

Stan Grof Contributions to FDA Drug Development Research With Psychedelics

Contribuciones de Stan Grof a la Investigación Para el Desarrollo de Medicamentos con Psicodélicos de la FDA

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Abstract

In this reflection paper I'm going to talk about Stan Grof's contributions to the FDA drug development research with psychedelics. I'm going to share my personal evolution, how I interacted with Stan Grof during different periods of my life, and how these interactions influenced my career goal towards bringing psychedelic psychotherapy back to legal contexts and becoming a legal psychedelic psychotherapist. I'm going to explain how that ended up producing the Multidisciplinary Association for Psychedelic Studies (MAPS), and how Stan and his work influenced MAPS and the psychedelic research that we are conducting. I will also describe MAPS's drug development plan for the next years. It's likely that without Stan Grof's contributions, there would be no MAPS, and I'm so proud to be able to say that I'm a friend of Stan and that he is my professional and spiritual father.

Keywords: Stan Grof, psychedelics, psychedelic research, MDMA, FDA, MAPS

Resumen

En este artículo de reflexión yo voy a hablar de las contribuciones de Stan Grof a la investigación para el desarrollo de medicamentos con psicodélicos de la FDA. Voy a explicar mi evolución personal, cómo me relacioné con Stan Grof durante diferentes periodos de mi vida, y cómo estas interacciones influyeron en mi objetivo profesional de llevar la psicoterapia psicodélica de nuevo a contextos legales y de convertirme en un psicoterapeuta con psicodélicos. Voy a explicar cómo esta influencia terminó produciendo la Asociación Multidisciplinaria para Estudios Psicodélicos (MAPS), y cómo Stan y su obra influyeron en MAPS y en la investigación psicodélica que estamos llevando a cabo. También voy a describir el plan de desarrollo de medicamentos de MAPS para los próximos años. Probablemente sin las contribuciones de Stan Grof no habría MAPS, y es un orgullo para mi poder decir que soy amigo de Stan y que él es mi padre profesional y espiritual.

Palabras clave: Stan Grof, psicodélicos, investigación psicodélica, MDMA, FDA, MAPS

Received: April 12, 2015

Accepted: July 29, 2015

My name is Rick Doblin. I'm the founder and executive director of the Multidisciplinary Association for Psychedelic Studies (MAPS). I received my doctorate in Public Policy from the Harvard Kennedy School of government, where I wrote my dissertation on the regulation of medical uses of psychedelics and marijuana (Doblin, 2001). I also studied with Dr. Stan Grof and I was among the first to be certified as a Holotropic Breathwork practitioner. My professional goal is to help develop legal contexts for the beneficial uses of psychedelics and marijuana, primarily as prescription medicines, but also for personal growth and otherwise healthy people. Eventually I also hope to become a legally licensed psychedelic therapist. What I'm going to talk about in this reflection paper is just how probably without Stan Grof there would be no MAPS. I'm going to share a little bit of my evolution and how it interacted with Stan Grof, and how that ended up producing MAPS and how Stan influenced MAPS to do what it does.

I was born Jewish in 1953 and was heavily educated about the Holocaust as I was growing up. I think it was multigenerational trauma in a way. So I just grew up aware of the power of the irrational and how important that was to cope with it in some way or another. Then I started learning about Hiroshima, about WWII. I had the reinforcing aspect of being around 10 years old during the Cuban Missile Crisis and really having that kind of a situation in school where you're told hide under your desk, you'll be fine and duck and cover. Again this idea of the annihilation of Jews and the entire world was something that was a real phenomenon. I also became aware a little of the concerns intellectuals had. For example, Albert Einstein said at that time that it was becoming appallingly obvious that our technology has exceeded our humanity.

Then I had my *bar mitzvah* and, despite my best hopes, did not turn me into a man. I thought somehow it would vault all over this uncomfortable adolescence and I would have this transformative experience through this thousand's of year old ritual. It really didn't do much for me. When I was 16 year old, I was very interested in the other. My parents sent me to Russia. I studied Russian in high school in order to really understand the other. I spent the summer in Russia learning the language and also meeting with the young underground Russian kids because I could speak Russian. I was with a group of 60 other high school students, and me and two other guys were the designated liaison to selling all of our stuff. We

had a copy of Abbey Road by the Beatles sold for 100 rubles. It cost like 2 bucks. We had all sorts of stuff. So here it is, I've got thousands of rubles and I'm lighting a Cuban cigar. The important thing here is that I went for a walk on the beach where we were with a Russian girl. And I was just super shy in high school, but to be able to have a friendly conversation with somebody from a culture that I was trained wanted to kill us and were in a deathly battle for control of the world with and to see that wasn't really what she was interested in, it wasn't what I was interested in. There was a lot more that we had in common than difference.

So I started being radicalized at this early age and recognizing that we are all in this together. Then I had to cope with Vietnam and I was in the last year of the lottery. I was trying to figure out really how to address that. I didn't really want to kill people. I didn't really see that they were the enemies. I didn't feel that they were a threat. And this was of course the Civil Rights period and so I read this from Dr. Martin Luther King Jr.:

I submit that an individual who breaks a law that his conscience tells him is unjust, and who willingly accepts the penalty of imprisonment in order to arouse the conscience of the community over its injustice in reality expressing the highest respect for the law.

So based on this, I decided that I was going to be a draft resister and I was going to go to jail. My parents were sympathetic but they were like: "okay you're not going to be able to become a doctor or lawyer or anything that requires a license".

So I was now adrift in my career, but I felt like killing people was not a price that I was willing to pay to have a traditional career. And needless to say I was also in the era of Timothy Leary and the whole psychedelic 60s and I initially thought that LSD made you permanently crazy. It was something that if you took it just once you were always off balance and in serious risk of mental institutions. I believed that initially. There was this whole thing about tune in turn on drop out. I was raised to be part of the mainstream. I didn't really like this idea of dropping out, but it was LSD became the symbol of cultural rebellion. It got connected with the Beatles who were protesting the Vietnam War, so that started making me wonder: "maybe this isn't a social menace maybe this drug really has some kind of important potential for consciousness". But it wasn't exactly clear to me what to do, so my image of myself at

age 18 was that I was a counter culture drug using draft resisting criminal. Fortunately, I had a trust fund from my grandfather. It wasn't a whole lot but it was enough to pay for food and rent. That made me independent in my mind. I thought: okay now I can do anything that I want. I don't have a whole lot of needs. If I just have survival covered and I can't be something normal.

I started doing LSD more and more as a way to try to get in touch with myself. And it was very difficult because I was so emotionally constricted, really overly intellectualized. I had these series of increasingly difficult trips where I could never let go. I would get to this point I had this one trip where I was feeling that my brain was melting. It was sloshing around in my head. I had like a nasal drip and I was convinced that it was my brain leaking out because I was resisting so much that it was overheating. I felt like I had to do something. I kept doing it but I finally was at this college, I decided I needed to go talk to the guidance counselor and get some advice. And so this is where the turning point of my life took place.

I went to the guidance counselor and low and behold he gives me a manuscript copy of Stan Grof's *Realms of the Human Unconscious* (Grof, 1975) in 1972, before it was published. When I read that book, I was just utterly transformed and shocked, because there was something about the way Stan wrote about it, and the values that he had in there, and the signs that he was talking about, that it all came clear to me what I needed to do. What I felt Stan was doing wasn't philosophy, which in a sense could go on and on forever. It wasn't about power. I was reading Carlos Castaneda at the time and, if you look at the books, they're about struggles for power. One of them was called *Tales of Power* (Castaneda, 1974) I think you can actually see in some way that's why I think Castaneda went off the path and it wasn't dogma. Stan was really coming from, it was about spirituality but it was science. It was the mystical experience. It had the unitive aspect that had political implications and it had the reality check of healing, and I think that mix of elements made me feel calm. I need science; I don't trust religion. Science is more of my religion. But I need spirituality and I felt the political implications were there.

I started reading more and more of what Stan was writing. And then I learned about the *Good Friday Experiment*. And that experiment was further scientific confirmation that people could what was either resembling life or actually a genuine spiritual experience (Pahnke, 1963, 1966,

1969). And people reported positive benefits from it. The core of it was a sense of unity. I think this idea that we live in a world, Stan talks about a little bit earlier, how religion makes you divide into "us and them", and that there's not enough empathy for the other. There's not enough identification with them. They're not really the other. We're all in this together. I think the mystical experience, which didn't come to me from *bar mitzvah*, doesn't come to most people through the religion that they were born into and that we experience. Here was a way with psychedelics and it felt like what Stan was saying it was genuine. Then I learned that it was part of the Western cultural heritage. It wasn't some foreign thing. It had been for 2,000 years the world's longest mystery ceremony. The Eleusinian Mystery involved a psychedelic drug, involved the mystical experience and it was wiped out in 396 by the Catholic Church, but its part of our Western cultural history. It didn't seem alien. And then I read this from Albert Einstein:

The splitting of the atom changed everything save man's mode of thinking, thus we drift towards unparalleled catastrophe. We shall require a substantially new manner of thinking if mankind is to survive.

So what is this new manner of thinking? I think its about this sense of togetherness, it's about how we really share more in common than not, and if we can think that way, then maybe we can save ourselves from what's going on. I read the UNESCO Charter:

Since wars begin in the minds of men, it is in the minds of men that the defenses of peace must be constructed.

And all of this really led me in the summer of 1972 to take a seminar with Stan Grof and Joan Halifax. That was a great experience. But I was this 18 year old, and so Stan would and they would be there during the scheduled times and then they'd be gone. You know. And then they had just gotten married a week before something like that. So we had this rumor that they were off doing this special thing called tantric sex and that was this magical mystical thing. I felt like again the road was clear but I wasn't able to fully embrace it. I wasn't mature enough. I couldn't really do it. But I did change my self-concept.

So now I was a countercultural drug using draft resisting criminal with trust funds to pay food and rent, but my career goal now was to become a legal psychedelic psychotherapist and to bring

psychedelic psychotherapy back, and it was in order to provide an antidote to all these things that were impairing me and the world. Finally I had this anchor in my life. This is now what I'm going to try to do. It took basically ten years of working little bits of LSD small trips on my own, not being connected in anyway to the psychedelic community. Just reading books, trying to work on myself getting grounded building houses, being in construction. And after ten years I felt ready to go back, and where I went was Acid Land, and then I went back ten years later and did a week long and then a month long workshop with Stan and Christina Grof. And what I was so impressed by and I think one of the most important things I learned from Stan and Christina was the work with the Holotropic Breathwork (HB) (Grof and Grof, 2010). Because when the main road, it's like a river falling, you know, down the hill, and there's an obstacle. The river goes around it, but it's still going in the same direction. So the work most people had involved with psychedelics had left to do non-drug alternatives, different kind of things.

HB is evocative and psychedelic in its own right, and it's with breath, that cannot be made easily illegal. I just was really impressed by the way Stan and Christina kept going forward, that they found a way creatively. That was a message for me for the rest of my life. The other thing is that I learned about MDMA at that workshop; not from Stan and Christina, someone came to Esalen who talked to others and me about MDMA. And my first thought was "this is not very interesting". This is supposed to feel better and you can talk more with people, and I saw groups of people doing it together. And I'm like "I love the fireworks of LSD, the drama of mescaline and here they don't even seem like they're affected that much. They're sitting around talking, they're still conscious in the same way that they were before". But I was smart enough to buy some and take it home. Once I did that I was amazed at how subtle it was and how deep and powerful it was, and it was still legal.

I felt like I came to the party of LSD when it was too late. Right when it was shut down I woke up to the potential, and here it was, and I learned about MDMA when it was still legal. And I start trying to get more and more involved, and one of the things I did was to write to Robert Mueller, who was the Assistant Secretary General of the United Nations, and he had just written a book, *New Genesis: Shaping a Global Spirituality* (Mueller, 1982) and he's the mystic of the UN there for about 30 years or so. And what he basically was saying was that we have the religions

of the world and they're in conflict. We have the United Nations to mediate conflicts between nations. But we don't have anything to mediate conflicts between religions. And what he said would do that would be the mystics, and the mystics of the different religions would have things similar to each other, and they would appreciate each other, and if we could have people move from fundamentals to mysticism and global spirituality, that would be a deeper source of grounding of peace.

I wrote to him and I said "I really understand what you say, but you don't say a word about psychedelics in your book". And I told him about the *Good Friday Experiment*, I told him about MDMA. To my shock he wrote me back and he ended up encouraging me to write to a bunch of different people who were mystics: Brother David Steindl-Rast, Vanja Palmers, Rabbi Hershel Schacter, Wayne Teasdale, all these people. And the subtext was: send them MDMA. So I did that, and they also reported back to him actually.

One of the ironies of Stan and Paul Grofs life together is that when the Drug Enforcement Administration (DEA) tried to criminalize MDMA in the United States and we filed a lawsuit to try to stop that. Then it became clear to us that the DEA was trying to criminalize MDMA internationally through the World Health Organization (WHO). And Paul Grof, Stan Grof brother, was the chairman of the WHO expert committee that was evaluating the data about whether MDMA should be criminalized or not. Astonishing. Robert Muller helped me go to the committee and present information about MDMA. And the committee unanimously, except for Paul, voted to criminalize MDMA, over the objections of the Chairman, because Paul was the chairman. There was able to add a little footnote that said that this could inherit research, nations of the world should facilitate research. It felt like a big defeat, they voted to criminalize. But it was also a tiny little victory. But only a few years later the Swiss government cited that footnote to open the door to MDMA research in Switzerland in 1988.

And so it was the Stan and Paul Grof connection that helped that to happen. Then I started doing research. I did a follow up to the *Good Friday Experiment*, because in the '80s you couldn't get permission to give MDMA or any psychedelics to anybody. But you could ask people their reflections on something that had happened before. You could do a long-term follow up. And Walter Pahnke, who conducted the experiment, died in a scuba diving accident. So I did that 25 year follow up and I interviewed these people

(Doblin, 1991). To find them was hard enough, but then I found them and I interviewed them. They were all men. What they said was that the mystical experience they felt was valid, they felt that it had long-term implications, they felt that it contributed to their movements with social justice activism. It increased their tolerance of other religions, deepened equanimity in the face of difficult life crises; develop greater solidarity and identification with foreign people, minorities, women and nature. And reduce the fear of death. So again this is a confirmation of the political implications of the mystical experience and whether it is psychedelic or not.

This led me to think, "Okay we're going to try to start MAPS. We're going to try to do non-profit drug development". And at the time there had never been a drug developed by a non-profit organization, in 1986, when I started MAPS. The first drug that succeeded in becoming a Madison was in 1999, and it was the abortion pill, RU-486, funded by the Rockefellers, the Pritzkers, and the Buffets. Warren Buffett donated about \$10 million. It was John D. Rockefeller's population council and then the Pritzkers put in a bunch of money too. So now we're actually been getting funding from the Pritzkers and the Rockefellers, we're waiting on the Buffets. In 2000, *One World Health* began as a non-profit to create drugs for the Third World. The Gates Foundation stuff MAPS and Hefters.

Non-profit drug development is not so unusual. In the methods that we are trying to develop psychedelics into medicines, particularly MDMA, we've learned a lot from what Stan Grof has done. I would say that the entire therapeutic approach that we have in the MDMA studies (M.C. Mithoefer, Wagner, A.T. Mithoefer, Jerome & Doblin, 2011a; Mithoefer et al., 2013). We look for therapists that have been through the HB training with Stan Grof. Michael and Annie Mithoefer have been through the HB training. The person who was in charge of our Canadian Study, Ingrid Pacey, was in that early group of people trained by Stan Grof in HB also. I also was in this first group of training with Stan. So we looked for people who had done HB training and, at the same time, in our therapist training programs we utilize HB, and we have done that. We brought people from a bunch of different countries for our first training in Austria in 2010. And these were people who were legitimate mainstream psychiatrist and other, and they wouldn't do something illegal. But we could do HB with them. And then, in the actual therapeutic approach and the MDMA treatment manual (Mithoefer, Jerome, Ruse, Doblin & Gibson, 2011b), again we've learned from Stan and

his therapeutic approach. So what we're primarily doing is a non-directive approach, we believe in the inner healer, the wisdom of the psyche. We're not the guide, we're the sitter, the supporter. We let it calm and the material emerge from the psyche, from the people themselves. We have this fundamental trust that is really hard to have without going through a personal process of self-exploration with non-ordinary states of consciousness.

I drew a lot of strength from Stan and Christina and others. If you can learn to trust this death-rebirth process, when you feel like you're about to die, that you're not going to come back, that you could go crazy if you can just let go and let something happen as the funeral pyre is letting and fully experiencing it. It's very hard to do, it's really scary. But that's kind of the essence of the treatment approach. And we also use a male-female co-therapist team, which was one of the ideas that Stan developed as well. And I think that has been a real key to our success in terms of how we do our studies, who is interested in working with us, just that kind of balance pairing. Not to say that you couldn't have two sensitive guys or one person or you know, it's not like it has to be this way. It is just a really good way to do things. Then the other thing that's not really talked about much, but there's enormous prejudice I'd say for plant based medicine. That if it's from nature it's good and if it's from the laboratory it's somehow tainted by humanity. And we have these discussions with Terence McKenna and others. But I think Stan was supportive to synthetic medicines by his acknowledgement of the fundamental healing and spiritual potential of LSD, which was a synthetic molecule, made by the mind of Albert Hoffmann. It's not about "does it come from the plants or does it come from the lab?" It's about how you use it, what it is. I think that's something we don't really acknowledge. I think that it's a strong counter to a lot of the cultural tendencies that we see that I learned from Stan.

Now we've had a lot of work trying to work with the other, with the military. For now a lot of it is because I was a draft resister. Years ago it was a meeting with the assistant secretary of the Navy. Richard Rockefeller arranged the navy surgeon general where Michael Mithoefer and I met. We didn't make much progress and we didn't get inside. So now we're getting inside with psychedelic healing, and then we have the support of Senator Rockefeller, who is on the Veterans Affairs Committee. He wrote this to the Assistant Secretary of Defense "I'm writing to encourage you to explore innovative treatments for Post-

traumatic Stress Disorder (PTSD) including but not limited to MDMA". And the new head of the Veterans Administration (VA) Robert McDonald, the night before his confirmation hearing, Jay had a meeting with him and said: "my cousin Richard died and it was his main legacy. This is very important for soldiers I want you to make sure that the VA continues to support MDMA research for PTSD". And this was the transformative meeting where Richard and I went to the VA and they agreed to let us fund some collaborative studies with VA therapist. So we are really moving in collaboration with the VA.

We're talking now a lot about medicines, but I began talking about how we need cultural change. We need millions, tens of millions, hundreds of millions of people that are grounded in a mystical consciousness. That really not a few politicians, but if we can have loads and loads of people, so here's how the medicine leads to that. If we look to the surveys looking to the attitude of Americans towards legalization of marijuana, in 2011, for the first time in over 40 years, more than 50% of the US was in favor of medical marijuana. I mean in legalization. The people's attitudes start changing in 1996 when California and Arizona legalized medical marijuana. And exit polls have shown that the most important factor of why someone votes for medical marijuana legalization is if they know a medical marijuana patient. It's not even if they smoke marijuana themselves.

The medicalization of psychedelics diminishes the fear and paranoia in this society, increases the balance of hope over fear, and will cause people to rethink prohibitionist policies and really make it so that these substances have a wider use beyond just people with clinical indications. Amy Emerson, who developed our drug development plan, used to work for Novartis and Kyron. So this is a person from the big pharma coming to help little MAPS work on psychedelic medicine. Our plan is pretty complicated; there are hundreds of steps (see Appendix 1). But it basically shows that in 2021 we could make MDMA into a medicine. And we don't need \$1.5 billion dollars; we just need \$15 million dollars. And then we'll have the sale of prescription MDMA. One of the concerns that people have about the legalization of marijuana, and one of the concerns about even medical use of a lot of different drugs or psychedelics is that you get unbridled. American capitalism trying to maximize profit. And what you end up getting is a lot of people who are really scared about that. What we're talking about right now is to create a benefit corporation.

So if MAPS as a non-profit can make MDMA into a medicine then, once it's a medicine, it's not a non-profit anymore. We don't want it to be for profit, so we're going to create a wholly owned Benefit Corporation where social benefit is what we maximize, not profit. And then we'll move forward with the training of therapist. We'll set up a network of MAPS clinics. And other people will be able to do this as well. Then we'll have world peace, but it might take a little bit of time between those. All of this really comes back to Stan Grof, who had the courage in the midst of massive social condemnation of psychedelics to say "psychedelics used responsibly and with proper caution will be for psychiatry what the microscope is for biology and medicine or the telescope is for astronomy ". And we are coming forward to fulfill the promise. Stan led the way and it's so proud of me to be able to say that I'm a friend of Stan and that he is my professional and spiritual father.

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- of psychedelics and marijuana. His undergraduate thesis at New College of Florida was a 25-year follow-up to the classic Good Friday Experiment. He also studied with Dr. Stan Grof and was among the first to be certified as a Holotropic Breathwork practitioner. His professional goal is to help develop legal contexts for the beneficial uses of psychedelics and marijuana primarily as prescription medicines, but also for personal growth and otherwise healthy people. Eventually he also hope to become a legally licensed psychedelic therapist. Email: rick@maps.org.

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Appendix 1: MAPS Drug Development Plan, Clinical Overview

End-of-Phase 2/Start of Phase 3

Contract with a GMP manufacturer and begin work on GMP MDMA Q2 2015
 Generic name request submitted Jan 2015
 Request special protocol assessment: timing based on outcome of FDA Special Programs EoP2
 All dates below would be accelerated with breakthrough therapy status

Plan Two Phase 3 Studies and Expanded Access Study	Start	Stop
Develop Phase 3 protocol documents	10/15	06/16
Site selection for Phase 3	08/15	06/16
Finalize first Phase 3 protocol	06/16	10/16
SPA: Phase 3 protocol assessment and EA	11/16	04/17
Regulatory, ethics, DEA approvals Phase 3 #1	01/17	04/17
Finalize Phase 3 #2 and Expanded Access protocol	06/17	12/17
EMA Regulatory, ethics, DEA approvals Phase 3 #2	03/18	05/18

Phase 3

Phase 3 studies and Expanded Access enrollment to Final Report	06/17	08/22
Phase 3 #1 US: Multi-site: 200 subjects 10 sites 2 teams/site	06/17	02/20
Phase 3 #1 Enrollment 200 subjects	06/17	06/18
Phase 3 #1 End of Primary Endpoint	06/18	11/18
Phase 3 #1 End of LTFU	11/18	09/19
Phase 3 #1 Final Report	01/19	06/19
Phase 3 #1 LTFU Report	11/19	02/20
Conduct Expanded Access Study up to 50 sites	07/18	08/22
Enroll Expanded Access Protocol	07/18	08/22
Expanded Access Complete and Study Report	02/22	08/22
Phase 3 #2 EU: Multi-site: 200-280 subjects	08/18	04/21
Phase 3 #2 Enrollment 200-280 subjects	08/18	07/19
Phase 3 #2 End of Primary Endpoint	07/19	01/20
Phase 3 #2 End of LTFU	01/20	11/20
Phase 3 #2 Final Report	03/20	08/20
Phase 3 #2 LTFU Report	01/21	04/21
NDA Process	01/20	12/21
Write Expert Report, Safety Report, Package insert, CMC	01/20	10/20
Request Pre-NDA meeting	10/20	12/20
Submit Rolling New Drug Application (NDA) manufacturing, pre-clinical, and clinical data	12/20	12/21