



Living Our Values

MAPS Establishes an Ethics and Compliance Program

LESLIE BOOHER, J.D., M.B.A., MAPS LEGAL AND POLICY ASSOCIATE
in conversation with

SETH WHITELAW, J.D., LL.M., S.J.D., MAPS CHIEF ETHICS AND COMPLIANCE OFFICER



SINCE MAPS WAS FOUNDED, THE principles of transparency, trust, and accountability have governed how the organization works to achieve our mission of developing medical, legal, and cultural contexts for people to benefit from the careful uses of psychedelics and marijuana. Those principles were passed down to MAPS Public Benefit Corporation (MAPS PBC) to guide the development of MDMA-assisted psychotherapy. These principles define how we act in relationship to the wide variety of stakeholders with interests in our work.

Addressing the impact of trauma is a significant obstacle, but one worth tackling for the greater engagement and fullness of life it can offer. Our work applying research-based, psychedelic-assisted therapies requires some reimagining of not just the preexisting symptom management paradigm in mental healthcare, but also some aspects of conducting business and relating to the public. As MAPS Founder and Executive Director Rick Doblin, Ph.D., often says, “We are taking not just a new approach to mental health, which is psychedelic-assisted psychotherapy, but a new approach to marketing medical treatments and drugs. And so, we have a great responsibility on our shoulders.”

However, like most things in life, the words transparency, trust, and accountability come easily, while living them every day is much harder.

MAPS’ growing size, progress in clinical trials, increasing breadth of activities, and public awareness makes centralizing complex roles a worthwhile endeavor. So, to meet this expansion and remain consistent to our principles, MAPS decided it was vital to establish a formal Ethics and Compliance Program with a Chief Ethics and Compliance Officer taking the lead.

Dr. Seth Whitelaw, our new Chief Ethics and Compliance Officer, joined the MAPS family in June. As a food and drug lawyer, Seth has worked with numerous drug and medical device companies as both an in-house compliance officer and a consultant. He also teaches ethics and compliance for Mitchell Hamline School of Law and is the editor of a compliance publication, *Policy & Medicine Compliance Update*. Most recently, he served as a compliance expert for the plaintiffs in the ongoing Opioid Multidistrict Litigation. The father of two grown sons, he lives in West Chester, Pennsylvania, with his wife and four dogs.

Seth’s work on the ongoing implementation of an Ethics and Compliance Program is critical to MAPS’ mission, so we are pleased to share his perspective about his role and an overview of the program.

Leslie Booher (LB): How would you describe your role?

Seth Whitelaw (SW): I have struggled with how to describe what I do for people who are not familiar with my role or an Ethics and Compliance Program. However, if you think of MAPS as building, I am helping MAPS, and its subsidiaries, build and maintain a solidly supported ground floor that meets the local building codes (compliance) so that floor does not collapse. Since MAPS has significant aspirations, I help put the framing in place for the organization to successfully grow and be a leader. And like any building, there always is maintenance to do, so compliance is really a journey and not a destination.

Put another way, a former CEO of mine, J.P. Garnier, describes the role as having three primary components: missionary, diplomat, and police officer. A compliance officer needs to be a true believer in the goal of achieving the organization's objectives in the right way. They also need to convey the hard messages with diplomacy and tact lest the message becomes about the messenger. In the role of police officer, enforcing accountability must be tempered with justice and kindness. Sometimes mistakes are just mistakes.

LB: What skills and interests are important for your role?

SW: You need to be a quick study and always learning. The Chief Ethics and Compliance Officer doesn't always have the answers but needs to know how to get them. One of things I love most about teaching law school is that my students teach me as much as I hope I teach them. Everyone I've met so far in MAPS has been both patient and generous explaining things that are second nature to them but are new to me.

Finally, you need to be innately curious and willing to ask "why" when things don't make sense. However, that curiosity also needs to be tempered with skepticism and not accepting the easy answer of "because we've always done it that way." However, at MAPS, that does not seem to be an issue, as we are always challenging the status quo—in a good way.

LB: So, are ethics and compliance your responsibility?

SW: Yes and no. While I am the most visible face of the program, behaving ethically and compliantly is the responsibility of everyone in MAPS. When I first started in this role at another company more than 25 years ago, it was designated as the Compliance Coordinator. In some ways, that title is more appropriate because I help coordinate our ethics and compliance efforts, but I cannot do it alone. Ethics and compliance truly is a team sport, or as I have heard you say, "teamwork makes the dream work."

LB: If MAPS has a strong ethical foundation, why do we need an Ethics and Compliance Program?

SW: Yes, MAPS does have a strong ethical foundation. So many organizations that I have worked with are at the same point in the product development cycle and size as MAPS, but do not have that foundation. Instead, they are so focused on getting the product approved and on the market that they neglect the culture and values of the company. MAPS never did that, but rather framed its mission, including its efforts around MDMA-assisted psychotherapy and its efforts to change drug policy and make it more equitable for all, around its culture and values.

However, a strong culture and values are not enough. We need to have consistency. We also need to demonstrate to legislators and regulators that we indeed are being true to our values. Or to paraphrase William Duncan Vandiver, "I'm from Missouri, show me." The Ethics and Compliance Program provides a framework to accomplish both of these goals.

We also need the program because in this complex world, there is a broad spectrum of legal and regulatory requirements that organizations, especially drug development organizations, need to comply with beyond just the requirements of the U.S. Food and Drug Administration (FDA) or the Drug Enforcement Administration (DEA). These other legal and regulatory requirements often intersect with, or in some cases overlap, one another. Having an Ethics and Compliance Program helps ensure that we see the forest and not just the trees to avoid missteps.

LB: What makes up an Ethics and Compliance Program?

SW: Without going into too much detail, the framework, as it has evolved since the mid-1980s, encompasses eight standard elements of an organizational program of due diligence, reasonably designed to prevent and detect violations of law. Those elements, put simply, are: (1) having policies and procedures, (2) having a compliance officer, (3) avoidance of improper delegation of organizational authority, (4) communication of standards and procedures to staff, (5) monitoring, auditing, and reporting functions, (6) consistent enforcement, (7) effective response and mitigation, and (8) ongoing risk assessment. (To learn more see pharmacongress.com/wp-content/themes/ipc/documents/LS_Compliance_From_the_Beginning.pdf).

Although eight elements apply to all organizations, they require tailoring and adaptation because industries and individual organizations face different circumstances and develop tailored standards over time. The core issue is that the program must work to catch and prevent transgressions. It cannot be a paper-driven exercise, but something that lives and breathes, and is embedded in how we live and work. Therefore, the program must be practical, and more importantly, sustainable.

Because so many ethics and compliance issues are not black and white, for our Ethics and Compliance Program to work, it also must achieve a balance between our freedom to get the job done and the risks associated with getting it wrong. In the end, if we do it right, the program will help make us more consistent and efficient, which is good for everyone, including our study participants, future patients, and donors.

LB: You said ethics and compliance is a journey and not a destination, so where is MAPS on that journey and what does success look like?

SW: We are still in the early stages. We are working on putting the necessary framework and processes in place, which Rick Doblin has said are crucial for MAPS' continued growth and expansion. While it is hard to describe in terms of a single instance or outcome, success, to me, means having both an organizational framework and a culture where it is second nature to manage risk, protect MAPS' reputation, and, most importantly, to identify as many of our stakeholders as possible and work to protect and respect their interests and ours, even in the face of challenges and tough decisions.

While we still have much to do, we are heading in the right direction. Together, I believe we truly will change the world of mental health, and more broadly, the healthcare system. It is an exciting time to be a part of MAPS and I am honored to be a part of it.

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LESLIE BOOHER, J.D., M.B.A., is the most recent addition to the MAPS Policy and Advocacy Department. Leslie received her bachelor of science in business administration and her master of business administration from Southeast Missouri State University, as well as her juris doctor from University of California, Berkeley, School of Law. Before joining MAPS, Leslie gained litigation experience at large and small law firms, from both the plaintiff and defense sides. Leslie is excited because her work at MAPS combines many of her passions: learning and educating others about our shared human physiology and psychology, striving for social contentment through imaginative socio-economic structures, aspiring for criminal justice reform, and calling attention to the unique role that altered states of perception play in conceptualizing, contextualizing, and coping with our own consciousness. She's currently interested in topics like behavioral economics, novel economies, technology and privacy, peer support, and rural community issues.

SETH WHITELAW, J.D., LL.M., S.J.D., has almost 30 years of industry experience in the life sciences and health care sectors, as an attorney, compliance officer (C.R. Bard, Inc., GlaxoSmithKline, and Misonix, Inc.) and industry consultant (Deloitte, Whitelaw Compliance Group LLC). Most recently, he served as a compliance expert in the Opioid Multidistrict Litigation. In addition to being a Food and Drug Law Institute (FDLI) fellow and having worked for both the FDA's Office of Chief Counsel, he has a J.D. from Washington & Lee School of Law, an LL.M. from George Washington University Law School, and a doctorate in Health Law from Widener University School of Law. Currently, Dr. Whitelaw is the Editor of the *Policy & Medicine Compliance Update* and teaches corporate governance and compliance at Mitchell Hamline School of Law where he is the Senior Fellow & Adjunct Professor, Life Sciences Compliance.