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January 5, 2006

Division of Dockets Management  
Food and Drug Administration  
5630 Fishers Lane  
Room 1061 (HFA-305)  
Rockville, MD 20852

Re: Docket No. 2005N-0479: International Drug Scheduling; Convention on Psychotropic Substances; Single Convention on Narcotic Drugs; Butorphanol; Delta-9-tetrahydrocannabinol (Dronabinol); Gamma-Hydroxybutyric Acid; Ketamine; Khat; Tramadol; Zopiclone; Buprenorphine; Oripavine. 70 Fed. Reg. 73,775 (Dec. 13, 2005).

Dear Sirs:

Hyman, Phelps & McNamara, P.C. objects to the abbreviated comment period the Food and Drug Administration (FDA) provided in its notice dated December 13, 2005. We request an extension of time to file comments and other specified actions by the U.S. Government. The notice states that the agency expects the public to "submit comments concerning abuse potential, actual abuse, medical usefulness, trafficking, and impact of scheduling changes on availability for medical use of nine drug substances." 70 Fed. Reg. at 73,775. A period of thirty days, through the Christmas holiday season to January 12, 2006, is plainly inadequate to provide the public the opportunity for meaningful comment on matters of such complexity and importance to domestic and international public health and safety. The Christmas holiday has severely limited the ability of most interested parties

**2005N-0479**

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in the U.S. and Europe to gather and submit useful, quality data and comments. Moreover, the abbreviated comment period is especially unjustified because FDA has acquiesced in the efforts of the World Health Organization (WHO), without merit, to cobble together a hastily scheduled meeting of its Expert Committee on Drug Dependence (ECDD) to be held less than three months from now.

In the United States, public participation in administrative processes is an essential means through which individuals manifest their consent, legitimate the actions of their government, and maintain the rule of law. That is why, for example, Section 201(d)(2)(A) of the Controlled Substances Act, 21 U.S.C. § 811(d)(2)(A), requires the U.S. Government to provide to the public notice and opportunity for meaningful participation on any scheduling action affecting the international conventions. The Administrative Procedure Act (APA), 5 U.S.C. § 553(c), provides persuasive, analogous authority with regard to the length of the comment period to be provided. In particular, the Attorney General's Manual on the APA states that "each agency should schedule its rule making in such fashion that there will be sufficient time for affording interested persons an opportunity to participate in the rule making as well as for insuring final publication of the rule at least thirty days prior to the desired effective date." Attorney General's Manual on the APA (1947), available at [http://www.oalj.dol.gov/PUBLIC/APA/REFERENCES/REFERENCE\\_WORKS/AG03.HTM#CONTENTS](http://www.oalj.dol.gov/PUBLIC/APA/REFERENCES/REFERENCE_WORKS/AG03.HTM#CONTENTS) (emphasis added). Additionally, Executive Order 12866 requires each agency to "provide the public with meaningful participation in the regulatory process;" specifically, "each agency should afford the public a meaningful opportunity to comment on any proposed regulation, which in most cases should include a comment period of not less than 60 days." Exec. Order No. 12866, 3 C.F.R. § 638 (1993), reprinted in 5 U.S.C. § 601. The data requested by HHS in the December 13, 2005 Federal Register notice are of an equal magnitude and importance to most rule makings requiring at least 60 days.

FDA explains the basis for its decision to provide only a thirty day comment period as follows: "The abbreviated comment period is necessary to allow [FDA] sufficient time to prepare and submit the domestic information package by the [January 3, 2006] deadline imposed by WHO." 70 Fed. Reg. at 73,779. The interested parties cannot be expected to do a proper job of data collection in these circumstances. Further, it is highly doubtful that FDA can collect and properly report the data it receives in the time that is allowed.

FDA's action is particularly untenable given the unfounded reasons for WHO's imposition of that deadline, and the seriousness of the matters at stake. The ECDD is supposed to convene every two years for the purpose of conducting the medical and scientific evaluation of dependence-producing drugs. Yet the last time the ECDD met was in September 2002, more than three years ago. The reason for the delay of more than

a year in conducting its mission is that the employee at WHO responsible for organizing the meetings was incapable of doing it. WHO's management tolerated this.

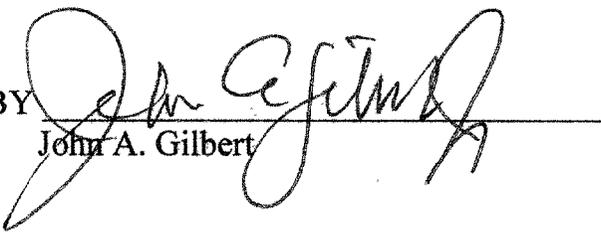
WHO now seeks to mitigate its own mismanagement by announcing on October 27, 2005 a meeting to be held only five months later, March 28, 2006. The apparent reason for this rush is that the Japanese government's commitment to fund the next ECDD meeting will expire at the end of March 2006. WHO appears more concerned about budgetary issues than that which it claims as its "principal objective—the attainment by all people of the highest possible level of health." WHO Expert Committee on Drug Dependence, Thirty-third Report, preface (2003). The quality of the data collected, developed, and submitted by member states, and the resulting merit of the decisions that will be made on the basis of these data should not be sacrificed just to have a meeting.

WHO has created this problem. It can solve it by moving the time of the meeting to allow for proper analysis and comment. Except for the desire to use funding, there is no urgent need for the meeting; any recommendations made by the 2006 ECDD will not be acted upon by the Commission on Narcotic Drugs until it meets in 2007.

We request that FDA extend the comment period for thirty days to provide sufficient time for public comment. We also request that the U.S. government bring this matter to the attention of the Executive Board of the World Health Assembly when next the Board meets in January 2006. WHO must not be allowed to compromise the important scientific and medical decisions that are critical to the scheduling process, and must account for failing to hold the ECDD meeting in 2004 and then hastily organizing a meeting at the expense of public health.

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BY

  
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