Challenges and Opportunities in the Development of Abuse Deterrent Transdermal Opioid Therapies

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Abstract:

Treatment of chronic pain with opioids is currently a therapeutic necessity, but it often causes problems with addiction and drug abuse. Moreover, opioid abuse presents a large burden to society on a global scale. In the United States, the Food and Drug Administration encourages development programs to bring abuse deterrent (AD) opioid medications to the market, and many of these programs have been executed via the 505(b)(2) regulatory pathway. Therefore, in recent years a number of products have successfuly achieved AD labeling status in the USA; however, none of those products have been transdermal drug delivery systems (TDDS). This discussion reviews current literature and offers perspectives on the challenges and opportunities in development of an AD TDDS. Technical and regulatory opportunities for the design of an AD TDDS are extensive, given that there is currently no FDA-approved TDDS product with an abuse deterrent claim. However, the challenges that attend the final design of a successful AD transdermal end product are also extensive. The patch product must maintain wearability, shelf life stability, and therapeutic drug delivery over the shelf life. Otherwise, the patch must be able to demonstrate the necessary AD characteristics that lead to a successful label claim for specified routes of abuse.

Biography:

Dr. Eldridge completed his PhD at the University of Kentucky, USA, and began a career in topical drug delivery in the pharmaceutical industry. He has held numerous research and development roles in several small and midsized US pharmaceutical companies, and he has served in leadership roles for two different start up companies, as Director and CTO respectively. Dr. Eldrige is currently working in CMC consulting for Camargo Pharmaceutical Services, LLC. He is also an inventor on one abuse deterrent opioid transdermal patch patent and another patent specific to transdermal delivery of oxymorphone.



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