Workers' Comp

FDA Approval of Dsuvia: Why Now and What Might it Mean for Workers' Compensation?

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The FDA recently approved a new opioid that is causing some concern. The new drug, Dsuvia, is reportedly 1,000 times more powerful than morphine and 10 more powerful than fentanyl. Many people are asking why, in the midst of the opioid crisis, are we approving a new, highly potent opioid?

FDA Commissioner, Scot Gottlieb, noted the irony and talked about the FDA's protocols for approving new opioids. He indicated that the criteria should include whether or not the new drug is sufficiently better than existing opioids in the marketplace.

Dsuvia does seem to meet that test. It is designed to be administered sublingually and will primarily be used if a patient is not a candidate for oral or intravenous administration routes.

Notably, Dsuvia will not be available in a retail pharmacy. It was developed in partnership with the Department of Defense to help provide rapid relief of pain on the battlefield in circumstances where an oral medication would not be practical or effective. For civilian use, Dsuvia is restricted to inpatient hospital settings and will be subject to tight restrictions.

Dsuvia is not without its critics. Raeford Brown, MD, chair of the FDA's Anesthetic and Analgesics Drug Products Committee, penned a letter to the FDA urging them not to approve the drug, even though his committee voted to recommend its approval. Dr. Brown noted in his letter that Dsuvia "…is thus an extremely divertible drug, and I predict that we will encounter diversion, abuse, and death within the early months of its availability on the market." Dr. Sidney Wolfe, senior advisor of Public Citizen's Health Research Group characterized the move by the FDA to approve the drug "a terrible decision."

The Pentagon needs a viable solution for battlefield pain relief and Dsuvia is unique in its placement in that role. However, the risks cannot be ignored. While the FDA has noted that the drug will be tightly controlled, history

has shown that even the best controls can be circumvented, and in the worst cases, ignored.

The good news for the workers' compensation industry is that there should be very little impact or use of Dsuvia for workplace injuries. Dsuvia will not be available in outpatient settings and is not approved for use by first responders. Workers' compensation payers would only see Dsuvia in very rare cases involving inpatient hospital settings where an injured worker was unable to receive pain medication through traditional routes of administration. We will continue to monitor the potential impact on the workers' compensation industry as Dsuvia enters the marketplace.



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