



## Successful Trial Caps 25-Year Buprenorphine Development Effort

Twenty-five years ago it would have been almost impossible to imagine a treatment for opiate addiction that could be prescribed in a physician's office, picked up at a pharmacy, and taken at home.

**First developed as a pain medication, buprenorphine was recognized in the 1970's as useful for addiction treatment.** An initial 1978 study demonstrated the drug's effectiveness with patients as a treatment for opiate dependence.

Early on, scientists realized that medications for addiction not only had to be safe and effective, but also had to be available in a form that would be practical for therapeutic use.

As with any opioid, however, there were concerns about buprenorphine diversion and the drug's potential for abuse. **By the mid-1990's, a combination tablet of buprenorphine and naloxone was developed that would minimize the potential for abuse.**

A nationwide study by the National Institute on Drug Addiction (NIDA) of opiate addicted men and women was recently published. The study confirmed that the efficacy and safety of the combined therapy are equivalent to those of buprenorphine alone. **The combination reduces craving for and use of opiates while presenting a limited potential for abuse.**

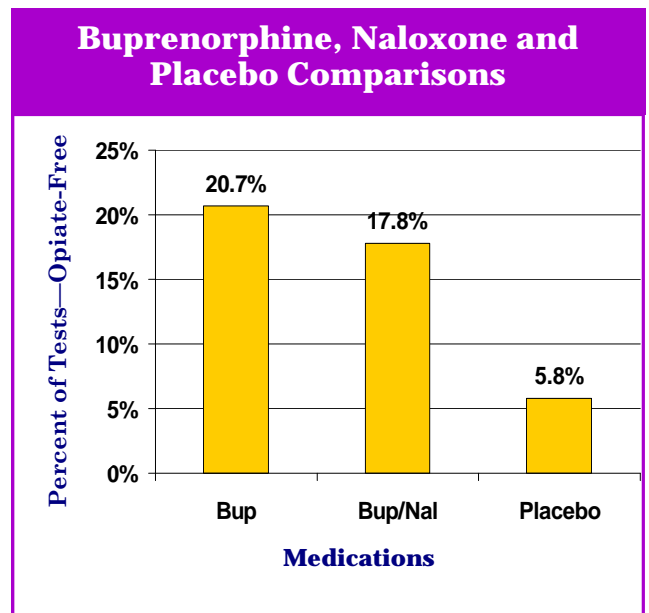
### Initial Treatment Outcomes

The study began with a double blind phase in which 323 opiate addicted individuals (ages 18 to 59) received one of three treatments for 4 weeks. All tablets were identical in appearance and taste. Patients reported to the clinics for dosing every week-day and took their medications home for

weekends and holidays. Study patients and placebo patients also participated in one hour of individualized counseling per week. Opiate use was monitored through urine tests every Monday, Wednesday, and Friday.

Both medication groups showed significant reductions in opiate use and craving and significant improvements in perceptions of overall health compared with those receiving placebo. **(Please see Exhibit I)**

Exhibit I



*Patients undergoing treatment for opiate addiction who received buprenorphine or buprenorphine plus naloxone were more likely to test negative for opiate abuse than patients given a placebo.*

**Patients in both medication groups also reported reduced craving for opiates.** All groups showed the same average self-reported craving level before treatment. By week four of the study, the average craving scores fell by over 50% for both medication groups but did not change for the placebo group.

Summary

Patients receiving medications reported greater improvement in overall health and well-being than those in the placebo group.

Because both medications were clearly effective, the researchers halted the first phase of the study. Patients receiving a placebo during this phase went on to receive the buprenorphine-naloxone combination treatment in the second phase of the study.

In the two years since the medication was approved, clinicians have gained an even greater understanding of which patients are most likely to benefit from buprenorphine-naloxone treatment.

It is believed suitable populations would be addicted professionals, including those in health care, who are motivated to seek treatment in the privacy of an addictions treatment setting.

Editorial Staff

Editor in Chief:  
David W. Cunningham

Assistant Editors:  
Hugh Kilbourne  
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Art/Graphics Designer:  
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Center for Behavioral  
Health Studies

Rimrock Foundation  
P.O. Box 30374  
Billings, MT 59107

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