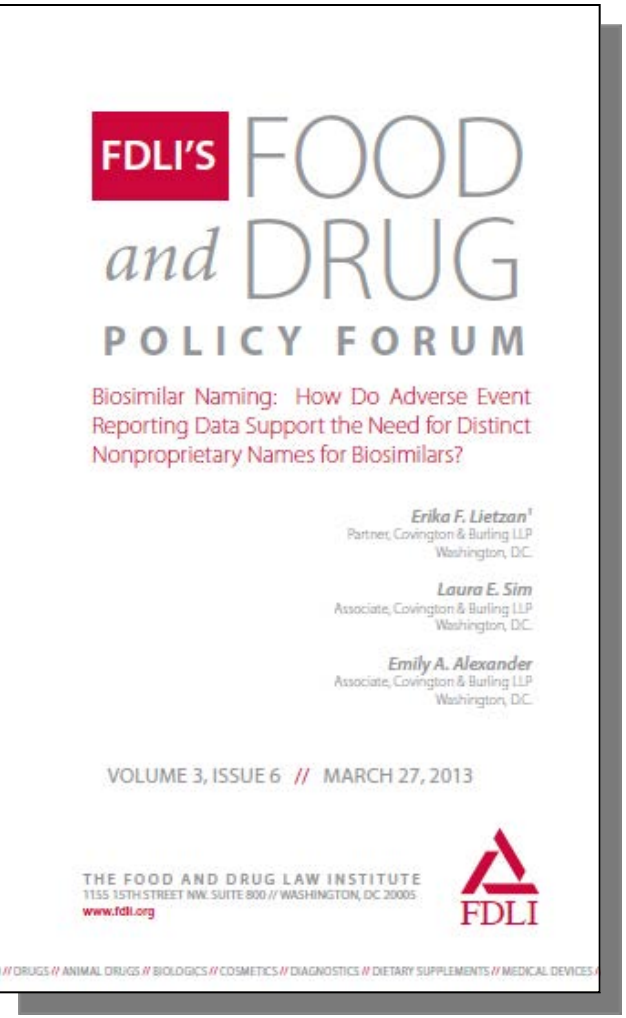
# Pharmacovigilance Is Critical for All Products

- Pharmacovigilance is the process of identifying and assessing adverse events (possible side effects) associated with a product
- All biologics raise unique pharmacovigilance challenges
  - Rare, but potentially serious side effects
  - Sensitivity to manufacturing process
  - Limited ability to predict clinical effect of manufacturing changes
- Effective pharmacovigilance requires the ability to link specific adverse events or adverse event trends with the responsible product

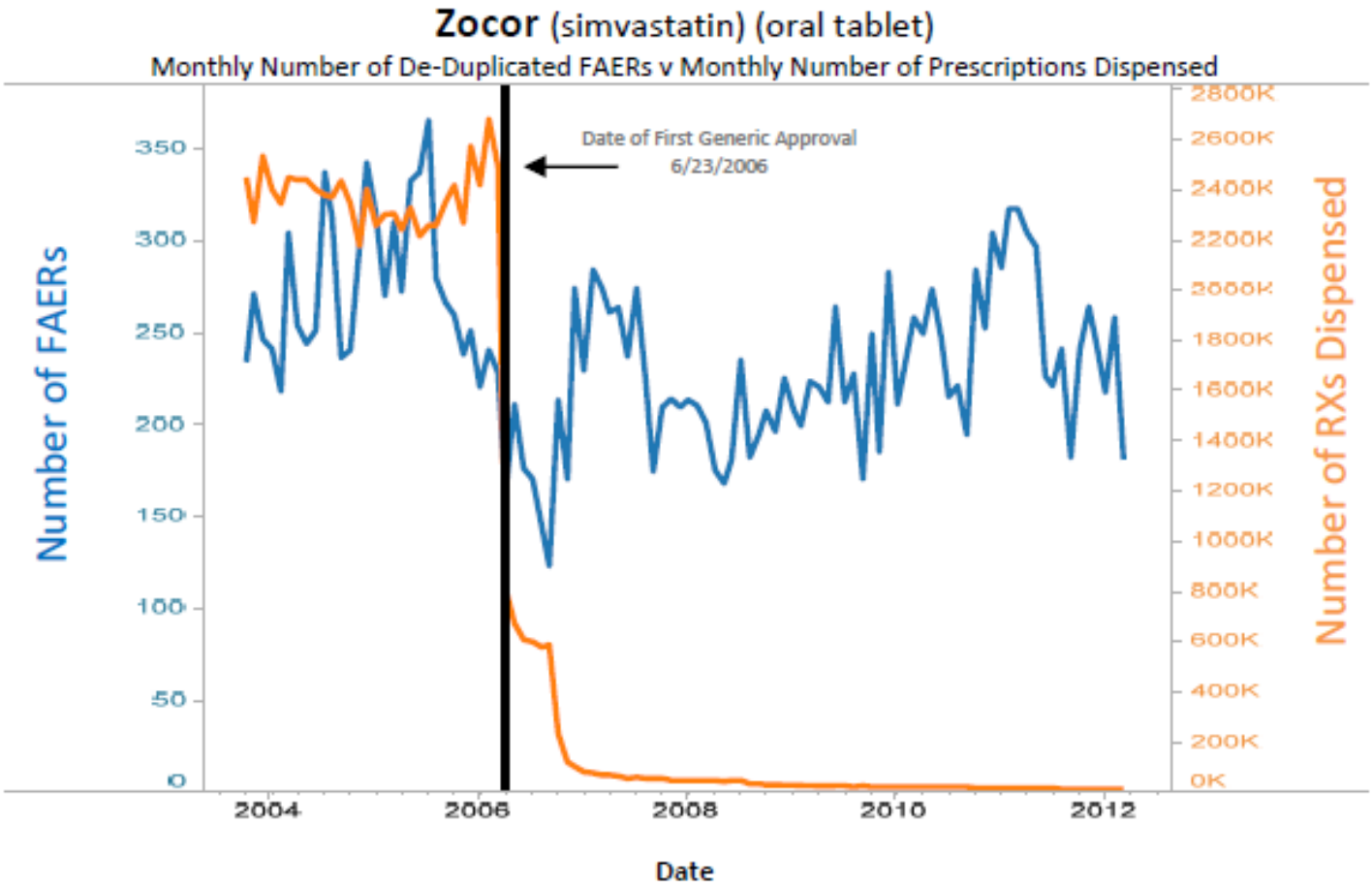
# Widespread Misattribution of Adverse Events in U.S.




- Analysis of adverse event reporting trends for eight small-molecule drug products, before and after generic entry
- The rate of adverse events reported for the brand product remained roughly the same after generic entry (for 6 of 8 drugs)
- Adverse events were being attributed to the brand name product when the patient was actually taking the generic

Biosimilar Naming: How Do Adverse Event Reporting Data Support the Need for Distinct Nonproprietary Names for Biosimilars? Lietzan, E. et al, FDLI's Food and Drug Policy Forum, March 27, 2013

# Zocor Example




Result: Pooling of adverse events for products that share the same non-proprietary name

# Limited Product-Identifying Information in AE Reports

- Research also revealed that product name is often the only product identifying information included in adverse event reports
  - 90% of all reports in FDA's adverse event database (FAERS) do not have lot numbers
  - There is no data field provided in the FAERS database for a national drug code (NDC) number, but NDC number is included in fewer than 1 in 10,000 FAERS reports

# FDA: Need for Distinct Names to Facilitate Pharmacovigilance and Prevent Medication Errors

***tbo-filgrastim*:** "unique nonproprietary names will facilitate postmarketing safety monitoring by providing a clear means of determining which 'filgrastim' product is dispensed to patients"

***ziv-aflibercept*:** "unique nonproprietary names will facilitate postmarketing safety monitoring by providing a clear means of determining which 'afilbercept' product is dispensed to patients"

***ado-trastuzumab emtansine*:** "FDA identified a potential for error between the currently marketed Herceptin (trastuzumab) and the proposed Kadcyla ("trastuzumab emtansine") due to the similarity of the nonproprietary names as well as overlapping product characteristics"

# Limitations of Using Distinct Brand Names

- Distinct brand names will help facilitate pharmacovigilance
- But, there are some limitations:
  - Lack of explicit statutory authority for FDA
  - Adverse event reports often do not include brand names or other meaningful product-identifying information beyond a product's non-proprietary name
  - Prescribing can occur by non-proprietary name
    - "Due to the fact that healthcare providers may use nonproprietary names instead of proprietary names when prescribing and ordering products . . . FDA has determined the use of distinct proprietary names is insufficient to adequately address these concerns." – FDA Proprietary Name Review for tbo-filgrastim

# Global Perspective

- Some jurisdictions prohibit or discourage prescribing by brand name
  - China effectively prohibits prescribing biotherapeutics by proprietary name (with an exception for a patented biotherapeutic with a new active ingredient)
  - Colombia prohibits prescribing government-reimbursed biotherapeutics by proprietary name
- Clinicians and patients outside the United States report adverse events to FDA

# Identical Names May Cause Confusion

- In a recent survey, 76% of physicians said having an identical nonproprietary name implies that two products have identical structures
- Biosimilars are highly similar, but not identical in structure
- FDA has recognized that identical names may cause confusion:
  - Using a distinct non-proprietary name for ziv-aflibercept would help reduce medication errors by “reducing confusion among healthcare providers who may consider use of the same nonproprietary name to mean that the biological products are indistinguishable from a clinical standpoint”

# Distinct, But Related Non-Proprietary Names Protect Patients

- Approach taken by Australia and Japan
- Related “core” non-proprietary name will help to assess adverse events across a class of products, but distinguishing prefix or suffix allows for differentiation
- Distinct names will not present barrier to patient access

All patients deserve to have access to these life-changing biologic therapies

Every adverse event matters, and patients deserve and expect to have every adverse event counted