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January 24, 2006

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VIA FACSIMILE AND REGULAR U.S. MAIL

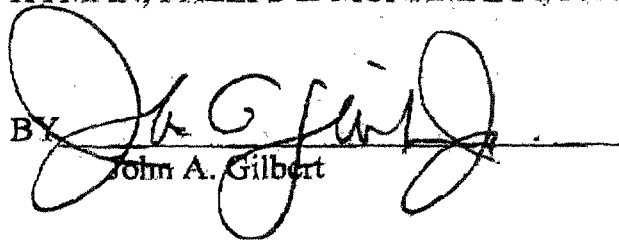
Division of Dockets Management
 Food and Drug Administration
 5630 Fishers Lane, Room 1061 (HFA-305)
 Rockville, MD 20852

**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. requests that the attached letter be submitted to the record in the above-referenced docket.

HYMAN, PHELPS & McNAMARA, P.C.

BY 
 John A. Gilbert

JAG/BJW/dcp

Attachment

2005N0479

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January 22, 2006

Director General
Dr. Lee Jong-Wook
World Health Organization
CH-1211 Geneva 27, Suisse

Dear Dr. Lee:

We have recently learned that the thirty-fourth Expert Committee On Drug Dependence (ECDD), which will meet in Geneva on 28-31 March, has included on its agenda a "final decision" on the rescheduling of buprenorphine, a medication used for pain relief and for the treatment of opiate dependence. We understand that under consideration is whether to place buprenorphine under the stricter 1961 Single Convention on Narcotic Drugs.

We believe that the rescheduling of buprenorphine will have serious public health and human rights implications and that WHO has not allowed sufficient time for full consultation and for scientific scrutiny of this proposal.

We urge that consideration of buprenorphine be postponed for a later meeting of the ECDD.

In keeping with WHO guidelines, postponement would allow proper scrutiny of the scientific, public health and social issues raised. A decision by the committee without such a review would appear to violate the spirit and intent of WHO's guidelines (*Guidelines for the WHO Review of dependence-producing psychoactive substances for international control, WHO/EDM/QSM/2000.5*).

At the request of the International Narcotics Control Board, buprenorphine was considered for rescheduling in 2002. At that time, the committee did not make a decision on rescheduling buprenorphine.

WHO guidelines note that the ECDD has to undertake a 'pre-review' and then a 'critical review' as part of the process of considering a drug for scheduling. This does not appear to have happened ahead of the March 2006 meeting. The guidelines do not authorize holding data over from previous meetings. This is particularly important when significant new data become available. Further, in other instances where drugs have been considered for scheduling more than once, as with diazepam, critical data review has occurred in advance of each discussion.

This is far more than a technical issue. Buprenorphine is increasingly used world wide in the treatment of heroin dependence, especially in countries where medical prejudice or laws and regulations have restricted the availability of methadone. Further, buprenorphine has become an increasingly important component of HIV prevention and treatment efforts, used to reduce HIV risk and increase adherence to antiretroviral medications. In a time when contaminated injection equipment accounts for large numbers of HIV infections, and the largest share of infections in many countries of Asia and the former Soviet Union, the new reporting requirements and restrictions that will

come with rescheduling may sharply decrease access to an effective measure to reduce risk of blood-borne illness.

We understand that some governments have objected to the short notice about the hearing. WHO *Guidelines* note that there also should be systematic collection of relevant information from non-governmental organizations. We are not aware that this has happened. The WHO website has no information about the agenda of the proposed meeting in March. We have not seen the data submitted to committee members that reflect current knowledge or practices. Communities and organizations impacted by the decision have not had the chance to comment. This is a marked and ironic contrast to the consultative process that WHO's expert committee engaged in prior to addition of buprenorphine to WHO's List of Essential Medicines in 2005.

We strongly urge you to share this letter with the chair and members of the WHO Executive Board when they meet from January 23-28, 2006 in Geneva.

Postponing discussion of buprenorphine to a later meeting of the ECDD will allow adequate public notice, scientific review of current data, and consultation with NGOs and others whose work will be affected by the ECDD recommendation. Any decision of the committee reached without due regard to openness, consultation and consideration of current data will be open to challenge. In the case of buprenorphine, a hasty decision to reschedule may also mean increased HIV infections, greatly limited access to opiate dependence and antiretroviral treatment, and more lives lost in violation of drug users' fundamental rights to health and life.

Sincerely,

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