

THE CENTER FOR
COGNITIVE LIBERTY & ETHICS

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RICHARD GLEN BOIRE, J.D.
EXECUTIVE DIRECTOR

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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

RE: [Docket No. 00N-1257]

International Drug Scheduling; Convention on Psychotropic Substances; 4-Bromo-2,5-dimethoxyphenethylamine (2C-B); Gamma-hydroxybutyric acid (GHB); 4-Methylthioamphetamine (4-MTA); N-Methyl-1-(3,4-methylenedioxyphenyl)-2-butanamine (MBDB); Diazepam (INN); Zolpidem (INN)

Dear Dockets Management Branch:

The Center for Cognitive Liberty & Ethics submits the following comments and recommendations to the Food and Drug Administration with respect to the FDA's notice (See, 65(83) *Federal Register* pp. 24969-24970, April 28, 2000) inviting interested persons to submit comments concerning several drugs that the World Health Organization is considering for increased international restrictions.

I. N-METHYL-1-(3,4-METHYLENEDIOXYPHENYL)-2-BUTANAMINE (MBDB)

The Center for Cognitive Liberty and Ethics respectfully recommends against the scheduling of MBDB under the 1971 UN Convention on Psychotropic Substances for the following reasons:

1. A European assessment of MBDB failed to reach a consensus on Prohibition.

On Nov. 10, 1998, the Scientific Committee of European Monitoring Centre for Drugs and Drug Addiction (EMCDDA), and additional experts named by the Member States, Europol, the European Commission and the London-based European Agency for the Evaluation of Medicinal Products (EMA) adopted a report on the risk assessment for MBDB which was submitted the same month to the Council of the European Union and the European Commission for consideration. After assessing the risk profiles of MBDB, the committee was unable reach a consensus on whether or not to place MBDB under control measures. (See, European Monitoring Centre for Drugs and Drug Addiction, "Report on the Risk Assessment of MBDB in the Framework of the Joint Action on New Synthetic Drugs," (Herein after "Report".)

[Available online at: <http://www.emcdda.org/multimedia/Publications/MBDB.pdf>].

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2. There is insufficient evidence that MBDB is addictive or dependency producing.

As noted in the EMCDDA's risk assessment report, *supra*: "Based on animal studies, the dependence potential of MBDB appears to be small, probably even smaller than that of MDMA." (Report, Sec. 4.1(b).)

3. MBDB appears to have great potential as an adjunct to psychotherapy. Prohibiting it will significantly hinder scientific study of the substance's therapeutic potential.

As noted in the EMCDDA's risk assessment report, *supra*: "[t]he main subjective effects of MBDB in man are a pleasant state of introspection, with greatly facilitated interpersonal communication and a pronounced sense of empathy and compassion between subjects. In this respect, MBDB again resembles MDMA. However, there are also differences. MBDB has a slower and more gentle onset of action than MDMA, produces less euphoria and has less stimulant properties." (Report, Sec. 4.1(c).)

4. MBDB is not presenting a significant harm to individuals or society.

With respect to individuals, the Center for Cognitive Liberty and Ethics is unaware of even a single report of emergency room admissions or treatment requests based on the ingestion of MBDB in North America. With respect to social harm, the EMCDDA's risk assessment report, *supra*, noted: "There is no evidence specifically on MBDB and consequences linked to disorderly conduct, acquisitive crime or violence. However, it might be considered even more unlikely than with MDMA that there is any important link between the use of MBDB and such consequences. The effect on driving is unknown but, as with any drug, is a matter of concern.... There is no indication that MBDB in particular is associated with any major value conflicts or has any important implications for social institutions beyond those described for MDMA." (Report, Sec. 5(b) & (c).)

5. Prohibiting MBDB will likely prompt increased use and underground manufacture.

Given that MBDB is all but unheard of in North America, the publicity suddenly given to the drug by prohibiting it could produce a sudden and sustained interest in the drug among new users. This, in turn, would encourage its manufacture by underground laboratories seeking to capitalize on the artificially inflated price caused by increased demand and prohibition.

6. Prohibiting the mere possession of MBDB violates the moral right of adults to control their own mental processes.

Prohibiting MBDB will make criminals out of otherwise law-abiding citizens who merely possess the substance, and/or ingest it responsibly. This prohibition on mere possession is overbroad in application because it indiscriminately criminalizes adults who operate their own consciousness without causing any harm to others. In the opinion of the Center for Cognitive Liberty & Ethics, any prohibition concerning MBDB should be strictly limited to criminalizing *conduct* that harms others, or which poses an immediate harm to others.

II. GAMMA-HYDROXYBUTYRIC ACID (GHB)

The Center for Cognitive Liberty and Ethics respectfully recommends against the scheduling of GHB under the 1971 UN Convention on Psychotropic Substances for the following reasons:

1. Studies have shown that GHB has an accepted medical use. Scheduling GHB will significantly hinder scientific and medical study of the substance.
 - Gamma-hydroxybutyric acid (GHB) has been shown to reduce ethanol consumption and suppress ethanol withdrawal syndrome both in laboratory animals and humans. (See, G. Colombo; R. Agabio; C. Lobina; R. Reali; F. Fadda; G.L. Gessa, "Symmetrical generalization between the discriminative stimulus effects of gamma-hydroxybutyric acid and ethanol," *Physiol Behavior* Vol 57 (No. 1) Jan. 1995; 105-111.)
 - Experiments have shown that GHB, can produce a rapid and complete suppression of alcohol withdrawal symptoms. (See, G.L. Gessa, "Guidelines for the drug therapy of alcoholism," *Recenti-Prog-Med*, Vol 81 (No. 3) Mar. 1990; 171-175.)
 - GHB has also shown promise in the treatment of opiate withdrawal syndrome. (See, by L. Gallimberti; F. Schifano; G. Forza; L. Miconi; S.D. Ferrara, "Clinical efficacy of gamma-hydroxybutyric acid in treatment of opiate withdrawal," *European Archive of Psychiatry and Clinical Neuroscience*, Vol 244 (No. 3) 1994; 113-114.)
 - With respect to cocaine addiction, GHB has been shown to decrease intravenous cocaine self-administration in rats. (See, M.C. Martellotta; C. Balducci; L. Fattore; G. Cossu; G.L. Gessa, L. Pulvirenti; W. Fratta "Gamma-hydroxybutyric acid decreases intravenous cocaine self-administration in rats," *Pharmacology & Biochem Behavior* Vol 59 (No. 3) Mar. 1998, 697-702.)
 - Gamma-hydroxybutyrate (GHB) is a drug currently used to treat narcolepsy. (See, Scrima-L; Hartman-PG; Johnson-FH Jr; Thomas-EE; Hiller-FC "The effects of gamma-hydroxybutyrate on the sleep of narcolepsy patients: a double-blind study." *Sleep*, 1990 Dec. 13(6): 479-90.)
 - In healthy subjects, GHB has been shown to improve REM efficiency at night and reduces wake time after sleep onset. (See, O. Lapierre; J. Montplaisir; M. Lamarre; M.A. Bedard, "The effect of gamma-hydroxybutyrate on nocturnal and diurnal sleep of normal subjects: further considerations on REM sleep-triggering mechanisms," *Sleep*, Vol 13 (No. 1) Feb 1990; 24-30.)
2. Prohibiting the mere possession of GHB violates the moral right of adults to control their own mental processes.

In March 2000, the United States DEA placed GHB (for unregistered persons) in Schedule I. One result of this prohibition has been to make criminals out of otherwise law-abiding citizens who merely possess GHB, and/or ingest it responsibly. This prohibition on mere possession is overbroad in application because it makes criminals out of adults who operate their own consciousness with a naturally occurring cerebral nutrient and without causing harm to others. In the opinion of the Center for Cognitive Liberty & Ethics, any international

prohibition concerning GHB should be strictly limited to criminalizing *conduct* that harms others, or which poses an immediate harm to others. For example, in our opinion, using GHB (or any other substance, including alcohol) to facilitate rape should be a crime. However, in order to respect the moral rights of adults to autonomy over their own minds and cognitive processes, the Center for Cognitive Liberty & Ethics respectfully submits that the mere possession and/or use of GHB should not be a crime.

III. 4-BROMO-2,5-DIMETHOXYPHENETHYLAMINE (2C-B)

IV. 4-METHYLTHIOAMPHETAMINE (4-MTA)

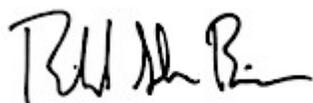
The Center for Cognitive Liberty and Ethics respectfully recommends against the scheduling of 2C-B and 4-MTA under the 1971 UN Convention on Psychotropic Substances for the following reason:

1. Prohibiting the mere possession of 2C-B and/or 4-MTA violates the moral right of adults to control their own mental processes.

The Center for Cognitive Liberty and Ethics submits that criminal prohibition of the mere possession or use of a psychoactive substance violates the fundamental right of responsible adults to control their own consciousness. In the opinion of the Center for Cognitive Liberty & Ethics, any international prohibition concerning 2C-B and/or 4-MTA should be strictly limited to criminalizing *conduct that harms others*, or which poses an immediate harm to others.

Criminal prohibition is an ineffectual, immoral, unsophisticated, and socially harmful drug policy. The Center for Cognitive Liberty and Ethics respectfully submits that the World Health Organization should take the lead in considering alternatives to the failed “zero-tolerance” Prohibition-model of drug control.

Respectfully submitted,



Richard Glen Boire, J.D.
Center for Cognitive Liberty & Ethics

ABOUT THE CENTER FOR COGNITIVE LIBERTY & ETHICS

The Center for Cognitive Liberty and Ethics is a nonprofit law and policy center working in the public interest to protect fundamental civil liberties. The Center seeks to foster cognitive liberty – the basic human right to unrestrained independent thinking, including the right to control one’s own mental processes and to experience the full spectrum of possible thought.