

Suboxone Pharma Foibles/FDA Does Its Job Well

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OF THE 37,485 AMERICANS WHO LOST their lives in 2009 to illicit drug use, prescription pain medications caused more deaths than heroin and cocaine combined. Opiates are misused more than any other class of prescription medications. Opiate dependence affects an estimated 1.9 million Americans. Reckitt Benckiser, a British-based company, brought Suboxone (buprenorphine/naloxone) to market in 2002. Since then, Suboxone has made a very valuable contribution to treating those with an addiction to prescription pain medications and heroin. Suboxone is an effective medication, and studies have shown that patients on Suboxone maintenance therapy have a significantly reduced chance of relapse on opiates.¹ The availability of Suboxone has saved untold lives but has been costly as a patented product.

Reckitt Benckiser's U.S. patent on Suboxone tablets expired in 2009. Since then, it has encouraged physicians and patients to change to its patented sublingual film-strip version of Suboxone. Though exclusivity for the Suboxone film ends in 2013, the patent for the technology itself extends through 2023. Encouragement changed to dictation on September 25, 2012, when the company stopped manufacturing Suboxone tablets. Furthermore, it asked the U.S. Food and Drug Administration (FDA) to prevent future production of tablets, including generic versions via a citizen petition.

Reckitt Benckiser based its petition on data the company "received" (i.e. commissioned itself) from an organization called RADARS (Researched Abuse, Diversion and Addiction-Related Surveillance). Reckitt Benckiser argued its own tablets were unsafe to children and presented an unacceptable risk of

pediatric exposure. This argument was particularly disingenuous and cynical given the timing of the expiration of its tablet patent. As noted by Alison Knopf, editor at *Alcoholism & Drug Abuse Weekly*, "there are tons of kids who die from ingesting other narcotics, including methadone, and these aren't required to be (packaged) in film or are in film."

Like many other pharmaceutical companies, Reckitt Benckiser tried to exploit the use of a citizen petition to the FDA to preserve their market. The FDA is a consumer protection agency – all prescription medications have to pass a lengthy review process before they are available to physicians and their patients. In order to ensure that these concerns are addressed, the FDA is mandated to review these petitions. However, most of these petitions are submitted not by laypersons but by large pharmaceutical companies, often as a mechanism to block the development of generic versions of drugs with recently expired patents. Congress recognized this problem, and passed the FDA Revitalization Act of 2007, which attempted to limit abuse of citizen petitions by large corporations. Unfortunately, large pharmaceutical companies have managed to find ways to bypass these restrictions.

This example of a pharmaceutical company trying to protect profits under the veil of safety highlights one of the problems with the American healthcare system and the need for a more thoughtful FDA body. Misuse of prescription opiate medication incurs direct costs of up to \$72.5 billion a year, in addition to 300,000 ER visits, according to the results of a national survey by the Substance Abuse and Mental Health

Services Administration (SAMHSA 2009), as well as contributes to a significant portion of poisoning deaths. Reducing access to an effective treatment of opiate dependence would have delivered an incredible financial blow to a health system that is already struggling.

The good news is that the FDA threw out Reckitt Benckiser's petition, even referring the matter to investigators at the Federal Trade Commission. In addition, the FDA gave two generic drug makers, Anael and Actavis, both based in New Jersey, the green light to market buprenorphine/naloxone tabs. Actavis said that it "intends to begin shipping the product immediately." This is a wonderful example of the FDA protecting Americans – increasing access to life saving treatment and reducing healthcare costs. ❖

Reference

1. Weiss RD, et al. Adjunctive Counseling During Brief and Extended Buprenorphine-Naloxone Treatment for Prescription Opioid Dependence: A 2-Phase Randomized Controlled Trial. *Arch Gen Psych*. 2011;68(12):1238-1246.

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Disclosures

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