



APR 3 2006

Center for Mental Health Services
Center for Substance Abuse
Prevention
Center for Substance Abuse
Treatment
Rockville MD 20857

Dear Colleague:

This letter is to notify you that certain pharmacies may be compounding and selling buprenorphine and buprenorphine/naloxone combination products in various strengths, colors, and flavors. These products are being marketed to treat opioid dependence and pain.

The compounding and sale of buprenorphine and buprenorphine/naloxone products present potentially serious public health and safety issues. These issues are distinct to compounded formulations and do not arise with the manufacture, distribution, and sale of Food and Drug Administration (FDA)-approved products Subutex (buprenorphine) and Suboxone (**buprenorphine/naloxone**).

Addiction Treatment

The Drug Addiction Treatment Act (DATA) allows certain Schedule III, IV, and V, controlled substances to be prescribed in an office-based setting to treat opioid dependence. DATA requires registration of qualified practitioners to prescribe these controlled substances and limits the medications that may be prescribed to those products that have been approved by FDA for maintenance or detoxification treatment.

Further, prescribing physicians must certify that they will use only Schedule III, IV, or V drugs that are FDA approved for maintenance or detoxification treatment.

The only Schedule III, IV, or V, medications to receive FDA approval for opioid addiction treatment are Subutex and Suboxone. No other medications, including Buprenex (buprenorphine hydrochloride injectable) and compounded buprenorphine products, are eligible for opioid addiction treatment under DATA.

Patient Safety

Buprenorphine and naloxone are prone to oxidation and are sensitive to moisture, leading to potentially toxic degradation. This degradation can be extensive and is affected by the drug formulation process. The use of unapproved chemicals (e.g., dyes and excipients) to manufacture these products may cause product degradation, which could lead to serious health risks for your patients.

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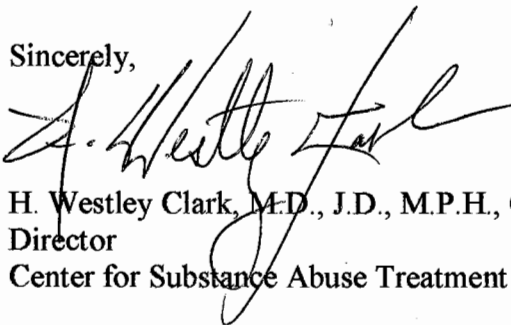
Further, the sublingual administration of Suboxone and Subutex can be extremely sensitive to formulation changes. Differences in formulation and pharmacokinetics can lead to significant under or over-dosing, both of which can be dangerous (e.g., leading to symptoms of withdrawal and craving) to patients who are sensitive to dose and formulation changes. Without extensive pharmacokinetic comparisons, the bioequivalence of compounded products to the FDA-approved products cannot be assured.

Risk Management

Reckitt Benckiser Pharmaceuticals, Inc. (RBPI), the manufacturer of Subutex and Suboxone, administers a comprehensive Risk Management Program designed to reduce the risks and consequences of the diversion of this abuseable substance. This plan allows the FDA and the Drug Enforcement Administration to monitor the approved products' safety, and to guard against their diversion and abuse. Because it is not possible to identify and track unregistered and unapproved products, the use of unapproved buprenorphine products circumvents the public health purpose of the Risk Management Program.

In the interest of patient safety and the public health, we advise you of these concerns. Thank you for your attention to this important matter.

Sincerely,



H. Westley Clark, M.D., J.D., M.P.H., CAS, FASAM
Director
Center for Substance Abuse Treatment