Disclaimer

The following report(s) provides findings from an FDA-initiated query using Sentinel. While Sentinel queries may be undertaken to assess potential medical product safety risks, they may also be initiated for various other reasons. Some examples include determining a rate or count of an identified health outcome of interest, examining medical product use, exploring the feasibility of future, more detailed analyses within Sentinel, and seeking to better understand Sentinel capabilities.

Data obtained through Sentinel are intended to complement other types of evidence such as preclinical studies, clinical trials, postmarket studies, and adverse event reports, all of which are used by FDA to inform regulatory decisions regarding medical product safety. The information contained in this report is provided as part of FDA's commitment to place knowledge acquired from Sentinel in the public domain as soon as possible. Any public health actions taken by FDA regarding products involved in Sentinel queries will continue to be communicated through existing channels.

FDA wants to emphasize that the fact that FDA has initiated a query involving a medical product and is reporting findings related to that query does not mean that FDA is suggesting health care practitioners should change their prescribing practices for the medical product or that patients taking the medical product should stop using it. Patients who have questions about the use of an identified medical product should contact their health care practitioners.

The following report contains a description of the request, request specifications, and results from the modular program run(s).

If you are using a web page screen reader and are unable to access this document, please contact the Sentinel Operations Center for assistance at info@sentinelsystem.org.

Appendix F. Specifications of Parameters for this Request

This request used the Cohort Identification and Descriptive Analysis (CIDA) tool, version 6.0.0, to characterize user demographics and treatment duration of higher dosage strength opioid analgesics in the Sentinel Distributed Database (SDD).

Query Period: January 1, 2012- June 30, 2018
Coverage requirement: Medical & Drug Coverage
Pre-index enrollment requirement: 7 days
Post-index enrollment requirement: 7 days
Enrollment gap: 45 days
Age Groups (Years): 0-17, 18-29, 30-49, 50-64, 65+ years
Stratifications, Type 1 Output: Year, Year by Age, Year by Sex
Stratifications, Baseline: None
Envelope macro: Reclassify encounters during inpatient stay as inpatient
Freeze data: No
Baseline table: Yes

Exposure

Scenario	Index Exposure/ Event	Care setting	Cohort Definition	Incident with respect to:	Washout period	Censor enrollment at evidence of
1	Higher dosage strength oral and transmucosal opioid analgesics	Any care setting	All valid index dates during query period	None	0	Death, DP end date, Query end date
2	Lower dosage strength oral and transmucosal opioid analgesics	Any care setting	All valid index dates during query period	None	0	Death, DP end date, Query end date
3	All oral and transmucosal opioid analgesics	Any care setting	All valid index dates during query period	None	0	Death, DP end date, Query end date
4	Transdermal opioid analgesics (fentanyl and buprenorphine)	Any care setting	All valid index dates during query period	None	0	Death, DP end date, Query end date

Healthcare Common Procedure Coding System (HCPCS) codes are provided by Optum360.

National Drug Codes (NCDs) are checked against First Data Bank's "National Drug Data File (NDDF®) Plus."