Real-World Evidence for Generic Drug-Device Combinations

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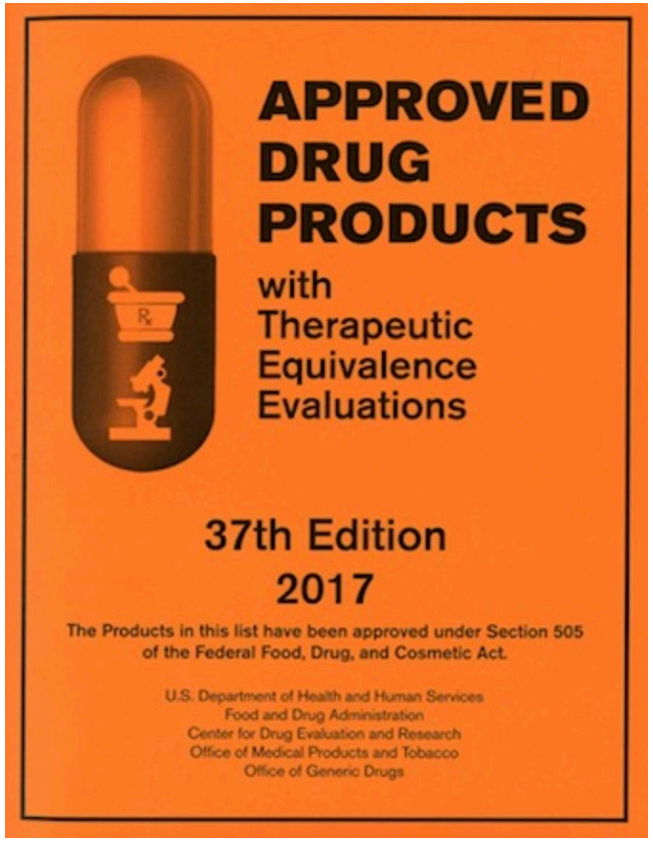
Spending on Drug-Device Combinations

- 20 (40%) of the top 50 drugs by gross Medicare Part D spending in 2022 were drug-device combinations.
  - Ozempic (semaglutide)
  - Lantus Solostar (insulin glargine)
  - Trelegy Ellipta (fluticasone-umeclidinium-vilanterol)
  - Symbicort (budesonide-formoterol)

Medicare Part D Dashboard and Data: https://data.cms.gov/summary-statistics-on-use-and-payments/medicare-medicaid-spending-by-drug/medicare-part-d-spending-by-drug.

Barriers to generic entry

- Patent thickets that delay generic competition and raise (litigation) costs for bringing generics to market.
- Demonstrations of bioequivalence for complex drug-device combinations, which can be difficult given the complex interactions between the device and the active ingredient and the need for proper technique by patients.



Surveillance of adverse events

- **Current model**: FDA Adverse Event Reporting System (FAERS) and manufacturer pharmacovigilance databases
  - Suffers from potential reporting bias, underreporting, difficulty capturing event rates due to missing denominator information, insufficient granularity to distinguish between specific brand-name and generic products.
- **Proposed model**: Data from routine clinical use, also called real-world evidence (RWE)
  - Can evaluate adverse events systematically with rigorous control for confounding and broad inclusion of patients across racial, ethnic, and socioeconomic groups.

Regulatory implications

- **Implications**: Evaluation of routine clinical use data in the post-marketing setting could provide reassurance to patients and physicians. It could also potentially allow the FDA more flexibility when approving complex generic products.
- **Recommendations**
    1. Develop a rigorous, replicable surveillance system for drug-device combinations that relies on routine clinical use data.
    2. Develop policies and procedures for triggering further studies from generic manufacturers if safety signals are detected using routine clinical use data.
    3. Obtain feedback from the public, academics, and industry on ways to streamline the approval process for generic drug-device combinations knowing that post-marketing studies using routine clinical use data will be completed.