

February 2, 2017

U.S. Food and Drug Administration  
Center for Drug Evaluation and Research  
10903 New Hampshire Avenue  
Silver Spring, MD 20993

RE: FDA review of the proposed use of sublingual formulations of synthetic fentanyl analogs, including sufentanil.

The American College of Emergency Physicians (ACEP) submits the following comments regarding the FDA review of the proposed use of sublingual formulations of synthetic fentanyl analogs, including sufentanil. Opioid abuse and overdose are serious global health crises that demand our immediate attention and intervention to curb the escalating increase.

Opioids, including prescription opioids, killed more than 28,000 Americans in 2014 (the most recent year of full national data) and approximately half of all opioid deaths in the U.S are due to prescription opioids according to data from the CDC. Deaths from fentanyl and other synthetic opioids increased by at least 80% between 2013 – 2014, and recent data suggest increasing rates of overdose from synthetic opioids as reported in the December 2016 MMWR. Data also suggest that instant release or quick release formulation of opioids are more easily abused than controlled release formulations as reported in the July 2012 edition of Pharmacy and Therapeutics.

AcelRx Pharmaceuticals, Inc. has completed Phase 3 clinical trials of ARX-04, a 30 mcg sublingual instant release sufentanil tablet for the treatment of moderate to severe pain to be used in the prehospital, emergency department, or post-op setting, and is currently in the FDA New Drug Application review process. Promotional materials from AcelRx Pharmaceuticals, Inc. indicate they believe that ARX-04 is best utilized in EMS and Emergency Medicine settings. There are no data to indicate that pharmacokinetic failure of currently available narcotics via existing routes and formulations is a problem in EMS or Emergency Medicine.

ACEP actively opposes the prehospital use by EMS of sublingual formulations of synthetic fentanyl analogs, including sufentanil. Our experts do not believe that this drug has a role in prehospital EMS or emergency department use in the civilian sector. Further, we believe it has a higher chance of abuse and diversion, and should not be marketed to EMS. ACEP strongly opposes the approval of any new synthetic opioids in civilian EMS prehospital care while we are battling the current opioid abuse crisis, a battle that is consuming significant resources of other agencies within the Department of Health and Human Services.

If additional information or testimony is needed we would be glad to provide it if requested.

Sincerely,

*Rebecca B. Parker, MD, FACEP*

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ACEP President

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