

# New Legislation Proposed in The U.S. To Stop People Dying Due to The Widespread Availability of Counterfeit Opioid Medicines

The Modern Authentication of Pharma Act 2022 was introduced to the House of Representatives on 4th May 2022. The bipartisan legislation will require that controlled substances incorporate on-dose identifiers to ensure their authenticity and enhance the security of the U.S. supply chain. Congressman Mullin, the co-sponsor, says, "With this bill, Americans can have peace of mind that their opioid medications are authentic and safe to be used as directed."

**Over 60% of medicines purchased on-line are fake or substandard<sup>1</sup>**

The United States is facing an unprecedented crisis of overdose deaths due to a dramatic rise in the supply of counterfeit prescription drugs which typically use the powerful synthetic opioid fentanyl as the active ingredient.

From April 2020 to April 2021, more than 100,000 people died in the U.S. as the result of a drug overdose - an increase of over 28% in a single year.<sup>2</sup>

Pills that contain illegally manufactured fentanyl are more lethal and more accessible than ever before but may be impossible to distinguish from authentic products. A lethal dosage of fentanyl may be as low as 2 mg, equivalent in size to a few grains of salt, compared to 30 mg for a lethal dose of heroin. It is estimated that 40% of fake pills incorporating fentanyl contain a potentially lethal dose.<sup>3</sup> These pills are often sold on social media and e-commerce platforms – making them available to anyone with a smartphone, including minors.

Forensic tests of suspect samples performed by the pharmaceutical industry demonstrate that counterfeit medicines, in 90% of those cases tested, could cause harm to the patient.<sup>4</sup>

As criminal gangs become more sophisticated, the only reliable way to verify that controlled medicines are authentic, whether purchased online or directly through the pharmacy, is the use of a verifiable covert taggant on each pill or capsule.

**On-dose identifiers means that suspected counterfeit or diverted tablets can be verified in real-time**

The inclusion of on-dose identifiers means that suspected counterfeit or diverted tablets can be verified in real-time, rather than waiting days or weeks for test results, thus increasing the speed of decision making and allowing immediate action to remove these dangerous substances from the supply chain.



The FDA supports the use of smart medicines that incorporate physical and chemical identifiers (PCIDs) and has published guidance on the application of markers directly onto drug products.<sup>5</sup>

The FDA recommends a PCID be pharmacologically inactive so the ingredient can be treated as an excipient. Microtaggant solutions (PCIDs) that can be easily added to film coatings are now commercially available and regulatory adoption is reasonably straightforward.

The inclusion of microtaggants is simple and cost-effective, providing a digital security layer to safeguard patients and uphold brand integrity.

**Inclusion of microtaggants provides a digital security layer to safeguard patients and uphold brand integrity**

Colorcon, a world leader in the development and supply of film-coating systems and excipients for the pharmaceutical industry, has developed the SoteriaRx<sup>®</sup> authentication platform which provides the most robust technology currently available for real-time verification of drugs at the dosage level.



References:

1. OECD Trade in Counterfeit Pharmaceutical Products; accessed June 2022
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4. Novartis in Society Report, 2019. [https://www.novartis.com/sites/novartis\\_com/files/novartis-in-society-report-2019.pdf](https://www.novartis.com/sites/novartis_com/files/novartis-in-society-report-2019.pdf), accessed June 2022
5. FDA Guidance for Industry Incorporation of Physical Chemical Identifiers into Solid Oral Dosage Form Drug Products for Anticounterfeiting, 2011, <https://www.fda.gov/media/116720/download>: accessed June 2022

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