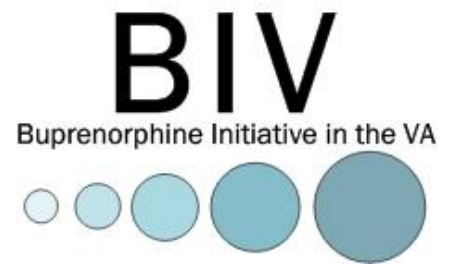


A Tool for Buprenorphine Care

(A series of monthly newsletters about buprenorphine treatment)

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INSIDE/OUTSIDE THE VA

The First Amendment affords citizens the opportunity to ask the government for concerns to be addressed via a citizen's petition. Certain states and government agencies have specific mandates to change their laws based on a petition. Requests are made often of the FDA using this method due to the nature of how the FDA's decisions impact citizens. The manufacturer of buprenorphine/naloxone (Reckitt-Benckiser) used the citizen's petition method to ask that the FDA adopt more stringent and child-resistant packaging requirements along with educational programs for buprenorphine products in order to stave off reports of accidental pediatric exposure to buprenorphine. [The FDA has denied the manufacturer's citizen petition](#). This effectively allows other manufacturers to pursue the tablet formulation for buprenorphine/naloxone. The FDA has approved two generic formulations (from Actavis, Inc. and Amneals Pharmaceuticals, LLC) and these products are expected to be available in March 2013. They are both AB-rated to Suboxone sublingual tablets; however, bioequivalence study results have not been released. Drug costs have not yet been made available.

The manufacturer has announced that they will discontinue the tablet formulation on March 18, 2013. The VA's Pharmacy Benefits Management (PBM) has announced that unless it issues further guidance, each VISN should determine how buprenorphine/naloxone treatment will be made available to patients (film or generic tablet).

Should providers wish to remain using the new manufacturer's product (film) or transition your patients to the film formulation, the previous PBM announcement, the manufacturer's announcement and instructions, and the BIV tablet-to-film switch document still apply. However, we have received some clarifying information from the manufacturer of the film product regarding the previous newsletter which providers should consider: **Greater Bioavailability:** Because the drug was the same in the film, the FDA did not require an efficacy trial but rather a bioequivalence study. The FDA indicated there was a "potentially greater bioavailability" of the film over the tablet product. **Mucous Membrane:** Suboxone (film or tab) has not been studied at the buccal route and so this is an off-label route. **Mint Prior to Dose:** Candies or mints just prior to administration (film or tablet) may interfere with absorption and increase mouth sensitivity. **Split Film:** It is not advisable to split or cut the film (or tablet). When drugs do not have a line or scoring the even distribution of the drug across the medium is not guaranteed. Also, without these scoring lines, patients may not be evenly cutting and cutting film leaves an open pouch for a child to get into.

MEDICATION-ASSISTED ADDICTION TREATMENT IN THE NEWS

1. [Therapy ineffective for opioid addiction](#)
2. [BioDelivery Sciences Announces Completion of BNX Safety Study](#)

RESEARCH UPDATE

1. J Psychopharmacol. 2013 Jan 29. [Epub ahead of print] [Opiate agonists and antagonists modulate taste perception in opiate-maintained and recently detoxified subjects](#). Green A, Kaul A, O'Shea J, Sharma E. **TAKE HOME POINT:** "Accumulating evidence therefore suggests that sweet taste hedonic measures and, as we have shown, possibly other perceptual measures such as intensity and thresholds may represent indicators of opiate tolerance and appropriate methadone-maintenance regimens."
2. J Pain Res. 2013;6:23-38. doi: 10.2147/JPR.S36827. Epub 2013 Jan 9. [Morphine- and buprenorphine-induced analgesia and antihyperalgesia in a human inflammatory pain model: a double-blind, randomized, placebo-controlled, five-arm crossover study](#). Ravn P, Secher EL, Skram U, Therkildsen T, Christrup LL, Werner MU. **TAKE HOME POINT:** "...could not demonstrate any significant differences between morphine and buprenorphine in the profiles of antihyperalgesia and analgesia. Only high-dose buprenorphine was associated with a significant effect on the descending inhibitory pain control system."

