

Evaluation of FDA Structured Product Labeling and the Biomarker Table for Pharmacogenomics Information

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Introduction

- PGx has the potential to reduce medication events and improve therapeutic outcomes
- Use of PGx information is limited
- Agencies
 - CPIC
 - DPWG
 - FDA: SPL

Objective

- Evaluated SPLs in presenting PGx information

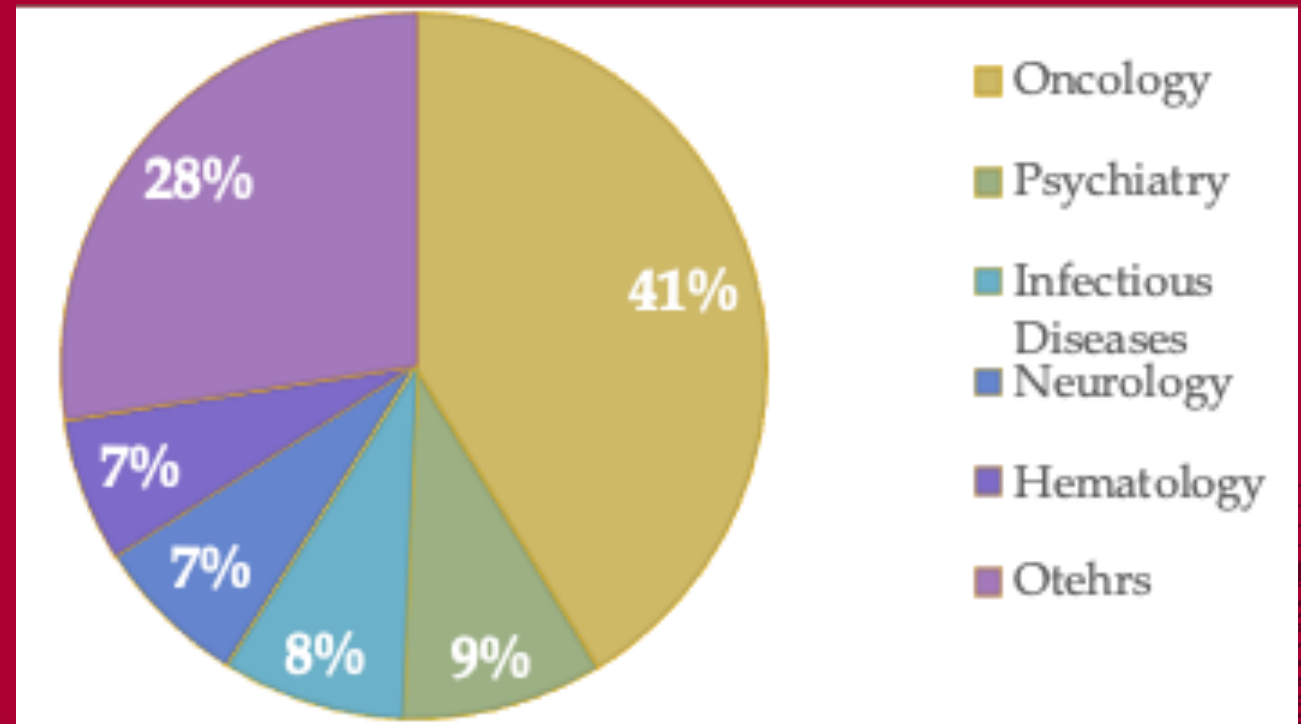
Method

- Data sources:
 - PGx information in the PGx Biomarker table
 - FDA Label Website
- Data analysis: Descriptive statistics
 - Frequencies
 - Percentages

Result

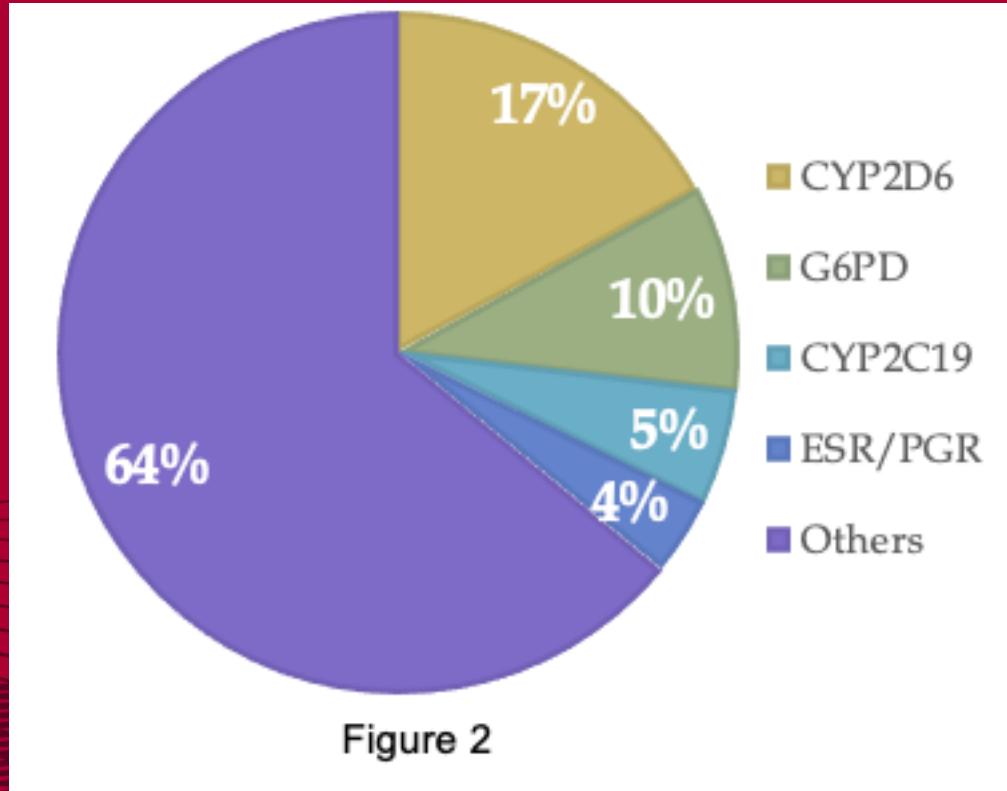
Figure 1 – Distribution of Therapeutic Classes for Unique Drug Gene Pairs

- 404 unique drug gene pairs
- 283 unique drugs or drug combinations



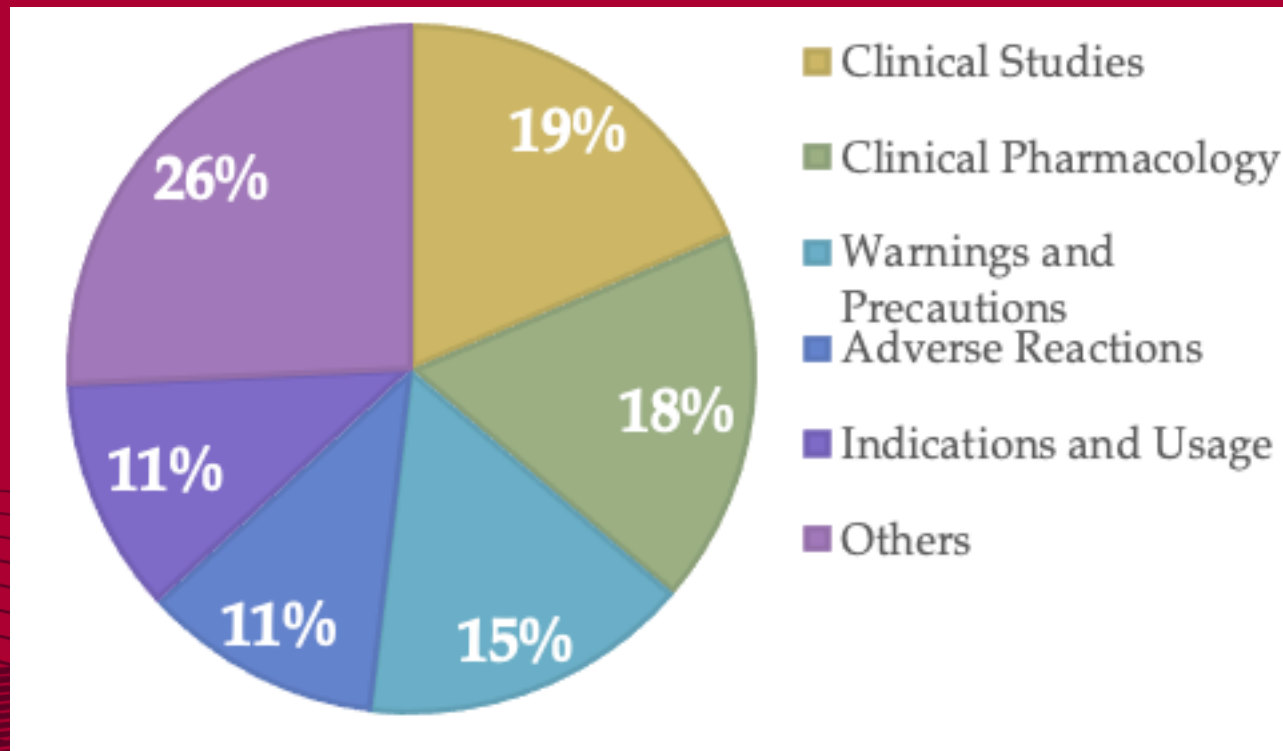
Result

- Figure 2: Frequently affected gene distribution



Result

- Figure 3: Distribution of PGx Information in FDA Labels



Conclusion

- Inconsistent location of PGx information in FDA labels
- Underutilization of “12.5 Pharmacogenomics” section
 - Only 43 drugs currently present PGx information in this section
- PGx biomarker table excludes gene variants from non-human genetic factors