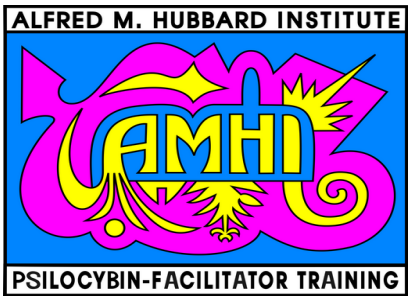

Reid Stuart, Director
Alfred M. Hubbard Institute
AlfredHubbard@protonmail.com
AlfredHubbard.com
September 13, 2024

Re: MDMA Approval

Dear FDA:

Since the early 20th century, federal regulation of medicine has steadily grown in complexity, and will continue to become more complex in the future. FDA is now bringing up concerns and objections that were not articulated when MAPS's clinical trials began. While fine-tuning the methodology using insights from MAPS's MDMA studies may be appropriately applied to future clinical trials for other drugs, it is not reasonable to delay MDMA's approval based on newly articulated methodological nuances. I am referring to FDA's objections such as the long-known fact that psychedelic-drug studies cannot be fully blind, or that MAPS's studies did not parse apart the role that any particular form of psychotherapy might have played in achieving the therapeutic results compared to just administering MDMA without therapy. The double-blind issue has been discussed in the technical literature since the late 1950s or early 1960s, and the common reply has usually been that we either have to compare psychedelic therapy to talk therapy or to therapy using another psychedelic. As for the question of whether MDMA can be effective alone without therapy, FDA could simply approve it now for use with therapy and then let clinicians conduct further studies using different therapeutic modalities and also studies administering it alone without any therapy. When the answer to this question becomes clear, then FDA could consider whether to loosen the restriction to broaden the circumstances in which MDMA may be administered.

The fact is that MDMA never should have been placed in Schedule I in the first place. After psychotherapists challenged the DEA's placing MDMA in Schedule I, DEA Administrative Law Judge Francis Young issued his opinion in May 1986 that MDMA should be placed in Schedule III to accommodate therapeutic use. DEA ignored this opinion, so a few months later Dr. Lester Grinspoon appealed DEA's rejection of Judge Young's recommendation to a federal appeals court. In 1987, the appeals-court judges ruled in Dr. Grinspoon's favor, stating that DEA's definition of accepted medical use was too narrow, contradicted Congressional intent, and needed to be revised.

But in February 1988, DEA again placed MDMA in Schedule I. If Gene Haislip, who ran DEA at that time, had allowed therapists to use MDMA as a Schedule III drug, then all of the questions that FDA is now posing would have been answered decades ago. For FDA to stymie MDMA at this point seems to be a continuation of decades of bureaucratic stonewalling whose effect inevitably prevents patients from having legal access to a medication that — if withheld from them in legal clinical settings — they might still access in the less-safe milieu of the underground marketplace. The public-health implications of granting FDA approval to MDMA are clear: approval would improve public health by giving desperate patients a safer context than they might encounter if they are (for all practical purposes) forced into taking the medicine on their own without the benefit of medical supervision.

As an outside observer, I sit scratching my head trying to figure out what is really going on beneath the surface of this situation. Is there some unspoken fear on the part of FDA regulators that approving a psychedelic might somehow shift larger cultural dynamics in ways that are either unpredictable or contrary to somebody's vested interests? If this is the underlying concern, then I suggest that FDA explicitly place this topic on the table for discussion. For the past several years, I actually have been studying the issue of how mind-expanding substances influence larger social dynamics, and if you are interested in my expertise on this matter then I would be willing to share my opinions with you. However, if this is the genuine objection underneath the stated objections, then please articulate it overtly so we can clear the air on this topic.

MDMA's pharmacological properties, abuse potential, contraindications, and therapeutic applications have all been well characterized after four decades of studies involving both patients and recreational users. The side effects for properly screened patients are minor, and rarely appear when doses (including boosters) are no more than 1.5 mg/K. There is no compelling reason to use post hoc objections to delay MDMA's passage through the regulatory pipeline. For these reasons, I request that FDA finalize approval for MDMA. Thank you for considering my comments.

Sincerely,
Reid Stuart