the use of eyeshades and silence.

MAPS' therapeutic manual lays out a number of postulates for guiding an MDMA session. An almost passing aside requires that the MDMA be handed to the patient in a bowl symbolizing the safe container that the therapists are creating for his/her experience. It is a small detail, and is not included in the protocol for the study, which simply states that: "At approximately 10:00 A.M., participants will receive the initial dose of MDMA along with a glass of water." While not significant for the regulatory or scientific logics governing the trial, the metaphor of the safe container is in fact deeply imbedded in both MAPS' and Oscar's vision for a successful therapeutic session. This metaphor is physically present in the way that the therapists sit flanking either side of the subject: physically bounding the space in which the subject's is mind expanding. There is a provoking contrast here between Oscar's narrative of self-expansion and the necessity of a bounded space provided by the therapists.

But how does one bind an experience? How does one provide or create a safe container? In short, what exactly does the therapist do? If the psychedelic experience reaches out beyond the structure of the chemical to encompass the work of the eyeshades, music, and silence in creating this interior space, what role do these therapists play?

Non-Doing Presence

Early on in my research, I attended a meeting of psychedelic researchers and therapists that followed the 2010 conference, *Psychedelic Science in the 21st Century*. MAPS is not the only non-profit sponsoring research on psychedelic therapy. Nor are the Mithoefers the only therapists currently working legally with psychedelics. The Heffter Foundation is another non-profit that is dedicated to funding scientific research with psychedelics. Heffter has sponsored a series of studies on end of life anxiety and psilocybin (the psychoactive component in mushrooms). Many of their therapists were invited to present on their research at the conference. After the conference, the presenters were invited to meet and talk through the future of psychedelic research. I was allowed to sit in as a note taker for the group.

Amidst technical discussions of protocol designs and more emotive digressions of the group's hopes and anxieties for the future of psychedelic therapy and research, there was a persistence theme of what psychedelic therapy could or should look like in a legal context. What would the best practices be? Should there be licensing? How would one be trained? If they, the therapists and researchers, were successful in clearing psychedelics good name, if a legal space for psychedelic therapy was to open up, what would that space look like?

As an exercise, the attendees broke up into four groups to discuss what either an ideal or a disastrous session with either MDMA or psilocybin would be like. The disastrous sessions were not that far apart for either MDMA or psilocybin—chaos, a panicking subject, a bad trip. As I flip back through my notes of the ideal session I find this written on a yellow legal pad:

"At the peak moment, the therapists are sitting quietly, the patient's eyes are covered and s/he is lying down…. They [all the participants] all came up with this identical scenario." One of the most experienced guides in the room summarizes: "Best guiding is not to interfere. Just presence. Nothing is in your awareness other than that person's well being during the onset of the drug."

Another therapist invoked the Buddhist notion of Skillful Means to explain the work of the therapist in a session: as little as possible at the right moment. As I read through these notes, it reminds me of something that I heard Michael Mithoefer say during a presentation on MDMA-assisted therapy. He was listing out techniques like Breathwork or bodywork that might be incorporated into a session, when he added, "And of course quite a bit of non-doing."

Towards the end of the interview, I hear myself bringing up non-doing and the researcher's meeting and the discussion of presence with Oscar: *But just that sense of being able to be a presence… how do you train "presence? How do you certify presence?*

Oscar's reply: *Right. That is absolutely the key. That is why I mentioned earlier Heidegger's idea, the angst we all feel in post industrial cultures is because we have forgotten how to be. In order to be present you first have to be. You have to know who you are. You have to be comfortable in your own skin. And then you can be that comfortable person with somebody else. And it is... its unquantifiable. It is literally unquantifiable. But I would honestly say that the Breathwork training, or you could transfer the Breathwork training to psychedelic training where you try different psychedelics and then have periods of integration and discussion and so on and so on. Could result in that. But you are absolutely right: it is the key thing. That somebody in that condition knows that the somebody who is there is really there. They are really there. And that they can ask anything of them. Anything from... I mean I have been in that state you know with medicines and also Breathwork and you realize what a joy that is. What an absolute piece of healing just to have somebody who is just sitting there, watching out for you. Not doing anything, but just sitting there watching out for you. It is like, "Ahh!" It is really validating. It really engages that sense of ones literally own being. So I would think that that....That is absolutely the key thing.*

Oscar goes on later to say: *It is just somebody present. And that really to my mind is ninety percent of what I do: presence. Just the presence that is on your side. Supporting what comes up. Will get you anything. Do anything for you. Absolutely in service to you.*

But whatever this presence is, it is not a part of the content of the psychedelic experience, according to Oscar.

Oscar: *I mean one of the things I love is the understanding that the word therapists comes from the Greek word* therapon *and the meaning of the word* therapon *was an attendant at the healing process. Not part of the healing. You're just an attendant. And that really is the role I think that I play and other people play in sitting with people for psychedelics… The healing is intra psychic. It is not inter psychic.... This is all within! And that I think is going to be a very difficult thing for most therapists to understand.*

What is more, part of his presence in a patient's psychedelic journey, was helping the patient to recognize that the content of the experience was from within—both physically and verbally. When asked what he would do if something difficult would come up, Oscar responded: *Reference that you have lived with this all your life. You are just seeing for the first time... that you have already contained this and lived within this. This is nothing to be coming from the outside. This is all stuff that is within you that is manifesting.*

And, he adds, touch, the grounding of a patient through physical contact: *And again, very often, just the physical touch of a hand. Just a hand to hold. And the hand is steady. And the hand is not demanding anything.*

In MAPS' treatment manual, Appendix B "Focused Bodywork" discusses the ways that touch might be used by therapists to help guide the session. "The term focused bodywork is used to refer to touch, (usually in the form of giving resistance for the subject to push against) which is aimed at intensifying and thereby releasing tensions or pains in the body that arise during therapy." Before proceeding into the benefits and guidelines for touch, the manual warns that touch "might distract the participant from his/her inner experience." The manual describes touch not as therapeutic in and of itself, but as a way of working through anxiety and psychosomatic distress. But of course, why or how touch alleviates anxiety and distress is left open.

The therapist, in Oscar's narrative, is both a verbal and a physical presence that allows the self to recognize itself. A touch that can ground the patient. Perhaps to pose a limit, an exterior against which the patient can touch and know it's own boundaries.

Conclusion

The material presented in this chapter points in two critical directions for future research. One, the deep interiority this is being cultivated in MDMA and psychedelic therapy needs to be connected to the history of both mysticism and Protestantism in America. Discussions of psychedelic therapy often have a quality of bricolage—drawing Buddhist concepts like non-doing and skillful means, alongside neurobiology, transpersonal psychology, and Jungian psychology. However, whatever genealogy of interiority one writes, I argue that the practices that create it must be central to the discussion. Only when attending to how one facilitates a subject going inside, do the boundaries that produce this interiority come to the forefront. Even in an ordinary state of consciousness, according to Oscar, the mind is a reducing valve that is unlocked or opened up by psychedelics. But at the same time, this expansion requires the intervention of the eyeshades, to contract that movement outward and direct it inward. The expansion of the mind, must encounter a limit. In a similar way, Oscar as the guide provides a boundary, a limit, or more precisely a frame for the patient's experience of an inner realm. Further inquiry should track not just what the limits and boundaries are, but also how they flow back and forth between that which they divide.

Two, what is the work of the chemical? Or more precisely, how should the work of the chemical be framed? Even within the neurobiological models of MDMA's mechanism of action, the chemical is caught up in the interactions of the subject with the therapist. Following historian Michelle Murphy, I would like to propose the use of a Deleuzian inspired *assemblage* to capture the complicity of subjects, eye shades, brains, therapists and chemicals in constituting the expansion of self which constitutes the healing power of psychedelic therapy (Murphy 2006). In Murphy's historical account of the emergence of Sick Building Syndrome, she wrestles in similar ways with the relational nature of chemical effects. As she writes*, "Assemblages are formed of organic and inorganic objects technologies bodies and architecture.... I therefore use the concept of assemblage to describe the material and yet relational way things come to matter... An assemblage materialized an object by placing it in a specific social and technical constellation, making it perceptible, outline form, drawing out possibilities and investing meanings by virtue of its linkages, effects and relationships."*

The two questions touch back upon each other, when one asks: what exactly is being materialized here. At one level, it is both MDMA and a therapeutic technique. But of course it is not just the MDMA that is being materialized here, there is also something, I would argue, about the inner realm of the subject. This is a question (or maybe a provocation) I will return to in Chapter 5.

Chapter 4: Documenting Adherence

Introduction

On the MAPS website, under clinical intern, the following description is posted: "As our clinical research program grows, so does the associated paperwork, and MAPS needs an enthusiastic, detail-oriented assistant for our Lead Clinical Research Associate in order to keep us ahead of the game." I laughed when I read this, as it summed up much of my fieldwork. My first task as part of the clinical research team was to review an Informed Consent Form (ICF)—an ordinary task that I would come to be quite practiced at during my year and a half of fieldwork. The ICF was an intimidating eighteen pages of singled spaced description of study procedures, treatment benefits and risks[28]. I must confess that I wasn't quite sure what I was reviewing it for, and I remember the relief I felt when I found a grammatical mistake about midway through the document; finding the small mistake felt like passing a test.

When I was brought on board the clinical team, I was warned that clinical research had its own specialized vocabulary, and that it would take a while for me to learn the language. My notes for the first few conference calls I sat in on were mostly hastily scrambled phonetic guesses as I struggled to keep pace with the conversation. The language of clinical research is dense. Anything that can be shorted to an acronym—from study names, to study documents to psychometric tests—is. What was left unsaid when I joined the clinical department was that these acronyms are tightly intertwined with the documents through which clinical research is enacted. Prior to reviewing that first ICF, I had to first to read the SOP, that is Standard Operating Procedure—on reviewing ICF's, and then sign off on a read and received indicating that I had, ahem, received and read it. Once finished with my review of the ICF, I had to then sign a checklist documenting the fact that the ICF contained all of the required elements of informed consent.

I begin this chapter with the claim that clinical research is enacted through documents—a claim that will be sustained through the ethnographic material presented. However, buttressing that claim is but one task of this chapter. Documents perform multiple kinds of work in the process of clinical research and are themselves worked upon in different ways. If anything, this chapter asks: how is MDMA-as-therapeutic-technique enacted in the practice of clinical trials? To put it another way: the MDMA trials are unusual in that they are not just looking at a pharmaceutical, but a therapeutic technique that utilizes the chemical as a catalyst to an experience of non-ordinary conciseness. As the previous chapter demonstrated, the therapist or guide is critical to the way that experience takes shape. While Chapter 1, "Effecting Substance," focused on effecting chemical structures in the experiment, this chapter will look at how a therapeutic technique is standardized through the work of documentation.

This chapter intervenes in two different discussions in anthropology: one on clinical research and the other on documents. For the most part, the former conversation has focused on the ethical quandaries (S. Jain 2010; Petryna 2009), complexities of cross-cultural exchange (Adams et al. 2005) and market logics shaping pharmaceutical research (Dumit, 2012), as well as the experience of patients participating in clinical research (Meyers 2013). However, this chapter

[28] This is not an uncommon length in the clinical trial industry. However, there have been studies indicating that increased length inhibits subject's comprehension of the material (Kass et al. 2011).

delves into the ways that clinical research enacts knowledge through documentation—not just of the chemical, but also of the therapeutic technique itself. I touched on the role of documents in Chapter 1, but I am focusing on the kinds of work they do in clinical research in this chapter because I want to call attention to their relationship to MDMA-assisted therapy as a technique. As discussed in Chapter 3, the therapists are critical to shaping the experience of the chemical. As such, their actions became subject to forms of surveillance and standardization in the course of the clinical trial—documents were critical to both of these endeavors.

Drugs and treatment subjects move in tightly controlled orbits, but documents are copied, emailed, flown (I took binders of study documents to a site in my carry on), and mailed around the world. Before a study can begin, there is a protocol. The protocol begets the source records, which beget the case report forms (CRFs). Then there are the Read and Received for each person working with a given document. And of course, there are the psychometric tests themselves—the very documents through which traumatic events as well as the psychological effects of the treatment are manifested.

Matthew Hull argues that anthropologists have started looking *at* rather than *through* documents. In the contemporary anthropology of organizations, documents are not simply instruments, but are constitutive of the knowledge, objects and subjects which they purport to represent (Hull 2012). While on the one hand, documents in clinical research can act as contracts—binding particular actors to the execution of certain tasks—they are also critical to reconstructing the trial for monitoring visits and audits of the data. "The most important purpose of source documentation in a clinical trial is to reconstruct the trial as it happened." (Bargaje 2011) As a treatment, MDMA-assisted therapy might rely on the production of immediacy, "staying in the experience," but as a clinical trial, the study produces layers and layers of mediation between the experiment and the data, such that the density of the layers can reproduce the trial for either a monitor or auditor.

In the first section of the chapter, I look at the role of documentation in producing GMP—short for Good Manufacturing Practice—MDMA. In the second section, I look at the significance of "pen to paper" as the moment defining the beginning the documentation of clinical research, and the significance of psychometric tests to establishing clinical knowledge about psycho-pharmaceuticals. At least for now, when psychological diagnoses are still determined by symptoms listed in the DSM (and not biomarkers[29]), psychometric tests constitute the critical outcome measure for clinical studies. In the third section, I through the development of the Adherence Rating program by the clinical staff. For all of the documentation of safety and efficacy, the actions of the therapists remained unverified in early protocols. The clinical staff needed to develop a method for turning videos of therapeutic sessions into clinical trial data, which could both monitor and document the actions of therapists.

Throughout this chapter, documents are critical to the standardization of the clinical trial—and to repeating the study from subject to subject and site to site. But the documents themselves are not transparent. Skill and expertise is required to produce clinical-grade documents; and training is required to use them correctly. Chemicals are difficulty to control in their own right (see Chapter 1 on ensuring that MDMA is always MDMA). Keeping a chemical in its necessary orbit, consistent, identical is not simple. Chemical structures do not reproduce

[29] The National Institute of Mental Health has announced that it is developing a new nosology of mental illness, which will do away with the DSM and will instead focus on biological markers of mental illness (Insel 2015).

identity on their own—in fact documents play a critical role in ensuring chemical identity. However, as this chapter will show: not all documentation is the same, and not all documents are created equally.

Good Manufacturing Practice and Documenting Production

The expansion of the clinical trial program meant that not only would the actions of the therapists come under increased scrutiny, but also the provenance of the chemicals themselves would become a variable in the studies. For the initial US studies, the MDMA had been purchased from Dr. Dave Nichols. The clinical team had been working on developing a system for lot numbers for the MDMA, which would track which MDMA used in which study came from what source. Lot numbers are a part of the GMP regulations. GMP stands for Good Manufacturing Practices—the regulations guiding the manufacture of pharmaceuticals—or CGMP (Current Good Manufacturing Practices) in FDA terminology. Given the capriciousness of chemical identity, the stakes are quite high for ensuring that manufactured pharmaceuticals are what the label says they are. Hence, GMP refers to not only guidelines for production, but also inspection of laboratory space and documentation of the manufacturing process. According to the FDA website, "CGMPs provide for systems that assure proper design, monitoring, and control of manufacturing processes and facilities. Adherence to the CGMP regulations assures the identity, strength, quality, and purity of drug products by requiring that manufacturers of medications adequately control manufacturing operations."

If the FDA Okays Phase 3 of the study, the MAPS clinical team will need to procure MDMA from more than one source. Lot numbers are commonly used to track different batches of pharmaceuticals, and become critical to recalling a product if a problem is identified in the manufacturing process. In 2010, while I was conducting fieldwork, there was a massive recall of 60 million bottles of over the counter pain relievers, including Regular and Extra Strength Tylenol, Motrin, Benadryl, and St. Joseph Aspirin (Singer 2010). The containers had become contaminated with a fungicide, which had been used to treat the wooden pallets that the plastic bottles were stored on. The chemical released from the fungicide breaking down the fungus produced an odor inside the bottles, which was what initiated the recall.

"There was that recall a couple of months ago, do you think I should just throw the whole bottle away?" My mother was standing in the bathroom holding a bottle of Extra Strength Tylenol. There wasn't any smell, yet she was still unsure. We flipped the bottle on its side and found the lot number. I explained to my mother that this number is linked to the *place* and the *date* of the manufacture. If we looked up the lot number on line we should be able to tell if it was produced at a plant within the correct time frame for us to be worried. It wasn't, but she threw the bottle out anyways.

As an academic chemist, Dave Nichols didn't possess the export license necessary to transport his MDMA across intentional boundaries. Lipomed AG—a small company specializing in unusual chemicals, like thalidomide—produced the MDMA used in the Swiss studies. So in thinking forward to the expansion of the clinical trial program and Phase 3, Amy raised the question of garnering MDMA from other sources. "I think we at some point we will need one study with MDMA from two different sources. So that we can show bioequivalence."

"We are trying to buy whatever we can," answered Rick. Procuring legal MDMA does have its hassles. Procuring GMP-level MDMA is quite expensive, as the market for legal purchase for a controlled substance is quite small. "We have a company in Germany that will do GMP MDMA and export anywhere in the world. Right now we have enough from Canada and Jordan. If we can get this other gram that I am trying to buy. The big thing for me would be to

buy from Dave Nichols before he retires. If we could put it someplace and then have it exported"

"There are places that will hold the drug as "contract manufacturer, but it is expensive. It may cost as much as GMP," advises Amy.

"Is Nichols stuff GMP," asks Linnae?

"No," I automatically reply along with Berra. "He has cited lab notebook entries for us, but essentially it is done in a academic setting," finishes Berra.

"There is a ways to do work abounds," adds Amy. "These are the precursors. Take some of the product 're-manufacture' it in some way."

Several issues come to light in this exchange. First, MAPS may call itself a non-profit pharmaceutical company, however, it lacks the manufacturing arm built into pharmaceutical companies. And in recent press releases, MAPS has announced plans to eventually produce it's own MDMA, which it would then control in conjunction with therapists training—a plan that highlights the intertwined nature of drug and therapist. Second, the discussion of Nichol's MDMA brings forward an important difference between academic research and clinical research: documentation procedure. Academic research has a set of norms for documenting research procedures—academic notebooks. However, these notebooks do not meet the standards set for pharmaceutical production. Lastly—and this is intimately tied to GMP and documentation—Amy asserts that they will need to demonstrate bioequivalence at some point by using MDMA from two sources in one study. The Food and Drug Administration defines bioequivalence as: "the absence of a significant difference in the rate and extent to which the active ingredient or active moiety in pharmaceutical equivalents or pharmaceutical alternatives becomes available at the site of drug action when administered at the same molar dose under similar conditions in an appropriately designed study." (Guidance for Industry: Bioavailability and Bioequivalence Studies for Orally Administered Drug Products — General Considerations, 2003)

Chemical equivalence is a not a product of chemical structures but of bureaucratic structures of testing and regulation. Cori Hayden has tracked the battle over copied pharmaceuticals in Mexico. As she points out, even though the chemicals in question are out of patent and a part of the public sphere, the public pharmaceutical domain turns out to be "a highly stratified, densely populated, and extremely complex zone."(Hayden, 2007) Hayden argues that while intellectual property arguments are still at play, it is quality that is at stake in the manufacturing and marketing of generic drugs. There is much to be done with the fact that a chemical takes on particularized identities outside of its chemical structure, but for now let me point out that documentation is critical to these processes.

Recording Data

"The first time pen touches paper that is the source," Berra is patiently explaining. "In most cases the source records would just be a file with test results and lab notes, but our studies require more specialized documentation." We are sitting in the small clinical research office on the second floor of MAPS building. For the last couple of weeks, I have been working with Berra on auditing of database of the Swiss MDMA study.

"So what *is* the difference between case report forms and the source records?" I finally ask. I know that I have been editing the data entry conventions (the rules for how to enter data into the database), but I realize that I don't really understand the process by which the data is being generated. I know that "source records" precede case report forms (CRF's), but I am pretty sure I do not understand what makes them different. Berra grabs a piece of paper and draws a diagram for me. "The source record is the first time pen touches paper. It includes all

information about a subject, but that would be unwieldy to enter into a database. And most of it is unnecessary for doing data analysis. So the necessary information is entered from the source to the case report forms by the site. The CRF's are what leave the site and travel here to the sponsor's office. The data is on the CRF's is what is entered into the database. Monitoring the study, which is what we are doing now, means that we are making sure that the data entered into the database matches the CRF's and that the CRF's match the source." CRF's from completed studies are brought back to the sponsor once the study is closed out. They are stored in fireproof cabinets—a material reference for the data being entered into the database.

All kinds of discrepancies can appear in the database: sometimes a date has been entered in the wrong format and needs to be corrected; sometimes a field has been left blank, and it needs to be determined if the data was not entered or simply not collected. Hundreds of queries can be generated in a data review. It will be up to Berra to review all of the queries and determine if there is an error and if so, where it occurred in the collection process. Where in the chain of paperwork and documentation did the error occur? More importantly, every step in the processes: from the generation of queries to their resolution will be documented. The review and monitoring process are not only to make sure the data is "clean"(aka to improve the data), but to also document discrepancies in case of an audit. Only once the queries have been generated and reviewed, can Berra go into the database and fix them. And once the errors have been recorded and corrected, then the database can be locked.

The first time pen touches paper. The example Berra went on to use is if a nurse writes down a subject's blood pressure on a post-it note, then that post-it note is the source record. Ideally, that nurse should then sign and date the post-it note—so that the data is attributable. It might be transferred to a CRF at some point, but for the purposes of the study, that sticky note is the source record. If an edit needs to be made to either a source or CRF, it is must be initialed and dated using ink (white out or eraser is strictly verboten). There is something here about that moment of pen and paper. The critical moment is the committing of the blood pressure to the materiality of writing.

The study collects a wide range of data—some of them bodily like temperature and blood pressure. However, because the MDMA-trials are looking at a psychiatric disorder—posttraumatic stress disorder—they also use a range of psychometric tests. A subject's degree of trauma, distress during the study, and risk of suicide are all measured using a menagerie of different tests, which are a their most basic level documents. It is not yet possible to diagnose mental illness on the basis of biomarkers (though there is pressure for this to change); PTSD studies that incorporate PET scans or MRI's to determine if the amygdala is enlarged, or blood samples to see if a subject has increased levels of norepinephrine, are correlating these biological tests with psychometric tests, primarily the CAPS.

So what is the CAPS? On the one hand it is a numerical score on a psychometric test. As a psychometric test, it is based upon a clinical interview between a subject and a trained clinician. The interview guides the clinician through a series of prompts. Imbedded in the text of the document, under individual prompts, are particular rating scales. For instance, underneath a question about unwanted memories is a scale for assessing the frequency with which this occurs and two different boxes in which the clinician can record the subject's answer for two different time scales—lifetime and past month. In order to train clinicians in how to administer the CAPS, there is a training manual that walks through the different items—how to ask the prompts, how to score responses. And at the end, there is also the question of how to score the overall interview. So, yes, on the one hand, the CAPS is a face-to-face interview between subject and

clinician. On the other it is a series of documents that train, and then guide the clinician as they administer and then ultimately score the document. In a clinical trial that is investigating whether or not a subject's level of trauma improves with a given treatment, the efficacy of MDMA comes down to the use of a document.

The textual level of the CAPS was highlighted when the clinical trial team was preparing to initiate studies in Jordan and Israel. Most of the study measures needed to be translated into Hebrew and Arabic. At first it was proposed that the therapists would just translate the tests on the fly: reading the English and then asking the questions in the given vernacular. But the clinical trial team quickly dismissed that possibility. They needed to be sure that the questions were all asked the same way each time. But translating the documents revealed the fact that the documents themselves had a complex architecture. Subtle instructions were given to raters based on whether the text was italicized or not. The translation of the document would need to recreate the subtleties of formatting in addition to simply translating the language. However, the cost of having a document professionally translated was quite expensive—to the tune of several thousand dollars. As a cost cutting measure, MAPS was able to recruit volunteers to do the translations, however, these lay translations needed to be certified by a professional translation company.

However, translating and certifying the translations was only one step in the process of preparing the CAPS for studies abroad. The Independent Raters who were administering the CAPS would have to be trained remotely to use the measure. MAPS developed a training procedure, in which raters would read training materials, then watch videos provided by the National Center for PTSD, and rate them. Their ratings would then be reviewed and feedback given. This entire process culminated in the issuance of a certificate of training (designed by the anthropologist-as-intern). This process of training independent raters would the model for the development of the Adherence Rating Program, which would monitor and document that the therapists were following the same techniques.

Adherence Rater Training

The Problem

The MDMA trials were just catching momentum during my fieldwork. The first pilot study had yielded positive results, and the FDA and other agencies were swiftly approving more pilot studies. The treatment showed promise. More importantly, MAPS was demonstrating that they could conduct the studies safely. However, "Looking forward to Phase 3" was a frequent topic of conversation during meetings. But repeating the experiment—which is fundamental to the scientific method—also meant introducing variability: new study sites, new therapists, new MDMA.

The expansion of the study to new sites meant that new study personnel would have to be trained—most importantly new therapists. In the first two studies—US and Swiss—the therapists were all experienced with guiding patients through non-ordinary states of consciousness (The exact training and back ground is discussed further in Chapter 5). However, in the studies planned for the Middle East—Jordan and Israel—the therapists were recruited for their location [30]and not for their experience with non-ordinary states of consciousness or their personal investment in developing MDMA as a legal therapeutic tool.

[30] There was debate within the MAPS organization about the value of running clinical trials in Israel and Jordan. The president, Rick Doblin, was heavily invested in running clinical trials in

Amidst all of this, the data from the second MDMA-PTSD study in Switzerland had finally been cleaned, the database locked and the initial analysis performed.

It was good, but not as good as the data from the first US study conducted by Michael and Annie Mithoefer. At a moment when the clinical trial program was bursting forth with new studies on the verge of initiation, these results raised anxieties. Why weren't the results the as good? Why hadn't the study repeated itself? What would it mean for future studies?

There were many differences between the Swiss and the first US study. The placebos had been different. The treatment population had been different. And of course, the therapists had been different. The easiest way to read the difference was to look at the therapists and the technique that they were using.

These issues spurred the development of the Adherence Rating Program—a monitoring program in which videos of therapeutic sessions would be rated according to how closely the therapists followed the therapeutic manual. The Mithoefers had been developing a therapeutic manual for some time, but it had not been in place at the start of the Swiss study—which in part explained the difference in therapeutic technique[31]. However, the differences between the US and Swiss studies made them a useful for testing the Adherence Rating program.

The clinical team debated all of these questions and the significance of difference at its annual goal-setting meeting.

"You know," said Valerie, the Director of Operations, *"it could even be premature to be rating people to copy Michael and Annie. It may not work for them. We have to figure out what the critical components [of the therapy] are. We can't just replicate. We might have to let people do things their own way."*

"Yes, but we do have to make it precise," replied Rick. *"Part of Michael's presentation on the therapy is making certain things constant and vary other things."* In his doctoral thesis for the Kennedy School of Government, Doblin outlined how, if legalized, there would need to be a licensing program, which required that the therapists allowed to administer MDMA-assisted therapy attend specialized training courses. There has always been a latent sense that controlling MDMA in the imagined legalized future would also entail controlling the therapists.

"Okay," Valerie countered*, "But what if you are using different elements and getting good outcomes.*

"That may be a possibility," said Rick*, "But we want some set of core methods. "*

"We know some of it, but we don't know all of it," added Amy.

"Right that is why we need something," says Rick.

"What we need are two studies that work equally well and then we need to figure out what is the same," concluded Amy.

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the Middle East. When someone asked at a clinical trial meeting why MAPS was attempting to initiate studies in the Middle East, Dr. Mithoefer jokingly responded, "World Peace." The less joking answer is that Doblin feels deeply that psychedelics can help in areas of deep conflict and violence.

[31] It is important to note that the Adherence Rating scale didn't characterize the therapeutic technique being used; instead it rated how closely their actions followed a particular model. Thus, I didn't encounter any concrete discussions of what the Swiss therapists were doing, only a discussion of how they were not following the manual. This lack of discussion around the particularity of the therapeutic technique however fits in with the overall goals of the clinical trial team, which is not to develop a therapeutic technique, but to administer the studies.

Amy's resolution to the problem is quite telling. The difference between the US and Swiss studies doesn't mean that one method is correct and one method is deficient. From a researcher's point of view, it is repetition and not difference that will demonstrate the effectiveness of the therapeutic method. Seen in this light, the Adherence Rating Program was not about evaluating the correct method, but creating a program for monitoring the therapists. It is one thing to make the therapy precise in a manual and another thing to enact in a study. For the purposes of a clinical trial, in which that which is not documented is not done, enactment of the therapy depended on creating a method of documenting the therapists' actions.

In this next section, I examine the transformation of videos of the therapeutic sessions into clinical trial data and discuss the work of rating scales in witnessing the therapeutic sessions.

A Brown Box Arrives

The videos from South Carolina arrived via Fed Ex at my front door in a plain brown box. Tucked inside of Styrofoam peanuts was an external hard drive containing videos of therapeutic sessions in the ongoing study of MDMA-assisted therapy for veterans taking place in South Carolina.

These videos are part of my last task as part of the clinical research team: to develop training materials for the Adherence Rating team.

Videos from the study have been pilling up for years now. As the studies progressed, terabytes of hard-drives were constantly filling with videos recording of all of the sessions. Originally, informed consent for the first MDMA-study had called for only audio recording, but it had been modified early on to include permission for video tapping the sessions, as well as permission for the videos to be used in future studies. Which meant that the videos were not just part of the study data—they were possibly the data for studies that had yet to be designed. The researchers continued to record all of the twelve talk therapy sessions lasting between sixty and ninety minutes and three experimental sessions—sessions where either MDMA or the placebo would be administered. There are variations, but that basic design led to over thirty-five hours of video per subject. An every mounting record of the study was building in Switzerland and South Carolina, but nothing had been done with it.

The first time I heard about the videos, was at the at the researchers summit following the *Psychedelic Science* conference. Rick asked the psilocybin researchers if they made video recordings of their sessions and if so what had they done with their recordings. "Eventually," Rick told the psilocybin researchers, "we want to be able to do monitoring to show that we are following our therapy manual." The psilocybin researchers shrugged: they had videos, but no one had any time to watch them.

And so it went for MAPS' videos for the next several years. Until now.

As this section illustrates, watching the videos was just one step. The videos might document the session, but the videos would need to be rated in order to make them into clinical data. The idea behind the Adherence Rating Program worked like this: therapeutic sessions had been video recorded. Adherence Raters would then watch these videos and, using a rating scale based on the treatment manual, they would rate whether or not the therapists had followed said manual. The degree of adherence could be used both as a way to 'correct' therapists, and as a variable to compare across studies—a way to account for difference.

The original plan for training the Adherence Raters had also been simple enough. Michael and Annie had trained one of the raters on the East coast who then trained a second rater. On the West coast there were two raters who had been through the non-drug training—as the seminar with Michael and Annie was called—and were considered qualified to watch the

videos. These two teams, one East and one West coast, each watched and then discussed the videos. Then each person independently rated them. Despite what seemed like a seamless transfer of knowledge, of expertise, of collaboration—a Tardian circuit of imitation—the system failed (Tarde 1903). The raters had widely varying scores. Yes, the general agreement had been that Michael and Annie followed the treatment manual that they wrote, and that the Swiss team didn't, but the raters also produced widely varying scores of the same videos.

I had been sent these videos to produce clips for a new training program: a more comprehensive system for teaching the raters how to watch and evaluate the videos.

I plugged in the hard drive expecting to find dozens of files from multiple subjects, but the files were so massive that videos from just one subject had easily filled the hard drive. I hooked them up to my computer only to find that they crashed it. Each file was only twenty minutes long, and there were almost a hundred of them. I had to convert them to a new format in order to view them. So each evening, before going to bed, I would set a dozen or so to convert.

And each morning for two weeks I awoke and sat down at my computer, coffee and note pad on the right and the treatment manual on the left. And I watched. I kept notes as I watched, marking down bits of dialog, jotting which element of the therapy might be visible at what particular time on each video.

Eventually, the clinical team settled on a procedure for training the raters, which closely followed the procedures for training independent raters to use the CAPS. Trainees would need to submit their Curriculum Vitae to the clinical team to be kept on record. Trainees would need to sign a confidentiality agreement. A list was drafted, wherein the following steps would be checked off and dated as a trainee completed: review the therapy manual, review training videos with trainer, watch videos and submit rating to trainer for review. Review ratings with trainer. Repeat if necessary.

The goal of the training program was to produce ratings with an acceptable level of inter-rater reliability, meaning that the degree of agreement between two different raters using the same scale. As part of the training process, the trainees would watch videos that had already been rated by the trainers. In order to "pass" the training, the trainees would need to rate the videos with an acceptable level of "inter-rater-reliability." The question of how to rate the videos in the end came down to what degree of agreement was necessary to consider the trainee's rating valid. Thus, even training had an outcome measure that could be documented.

Amy-Adherence is a living document. I find this note scribbled in the margins of the minutes I was taking at the Adherence Rating meeting. The brevity of the message cuts cleanly through what I remember as a rambling meeting in which various options for the Adherence Rating program were discussed, but few decisions were made. I don't think that I thought much of the comment at the time—enough to write it down, but not enough to elaborate on it in subsequent notes. But as I go back through my notes for the Adherence Rater Training Program, the phrase catches me. For all of the watching—the training of the therapists and raters—clinical research always seems to resolve itself into documents. What Amy meant of course is that the Adherence Rating Program was open to change and adjustment—hence the metaphorical invocation of the living, organic world. However, what her comment also calls attention to is the fact that Adherence was not just about raters watching videos; it was also a program of documentation.

When Amy states that Adherence is a living document, that it is in fact a document, it begs the question: are documents in this case only mediators, or representations? Or is in fact the entire point of the Adherence Rating Program to produce documents? In other words, do these

documents represent the actions of the therapists or are they actually the object at stake? In the case of the Adherence Rating Training program the goal was not just to produce trained raters. It was also to produce documentation of that rater's training and to quantify their qualification through the inter-rater reliability score.

There are two important points to be drawn from all of this. The first is that the documents that guarantee the data—that prove what did or did not happen in an experimental session—do not work on their own. They are tools that one must be trained to use. The second is that clinical research constantly begets new forms of documentation. However, as I discuss in the next section, not all documents are created equally.

The Stakes

"If they don't adhere it will be shut down."

The Mithoefers, most of the clinical trial research staff, and a number of other people are gathered together around a hotel conference table. It was a relatively rare face-to-face meeting for a group whose research planning made use of conference calls and electronically shared documents. At this moment, the Israeli study is on the cusp of being initiated. If successfully completed, the Israeli study would be MAPS' first study to train therapists in their method and execute the study. And as soon as the Israeli study is initiated, as soon as subjects are enrolled, and treatment begins then there will be videos to rate. It is critical that once the study starts there is a way to monitor what the therapists are doing. The stakes of adherence have heightened. In the first meeting, when adherence was still under development and the question on the table was why the Swiss study results were not as promising as the first US study's results, then there were more questions about what kind of therapy might work. But now, six months later, the stakes are different. As Amy has mentioned, it will be necessary to use the program to explain differences in data, but it will also be a form of monitoring. The Adherence Rating Program won't simply be used to compare studies: it will be used to make sure that the therapists are following the study procedures. In its own way, the Adherence Rating Program is a form of surveillance, like those discussed in Chapter 2. It will be used to monitor the therapists from afar and to make sure that they are acting in accordance with the therapy manual.

On the weekly conference call, Amy and Ilsa asked if we should start incorporating references to the therapy manual in the protocol.

"Is this," I ask*, "because we are worried about accountability or is there a reason to do it from a regulatory perspective?"*

"If we want them to follow the therapy then we have to say it," Amy replies*. "If they are violating the therapy manual then they are also violating the protocol."*

"Yes. But, if we make reference to the manual in the protocol then we will have to submit it to the FDA. And at this point in time, the manual isn't ready for that." Berra points out. *"We would have to get involved with editing it."*

This last comment calls attention to the fact that much of the work of the clinical team centers on editing, drafting and writing. Over the course of my year and a half with the clinical team, I watched as the researchers focused on fine-tuning the language in the documents. The changes were subtle and constant. References to "patients" which had been in earlier versions of protocols were replaced with "subjects." Not only does the term patient imply a specific ethical relationship with a doctor regarding treatment that is inappropriate given the experimental design, but also "subject" is in keeping with the vocabulary used in federal regulation. Careful consideration was given to what information needed to be presented in what document. The goal was to make the language used in protocols consistent across studies. In fact, a shell format for

various study documents was being developed and which would allow the clinical staff to quickly develop new study protocols by standardizing certain sections.

The discussion is also quite telling in that the contractual stakes of the documents are laid out. One of the many documents that must be submitted before the study begins is a contract between the investigator and sponsor. The agreement lays out ownership of the documents, financial arrangements between the sponsor and the investigator, and the duties of the investigator—among which is following the protocol. Thus, if the investigators, as therapists, are required to follow the treatment manual, then that must be stated in the protocol. However, if the protocol refers to the treatment manual, then the FDA will want to see it. And once the therapy manual is submitted to the FDA, once it becomes the domain of the clinical staff, then it will be held to a different standard. As I stated at the beginning of this chapter: not all documents are created equal.

Conclusion

Clinical research does not always lend itself to theater. Treatment with Prozac or Zoloft is made up with thousands of quotidian, private moments. The form of the pill—compact, portable—renders treatment unobtrusive. Even when treatment is rendered publically in concentrated doses through intravenous therapy (IV)—as in certain forms of chemotherapy—the technique of administration is not under scrutiny. The spectacle of effectiveness (or not) comes later, in the viewing of MRI Scans. Which is all to say that as spectacle, or theater, or witnessing to the experimental session, these videos were unusual.

The video taping of the therapeutic sessions in the MDMA study created a scene in which the experiment could be witnessed—one in which I participated. The community of witnesses to these sessions was tightly controlled—only trained raters who had signed consent forms were able to watch. And yet, the videos could not document the experiment on their own. Rather, the videos required another form of mediation; they required documents to render the actions of the therapists quantifiable, ratable, and documentable.

In the *Leviathan and the Air Pump: Hobbes, Boyle and the Experimental Live*, Steve Shapin and Simon Shaffer make reference to the multiple forms of witnessing employed by Robert Boyle in the development of the experimental method (Shapin and Schaffer 1985). In addition to the public witnessing of experiments, Boyle envisioned that publishing descriptions of experiments would create a virtual scene for the reader to witness the experiment in through carefully crafted images and text. The circulation of these texts expanded the public who was allowed to stand in the auditorium and personally witness the experiment. This public is of course not a free or open space—a point that was central to Thomas Hobbes critique of Boyle's new paradigm. But the creation of a public, both immediate to the experiment and virtually through the circulation of texts, was critical to the implementation of the new experimental paradigm. The critical question raised by this chapter is what is this new relationship between witnessing, texts and the experiment being practiced within clinical research? Is this simply the extension of bureaucratic paperwork to pharmaceutical research? Or is there a different story here in which objectivity and the mediation of paperwork are working in a new form of alignment?

Chapter 5: Experiential Politics

You can't understand

"You just can't understand, Katie. You can't."

Geoffrey leans forward with intensity, his eyes focused not quite on me, but somewhere just past me. And as his voice goes on, I become unsure if I am even still there for him. I hope very much that someone will interrupt us. I wish I hadn't brought up my dissertation. I am discomforted, stuck, and feeling slightly panicky—like a bad trip. I feel as if I have become a sounding board to pummeled over and over again with the refrain: You just can't understand.

He goes on, "Unless you have taken MDMA with a guide, an experienced guide. You see these medicines are different. You can't know the experience." I start to say that I am familiar with MDMA, that I have experience with the drug, but this isn't a discussion or a debate—this is for Geoffrey a matter of fact. I leave flustered, not realizing that I have left my jacket behind.

I have been circling about this drug and therapy for a year and a half—edging in at it from different angles. And always in the back of my mind is the question: have I gotten close enough? Geoffrey and I are at an impasse. I want to hear about his experience, to try to understand it or to understand something from hearing it, but for Geoffrey, experience cannot be understood—it cannot be transmitted through discourse. It can only be experienced. When experience and narrative, discourse and knowledge are incompatible, what is left for a writer, a scholar?

Geoffrey's position is slightly extreme. For him, the experience of the medicine in the presence of an experienced guide is unique, going beyond the non-ordinary state that the chemical itself produces to something that is categorically *other*. Throughout my fieldwork I encountered invocations of the importance of being experienced with psychedelics—though more moderate. At its most basic, experience was invoked both by MAPS' therapists and researchers, as well as the guides I interviewed, to mark the therapeutic efficacy of the psychedelics. Whatever the drug does, it does through the experience it provides—an experience of the self, an experience of the universe, or the divine[32]. It is not the treatment, but the mode of accessing the treatment, which is experiential.

In this final chapter, I turn to the category of experience, but not from the point of view of the patients or subjects in MAPS clinical trials. This dissertation has focused on the practicalities of clinical research with psychedelics, choosing to examine how the chemical's effects are manifested in complex entanglements of videos, protocols, psychometric tests, eyeshades, inner space. Narratives of MDMA's effects have been brought together with the practices that make those effects possible. Here, I turn to the relationship between therapists and experience. I interrogate a contradiction at the heart of the MDMA clinical trials: a desire to produce a therapy that endows the chemical with therapeutic efficacy through cultivating the experiential knowledge of the therapist, and a set of research practices that actively seek to decouple the production of knowledge from the self.

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[32] This knowledge was sometimes described through the register of a personal capacity: as when subjects talked about knowing that MDMA reminded them that they had the capacity to feel pleasure. It was also described through the register of re-experiencing memories—even memories that one had repressed.

Whatever the im/possibilities of transmitting knowledge about psychedelics in discursive form, the psychedelic imperative remains: a psychedelic therapist/guide should be experienced in the substances that s/he is administering[33]. In other words, in order to sit for someone, to guide them on a journey, to act as a safe container, one must be experientially knowledgeable about what this person is going through. Being experienced, that quality of *having done* something, makes one capable of inhabiting a particular subject position—a subject capable of authoritative speech about these medicines and also a subject capable of therapeutic practice.

And yet, as I will develop shortly, this imperative sat in unacknowledged tension with efforts to develop a double blind placebo controlled trial. As therapists were asked to develop experiential knowledge—knowledge that would place them in empathetic alignment with their subjects—they were also asked to remain blinded to the treatment condition of their subjects.

MAPS' therapy manual follows the widely agreed upon psychedelic mandate that in order to guide a patient, a therapist should be experienced with non-ordinary states of consciousness. In the manual, the specificity of the chemical state—an MDMA versus a mushroom journey—is not necessarily important. A wide range of practices—from meditation to psychedelics to Holotropic Breathwork™—are counted as inducing non-ordinary states of consciousness. However, the manual emphases that the therapist's experiential knowledge is critical to their effectiveness as healers.

This became an issue as MAPS' clinical trial program expanded and therapists were recruited who were not personally experienced with psychedelics or non-ordinary states of consciousness. Thus, as part of their training, these therapists themselves underwent MDMA-assisted therapy. It was—or is—all perfectly legal. MAPS has approval from the FDA to run a study on MDMA-assisted therapy with healthy volunteers. And the volunteers are all therapists in the studies.

However, even as therapists were being trained to recognize and empathize with the experience of non-ordinary states of consciousness, they were also subject to research techniques that sought to blind them to the treatment condition—through the use of computerized randomization procedures and a placebo. As I discuss, placebos do not have a single function in clinical research. While anthropology for the most part has attended to the placebo effect in relation to patients, placebos are also used to control for the normal progression of disease, as well as to prevent bias from an investigator. This chapter examines the latter use of placebos in relationship to the scientist-as-subject. I argue that clinical research, as an exercise in scientific objectivity rests upon a set of anti-techniques of the self, in which the subject-as-researcher is actively curated as absent, blinded, and therefore objective (Daston & Galison, 2008).

In the conclusion of the chapter, I argue that the objectivity-of-the-placebo points to a conflicted space from which MAPS political claims emanate. Drawing upon interviews and fieldwork, I examine the latent notions of freedom, autonomy and cognitive liberty that

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[33] There is room here in the footnotes for speculation about what I might term a psychedelic public, in which entrance is earned through the cultivation of experiences and not discourse. In this sense, Geoffrey's rejection is not only a political rejection, but also more deeply attempts to assert new terms for inclusion and discussion. At a future date, this might be an intriguing line of inquiry to pursue. The Habermasean public sphere overlaps with discussions of the bourgeois interiority, which are deeply present in psychedelic therapy and which I have hesitated to find a language to talk about.

undergird MAPS clinical trial project, and think about the conflict between a therapy that depends upon personal experience, and a mode of political action that depends upon negating that link between subject and knowledge. The work of Nikolas Rose has influenced a line of scholarship attentive to the relationship between neoliberal logics of self-governance and the biomedicalization of psychiatry (Rose 2007). This chapter is the beginning of an inquiry into a different line of thinking that bridges liberalism, the self and biomedicine. One in which the knowledge practices upon which biomedicine depends—namely the clinical trial—are brought to the forefront of discussion of politics.

Anthropology and Experience

This chapter follows Robert Desjarlais' provocation that experience "is not an existential given but rather a historical possibility predicated on a certain way of being in the world." (Desjarlais 1997). Desjarlais points out that experience often seems to mean something more than the German *erleban*, "to be alive when something happens." This excess is referenced when psychedelic therapists encourage subjects to "stay in the experience." Experiencing a psychoactive substance is more than just having taken it. Experience and experiment have the same etymological roots: *experirir*, the Latin for "to try out." While experiment remains closer to the original Latinate connotations, experience has undergone a critical shift. Dejarlais argues that the modern, subjectivist connotations of experience are not only relatively recent (he traces them to 1588), but also in parallel with a deepening interiority of the Western self. Dejarlais writes: "In contrast to Heidegger, however, I want to argue that experience is not a primordial existential given but rather a historically and culturally constituted process predicated on certain ways of being in the world. Experience is the result of specific cultural articulations of self hood (namely, a sense of the self as possessing depth, interiority, unity, stability, and the capacity for transcendence) as well as certain social and technological conditions that foster and legitimate that sense of self."

My sense, throughout fieldwork and writing up, has been that while many things are drawn together under the sign of experience—and here I am referring to discussions of psychedelics—the term itself is often used as if its meaning and value were self evident. When we use the term experience—and I am purposely roping myself in with my informants—what exactly is being referenced? What is *not* counted as experience? And *how* does one experience? Is it through the mind, or the body? Is it rational or sensorial? When the guides or psychedelic therapists tell their patients to "stay in the experience," what does that entail? And most important, what is the status of knowledge produced from experience?

The website Erowid.org is a member supported non-profit whose mission is "providing access to reliable, non-judgmental information about psychoactive plants, chemicals, and related issues." The website complies extensive information on effects, dosage, history, and legal status of hundreds of psychoactive compounds ranging from LSD to little known chemicals to alcohol to steroid hormones to ginseng—a wide embrace of the boundaries of psychoactive substances. In addition to the extensive catalog of the different effects and risks of various compounds, Erowid has a section titled the Erowid Experience Vaults: a searchable database of tens of thousands of user generated experience reports. The submission report page states: "We are looking for submissions of well-written experience reports about the use of psychoactive plants and chemicals as well as other forms of mind-altering activities such as yoga, meditation, and the use of mind machines." Experience Reports are reviewed before they are accepted, and the website clearly states that not all reports will be accepted. The form requests that the submitter

enter the dose, body weight, gender, age and "experience year." While the site doesn't give firm requirements for publishing experience reports, it does note that reports are more likely to be published if they detail any preparations taken, mindset and setting, other prescription medication or over the counter medications taken (i.e. what else was in your system?), and the timing of dosages. Reports that are less likely to be chosen use the term SWIM (someone who isn't me), or "Language that dictates what someone else will experience, rather than your own experience."

There are two things to note here. First, an immense amount of energy has been expended to create a space for the dissemination of carefully curated, first person descriptions of the mind-altering substances and practices. Erowid frames these records as providing both a historical record of the use of psychoactive substances, but also as a valuable corollary to data produced in scientific and medical settings. As an archive, the Experience Vaults are systematically organized. However, what is critical to note is that no matter how carefully reviewed, or organized these reports are, they will not be able to change the regulatory classification of any of the substances listed. The reports are data, but they are not the right kind

Secondly, the first person is fundamental to the description of experience. And in fact, writers are explicitly encouraged to limit their description to their own realm of experience. "I can only speak for myself here" seems to be the mantra guiding the vaults. This is all to say, that the interiority of experience and autobiographical discourse can merge—despite Geoffrey's concerns. But what this form of knowledge can do, what it can speak to is another thing. Within Erowid's vaults, the "I" of experience can take center stage. In the context of MAPS' studies, the "I" has not been entirely canceled out, as this next section will illustrate.

Drug Training

MAPS' training program for therapists had two components, which were referred to as the drug and non-drug training. The non-drug training consisted of a weeklong retreat filled with power point presentations, video clips and discussions of the therapy manual. The drug training however, referred to psychedelic therapy sessions under the influence of MDMA—a program that MAPS went to special lengths to get approved by the FDA.

There is no section in the American Psychiatric Association's handbook that says that a psychiatrist must try an antidepressant or even an antipsychotic before prescribing them to a patient. Experience with a drug is not necessary for administering most psychotropic medications[34]. While MAPS may use Zoloft and Paxil as its models when it comes to designing the clinical trial, when it comes to defining therapeutic technique, the pharmaceutical model is quickly destabilized. MDMA might be moving through the same regulatory channels as other pharmaceuticals, but the therapeutic model radically departs from that of most pharmaceutical treatments for mental illness.

MAPS' therapy manual provides the following diplomatic language when discussing the kinds of experiences that a therapist needs to guide a session.

Therapists are likely to substantially benefit from personal experience with non-ordinary states of consciousness. Ideally this includes personal experience with MDMA in a therapeutic setting. If this is not possible, a series of Holotropic Breathwork™ sessions (a non-drug method that activates a similar therapeutic process) would also be beneficial (Grof 2000).

[34] Humphry Osmond's early research with LSD in Saskatchewan, hypothesized that psychiatrists would benefit from an LSD journey as it would given them insight into the experience of their schizophrenic patients (Dyck 2010)

This maxim played an important role during the expansion of MAPS' clinical program. As discussed in Chapter 4, Michael and Annie Mithoefer have both trained in Holotropic Breathwork™ with Stan Grof[35]. Peter Oehen—the principle investigator for the second study conducted in Switzerland—had trained with the Swiss Medical Society for Psycholytic Therapy (SAPT)[36]. The Society was formed in 1985, and for a brief period—1988 to1992—the Swiss government granted the group special permission to administer LSD, MDMA and psilocybin to their patients—and to take the drugs themselves as part of training (Langlitz 2013; Saunders 1993). In the early years of developing MAPS clinical program, Doblin stuck to countries with a psychedelic base. However, he also pursued studies in Israel and Jordan, where the therapists were intrigued with the therapy but not experienced[37].

While MAPS' language is a study in neutrality, the long list of reasons supporting a personally experienced therapist belies its significance for the therapy:

- *Increases the therapist's level of comfort with intense emotional experience and its expression.*
- *Provides first-hand validation of and trust in the intelligence of the therapeutic process as it arises from an individual's psyche.*
- *Familiarizes the therapist with the terrain and flavor of non-ordinary states of consciousness. This can be invaluable to the therapist's effort to understand and empathize with the participant's experience. It may especially help therapists to identify features of the experience that might be most helpful and to be comfortable supporting people during times when the process is difficult and unsettling.*
- *Provides the therapist with an intrapersonal working knowledge of the integration process related to this therapeutic approach.*
- *Enhances the credibility of the therapist. The participant's sense of security and treatment alliance deepens with understanding that the therapist has had a similar kind of experience.*

There are two issues raised in this passage. The first is that the emphasis is not on the MDMA experience in particular, but on the non-ordinary state of consciousness. As emphasized in Chapter 3, the agency of the chemical is in tension with the agency of state of consciousness it induces. And secondly, my sense is that the invocation of empathy is central to understanding both why experience is significant and what kind of politics and knowledge that experience engenders. However, I must bookmark that question for future iterations of this work.

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[35] Holotripic Breathwork is a technique of controlled breathing—essentially hyperventilation—which can induce non-ordinary states of consciousness. Stan Grof developed and trademarked the technique in the wake of LSD's criminalization as a way of accessing what he argues is the same therapeutic state of consciousness without the aid of chemicals.

[36] Nicolas Langlitz has a fascinating discussion of the entangled relationship between Swiss psychedelic researchers and financial benefactors in the United States. He delves into critical historical detail around the unconventional development of Switzerland's drug policy—which has often deviated from international policy. And in fact, the Swiss neuroscience laboratory that he worked in as part of his doctoral fieldwork was involved with entangled in interesting ways with MAPS studies.

[37] I do not know what the motivations of the therapists in Israel and Jordan were for participating in the studies.

Psychedelic Placebos

In the months that followed *Psychedelic Science in the 21st Century*, new faces were constantly appearing in the office. The conference had generated a wave of national publicity for MAPS as well as unexpectedly bringing in new revenue for the organization. Building on the momentum of the conference, the board of directors approved the hire of several new staff members. What's more, the attention had spurred an increase in inquiries into volunteer and internship opportunities. MAPS acquired the second floor for its offices to allow for space for the constantly expanding staff.

To give all the new faces a chance to meet and mingle, Randy, the Communications Director, hosted an after hours potluck at the house that he shared with his girlfriend and Brian, his Deputy Communications Director. I stayed slightly late at the office, killing time, before heading out and picking up drinks to bring as my contribution. I settled down on the couch with Berra and Linnae—who had just been hired as a personal assistant for Doblin. However, Linnae, who wrote her senior thesis on the effects of sleep on memory, was actually more interested in the clinical research that Berra and I were working on.

"I keep telling Rick that there is no such thing as a triple blinded study." Berra is saying. Rick likes to throw this out when pitching MAPS' research agenda, since in his mind the fact that the therapists, subjects, and the independent raters who administer the study outcome measures do not know the treatment condition takes the study to the next level. But blinding the independent raters is nothing new.

"Next thing you know, Rick is going to be coming up with a quadruple blinded study. Hey, we don't even know what this powder is," she jokes. "We found it in Sasha's lab," someone from the group calls out. Laughter follows. Sasha Shulgin is the psychedelic chemist who gifted MDMA to psychedelic therapy. A gentleman scientist of a bygone era, Sasha published several tomes with his wife Anne describing their personal experimentations with all of Sasha's chemical-progeny. If there had been a place where one might stumble upon a wholly new psychoactive chemical, Sasha's lab would have been it. While it may ruin a joke to explain it: the idea of administering a wholly unknown chemical breaks not only any semblance of a safely controlled clinical trial, but it also breaks with one of the central tenants of safe experimentation with psychedelics: always know what you are taking. Know whom you bought if from. Know the drug's effects. Know the risks. The absurdity of just popping some white powder in service to the all-important Blind of a clinical trial, to Objectivity, to Science, is what makes the joke funny.

Of course, blinding the study has been the methodological sticking point for MAPS for years. When the results of the first MDMA-PTSD study were eventually published, reviewers critiqued the use of lactose as a placebo(Mithoefer et al. 2011). The substance was too inert, too inactive. How, reviewers asked, could MAPS claim that they had done a properly blinded study when the placebo would have been obvious to the researchers? After the first study, MAPS began using what they have called an "active placebo," meaning that the placebo was psychoactive. MAPS considered a number of options, including using Ritalin as the active placebo. For their second MDMA-PTSD study in the US, MAPS settled on using three dose conditions: a subclinical dose of MDMA, a medium dose and a full dose. In this case, the active placebo was 25mg of MDMA, the medium dose was 75mg and full dose condition was 125mg. The idea being that a low dose of MDMA would be "effective" enough to confuse the therapists as to what treatment condition the subject was in, but would not be therapeutic. As Rick summed it up during a meeting, "We are looking for the dose that fools us without working."

Being fooled was measured quite simply by recording the investigator's "Belief of Condition Assignment" at the end of the experimental session in the source records. In the first study, they had been "right" a hundred percent of the time. But as Michael asked the group, "How often do we need to be wrong," Michael asked, "in order to show that the blind is working?"

Medical anthropologists have typically focused on the placebo in relationship to the patient (Scheper-Hughes and Lock 1987; Moerman 2002). As Moerman argues, patients respond to the form not the content of the drug. However, placebos are used in order to fool doctors as well as patients, and it is on the former that the scientific merit of the study hinges. The institutionalization of the double-blind placebo controlled study (as discussed in Chapter 2) had much more to do with controlling for the progress of a disease and to prevent the investigator from biasing the outcome of the study. As Doblin and Mithoefer rephrased the problem, it became clear that the issue was not about the unexplained phenomena of psychosomatic healing, but instead the objectivity of the researchers.

Data can be controlled in a number of ways. Woven into the demand that investigators remain blind to the subject's treatment condition is the supposition that scientific research requires an objective researcher. However, this supposition is itself historically specific. Historians Lorraine Daston and Peter Galison have argued that objectivity should not be simply taken as a co-extensive with science, itself. Rather, the concept of objectivity has a complicated history (Daston and Galison 2008). In particular, the contemporary pairing of objectivity as the opposite of subjectivity—the point of view from which subjective knowledge becomes biased—arose as recently as the mid 19th century. They write: "The negating of subjectivity by the subject became objectivity." Thus the very concept of objectivity emerges as a negation of subjectivity—but one that paradoxically always requires a subject to do the negating.

Even when using an active placebo, MAPS study team still struggled with ensuring that the therapists were as blind as possible. One of the sticking points was the blood pressure monitor, which is both a study necessity and detrimental to the very design of the study itself. On the one hand, the machine is a safety measure. Because MDMA is part amphetamine, the FDA has required the use of a blood pressure monitor throughout the experimental sessions. However, in tracking the specific physiological effects and risks of the investigational product, the blood pressure monitor makes it very clear when a subject has received the placebo and when they have received MDMA. The fact that the machine effectively un-blinds the study has made it a source of consternation in study design.

There was speculation instigated by Michael that they could potentially cover the machine so that neither he nor Annie could see the ratings. Of course, they would still need some way of being alerted if the patient's blood pressure rose too high. But the idea was dismissed during clinical meetings since there would be no way to prove that Annie and Michael didn't peek at the machine during the session. To quote, Amy, the director of clinical research: "My beef with covering the machine is that we can't prove they didn't look." There is something insidious about the kind of imagination that one is asked to have here. There is no room in clinical research for the gentleman scientist whose word is his name. Rather, everything done or that is said that is done in the process of a study must have some form of verification. If one wants to create a control by covering the blood pressure monitor, then it must have a mode through which one can verify that the cover was not removed. As a researcher, Michael's actions are not just suspect, but in need of corroboration.

Daston and Galison argue that the opposition of objectivity to subjectivity required a particular understanding of the scientific self, one who posed a danger to objective knowledge.

More specifically, in Daston and Galison's reading, the negative imperative to actively delete oneself from the field of scientific inquiry depended on a specific, Kantian understanding of the self—a self that actively imposed itself on the world, in contrast, to an Enlightenment understanding of a malleable self. In this equation, the good scientist, the ethical scientist, must write himself out of the experiment in order to produce objective knowledge. Self-distortion of observation had posed a danger to Enlightenment thinkers as well, but they had a simple solution "Double ones passion for the truth."

Bringing this all together: if the institution of a double-blind, placebo controlled trial is in part about producing a historically situated notion of objective knowledge—one in which objectivity and subjectivity are opposites—then part of the goal of clinical research is to write the subject out of the production of knowledge. More to the point, the subject is not simply written out by employing a placebo in the research design. Going back to the discussion in Chapter 2 of the encapsulation of MDMA at the beginning of the clinical trial, an entire apparatus of envelopes, techniques operating procedures must be employed in order to ensure that the investigator, Michael, doesn't know what is in that envelope. Not only that, but Michael cannot speak to his own actions. Layers and layers of documentation must be employed such that every aspect of the clinical trial can be recreated (as discussed in Chapter 4). The guarantee of what did or did not happen in the clinical trial is always displaced to dense layers of documentation. And although subjects actively produce those documents—the investigators initial every page of the source and CRF's—ultimately it is the document that speaks for data in the trial.

And yet, the therapists, even if they must be blind, must be experienced.

Blinding a Technique

It is over a hundred degrees—or feels that way— in the clinical trial office at MAPS' headquarters. "If this was a psych study, blinding wouldn't matter"…. Berra and I are two of only four people in the office that day. Everyone else has already left for Burning Man. Berra and I are discussing plans to develop an adherence-rating program that will measure whether different therapists are all following the same procedures. "There is no way to blind a study that is testing a therapeutic technique, which is what we are doing." "What would you use as a placebo," I ask? "You wouldn't. You would just have a control group who received a different kind of therapy, or no therapy at all. In our case, perhaps just talk therapy." It is not just that it is difficult to blind the study because of the robust effects of MDMA on the affectual state of the subject. It is also difficult to blind a study when it is a therapeutic technique that is being studied.

MAPS' clinical trials may sit at a juncture between a therapeutic technique and a pharmaceutical treatment; however, it is the legal status of the pharmaceutical that is at stake, so they must follow the conventions of pharmaceutical research. Clinical knowledge about a therapeutic technique is not of political importance. What are important are the effects of the drug. Thus, it is not just objectivity that is at work here, but a specific form that has become tied to the pharmaceutical.

In the Desert

The camera was posed on each of them, as the man with the graying ponytail asked, "So have you taken LSD?" Each hesitated. Not for long, but long enough to give the impression that they were either uncomfortable or surprised. Was it the camera? Or was it the bluntness of being asked what they all considered to be a foregone conclusion? One of the younger

psychonauts, hair blown with dust from the playa[38], smiled and said, "Yes, I am experienced with that sacred medicine."—Acknowledging her experience but also invoking registers of healing, ritual and religion.

My mother has told me of coming home from the University of Portland to San Francisco in 1967, and seeing her cousin wearing a pin with Timothy Leary's infamous imperative: "tune in-turn on-drop out." "Really," my mother asked? "Really," her cousin replied. That pin marked a difference. A difference in orientation. A difference in politics. A difference in *experience*. A difference that still matters to the cameraman wandering Black Rock City, interviewing this younger generation garbed in artisan leather, asking to see whom else has turned on.

But psychedelic politics have changed since the 1960's—a fact that is underscored by the entire clinical trial project which rests not on turning on as many citizens as possible, but on establishing bureaucratically recognizable forms of knowledge around these chemicals. In Jay Stevens' pop historical account of rise of psychedelic in the United States, he writes of the call by figures like Allen Ginsberg that all Americans, from the president on down should try LSD, "Drop acid and change yourself, change yourself and then change the world" writes Stevens. In Ginsberg's formulation, the citizen was the unit of political change. But it doesn't seem to me that we are in that moment anymore. The politics of experience is changing. Yes, there might still be room for sharing being experienced in forums like Erowid's Experience Vaults. But the medicinal begs a different set of questions around politics and experience. I can't help feeling just a little sadness for that cameraman, and nostalgia for that kind of connection and politics that he wants to recreate.

Psychedelic Politics

It was fairly common that at a presentation on MAPS' clinical trial program someone from the audience would raise their hand and ask, "But what about psychedelic therapy for healthy people," followed by mummers of approval from the crowd. The implication hanging in the air: What about us? Shouldn't we have legal access to these drugs as well? These provocations would usually lead in to a discussion of the various non-pathological studies done around psychedelics—particularly of using psychedelics to facilitate creativity or spiritual growth (Sessa 2008; Griffiths et al. 2006; Doblin 1991).

These questions throw into relief the conservatism (or perhaps pragmatism) of MAPS' clinical trial program. MAPS is not developing MDMA as an enhancement technology (Hogle 2005). Though, one could speculate that there would be ample money from Silicon Valley donors to fund studies of creativity. Framing psychedelics as tools to self-enhancement and, by extension, to freedom of consciousness, has been percolating in the psychedelic community for years. The Center for Cognitive Liberty and Ethics was active in the Bay Area from about 2000 to 2005. While their following mission statement never mentions psychedelics, it is easy to see how psychedelics could fit into the category of neurotechnologies. "The Center for Cognitive Liberty & Ethics (CCLE) is a network of scholars elaborating the law, policy and ethics of freedom of thought. Our mission is to develop social policies that will preserve and enhance freedom of thought into the 21st century. Growing knowledge in the neurosciences, enhanced by exponential advances in pharmacology and other neurotechnologies (technologies that make it possible to monitor and manipulate the brain's electrochemistry) are rapidly moving brain

[38] The playa is the geographic name of the lake bed in Nevada where Burning Man is annually held.

research and clinical applications beyond the scope of purely medical use. The definitions of "medicine" and "mental health" are expanding from treatment and prevention, to improvement and enhancement. The CCLE is dedicated to protecting and advancing freedom of thought in the modern world of accelerating neurotechnologies. Our paramount concern is to foster the unlimited potential of the human mind and to protect freedom of thought." While the word psychedelic isn't used in any place on the website, the list of Board of Advisors features a number of psychedelic researchers and activists, ranging from Rick Doblin to Sasha Shulgin to Ralph Metzner—who got his start working with Timothy Leary at Harvard University on his experiments with psychedelics. While CCLE might have had a broader picture than psychedelics in mind when speaking of neurotechnologies—brain stimulators come to mind—it is clear that psychedelics are caught up in discourses of cognitive freedom—even if these are not the terms of current political action.

More important than cognitive freedom, MAPS is not pursing the psychedelic-as-sacrament intervention implicitly referenced by the studies of mystical experiences and psychedelics. MAPS and the Heffter Foundation may be the main sponsors of clinical research with psychedelic drugs, but there are a number of other small non-profits that contribute to the studies in various ways. The Council on Spiritual Practice, "covened" in 1993 and organized by Bob Jesse in 1994, is one such organization. The CSP website describes the mission of the organization as follows: "The Council on Spiritual Practices is a collaboration among spiritual guides, experts in the behavioral and biomedical sciences, and scholars of religion, dedicated to making direct experience of the sacred more available to more people. There is evidence that such encounters can have profound benefits for those who experience them, for their neighbors, and for the world. CSP has a twofold mission: to identify and develop approaches to primary religious experience that can be used safely and effectively, and to help individuals and spiritual communities bring the insights, grace, and joy that arise from direct perception of the divine into their daily lives." When psychedelics were criminalized at the end of the 1960's, resistance mobilized around the claim that as religious sacraments, use of LSD, mushrooms and peyote was protected under the First Amendment. However, outside of the Native American Church, there has been limited success[39]. The Council on Spiritual Practice has sponsored MAPS' conferences,

[39] The history of the various churches using psychedelics as sacraments formed during this era is in itself quite textured. In 1958, physicians John and Louisa Aiken founded a small reading group to explore meaning of life. Member of the local Presbyterian congregation, the couple felt that the Church failed to deeply address the questions they had in the wake of the deaths of two of their sons. The group began experimenting with peyote after reading Humphrey Osmond's research on psychedelics. They incorporated The Church of the Awakening, a non-profit religious organization in 1963, to protect their use of peyote for spiritual growth. The Neo-American Church was founded in 1964 by Author Kleps, who called himself Chief BooHoo. In contrast to the earnestness of The Church of the Awakening, the Neo-American church actively curated itself as a parody of organized religion, and took LSD as its sacrament. Lastly, in 1966, a month before LSD became illegal in California, Timothy Leary founded the League for Spiritual Discovery. Leary shut the organization down a few years later, but it was revitalized in 2006. The organization continues to maintain that use of entheogens (which means God manifesting and is often used in place of the term psychedelic) is protected under the First Amendment.

research on psychedelics and mysticism and is one instantiation of the continued association in the United States between spirituality and psychedelics.

The 1970 Controlled Substances Act granted an exemption for the use of peyote by the Native American Church. However, the limits of that permission have been variously defined in different states. In most cases, one cannot join the Native American Church and take peyote as a sacrament unless one can prove that one is a member of a Native American tribe. The claim to a supposedly transcendent religious spirituality has been limited by the particularity of racial descent. Elizabeth Povinelli has framed this clash through what she calls the conflicting binds of the autological and genealogical in late liberalism, wherein aims to autological self making are consistently in tension with mandates for the genealogical ties of tradition and decent—and vice versa (Povinelli 2006).

What is important is this: as a political tactic MDMA-as-therapy exists alongside a variety of other possible claim making strategies. Not all of them are employed around MDMA, per se, but they are all being made by people within the psychedelic community with the larger view of creating a legal venue for a particular type of *experience*—that is a non-ordinary state of consciousness. To go back to the hands raised in the crowd, asking for psychedelics for healthy people, the narrow use of MDMA-as-therapy only holds within the confines of the clinical trial. In the larger psychedelic community, the use of MDMA and other psychedelics for spiritual connection, self-enhancement, creativity, growth and therapy are all interconnected. MAPS is carving out one particular modality of use, isolating it within the space of a clinical trial, and seeking to create scientifically legitimate knowledge about its value.

The easy narrative that *could* emerge at this moment is that as claims to freedom of thought or religion have failed, biomedicine became the space of claim making. MAPS' president, Rick Doblin, often talks of mainstreaming psychedelics, saying that they want to be part of the culture—not the counter culture. Thus, developing MDMA as a psychopharmaceutical allows MAPS to accesses the biopolitical realm that has come to dominate contemporary social life. I propose three problems to this narrative. One, as outlined in Chapter 1, psychedelic chemicals emerge out of the industrial chemistry at the end of the 19th century had have always been entangled with medical and therapeutic use. In order to adequately address the kind of political action at work in these clinical trials, one must take this longer pharmaceutical history into account.

Two, the MDMA-clinical trials do not easily fit into the typical examples of patient-based movements. Numerous social scientists have called attention to the intersection between biomedicine, identity, emergent forms of sociality, and advocacy (Clarke et al. 2003; Rabinow 1996; Epstein 1996). MAPS' clinical trials at first seem to easily fit into that genre. Is this not a case where individuals are advocating for treatments not made available by the market or the state? Are they not themselves authoring the scientific change they want to see in the world? And yet, there are critical differences between the MDMA-clinical trials and the AIDS patients organizing their own clinical trials of experimental treatments or cancer patients. The fact of the matter is: MAPS is not treating itself or advocating on its own behalf. It is advocating for a patient population—in this case PTSD—which does not overlap with the people amassing at its conferences or writing checks to support the research. These studies aim to emancipate a chemical, not empower a patient population—even if MAPS does lean on Veterans with PTSD as sympathetic figures when making is case.

Three, and most important, the critical relationship between experience and knowledge, which still exists within MAPS studies is ignored with in a biopolitical framework. Scientific or

pharmaceutical knowledge is not the only kind at work here. There is still something deeply important about experience as a form of knowledge both within the therapeutic technique being studied and within the larger psychedelic community. However, the history, practice and efficacy of experiential knowledge are questions for future work.

Conclusion

In 2008, I decided to shift my doctoral research project from a loosely defined project on club drug use in Berlin to a loosely defined project on the Multidisciplinary Association for Psychedelic Studies. At the time, the clinical program was quite small, tenuous even. In 2015, as I am preparing the dissertation for filing, MAPS is projecting that it will complete its Phase 2 studies by the end of the year, and that the FDA may approve Phase 3 by mid 2016. According to the organization's annual financial reports, they have been setting aside a significant portion of revenue to fund the anticipated Phase 3 studies that will provide the basis of their application for the approval of MDMA as a prescription pharmaceutical.

Even more bold, MAPS is currently projecting that MDMA may be approved by the FDA as a prescription pharmaceutical by 2021. In anticipation of the approval of MDMA, MAPS announced the formation of MAPS Public Benefit Corporation (MPBC): "a new wholly owned subsidiary of MAPS. The special purpose of MPBC is to serve as a vehicle for conducting MAPS' research, and to balance social benefits with income from the legal prescription sale of MDMA, other psychedelics, and marijuana." (Burge 2015)

MAPS has long called itself a non-profit pharmaceutical company. However, the launch of MPBC (yes, one last acronym before the dissertation concludes) is in essence the launch of a for profit pharmaceutical company that will conduct research and sell prescription pharmaceuticals—just like any other pharmaceutical company. MAPS claims that MPBC will be able to sell prescription MDMA—a taxable activity not permissible under MAPS' current status—and that the funds will be used to further both their research program and public education. "Income from prescription sales of MDMA will help fund further research and educational projects in accordance with MAPS' mission, reducing MAPS' reliance on donations over the long term."

Given these developments, it is hard to frame these clinical trials as small or tentative.

And the farther that MAPS moves along its charted course, the more difficult it is to not see these clinical trials through the lens of the political.

This dissertation has attempted to circumvent this move, this trajectory by focusing on practice. What are the minute practices through which these claims are being made? Pen on paper, training adherence raters, the collection of spontaneously reported reactions, the use of eyeshades.

While many of the chapters opened up questions that must be pursued at a later date, the discussion on experience in the final chapter opens up several lines of inquiry that I hope to pursue in the future:

What would it mean to return to the questions raised by critical phenomenology in light of recent work that collectively decenters the human through its focus on multiple ontologies (Mol 2002) and the vibrancy of matter (Bennett)?

Two, if, following Dejarlais' chronicle of the deepening interior space of the subject in the vis-à-vis the work of Charles Taylor, the body becomes a vehicle for perceiving an increasingly exterior world, then what is the status of the neuroplasticity of the brain in this schema? What kind of interiority is at work in neuroplasticity, if any at all?

And lastly, if interiority is critical to liberal concepts of subjectivity, then how might a therapy that actively cultivates this kind of interiority be fit within theories of political action?

Bibliography

Abadie, Roberto. 2010. *The Professional Guinea Pig: Big Pharma and the Risky World of Human Subjects*. Durham: Duke University Press.

Acker, Caroline Jean. 2005. *Creating the American Junkie: Addiction Research in the Classic Era of Narcotic Control*. Baltimore: The Johns Hopkins University Press.

Adams, Vincanne, Suellen Miller, Sienna Craig, Nyima, Sonam, Droyoung, Lhakpen, and Michael Varner. 2005. "The Challenge of Cross-Cultural Clinical Trials Research: Case Report from the Tibetan Autonomous Region, People's Republic of China." *Medical Anthropology Quarterly* 19 (3): 267–89.

American Psychiatric Association. 2000. *Diagnostic and Statistical Manual of Mental Disorders*. 4th Editio. Washington DC.

Bargaje, Chitra. 2011. "Good Documentation in Clinical Research." *Perspetives in Clinical Research* 2 (2): 59–63.

Barry, a. 2005. "Pharmaceutical Matters: The Invention of Informed Materials." *Theory, Culture & Society* 22 (1): 51–69.

Bennett, J. 2010. *Vibrant Matter: A Political Ecology of Things*. Durham: Duke University Press.

Biehl, João. 2004. "The Activist State: Global Pharmaceuticals, AIDS, and Citizenship in Brazil." *Social Text* 22 (3).

Buckland, Michael K. 1998. "What Is a ' Document '?"

Burge, Brad. 2015. "Press Release: MAPS Announces Formation of New Public Benefit Corporation to Conduct Research and Sell MDMA by Prescription." *MAPS in the Media*. http://www.maps.org/maps-media/media/5555-press-release-maps-announces-formation-of-new-public-benefit-corporation-to-conduct-research-and-sell-mdma-by-prescription.

Center for Drug Evaluation and Research. 2015. "Information for Consumers (Drugs) - The FDA's Drug Review Process: Ensuring Drugs Are Safe and Effective." Center for Drug Evaluation and Research. Accessed May 8. http://www.fda.gov/Drugs/ResourcesForYou/Consumers/ucm143534.htm.

———. 2012. *Guidance for Industry Suicidal Ideation and Behavior : Prospective Assessment of Occurrence in Clinical Trials Guidance for Industry Suicidal Ideation and Behavior : Prospective Assessment of Occurrence in*.

Clarke, Adele E, Laura Mamo, Jennifer R Fishman, Janet K Shim, and Jennifer Ruth Fosket. 2003. “Biomedicalization: Technoscientific Transformations of Health, Illness, and U.S. Biomedicine.” *American Sociological Review* 68 (2). American Sociological Association: 161.

Cloud, John, Buia Carole, Fulton Greg, Park Alice, Shannon Elaine, and Thompson Dick. 2000. “The Lure of Ecstasy. (cover Story).” *Time* 155 (23): 62.

Courtwright, DT. 1982. *Dark Paradise: Opiate Addiction in America before 1940*. Cambridge, Massachusetts: Harvard University Press.

Craddock, Susan. 2004. “AIDS and Ethics: Clinical Trials Pharmaceuticals and Global Scientific Practice.” In *N HIV and AIDS in Africa: Beyond Epidemiology.*, edited by E. Kalipeni, S. Craddock, J. Oppong, and J. Ghosh, 240–51. Oxford: Blackwell Publishing.

Daston, Lorraine. 2000. “Introduction: The Coming into Being of Scientific Objects.” In *Biographies of Scientific Objects*, 1–14. Chicago: University of Chicago Press.

Daston, Lorraine, and Peter Galison. 2008. *Objectivity*. New York: Zone Books.

“DEA Office of Diversion Control - About Us.” 2015. Accessed May 8. http://www.deadiversion.usdoj.gov/Inside.html.

Desjarlais, Robert R. 1997. *Shelter Blues: Sanity and Selfhood Among the Homeless*. Philadelphia: University of Pennsylvania Press.

Doblin, Richard Elliot. 1991. “Pahnke’s ‘Good Friday Experiment’: A Long-Term Followup and Methodological Critique.” *Journal of Transpersonal Psychology* 23 (1).

———. 2000. “Regulation of the Medical Use of Psychedelics and Marijuana.” Harvard University.

Doidge, Norman. 2007. *The Brain That Changes Itself: Stories of Personal Triumph from the Frontiers of Brain Science*. New York City: Penguin Books.

“Drug History.” 2015. *TheDEA.org*. Accessed May 1. http://thedea.org/drughistory.html.

Dumit, J. 2004. *Picturing Personhood*. *Brain Scans and Biomedical Identity.* Princeton: Princeton University Press.

———. 2012. *Drugs for Life: How Pharmaceutical Companies Define Our Health*. Durham: Duke University Press.

Dyck, Erika. 2010. *Psychedelic Psychiatry: LSD from Clinic to Campus*. Baltimore: Johns Hopkins Univeristy Press.

Ecks, Stefan. 2005. “Pharmaceutical Citizenship: Antidepressant Marketing and the Promise of Demarginalization in India.” *Anthropology & Medicine* 12 (3): 239–54.

———. 2008. “Global Pharmaceutical Markets and Corporate Citizenship: The Case of Novartis’ Anti-Cancer Drug Glivec.” *BioSocieties* 3 (2): 165–81.

Epstein, Steven. 1996. *Impure Science: AIDS, Activism, And the Politics of Knowledge*. Berkeley: University of California Press.

Ferro, Shaunacy. 2015. “WHY DOCTORS CAN’T GIVE YOU LSD (BUT MAYBE THEY SHOULD).” *Popular Science*. Accessed May 10. http://www.popsci.com/science/article/2013-04/new-science-lsd-therapy.

Food and Drug Administration. 2014. “What Is a Serious Adverse Event?” Accessed October 1. http://www.fda.gov/Safety/MedWatch/HowToReport/ucm053087.htm.

Foucault, M. 1977. *Discipline and Punish: The Birth of the Prison*. *Alan Sheridan (New York: Vintage, 1979)*. New York: Pantheon.

Freudenmann, Roland W, Florian Oxler, and Sabine Bernschneider-Reif. 2006. “The Origin of MDMA (ecstasy) Revisited: The True Story Reconstructed from the Original Documents.” *Addiction* 101 (9): 1241–45.

Garriott, William Campbell. 2011. *Policing Methamphetamine: Narcopolitics In Rural America*. New York City: New York University Press.

Geest, S Van der, and SR Whyte. 1991. *The Context of Medicines in Developing Countries: Studies in Pharmaceutical Anthropology*. Amsterdam: Het Spinhuis.

Geest, S Van der, SR Whyte, and A Hardon. 1996. “The Anthropology of Pharmaceuticals: A Biographical Approach.” *Annual Review of Anthropology* 25: 153–78.

Gomart, Emilie. 2002. “Methadone: Six Effects in Search of a Substance.” *Social Studies of Science* 32: 93–135.

Greene, Jeremy A. 2007. *Prescribing by Numbers: Drugs and the Definition of Disease*. Baltimore: Johns Hopkins Univeristy Press.

Griffiths, R. R., W. a. Richards, U. McCann, and R. Jesse. 2006. “Psilocybin Can Occasion Mystical-Type Experiences Having Substantial and Sustained Personal Meaning and Spiritual Significance.” *Psychopharmacology* 187 (July): 268–83.

Grof, Stan, and Christina Grof. 2010. *Holotropic Breathwork: A New Approach to Self-Exploration and Therapy*. State University of New York Press.

Hardman, HF, CO Haavik, and MH Seevers. 1973. “Relationship of the Structure of Mescaline and Seven Analogs to Toxicity and Behavior in Five Species of Laboratory Animals.” *Toxicology and Applied …* 25 (2): 299–309.

Hayden, Cori. 2007. “A Generic Solution ? Pharmaceuticals and the Politics of the Similar in Mexico.” *Current Anthropology* 48 (4): 475–95.

“Headquarters News Releases, 09/23/14.” 2014. *DEA.gov*. http://www.dea.gov/divisions/hq/2014/hq092314.shtml.

Healy, David. 1997. *The Antidepressant Era*. Cambridge, Massachusetts: Harvard University Press.

Herzberg, David. 2006. “‘The Pill You Love Can Turn on You’: Feminism, Tranquilizers, and the Valium Panic of the 1970s.” *American Quarterly* 58 (1): 79–103.

Hoffman, Roald. 1995. *The Same and Not the Same*. Columbia University Press.

Hogle, Linda F. 2005. “Enhancement Technologies and the Body.” *Annual Review of Anthropology* 34 (1): 695–716.

Hull, Matthew S. 2012. “Documents and Bureaucracy*.” *Annual Review of Anthropology* 41 (August): 251–67.

Insel, Thomas. 2015. “Director’s Blog: Transforming Diagnosis.” *National Institute for Mental Health*. Accessed April 30. http://www.nimh.nih.gov/about/director/2013/transforming-diagnosis.shtml.

Jain, S. Lochlann. 2013. *Malignant: How Cancer Becomes Us*. University of California Press.

Jain, SL. 2010. “The Mortality Effect: Counting the Dead in the Cancer Trial.” *Public Culture* 22 (1): 89–117.

Jeffreys, Matt. 2014. “Clinician’s Guide to Medications for PTSD.” *National Center for PTSD*. http://www.ptsd.va.gov/professional/treatment/overview/clinicians-guide-to-medications-for-ptsd.asp.

Johnston, Lloyd D, Patrick M O Malley, Jerald G Bachman, and John E Schulenberg. 2006. *Demographic Subgroup Trends for Various Licit and Illicit Drugs, 1975-2005. Monitoring the Future Occasional Paper*.

Kass, Nancy E, Lelia Chaisson, Holly A Taylor, and Jennifer Lohse. 2011. “Length and Complexity of US and International HIV Consent Forms from Federal HIV Network Trials.” *Journal of General Internal Medicine* 26 (11): 1324–28.

Kleinman, Arthur, and Adriana Petryna. 2006. *Global Pharmaceuticals: Ethics, Markets, Practices*. Duke University Press.

Krasny, Michael. 2010. "Psychedelics Conference." *KQED-Forum*, April 15.

Kuzmarov, Jeremy. 2009. *The Myth of the Addicted Army: Vietnam and the Modern War on Drugs*. Univ of Massachusetts Press.

Lakoff, A. 2005. *Pharmaceutical Reason: Knowledge and Value in Global Psychiatry*. Cambridge: Cambridge University Press.

Langlitz, N. 2013. *Neuropsychedelia: The Revival of Hallucinogen Research since the Decade of the Brain*. Berkeley: University of California Press.

Lesch, JE. 2007. *The First Miracle Drugs: How the Sulfa Drugs Transformed Medicine*. Oxford: Oxford Unviersity Press.

Leys, Ruth. 2000. *Trauma: A Genealogy*. Chicago: University of Chicago Press.

Lloyd, Author C C. 1963. "The Conquest of Scurvy." *The British Society for the History of Science* 1 (4): 357–63.

Luhrmann, T.M. 2001. *Of Two Minds: An Anthropologist Looks at American Psychiatry*. New York City: Vintage Books.

Madrigal, Alexis. 2010. "Modern Psychedelic Scientists Find Data in Countercultural Past." *Wired.com*. http://www.wired.com/2010/04/the-new-psychedelic-science/#ixzz0m2MVtY9m.

Marks, Harry M. 2000. *The Progress of Experiment: Science and Therapeutic Reform in the United States, 1900-1990*. Cambridge University Press.

Mccann, U D, Z Szabo, U Scheffel, R F Dannals, and G A Ricaurte. 1998. "Positron Emission Tomographic Evidence of Toxic Effect of MDMA (' Ecstasy ') on Brain Serotonin Neurons in Human Beings." *The Lancet* 352: 1433–37.

Meyers, Todd. 2013. *The Clinic and Elsewhere: Addiction, Adolescents, and the Afterlife of Therapy*. University of Washington Press.

Mintzer, Scott, Susan Hickenbottom, and Sid Gilman. 1999. "Parkinsonism after Taking Ecstasy." *New England Journal of Medicine* 340 (18): 1443.

Mithoefer, Michael C, Mark T Wagner, Ann T Mithoefer, Lisa Jerome, and Rick Doblin. 2011. "The Safety and Efficacy of {+/-}3,4-Methylenedioxymethamphetamine-Assisted Psychotherapy in Subjects with Chronic, Treatment-Resistant Posttraumatic Stress

Disorder: The First Randomized Controlled Pilot Study." *Journal of Psychopharmacology (Oxford, England)* 25 (4): 439–52.

Moerman, Daniel. 2002. *Meaning, Medicine, and the" Placebo Effect."* Cambridge: University of Cambridge Press.

Mol, Annemarie. 2002. *The Body Multiple: Ontology in Medical Practice*. Durham: Duke University Press.

Murphy, M. 2006. *Sick Building Syndrome and the Problem of Uncertainty: Environmental Politics, Technoscience, and Women Workers*. Durham: Duke University Press.

Musto, David, and Pamela Korsmeyer. 2002. *The Quest for Drug Control: Politics and Federal Policy in a Period of Increasing Substance Abuse, 1963-1981*. New Haven, Conneticut: Yale University Press.

Musto, DF. 1987. "The American Disease: Origins of Narcotic Control." *NY: Oxford*.

Nguyen, Vinh-Kim. 2005. "Antiretroviral Globalism, Biopolitics, and Therapeutic Citizenship." In *Global Assemblages: Technology, Politics, and Ethics as Anthropological Problems*, edited by Aiwa Ong and S. Collier, 124–44. Blackwell Publishing.

Nichols, DE. 1986. "Differences between the Mechanism of Action of MDMA, MBDB, and the Classic Hallucinogens. Identification of a New Therapeutic Class: Entactogens." *Journal of Psychoactive Drugs* 18 (4).

Oram, Matthew. 2012. "Efficacy and Enlightenment: LSD Psychotherapy and the Drug Amendments of 1962." *Journal of the History of Medicine and Allied Sciences*, August, 1–30.

Paulozzi, Leonard, Grant Baldwin, Gary Franklin, R. Gil Kerlikowske, Christopher M. Jones, Neelam Ghiya, and Tanja Popovic. 2012. "CDC Grand Rounds: Prescription Drug Overdoses - a U.S. Epidemic." *Morbidity and Mortality Weekly Report* 61 (1): 10–13.

Peterson, Kristin. 2014. "On the Monopoly: Speculation, Pharmaceutical Markets, and Intellectual Property Law in Nigeria." *American Ethnologist* 41 (1): 128–42.

Petryna, Adriana. 2009. *When Experiments Travel: Clinical Trials and the Global Search for Human Subjects*. Princeton: Princeton University Press.

Povinelli, Elizabeth A. 2006. *The Empire of Love: Toward a Theory of Intimacy, Genealogy, and Carnality*. Duke University Press.

Rabinow, Paul. 1996. "Artificiality and Enlightenment: From Sociobiology to Biosociality." In *Essays on the Anthropology of Reason*, edited by Jonathan Crary and Sanford Kwinter, 91–111. Princeton University Press.

Raikhel, Eugene. 2010. “Post-Soviet Placebos : Epistemology and Authority in Russian Treatments for Alcoholism.” *Culture Medicine Psychiatry* 34: 132–68.

Reneman, L, J Booij, and J Lavalaye. 2002. “Use of Amphetamine by Recreational Users of Ecstasy (MDMA) Is Associated with Reduced Striatal Dopamine Transporter Densities: A B-CIT SPECT Study–preliminary Report.” *Psychopharmacology* 159: 335–40.

Ricaurte, GA, and J Yuan. 2002. “Severe Dopaminergic Neurotoxicity in Primates after a Common Recreational Dose Regimen of MDMA (‘ Ecstasy’).” *Science* 297 (5590): 2260–63.

Rose, N. 2007. “The Politics of Life Itself. Biomedicine, Power and Subjectivity in the 21st Century.” *Princeton, NJ: Princeton UP*.

Saethre, Eirik, and Jonathan Stadler. 2013. “Malicious Whites, Greedy Women, and Virtuous Volunteers: Negotiating Social Relations through Clinical Trial Narratives in South Africa Clinical Trial Narratives in South Africa.” *Medical Anthropology Quarterly* 27 (1): 103–20.

Sandison, R. A. 1954. “Psychological Aspects of the LSD Treatment of the Neuroses.” *The British Journal of Psychiatry* 100 (419): 508–15.

Saunders, Nicholas. 1993. *E Is for Ecstasy*. London: Nicholas Saunders.

Scheper-Hughes, Nancy, and Margaret M Lock. 1987. “The Mindful Body: A Prolegomenon to Future Work in Medical Anthropology.” *Medical Anthropology Quarterly* 1 (1): 6–41.

Semple, DM, KP Ebmeier, and MF Glabus. 1999. “Reduced in Vivo Binding to the Serotonin Transporter in the Cerebral Cortex of MDMA (’ecstasy') Users.” *The British Journal of Psychiatry* 175 (1): 63–69.

Sessa, B. 2008. “Is It Time to Revisit the Role of Psychedelic Drugs in Enhancing Human Creativity?” *Journal of Psychopharmacology (Oxford, England)* 22: 821–27.

Shapin, S, and S Schaffer. 1985. *Leviathan and the Air Pump: Hobbes, Boyle and the Experimental Life*. Princeton: Princeton University Press.

Shulgin, A. 1991. *PIHKAL: A Chemical Love Story*. Berkeley: Transform Press.

———. 1997. *TIHKAL: The Continuation*. Berkeley: Transform Press.

Singer, Natasha. 2010. “In Recall, a Role Model Stumbles - NYTimes.com.” *New York Times*, January 17.

Spivak, Gayatri Chakravorty. 1985. “Three Women’s Texts and a Critique of Imperialism.” *Critical Inquiry* 12 (1): 243.

Stolaroff, MJ. 1997. *The Secret Chief: Conversations with a Pioneer of the Underground Psychedelic Therapy Movement*. Multidisciplinary Association for Psychedelic Studies.

Tarde, G De. 1903. *The Laws of Imitation*. New York: Henry Holt and Company.

Tseng, Stephanie, Grace Pak, Kenneth Washenik, Miriam Keltz Pomeranz, and Jerome L Shupack. 1996. "Clinical Review: Rediscovering Thalidomide: A Review of Its Mechanism of Action, Side Effects, and Potential Uses." *Journal of American Academy of Dermatology* 35 (6): 969–79.

Vincent, Bernadette Bensaude, and Isabelle Stengers. 1996. *A History of Chemistry*. Harvard University Press.

Watkins, ES. 1998. *On the Pill: A Social History of Oral Contraceptives, 1950-1970*. Baltimore: Johns Hopkins Univeristy Press.

Zieger, Susan. 2007. "Pioneers of Inner Space: Drug Autobiography and Manifest Destiny." *PLMA* 122 (5): 1531–47.