Workers' Comp

Will Naloxone Become Available for Purchase without a Prescription?

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Nalaxone

Today, there are two prescription products for use by laypersons. Namely, auto-injector (Evzio®) and intranasal (Narcan® Nasal Spray) naloxone. While they can be administered by someone outside of the healthcare profession, they are only obtainable with a prescription. The Food and Drug Administration (FDA) believes an over the counter (OTC) version may remove barriers for obtaining naloxone, particularly for people who are not under the care of a physician or who may be hesitant to admit to issues with opioid abuse. One of the barriers to the availability of OTC naloxone products is the FDA's requirement of a consumer-friendly Drug Facts Label (DFL). Any new drug application or supplement for an OTC drug product, along with required studies demonstrating consumer understanding, must be submitted with the DFL. As a result, the FDA has taken some unprecedented steps to encourage drug companies to enter the OTC market with an over-arching goal of increasing access to naloxone. For the first time in its history, the FDA has created and tested a model DFL containing easy-to-understand pictograms demonstrating how to use naloxone. The required comprehension consumer testing for the model DFL was conducted through an independent research contractor. The model DFL was created in two versions, one for use with naloxone nasal spray and one for naloxone auto-injector. The actual medications weren't present in the DFL. Instead placeholders were used, and instructions given that would need to be added and tested where necessary by the product sponsor. This is intended to make it easier for drug companies to pursue OTC naloxone development. The FDA is urging manufacturers to take note and submit applications as soon as possible. Coventry and First Script will continue to monitor the progress and the introduction of any such OTC naloxone products.

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