Preliminary Analysis of Drug Utilization Data to Inform the Development of the Pregnancy Safety Study Framework

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Agenda

- Study objectives
- Product selection
- Study design
- Characterization of utilization during pregnancy
- Conclusions

Study Objectives

- Describe the product selection to understand exposure levels for assessing feasibility of using electronic healthcare claims data for pregnancy safety studies
- Characterize product utilization during pregnancy among pregnancies that ended in live births
- Explore product characteristics that may be used to estimate drug exposure during pregnancy

Product Selection

- Inclusion: A total of 249 products associated with studies in the analysis of postapproval pregnancy safety were identified for this preliminary analysis
- Exclusion: Products with pregnancy exposures ranging from 0 and 2,500 during the 15-year query period were not included in this analysis
  - The emphasis of this preliminary analysis is on products with medium and high exposure since low exposure drugs are not likely to be suitable for comparative studies in administrative healthcare data systems which are the focus of the demonstration projects
- A convenience sample of 28 products with pregnancy exposure <2,500 was included for representation of low exposure products to inform the framework development
- This preliminary analysis is limited to 72 products
  - 44 products with pregnancy exposure ≥2,500
  - 28 products with pregnancy exposure <2,500

Study Design

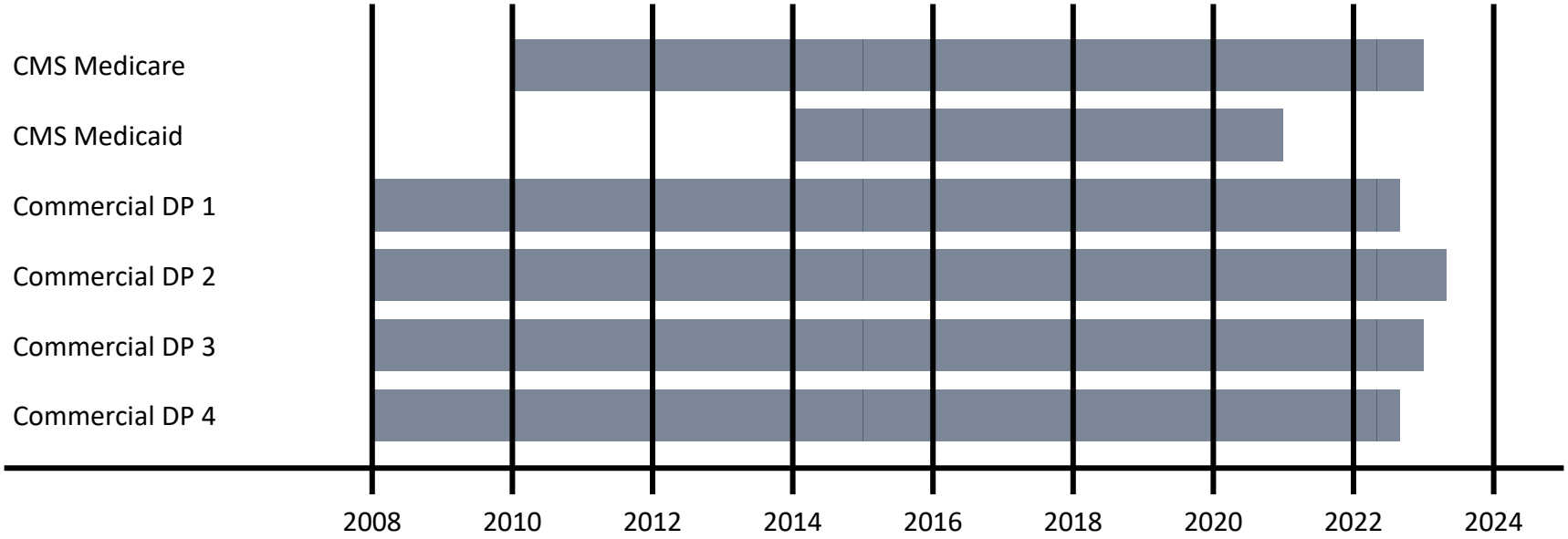
- **Data**: Six Data Partners from the Sentinel Distributed Data (SDD)
  - Four National Health Insurers
  - Medicaid and Medicare

- **Population**: Female members with evidence of live birth delivery during query period

- **Query Period**: January 1, 2008 –January 31, 2023
  - Data contribution varied by Data Partner

Study Design

Data Availability* by Data Partner

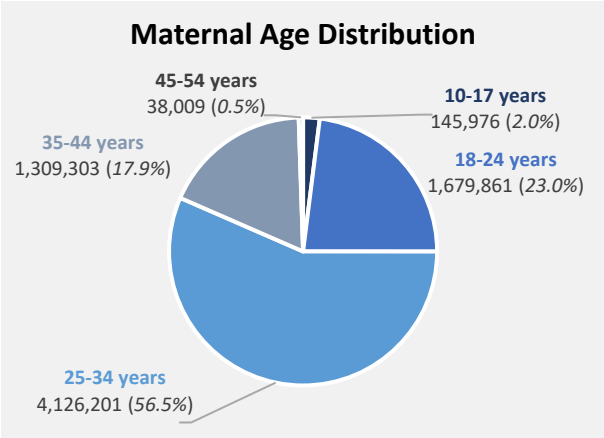


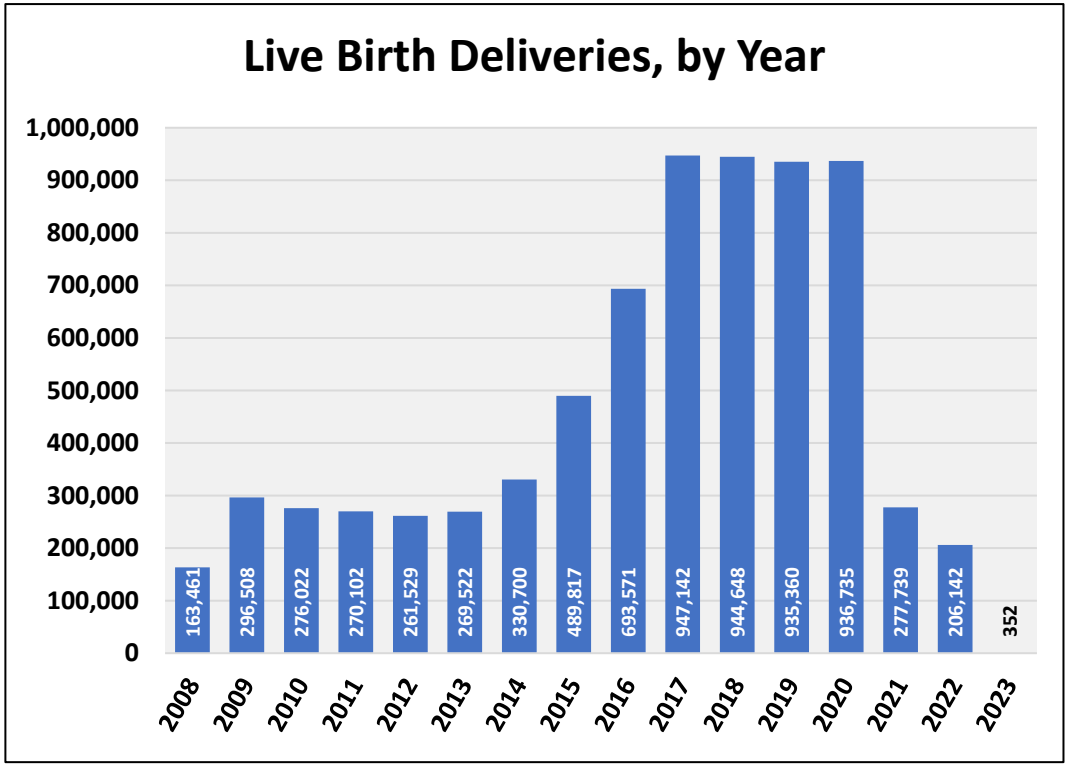
* Data prior to January 1, 2008, not utilized; dates are current as of August 4, 2023, query distribution
CMS: Centers for Medicare and Medicaid Services; DP: Data Partner; FFS: Fee-for-service

Characterization of Live Birth Deliveries in the Sentinel Distributed Database: January 1, 2008 – January 31, 2023

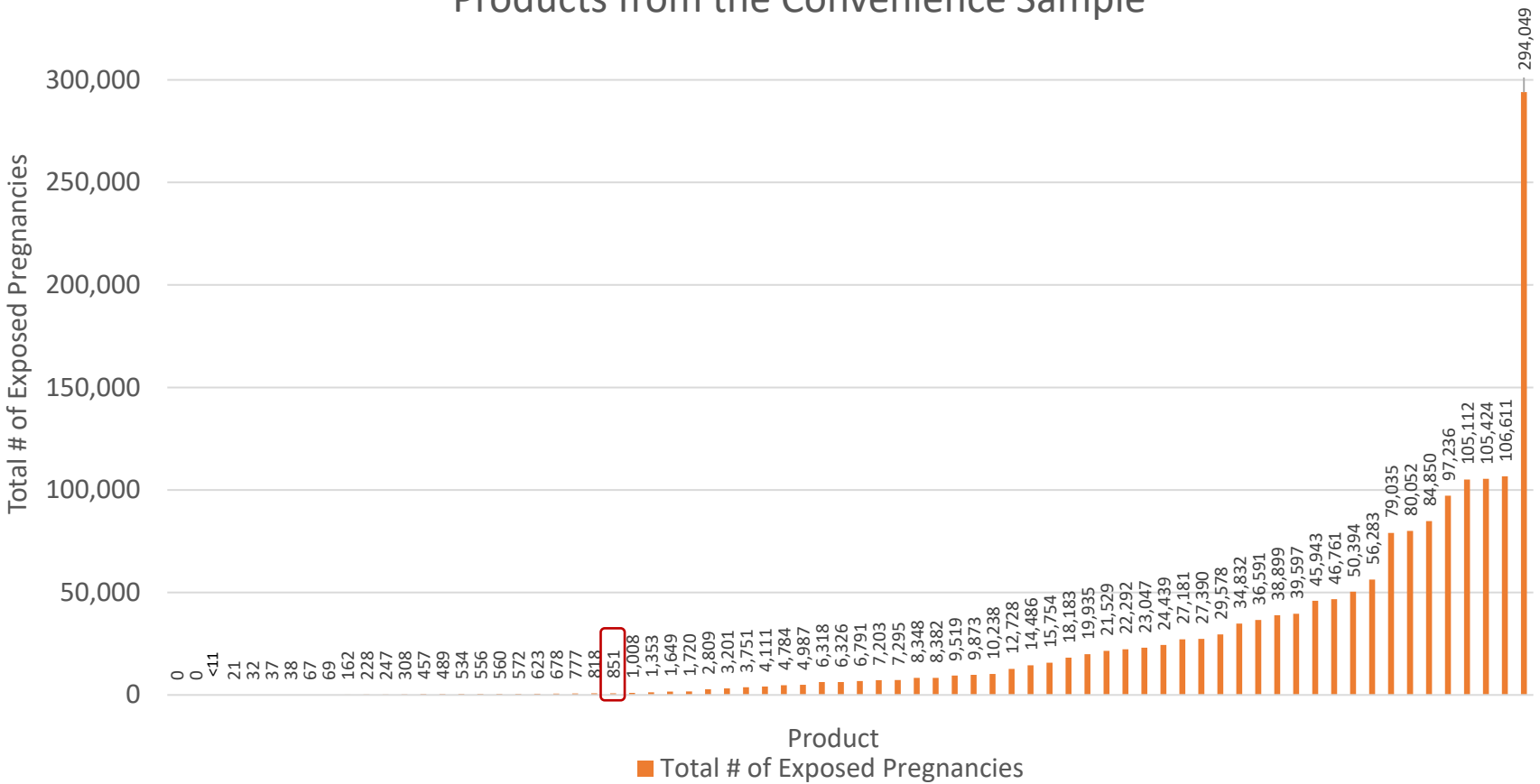
6,165,744
unique patients

7,299,350
live birth deliveries





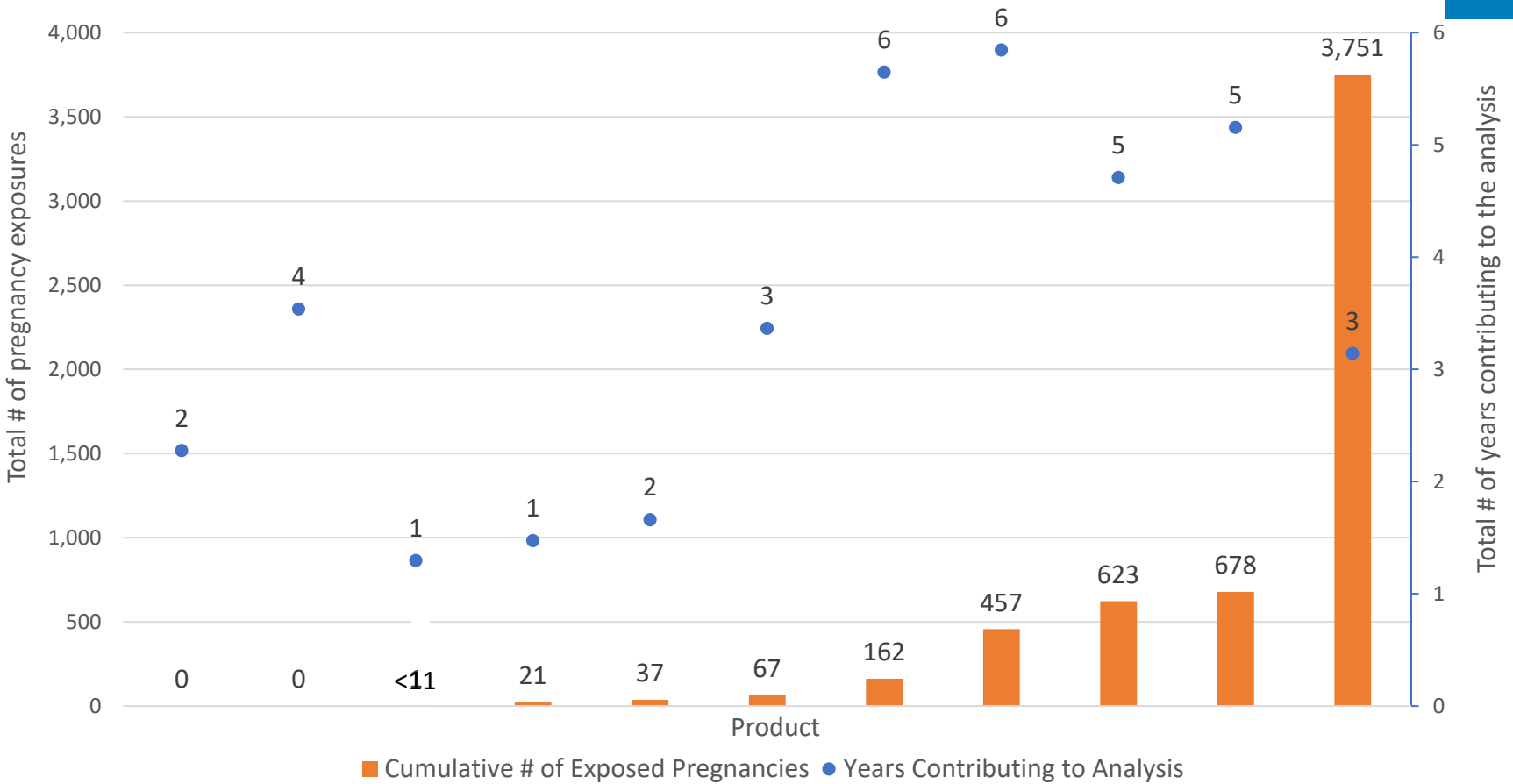
Total Number of Exposed Pregnancies from 2008-2023 for each of the 72 Products from the Convenience Sample



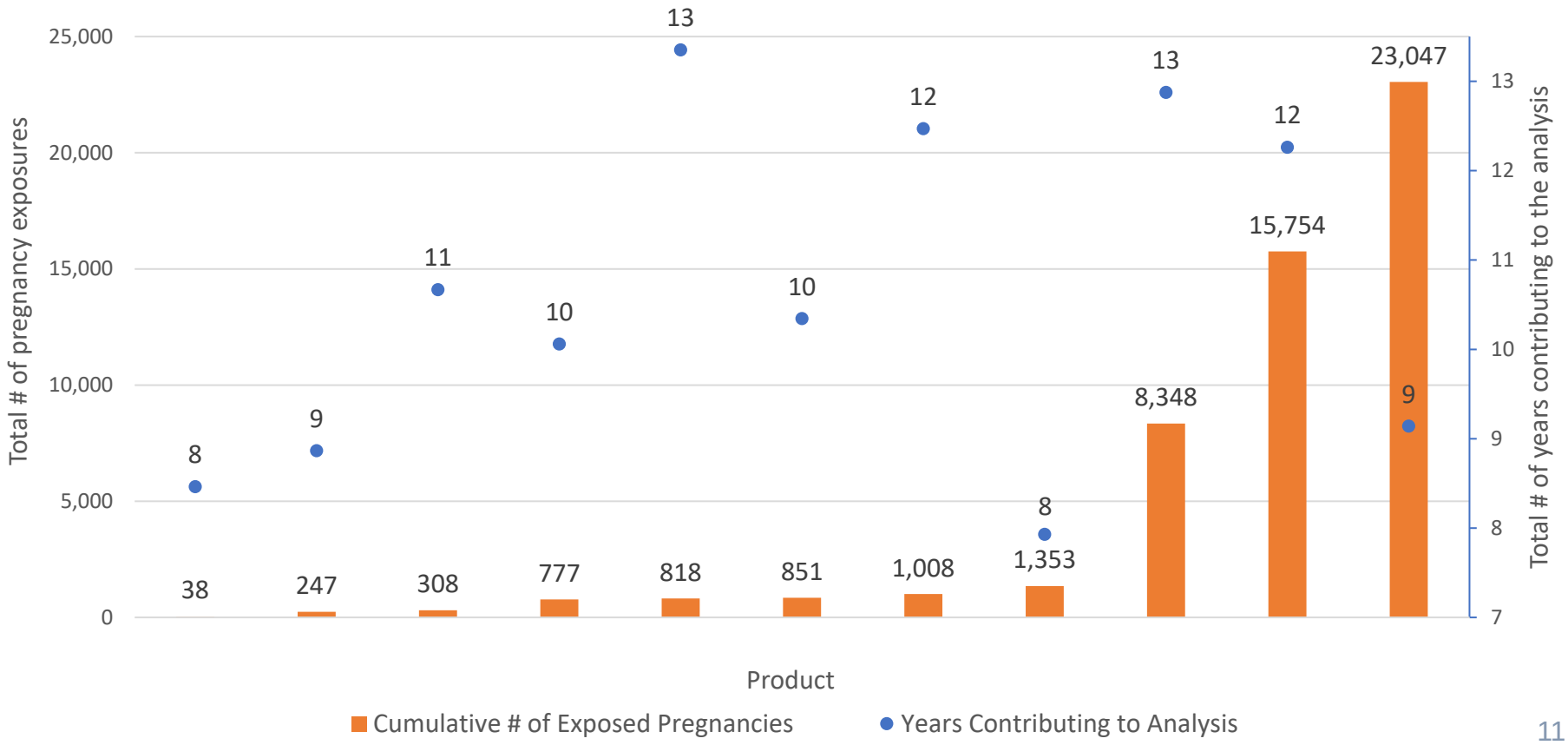
Characterization of utilization during pregnancy

- Time each product is contributing utilization data to the analysis
  - 0-6 years (approved on or after 01/01/2016)
    - Total of 11 products
  - 7-13 years (approved from 02/01/2009 to 12/31/2015)
    - Total of 11 products
  - 14-15 years (approved on or before 01/31/2009)
    - Total of 50 products

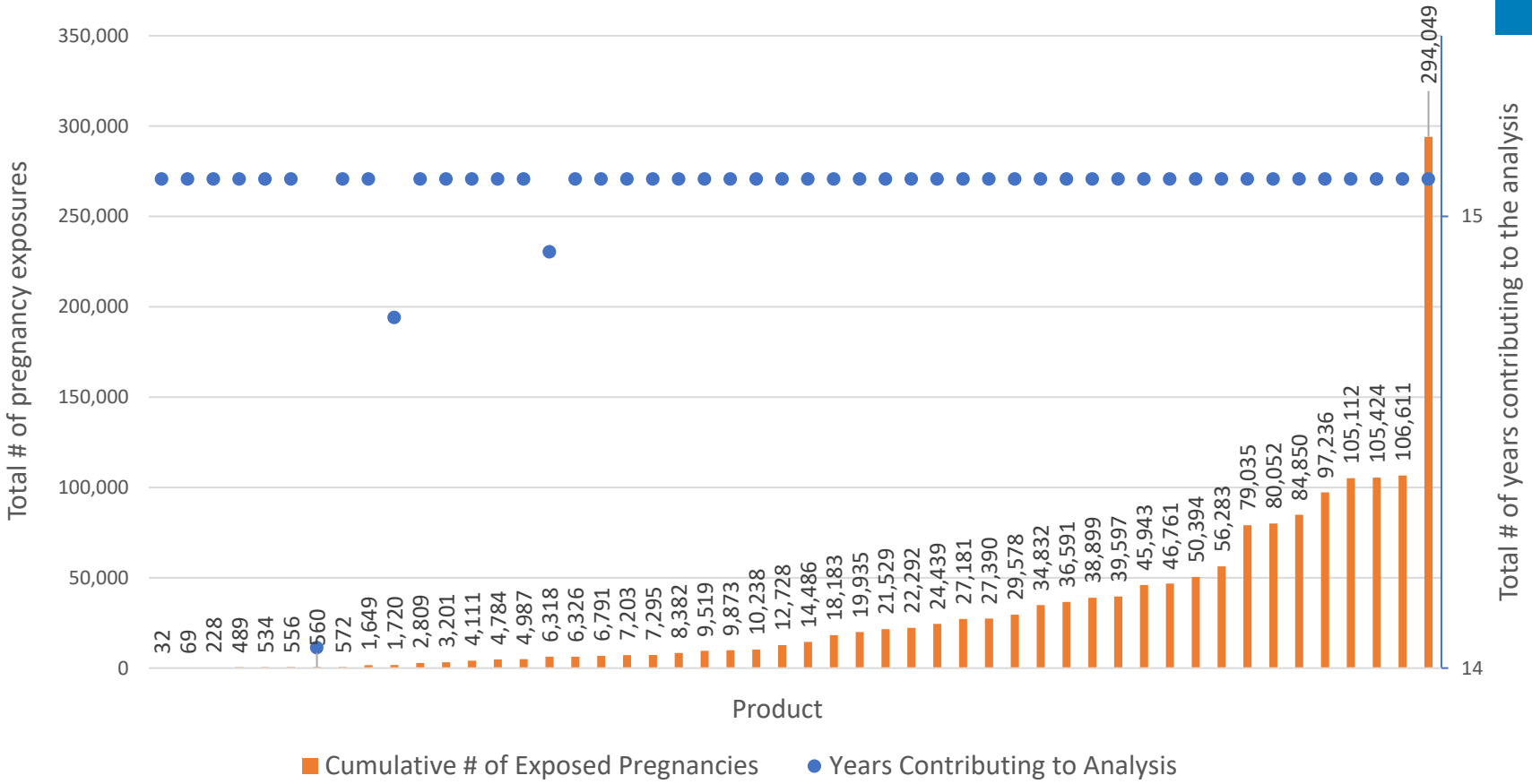
Total Number of Exposed Pregnancies for Products Contributing 0 to 6 Years of Utilization Data to the Analysis from the Convenience Sample



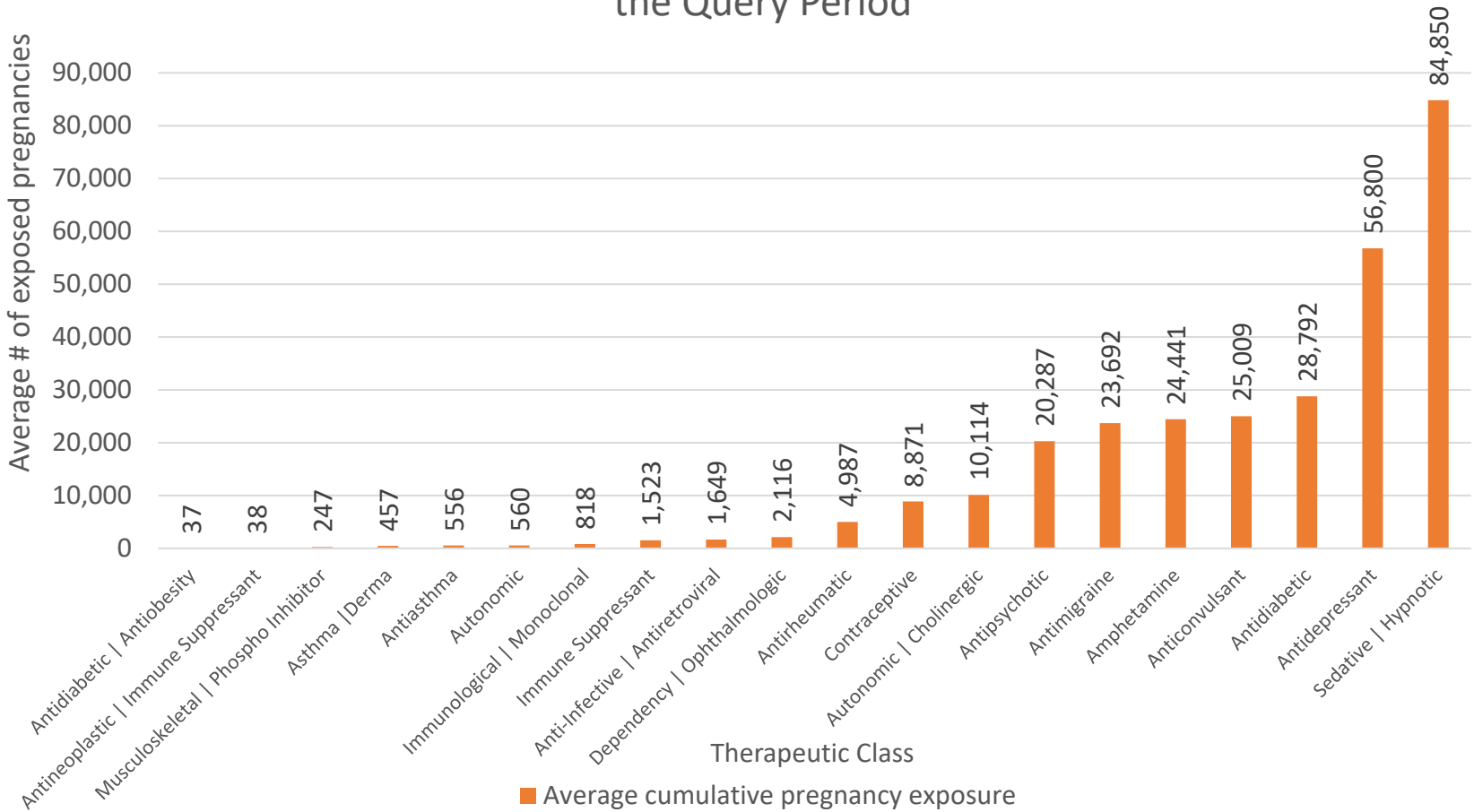
Total Number of Exposed Pregnancies for Products Contributing 7 to 13 Years of Utilization Data to the Analysis from the Convenience Sample



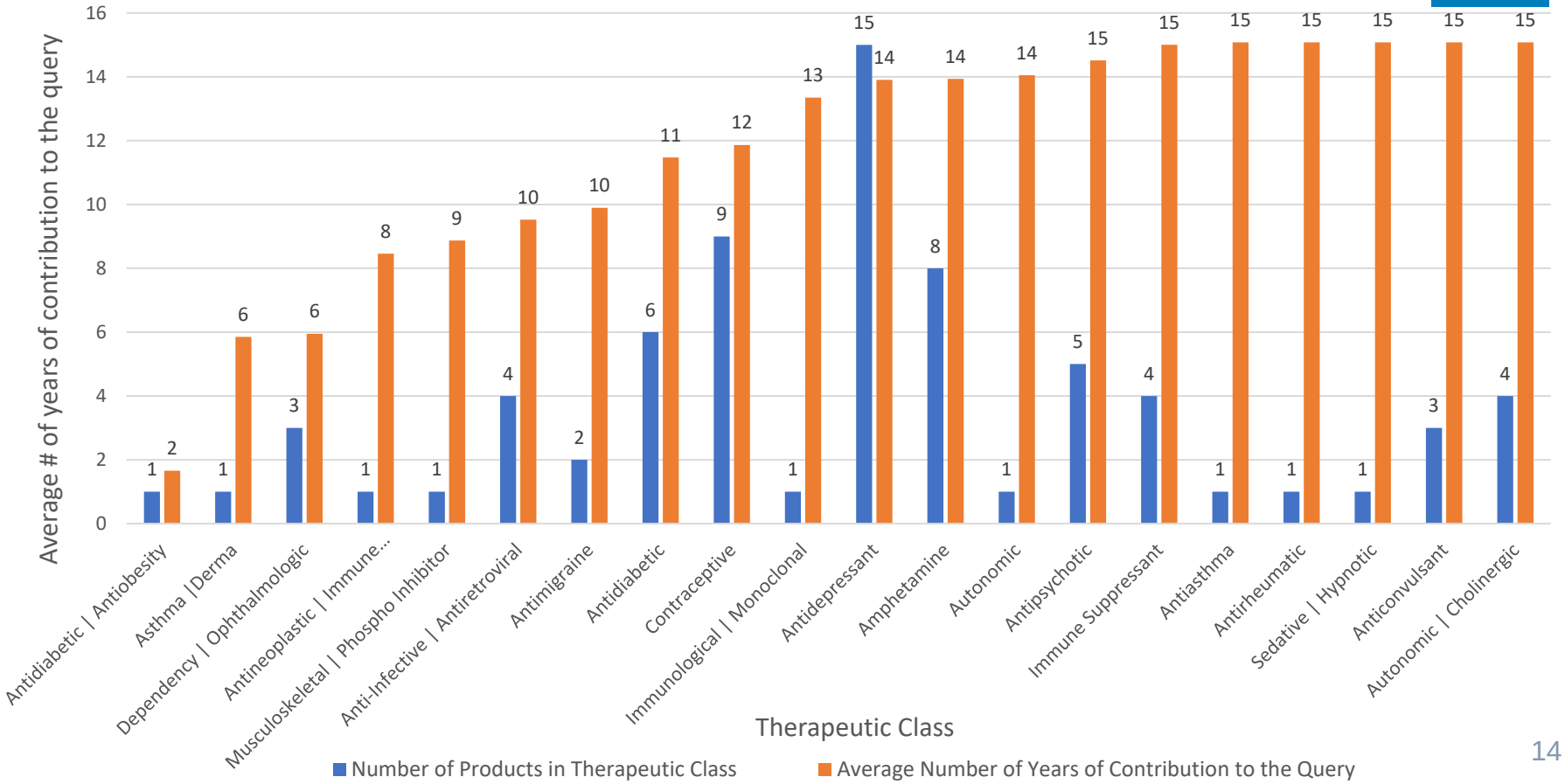
Total Number of Exposed Pregnancies for Products Contributing 14 to 15 Years of Utilization Data to the Analysis from the Convenience Sample



Average Number of Exposed Pregnancies by Therapeutic Class during the Query Period



Average Number of Years of Contribution to the Analysis by Products in each Therapeutic Class (1-15 years)



Conclusions

- Utilization of the 72 products from the convenience sample during pregnancy was low, especially among those approved after 2008

- 80% of the products included in this preliminary analysis had 10 or more years of utilization data in Sentinel to characterize their use during pregnancy

- Sedative/hypnotic and antidepressant products showed the highest exposure during pregnancy
  - The oldest sedative/hypnotic included in this query was approved in 1992 and the oldest antidepressant was approved in 1961

Next steps

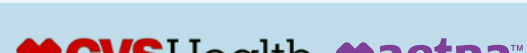
- The product exposure characterization during pregnancy among live birth deliveries will be updated to include products that were excluded from this convenience sample
    - These updates will be used to inform framework development and implementation of the demonstration projects
- Year of approval, disease, and product related factors will be further explored to inform observed patterns of utilization
- Product exposure by trimester of pregnancy will be described

Acknowledgements

FDA Query Team

Sentinel Operations Center

Participating Sentinel Data Partners



Aetna, part of the CVS Health Family of companies

Carelon Research, part of the Carelon Family of Companies under Elevance Health

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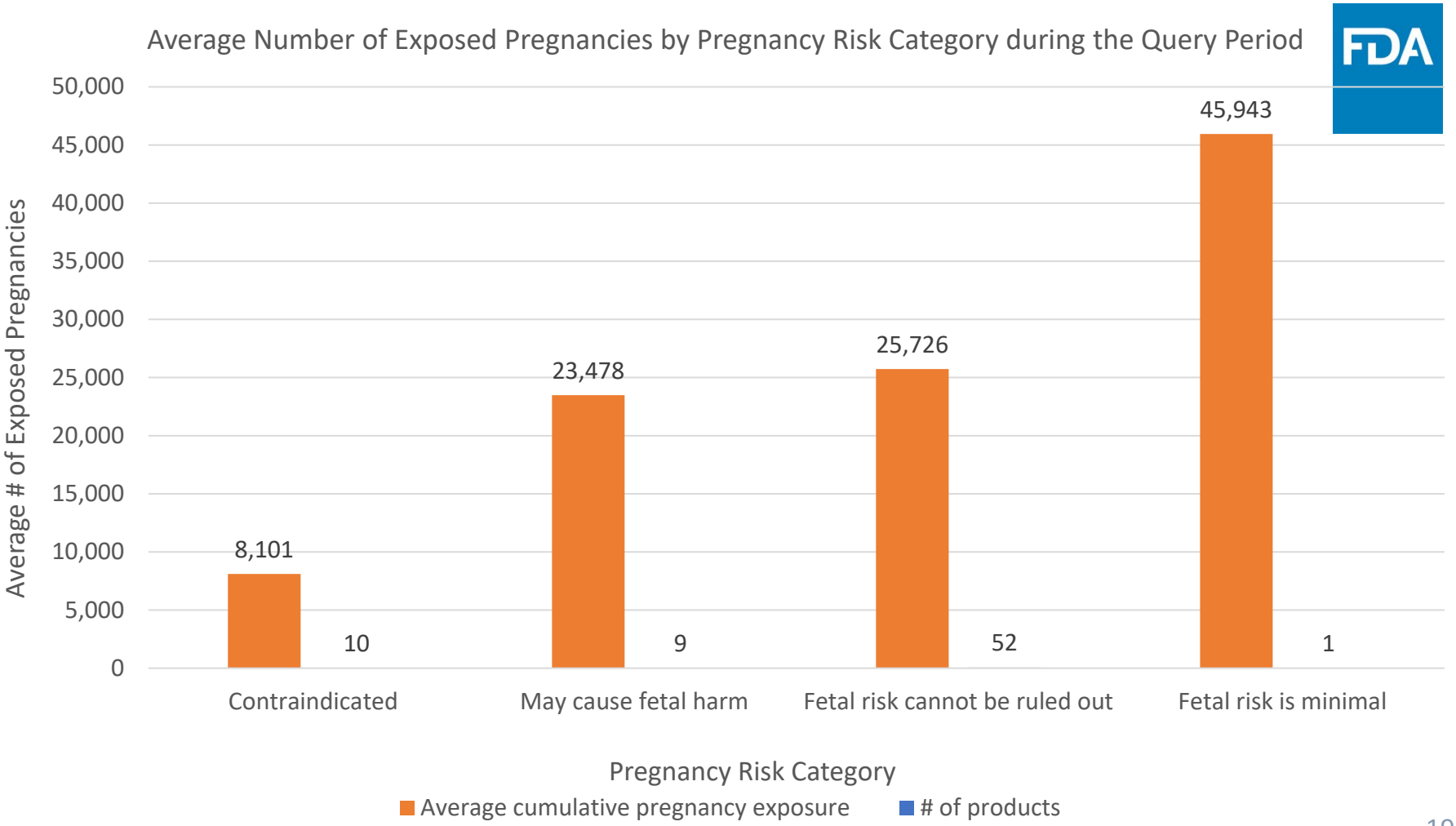
Humana Healthcare Research, Inc.

OptumInsight Life Sciences, Inc.

This Sentinel activity is a public health surveillance activity conducted under the authority of the Food and Drug Administration and, accordingly, is not subject to Institutional Review Board oversight. This activity leveraged Sentinel's Cohort Identification and Descriptive Analysis (CIDA) module, version 12.1.0, with custom programming.

Backup Slides


Average Number of Exposed Pregnancies by Pregnancy Risk Category during the Query Period
FDA
Average # of Exposed Pregnancies
50,000
45,000
40,000
35,000
30,000
25,000
20,000
15,000
10,000
5,000
0
8,101
10
23,478
9
25,726
52
45,943
1
Contraindicated
May cause fetal harm
Fetal risk cannot be ruled out
Fetal risk is minimal
Pregnancy Risk Category
Average cumulative pregnancy exposure
# of products