

## **NEW TREATMENT FOR HEROIN ADDICTION APPROVED BY FDA, 10/8/02**

We would like to inform our patients about a new treatment for heroin addiction which has recently become legal. The Drug Addiction Treatment Act of 2000 was signed by President Clinton on October 17, 2000. This law has several “firsts”. For the first time, a physician in the office setting will be able to prescribe a narcotic for treatment of addiction - following certain guidelines and restrictions. For the first time a patient who is addicted to heroin will be able to receive opioid medication for detoxification or for maintenance - again with certain restrictions - in a regular office setting, outside of the methadone treatment program. The only medication which is allowed is buprenorphine. Methadone still may not be prescribed in California in an office setting for the treatment of addiction.

THE NEW LAW: The Drug Addiction Treatment Act of 2000 (DATA) has the following restrictions:

- The physician has to have training in opioid addiction treatment.
- The physician has to register with the Secretary of Health and Human Services
- The physician will receive a special number to add to his or her DEA license to prescribe scheduled drugs
- The drug prescribed has to be approved by the FDA as useful in the treatment of addiction. Buprenorphine has been shown to be effective for heroin addiction, and two forms of it were approved by the FDA on October 8, 2002, for use in opiate addiction treatment.
- The drug prescribed may not be a schedule II narcotic, but only III, IV or V. (Buprenorphine is schedule III. Methadone is schedule II.)
- The physician may only have 30 patients on this treatment at one time.
- The physician must have access to counseling services for the addicted patient.

### THE NEW MEDICATION: BUPRENORPHINE

Buprenorphine is an opioid medication which has been used as an injection for treatment of pain while patients are hospitalized, for example for surgical patients. It is a long acting medication, and binds for a long time to the “*mu*” endorphin receptor. This means most patients don’t have to take medication every day. It is not absorbed very well orally (by swallowing) – so a sublingual (dissolve under the tongue) tablet has been developed for treatment of addiction. One form of this sublingual tablet, Suboxone, also contains a small amount of naloxone (Narcan ) which is an opioid antagonist and will cause withdrawal if injected. Buprenorphine without naloxone has been available in other countries, and has been used illicitly by addicted persons, but so far it hasn’t been abused when combined with naloxone.

Aside from being mixed with naloxone to discourage needle use, buprenorphine itself has a “ceiling” of narcotic effects (it is considered a “partial agonist”) which makes it safer in case of overdose. This means that by itself, even in large doses, it doesn’t suppress breathing to the point of death in the same way that heroin or methadone could do in huge doses. If a child swallowed a whole bottle of buprenorphine tablets (remember they are not absorbed very well by swallowing) it would probably not be lethal, whereas a single dose of methadone might be lethal to a child. These are some of the unusual qualities of this medication which make it safer to use outside of the usual strict methadone regulations at a clinic and, after stabilization, most patients would be prescribed as much as four weeks’ worth of buprenorphine at a time.

## WILL BUPRENORPHINE BE USEFUL FOR PATIENTS ON METHADONE?

Our methadone maintenance patients may be interested in whether this medication might help them. Unfortunately, because of the partial agonist nature of the medication, buprenorphine is not equivalent in maintenance strength to methadone. In order to even try buprenorphine without going into major withdrawal, a methadone-maintained patient would have to taper down to 30mg of methadone or lower. We are concerned that this medication may not be strong enough for most of our patients, and might lead to dangerous relapses if attempted. **If you decide to try it, please be aware of this danger of relapse**, and keep the door open for resuming methadone immediately if necessary.

There are also some studies which show that detoxification from buprenorphine is effective. Some of our 21-day-detoxification methadone-treated patients may want to transfer to buprenorphine to complete their tapers after the methadone dose has dropped to below 30 mg of methadone – this would usually be in the second week of 21-day detox. Whenever buprenorphine becomes available in the community we will try to set up a way to expedite this transfer. So far we don't know whether buprenorphine will be "covered" under Medi-Cal the way methadone detoxification is.

So far, remember the following tips:

- If you are offered buprenorphine by a "friend" and you are taking methadone or LAAM, the buprenorphine will push the other opioids off the receptor site, and you may be in withdrawal and very uncomfortable.
- If you dissolve and inject Suboxone - the buprenorphine-naloxone sublingual tablet - it may induce severe withdrawal because of the naloxone, which is an antagonist.
- If you are on methadone treatment and wish to transfer to buprenorphine, your dose has to be at or below 30mg.
- There have been deaths reported when buprenorphine is combined with benzodiazepines. (This family of drugs includes Klonopin, Ativan, Halcion, Valium, Xanax, Librium, etc.) If you are taking any of these drugs, either by prescription or on your own, buprenorphine is may not be a good treatment for you.

We will keep you posted as more practical facts develop about the use of this new treatment. It is available in pharmacies around the Bay Area. You may want to ask your family physician whether he or she is one of the registered physicians who will prescribe it in the office. Any physician can take the 8-hour training courses, and this course is also available on line. This treatment may be more expensive than methadone maintenance. So far, Medi-Cal does not pay for it.