ABUSE-DETERRENT OPIOIDS: ADVANCES IN TECHNOLOGY

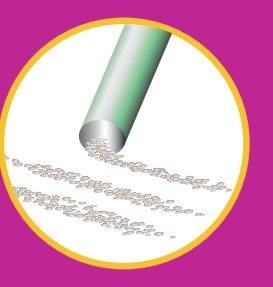
With an increase in prescription drug abuse, pharmaceutical manufacturers and the FDA have responded with product formulations that contain abuse-deterrent properties, as well as remote monitoring programs.

The following are routes of misuse and abuse seen today:

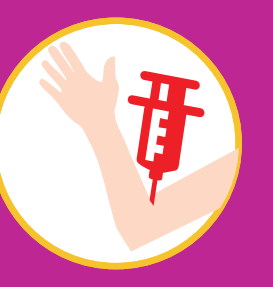
SWALLOWING INTACT TABLETS

CHEWING

SMOKING



SNORTING



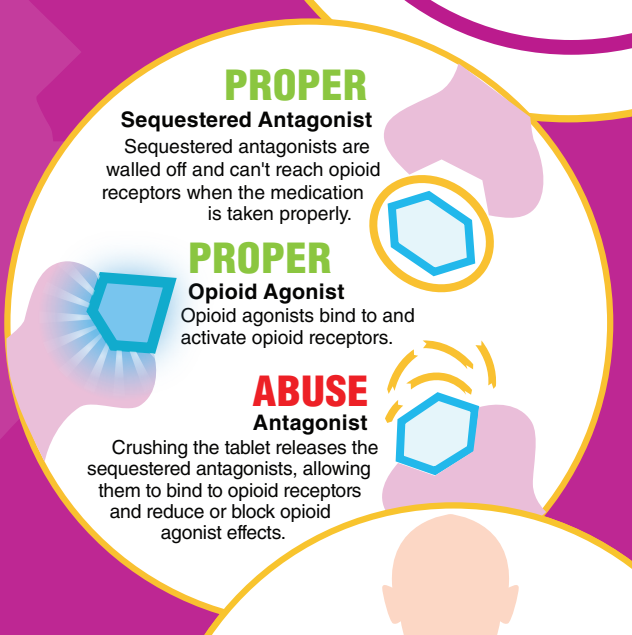
INJECTING

In April 2015, the US Food and Drug Administration issued final guidance to assist the pharmaceutical industry in developing opioid drug products with potentially abuse-deterrent properties.[1]

AS A GENERAL FRAMEWORK, THE FDA HAS CATEGORIZED ABUSE-DETERRENT PROPERTIES AS FOLLOWS:

PHYSICAL/CHEMICAL BARRIERS

Physical barriers can prevent chewing, crushing, cutting, grating, or grinding. Chemical barriers can resist extraction of the opioid using common solvents like water, alcohol, or other organic solvents. Physical and chemical barriers can change the physical form of an oral drug rendering it less amenable to abuse.

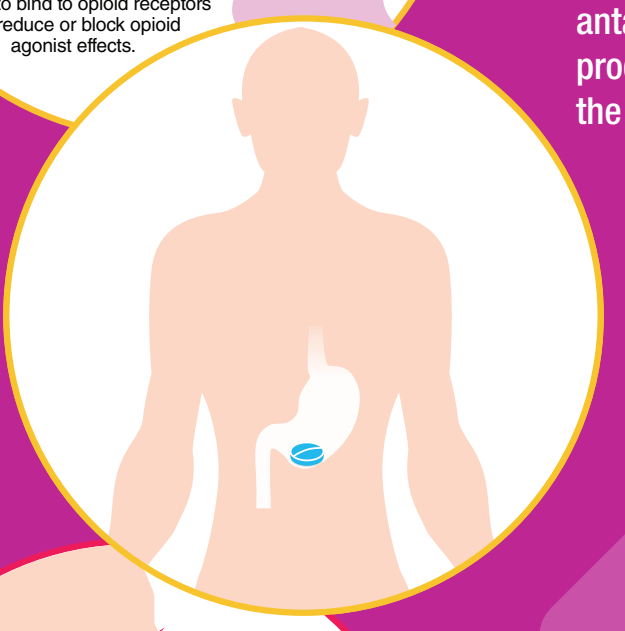


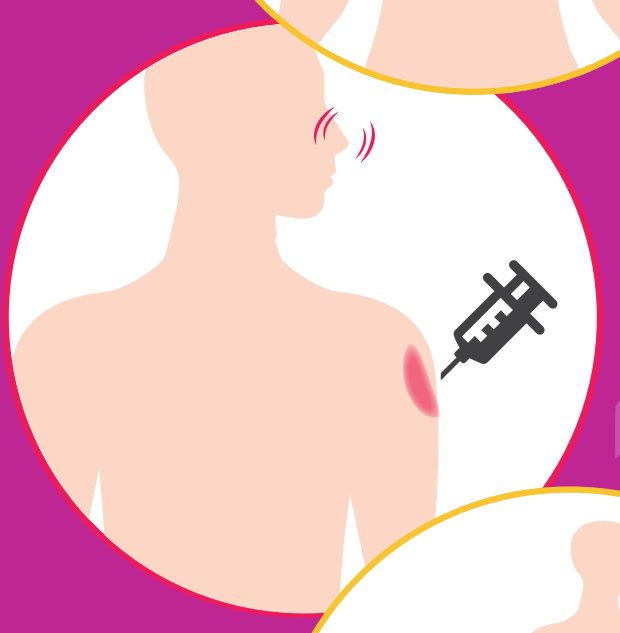
AGONIST/ANTAGONIST COMBINATIONS

An opioid antagonist can be added to an opioid medication to interfere with, reduce, or defeat the euphoria associated with abuse. The antagonist can be sequestered and released only upon manipulation of the product. For example, a drug product may be formulated such that the substance that acts as an antagonist is not clinically active when the product is swallowed but becomes active if the product is crushed and injected or snorted.

PRODRUG

A prodrug that lacks opioid activity until transformed in the gastrointestinal tract can be unattractive for intravenous injection or intranasal routes of abuse.



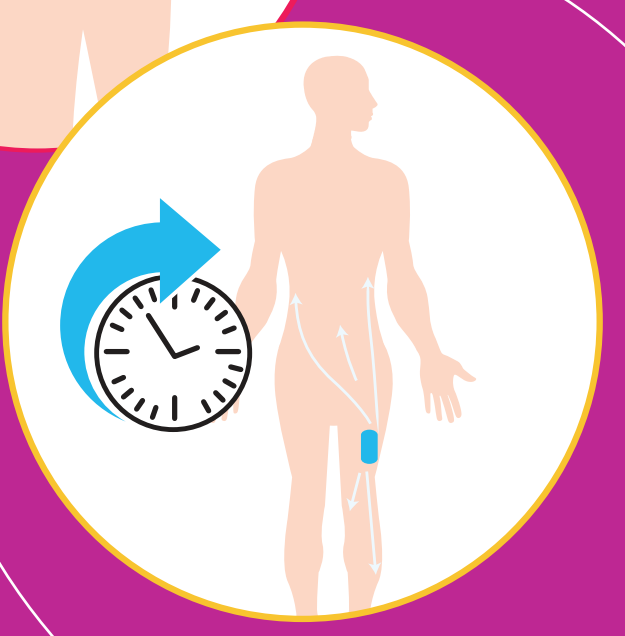


AVERSION

Substances can be combined to produce an unpleasant effect if the dosage form is manipulated prior to ingestion or a higher dosage than directed is used.

DELIVERY SYSTEM

(including depot injectable formulations and implants) – Certain drug release designs or the method of drug delivery can offer resistance to abuse. For example, a sustained-release depot injectable formulation that is administered intramuscularly or a subcutaneous implant can be more difficult to manipulate.



COMBINATION OF TWO OR MORE OF THE ABOVE TRAITS

1 Abuse-Deterrent Opioids - Evaluation and Labeling Guidance for Industry, U.S. Department of Health and Human Services Food and Drug Administration, Center for Drug Evaluation and Research (CDER). April 2015.

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