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

RE: Docket No. 2005N-0479

January 12, 2006

The American Academy of Addiction Psychiatry (AAAP) is offering the following comments in response to Docket No. 2005N-0479 in the Federal Registry regarding International Drug Scheduling; Convention on Psychotropic Substances; Single Convention on Narcotic Drugs.

We understand that the World Health Organization's (WHO) Expert Committee on Drug Dependence will be meeting from March 28 to 31, 2006 and will be considering the transfer of buprenorphine from Schedule III of the Convention on Psychotropic Substances, 1971, to Schedule I of the Single Convention on Narcotic Drugs, 1961.

We believe that adoption of these proposed changes would result in an inappropriate increase in the level of control of buprenorphine in the United States and the consequent elimination of the availability of treatment of opioid-dependent patients in an office-based setting as envisioned under the Drug Addiction Treatment Act of 2000.

The enclosed Resolution of the Academy of Addiction Psychiatry reflects our view that the imposition of such additional control is both unnecessary and would impose certain harm to patients suffering from addiction, and the public health.

The AAAP strongly urges the Department of Health and Human Services, as our government's representative to the Executive Committee on Drug Dependence, to take an unequivocal stand to oppose any change in the WHO's review process that will compromise the treatment of opioid-dependent patients.

Thank you for your attention to this matter.

Sincerely,

Michael Gendel, MD
President, AAAP

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Background Regarding
American Academy of Addiction Psychiatry
Resolution on the Availability and Control of Buprenorphine

1. DATA (The Drug Abuse Treatment Act of 2000) permitted office-based prescribing of opiates for treating opiate addiction but only if the medication was Schedule 3, 4, or 5 (methadone, for example, is Schedule 2) and if the physicians were appropriately certified.

2. Buprenorphine was approved by the FDA in October 2002 and classified as a Schedule 3 medication.

3. Even before it was so scheduled, various groups were trying to make buprenorphine a Schedule 2 so it could not be prescribed in an office-based setting.

4. Since October 2002, the struggle has continued but moved to the international arena.

    a. Buprenorphine has been controlled internationally since 1989 in Schedule III of the 1971 Convention on Psychotropic Substances, based on its low abuse potential, differences between it and drugs such as methadone that are subject to stricter control, and the need to ensure patient access for treatment.

    b. Various forces are trying to get it moved to be a controlled substance under the 1961 Single Convention on Narcotic Drugs where methadone is. A decision against this was made in 1988 and reviewed since then by the WHO Expert Committee on Drug Dependence (ECDD). A new attempt will be made in January 2005.

If it were successful, the net result would be a major setback, both in the United States and internationally, to the rational treatment of opiate dependence. It would end up with it being moved to Schedule 2 in the United States and, thus, not available under DATA for office-based prescribing. Further, it would deprive patients in many countries that do not have access to methadone or other drugs regulated under the 1961 Convention of the opportunity to have effective therapy. In short, it would be a disaster to humane, effective, and safe therapy for these millions of individuals.

AMERICAN ACADEMY OF ADDICTION PSYCHIATRY

Resolution on the Availability and Control of Buprenorphine

Whereas, opioid abuse and addiction (dependence) contribute to many serious public health problems including the spread of HIV, hepatitis, and premature death among addicts, as well as individual, family and community disintegration;

Whereas, the 30th Expert Committee on Drug Dependence (ECDD)[i] of the World Health Organization (WHO) recommended that "WHO should encourage countries to give equal attention to measures to reduce demand for psychoactive substances and to efforts to reduce their supply" and that "WHO should continue to seek ways of improving the access to treatment of population groups that are at high risk of developing health problems due to the use of psychoactive substances and have poor access to services";

Whereas, the 30th ECDD also noted that there was "widespread adoption in many countries of the use of methadone and other similar substances for the management of opioid dependence" and that this treatment "is supported by ample scientific evidence of its benefits when delivered in well-controlled settings conforming to high standards;"

Whereas, The National Consensus Development Panel on Effective Treatment of Opiate Addiction[ii] similarly concluded that "our society must make a commitment to offering effective treatment for opiate dependence to all who need it" and noted that "treatment must be tailored to the needs of the individual patient," a recommendation that emphasized the role of methadone maintenance treatment in reducing mortality and other medical and social consequences of opioid addiction;

Whereas, similar conclusions were reached by the Institute of Medicine[iii], which emphasized that regulatory reform of the methadone treatment system in the U.S. was a necessary component of improving access to treatment;

Whereas, many who suffer from opioid addiction are not able to obtain treatment with methadone because many countries do not have access to any drug controlled in schedule I of the 1961 Convention for any medical purpose;

Whereas, even in the US where methadone treatment is legally available more than several hundred thousand of those who would benefit from treatment with methadone do not receive this medication and the incidence, prevalence[iv] and consequences[v] of opioid abuse continue to increase;

Whereas, bringing addicts into treatment is highly effective at reducing morbidity and mortality of opioid abuse and addiction, including but not limited to high risk behaviors associated with the spread of HIV, and hepatitis and acute overdose;

Whereas, inadequate availability of treatment is a major impediment to reducing the morbidity and mortality associated with opioid abuse and addiction;

Whereas, buprenorphine is a partial μ-opioid agonist that has been in medical use as an analgesic since the 1970's and whose possible use as a treatment for opioid addiction was demonstrated by 1978[vi];

Whereas, buprenorphine was evaluated for international control at the 25th meeting of the WHO Expert Committee on Drug Dependence in 1988[vii] which determined that buprenorphine did not meet criteria for control under the 1961 Single Convention on Narcotic Drugs and recommended that buprenorphine be controlled in schedule III of the 1971 Convention because of concern that

increased abuse of buprenorphine might develop related to its ability to suppress withdrawal symptoms among heroin addicts;

Whereas, the Commission on Narcotic Drugs accepted this recommendation in 1989 and buprenorphine has been controlled internationally since that time;

Whereas, subsequent to the review of buprenorphine by the 25th ECDD their assessment was corroborated by the finding that a ceiling exists on the effects of buprenorphine in humans[viii]; that administration of buprenorphine to persons who are physically dependent on full μ-opioid agonists may precipitate an abstinence syndrome depending on the level of physical dependence, and the timing and dose of buprenorphine[ix]; that buprenorphine may attenuate the effects of concomitantly administered full μ-opioid agonists[x];

Whereas, in 2000, the U.S. Congress passed the Drug Addiction Treatment Act (DATA), to authorize office based use of schedule III, IV and V narcotics approved for treatment of addiction by specially qualified (i.e. trained and certified) physicians;

Whereas, in 2003, FDA approved buprenorphine formulations (Subutex® and Suboxone®) for use under DATA, the most substantial expansion of the availability of treatment of opioid addiction in the US in more than 30 years;

Whereas, buprenorphine has been demonstrated to have a low potential for abuse compared to heroin, morphine and methadone and is a safe and effective treatment for opioid addiction when used as directed according to accepted medical care standards;

Therefore be it resolved that the AAAP supports the following position in regard to the availability and control of buprenorphine:

That the U.S. and other countries should seek ways of improving the access to treatment of population groups that are at high risk of developing health problems due to the abuse of opioids and may have poor access to services;

That our society must make a commitment to offer effective treatment for opiate dependence to all who need it;

That buprenorphine is a safe and effective treatment for opioid addiction that is particularly well suited for use in a general practice, community-based settings, as well as certain specialty clinics, e.g. HIV clinics;

That the current level of control of buprenorphine in the United States in Schedule III of the federal Controlled Substances Act and internationally in Schedule III of the 1971 Convention on Psychotropic Substances is the appropriate level of control based on buprenorphine's low potential for abuse and based on differences between it and drugs such as methadone that are subject to stricter control as well as the need to ensure patient access for treatment;

That buprenorphine offers many countries that do not have access to methadone or other drugs regulated under the 1961 Convention for medical treatment the opportunity to provide effective treatment for opioid-addicted persons;

That further restriction of buprenorphine would be unwarranted and detrimental to public health;

Therefore be it resolved that the American Academy of Addiction Psychiatry opposes further control, more restrictive scheduling or additional constraints on the availability of buprenorphine and supports the current scheduling of buprenorphine in opioid treatment in the United States and in the international health care community.

References

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