



Sep 1, 2000

Substance Abuse and Mental
Health Services Administration
Rockville MD 20857

Dear Colleague:

The purpose of this letter is to clarify the status of buprenorphine, a partial opioid agonist drug substance that is under investigation at selected sites for the treatment of opiate addiction. The Center for Substance Abuse Treatment (CSAT), the Food and Drug Administration (FDA), and the Drug Enforcement Administration (DEA) have all received several inquiries on this issue. Further, these agencies have received anecdotal reports that buprenorphine is being used in the treatment of opiate addiction. Buprenorphine is not currently approved or legally available for the treatment of opiate addiction in the United States, except when used under an Investigational New Drug (IND) Study.

In 1985, FDA approved a new drug application for Buprenex® an injectable analgesic product containing buprenorphine as its active ingredient. At the same time and in association with FDA's approval of Buprenex®, DEA controlled buprenorphine as a narcotic in Schedule V of the Controlled Substance Act ("CSA," 21 U.S.C. § 811). From the questions received, there appears to be a misunderstanding that Buprenex® can be used in the treatment of opiate addiction as an "off label" use of an approved drug product. This is not accurate. Practitioners who dispense Buprenex® for the treatment of opiate addiction must comply with the Narcotic Addict Treatment Act (NATA) (21 U.S.C. 823(g)). Buprenex® may not be used for the treatment of opiate addiction unless and until it is approved for this use and there are standards in place to permit practitioners to be registered by DEA as required by NATA.

There has been considerable interest and activity in Congress on the issue of new medications for the treatment of opiate addiction. Measures have cleared both houses that, if passed and enacted into law, would provide waivers from the NATA requirements, discussed above, for certain narcotic drugs used in the treatment of opiate addiction if approved for that use by FDA. Buprenorphine has been discussed often within the context of these activities. As a result, some have mistakenly concluded that buprenorphine products are approved and available for use in the treatment of narcotic addiction.

There has also been rulemaking activity in this area. In May, the Department of Health and Human Services, which includes the Substance Abuse and Mental Health Services Administration and CSAT, published a Notice of Intent to allow for office-based treatment of opiate addiction using certain partial agonist medications. Please see the attached Notice for additional information. The purpose of this announcement was to notify affected parties of the agency's intent to propose new rules, which are subject to the notice and comment rulemaking process. As such, no regulations have been issued yet to permit the use of partial opioid agonist medications.

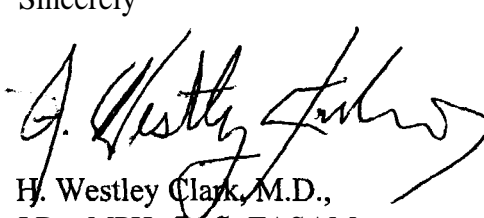
For the last several years, buprenorphine, in liquid and solid oral dosage form, has been under investigation for use in the treatment of opiate addiction. And, there are several multi-center clinical trials currently underway. Practitioners participating in these IND-sanctioned trials are entitled to conduct this research under the CSA and the Food, Drug, and Cosmetic Act without separate DEA registration. Practitioners interested in learning more about ongoing clinical trials with buprenorphine should contact the National Institute on Drug Abuse (NIDA), as noted below.

It is important to emphasize that at present there are no buprenorphine products approved and available for the treatment of opiate addiction. Buprenex® is not approved for the treatment of opiate addiction. Further, unlike methadone and ORLAAM, there are no treatment standards established by the Secretary of Health and Human Services to permit practitioners to be registered by DEA as required under the NATA. Therefore, buprenorphine products may not be used in the treatment of opiate addiction at this time.

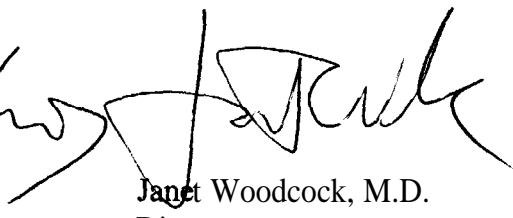
In closing, the undersigned would like to emphasize our shared goal to work together to expand patient access to safe and effective opiate addiction treatment.

For further information please contact Mr. Robert Lubran, Acting Director, Office of Pharmacological and Alternative Therapies, CSAT, at 301-443-0744. For further information about ongoing clinical trials with buprenorphine, contact Mr. Robert Walsh, Associate Chief, Regulatory Affairs Branch, Division of Treatment Research and Development, NIDA, at 301-443-5280.


Sincerely



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Enclosure: