PUBLICCITIZEN

1600 20th Street, NW • Washington, D.C. 20009 • 202/588-1000 • www.citizen.org

Advancing Treatments for Post-Traumatic Stress Disorder

Reagan Udall Foundation for the FDA
Hybrid Public Meeting

Friday, September 6, 1 - 3:30 pm Eastern Time

Stakeholder Comment by Michael T. Abrams, M.P.H., Ph.D.

I'm Michael Abrams, Senior Researcher with Public Citizen. We are a consumer advocacy organization with a long history of working towards making medical technologies more safe, effective and affordable. We have no financial conflicts on today's topic.

Post-Traumatic Stress Disorder (PTSD) and related anxiety disorders are an important treatment target of modern medicine, and we agree that many people with such debilitating illnesses go untreated or are inadequately treated. Such inadequacies are a function of the availability of current treatments, and the need for better treatments.

Much excitement now exists about psychedelic drug treatments for PTSD. Drugs like psylocibin (mushrooms), LSD and MDMA (ecstasy) clearly have powerful brain-based effects, but evidence regarding their precise and safe action to enable the treatment of PTSD and related pathologies remain unfulfilled— thus the FDA's recent rejection of the MDMA plus psychotherapy application.

We agree with the FDA's decision. The MDMA application had several problems, all which should be addressed in future trials before the FDA considers any additional psychedelic applications.

First, the unblinding-bias must be addressed. FDA scientists reviewing the MDMA application reported that the amount of such bias could not be estimated from the available data. Ways to address this bias include the use of competing substances such as niacin, varying doses of MDMA, the use of other stimulating experiences (exercise, etc.) to create feelings of openness and competency, and comparative-arms that involve stabilized doses of antidepressants. Though imperfect, such approaches need to be attempted to at least partially quantify the true effect of the drug.

Second, these trials must collect data about toxic physiologic effects of these drugs including effects on liver function and other organ-systems, and data that is relevant to the

addictive potential of such drugs, namely drug-induced feelings of euphoria and substance-liking. Notably, the FDA and the sponsor disclosed recently that such data was omitted from the MDMA application.

And finally, future trials with psychedelics combined with talk therapies must standardize the therapeutic approach to mitigate the potential for patient abuse and confounding due to therapist or treatment-site variability. Moreover, multi-modal psychedelic trials should be designed to differentiate the partial effects of the drug and the coupled non-drug intervention. Arguably the most important result of the failed-MDMA trial is that both arms— drug and placebo— showed favorable effects suggesting that intensive talk therapy alone is helpful. Therein lies substantial hope for an approach that should not be ignored.