U.S. FDA and FTC: Opioid Addiction and Health Fraud

LCDR Jeffery L. Sumter, DrPH; CDR Adrienne Goodrich-Doctor, PhD.
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Introduction

Opioid addiction is a serious health epidemic that affects millions of Americans. Opioids are a class of drugs that include: the illegal drug heroin, synthetic opioids (fentanyl), and pain relievers available legally by prescription, such as: oxycodone, hydrocodone, codeine, morphine and others. In part, increased prescription of opioid medications have led to widespread misuse of both prescription and non-prescription opioids, and resulted in an opioid addiction epidemic. Consumers with opioid addiction may seek medication-assisted treatments (MAT) or dietary supplements (DS) to treat opioid withdrawal. Treatments such as buprenorphine and methadone have been demonstrated to be safe and effective in combination with counseling and psychosocial support. There is strong scientific evidence that this combination of therapeutic interventions is life-saving and can enable people to recover to healthy lives. However, there are limited drugs approved by the U.S. Food and Drug Administration (FDA) for opioid addiction treatment. Some marketers and distributors are illegally marketing products with unproven claims about their ability to help in the treatment of opioid addiction and withdrawal. Such products have not been demonstrated to be safe or effective and may keep some consumers from seeking appropriate, FDA-approved therapies. Health fraud scams can pose serious health risks to consumers. Selling unapproved products with claims that they can treat opioid addiction and withdrawal is a violation of the Federal Food, Drug, and Cosmetic Act (FD&C) Act, and making unsubstantiated therapeutic claims are also a violation of the Federal Trade Commission Act, which prohibits deceptive advertising. It is unlawful to make any deceptive representation with respect to the cost, price, efficacy, performance, benefit, risk, or safety of any MAT or dietary supplement. FDA aims to reduce the number of Americans addicted to opioids, cut the rate of new addictions and promote innovative access to MAT for more than 2-million Americans with an opioid use disorder (OUD).

Figure 1. National Drug Overdose Deaths Number Among All Ages, by Gender, 1999-2017

Figure 2. National Drug Overdose Deaths Number Among All Ages, 1999-2017

Intervention

In 2018, FDA and the Federal Trade Commission (FTC) reviewed marketing claims on opiate withdrawal treatments. The results of the review revealed that some marketers and distributors illegally marketed products with unproven treatment claims. Both the FD&C and FTC Acts require that health-related claims, such as claims that a product will treat or cure a disease or other health condition, must be supported by competent and reliable scientific evidence. Therefore, it is unlawful to make health claims, whether directly or indirectly, through labels, labeling, advertising, the use of a product name, website name, or any other means, without adequate scientific support, or to exaggerate the benefits of products or services.

Past Year Opioid Misuse among People Aged 12 or Older: 2017

Past Year Opioid Misuse among People Aged 12 or Older, by Age Group: 2017

Actions

In response to the review of claims on opiate withdrawal treatments, the FDA and FTC found some marketers and distributors illegally marketed products with unproven treatment claims. FDA and FTC took action by issuing letters to 16 firms that used such questionable claims, reminding them that they needed solid scientific proof to support all health claims conveyed to consumers, especially representations about serious conditions like opioid dependence. The manufacturers were strongly urged to review all health-related claims by the firms' and any of their affiliates on all mediums. The FDA and FTC issued joint warning letters to 11 firms for their products: The FTC sent four additional warning letters to other marketers of opioid cessation products. All of the firms that received warning letters used online platforms to make unproven claims about their product's ability to cure, treat, or prevent OUD. Examples of such claims are listed below:

- “#1 Selling Opiate Withdrawal Brand”
- “Imagine a life without the irritability, cravings, restlessness, excitability, exhaustion and discomfort associated with the nightmare of addiction and withdrawal symptoms.”
- “Safe and effective natural supplements that work to ease many physical symptoms of opiate withdrawal.”
- “Break the pain killer habit.”
- “Relieve Your Symptoms...addiction, withdrawal, cravings.”

In addition, both the FDA and FTC reexamined their approach to homeopathic products (HP). Each agency adopted new enforcement policies in holding homeopathic drugs to the same standard as other products making drug related claims, including claims that such products can treat specific conditions. FDA's new enforcement approach also covers products labeled as homeopathic that contain potentially harmful ingredients or do not meet current good manufacturing practices.

FDA regulates HP as drugs, whereas it regulates dietary supplements (DS) as food. However, many DS contain ingredients with strong biological effects and some may contain hidden drugs that are falsely marketed as DS, thus putting consumers at risk. Recently, FDA has seen an increased number of companies illegally marketing DS and HP compounds for the treatment of OUD, pain and other unproven claims.

Getting the Right Help

Do you know someone seeking treatment for opioid dependence or withdrawal? If so, it's important to know this: products that promise miracle cures or fast results can cost precious time and money, lead to relapse, and even be dangerous.

- Dietary supplements – such as herbal blends, vitamins, and minerals have not been scientifically proven to ease withdrawal or to treat opioid dependence.
- Products like Kratom, which some claim can help, are actually not proven treatments, and can be addictive and dangerous to your health.
- Opioid dependence and withdrawal are serious health issues. You can address them with time, hard work, and help. But there are no quick fixes.
- Before taking any dietary supplement – for any medical reason – ask a health provider these questions:
 - Is there scientific proof it actually works?
 - How reliable is this brand?
 - How will it interact with other supplements or drugs I take?
 - What are the side effects?
 - If it's safe to take, what's the right amount?

Conclusion

To follow-up on the 2018 Warning Letters, FDA will coordinate a series of inspections which include firms producing products labeled as dietary supplements but marketed as unapproved opioid addiction and withdrawal treatments. During inspections, FDA will seek to remove misbranded and potentially harmful products from the market. While FDA has a role in the enforcement of federal laws, it also encourages innovation and the development of new therapies for those suffering from OUD.

Acknowledgements and Contacts

Health care professionals and consumers are encouraged to report any adverse events related to these products to the FDA's MedWatch Adverse Event Reporting program. To file a report, use the MedWatch Online Voluntary Reporting Form. The completed form can be submitted online or via fax to 800-FDA-0178.