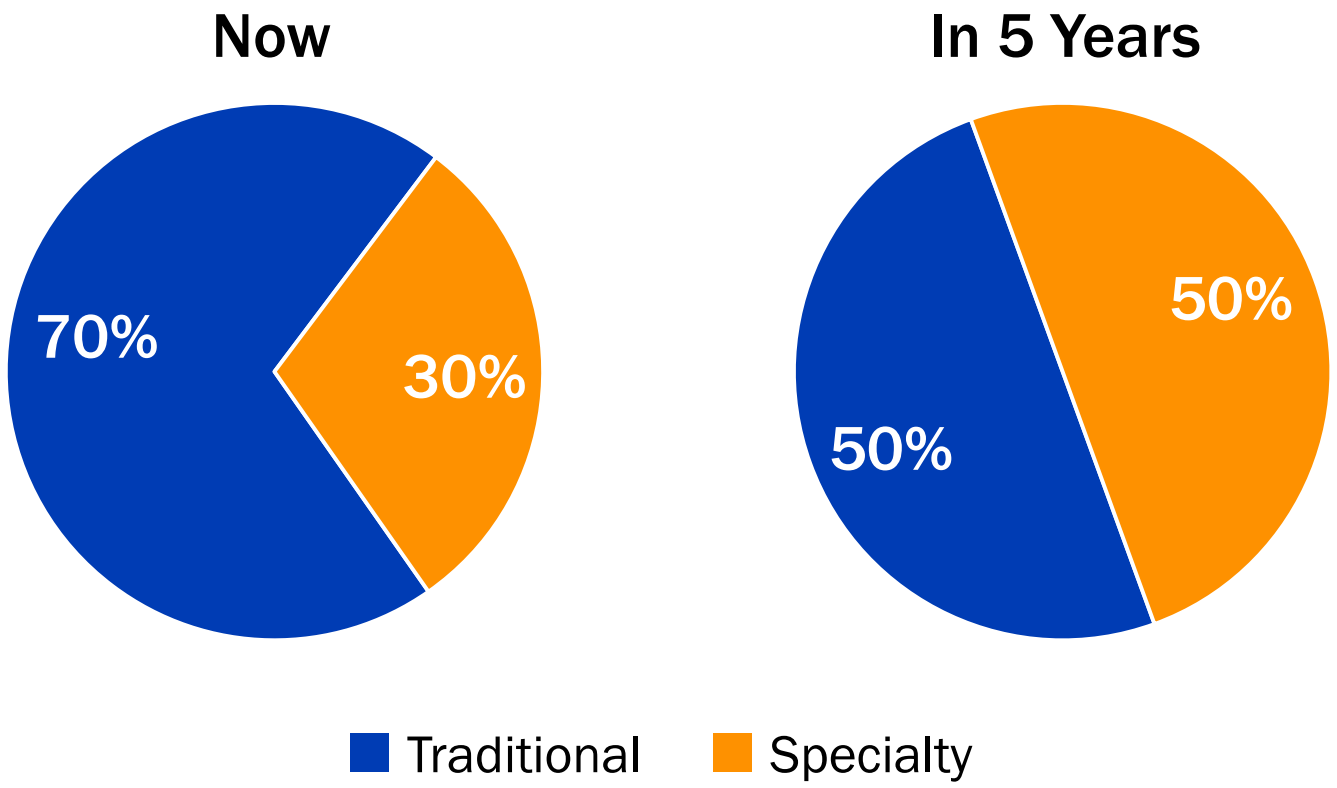
Defining biosimilars and their effect on healthcare: anticipated complications, possible solutions, and the need for pharmacovigilance

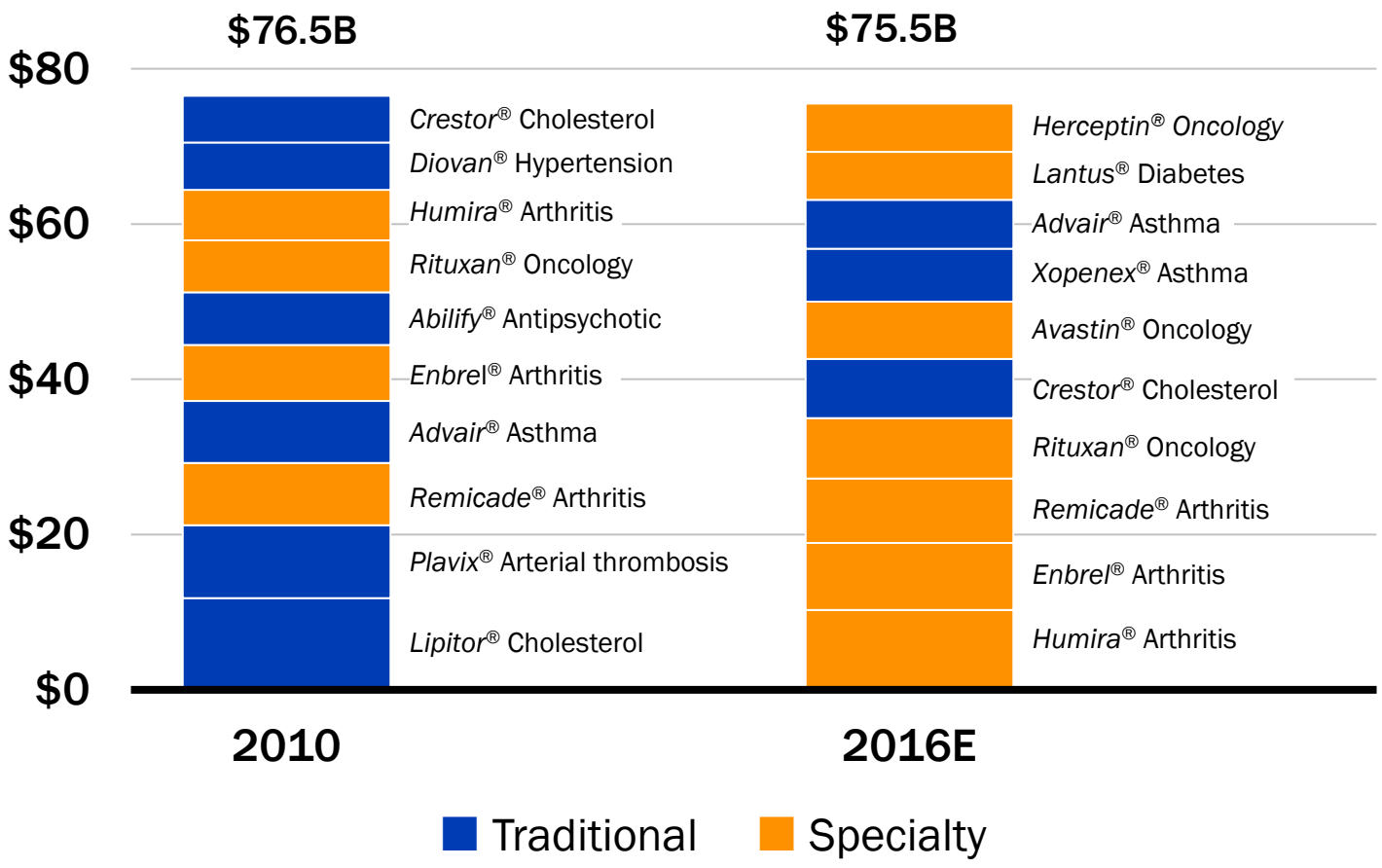
Steve Miller, MD

November 12, 2013

Specialty Growth Continues



Top 10 Worldwide Drug Sales



By 2016, Specialty Accounts for 64% of Top 10 Drugs

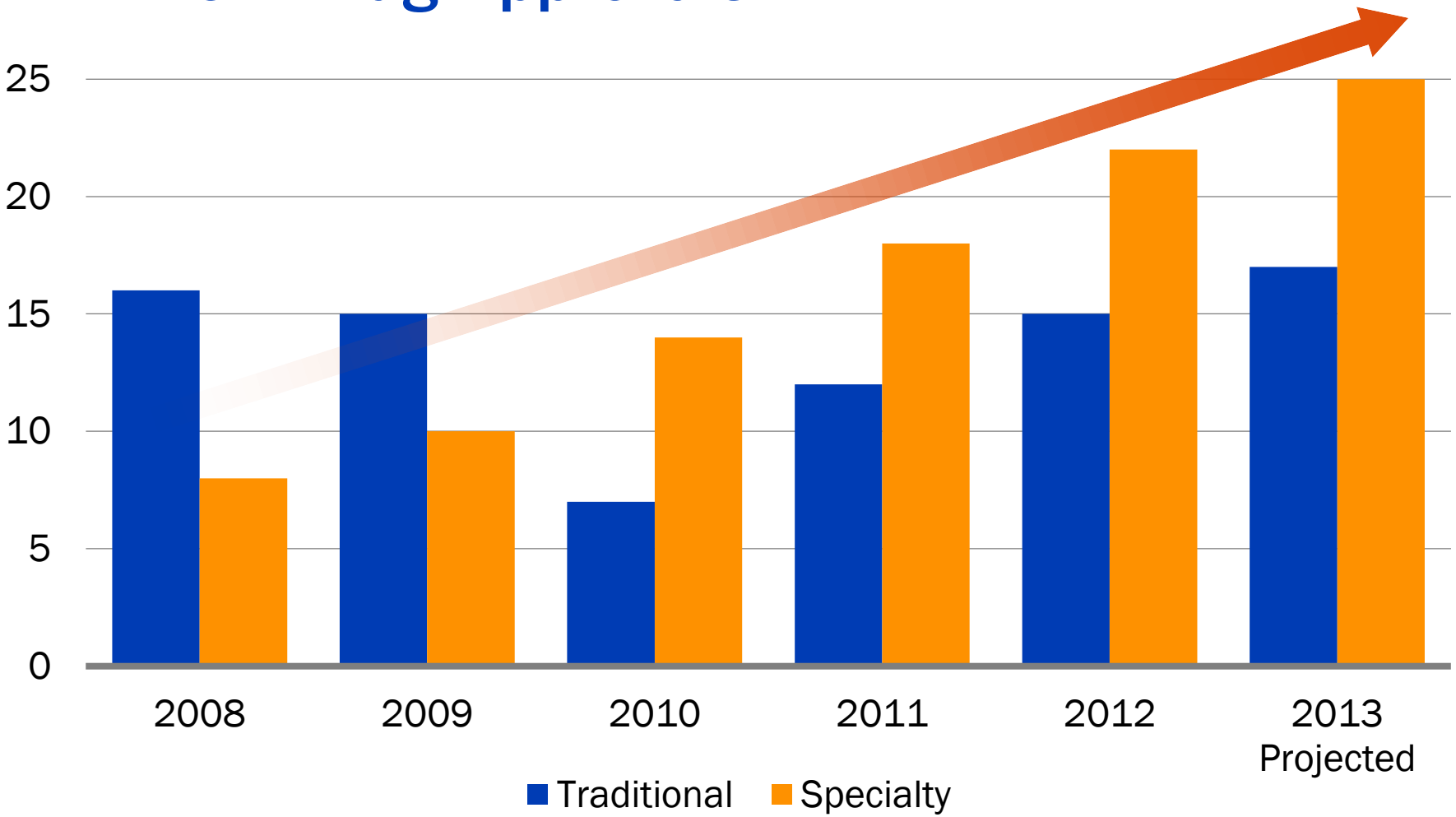
Your Know Specialty Patients

- Anemia
- Cancer
- Growth Deficiency
- Hemophilia
- Hepatitis
- Infertility
- Multiple Sclerosis
- Pulmonary HTN
- Rheumatoid Arthritis
- Many others

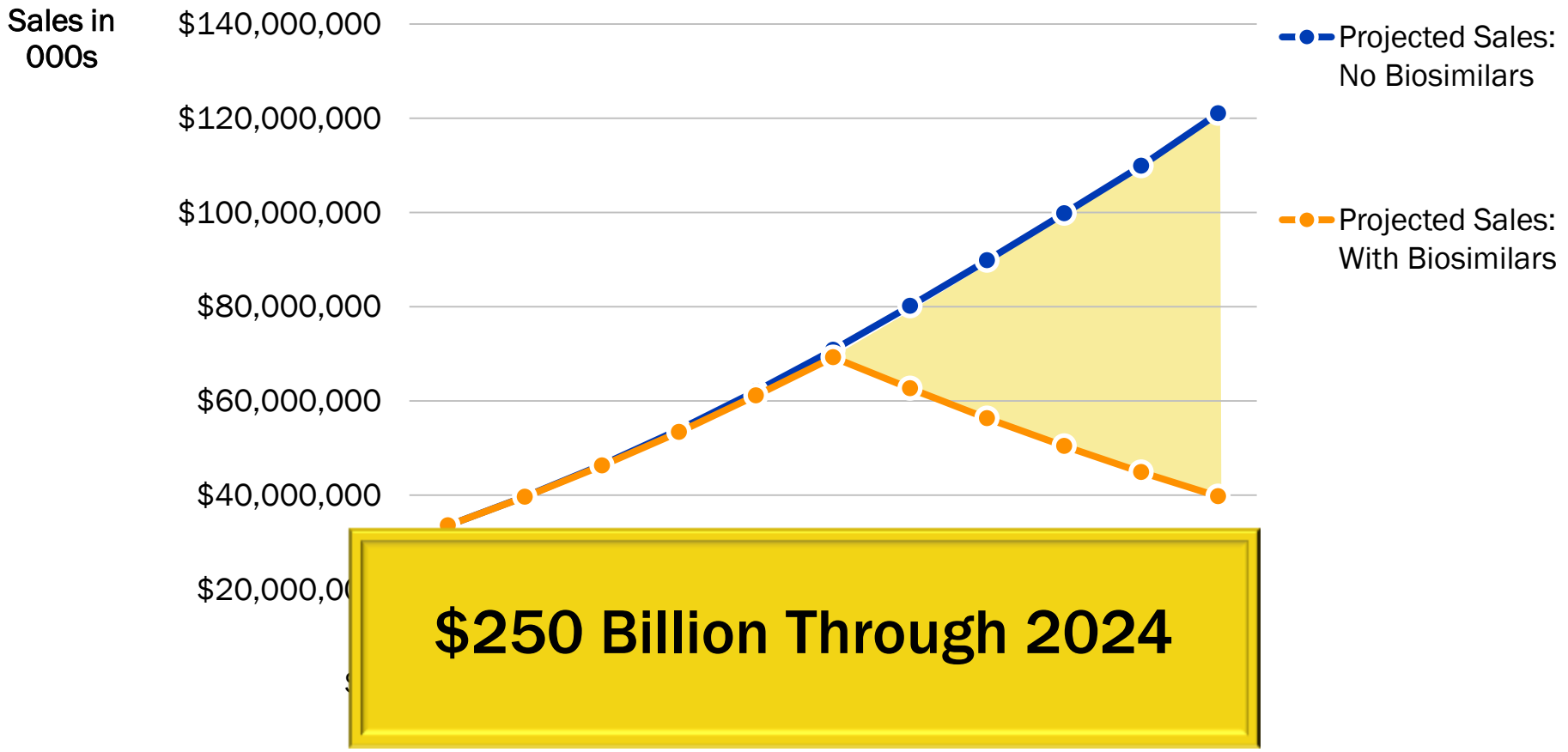
Biosimilars

Source: Sarah Palin – mistydawnphoto / Shutterstock.com

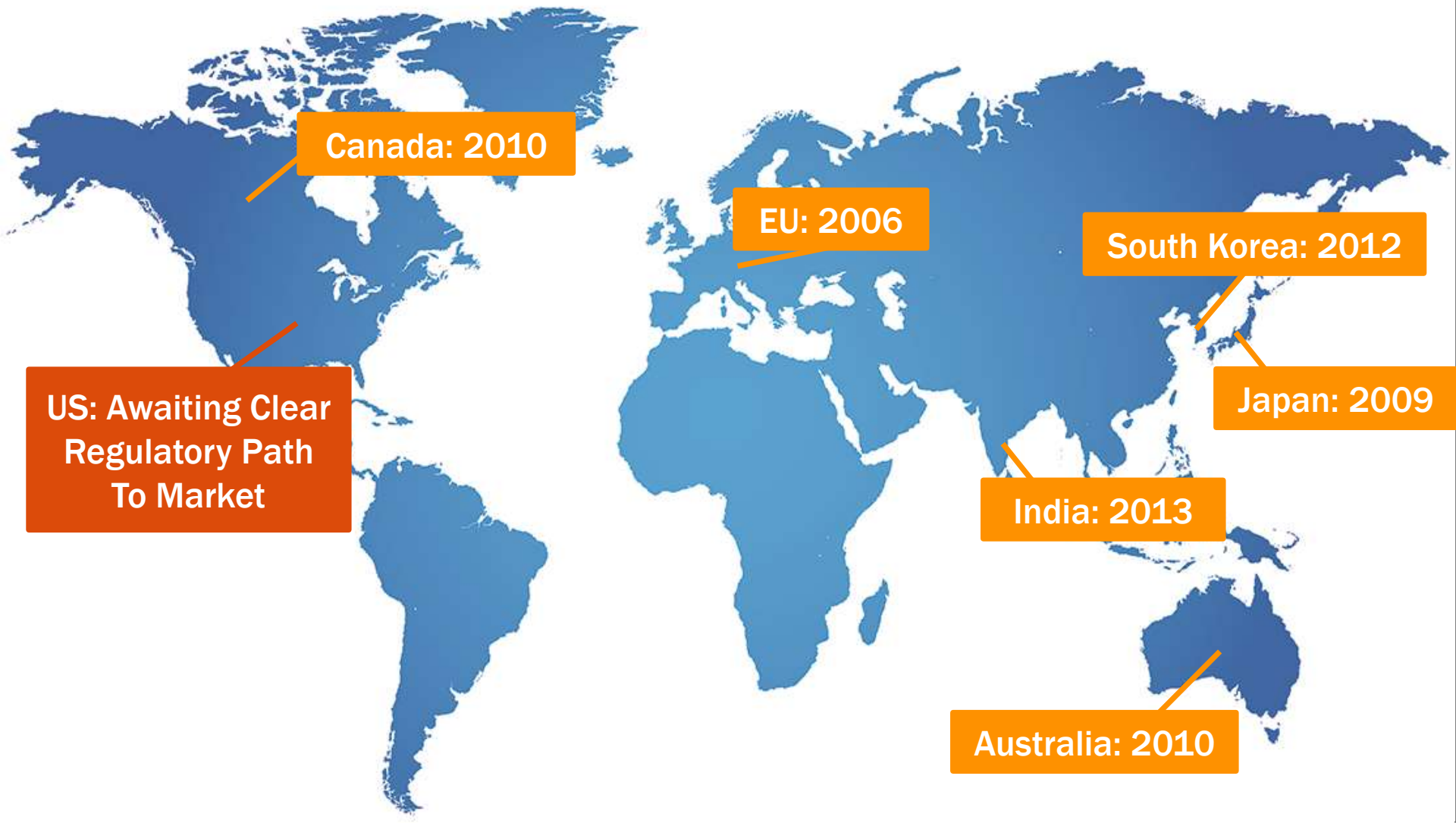
FDA New Drug Approvals



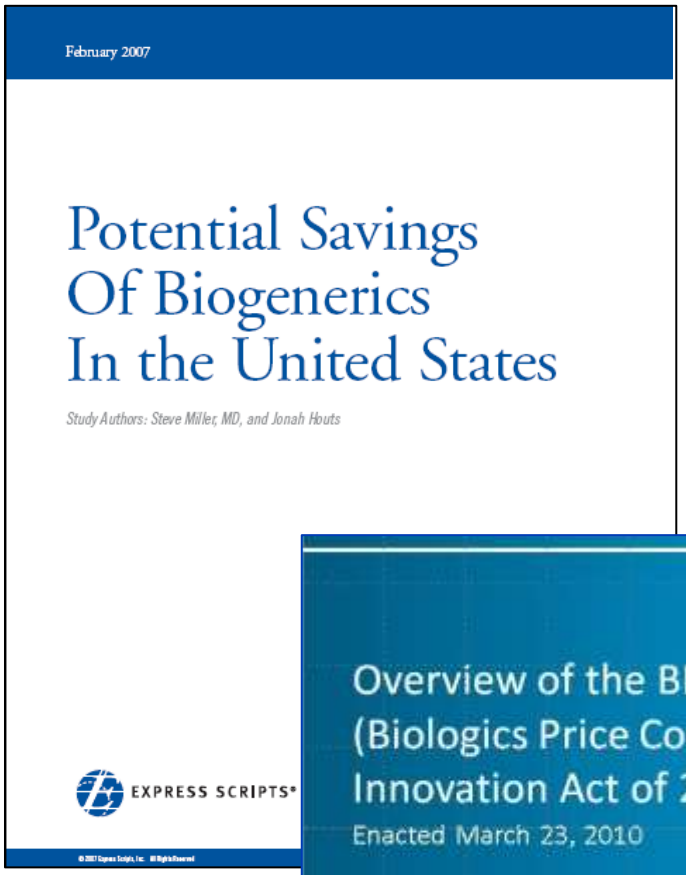
Biosimilars: A Path to Healthier Outcomes

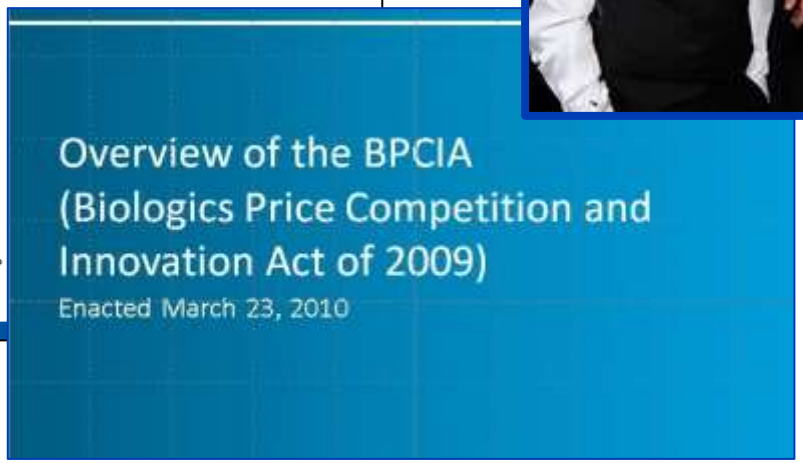


Biosimilars Approved Around the World



The Law of the Land





Déjà Vu All Over Again

"This drift in product quality attributes could be enough to be clinically meaningful, i.e. results in a change in **efficacy or safety**."

– BIO talking points, *2012*

"… FDA standards do not insure that two versions of a drug deemed equivalent will be equally **safe and effective** when used interchangeably by patients"

–President of PhRMA, *1987*

Biosimilars Pathway: *The Key Issues*

1. Guidelines
2. Totality of Evidence
3. Clinical Program
4. Global Studies
5. Immunogenicity
6. Multiple Pathways
7. Extrapolation
8. Common Reference Product
9. Common INN (international nonproprietary name)
10. Interchangablity

Originators Make "Biosimilars"

Acceptable changes in quality attributes of glycosylated biopharmaceuticals

To the Editor:

Since the first marketing approvals of recombina… question of… attributes, … and purity, … of these pr… product lab… This questi… context of … which happ… various rea… scale chang… companies … managing t… years based… quality attr… do not alter… peer-review… limited deb… variation to a discussion of principles rather than specifics. Here, we present a study that looks at variation in three major marketed biologics, the purpose of which is to provide more transparency and to anchor the debate about acceptable changes in quality attributes

clinical performance. Current analytical methods allow the detection of even small … changes in quality attributes, such changes cannot be avoided in every case.

Changes in the biologics manufacturing process are tightly regulated by the health authorities. Manufacturers need to demonstrate that the process change does

attributes have no adverse impact upon safety or efficacy of the drug product."

… t to … ment of … ding the … ionships. … at a … valuable … d … studies. … lized … main. … is gap, … Aranesp, … y the … nodern … market. … in the … naterials … 2.

The active pharmaceutical ingredient of Aranesp, darbepoetin alfa, is an erythropoiesis-stimulating protein. It represents an engineered analog of human erythropoietin. It differs from endogenous erythropoietin mainly by an alteration of the

- Brand products differ from batch to batch
  - ✓ Process improvements
  - ✓ Scale changes
  - ✓ Site transfers
  - ✓ Inherent variability
- Product labels unchanged

The Entire Marketplace Solution

- The National Council on Prescription Drug Programs
  - a multi-stakeholder forum for developing ANSI-accredited standards for electronic exchange of healthcare information
- Current (D.0) telecommunication standards include the following required fields for <u>each</u> claim:

- BIN Number
- Version/Release Number
- Transaction Code
- Processor Control Number
- Transaction Count
- Service Provider ID
- Date of Service
- Software Vendor/Cert ID
- Cardholder ID
- Group ID
- Prescription Reference #
- NDC
- Prescriber ID
- *(not a complete list)*

National Drug Code

- The National Drug Code is required of all manufacturers by federal law.
- The **labeler code** is 4 or 5 digits long and assigned by the FDA upon submission of a Labeler Code Request
- The **product code** is 3 or 4 digits long and identifies a specific strength, dosage form, and formulation for a particular manufacturer
- The **package code** is 1 or 2 digits long and identifies package forms and sizes

Pharmacy Systems in Practice - atorvastatin

- 259,040 claims for atorvastatin
- Filled at 51,839 pharmacies
- Includes 15 different manufacturers
  - 80% of volume concentrated in four manufacturers

Pharmacy Systems in Practice - somatropin

- 419 claims for somatropin growth hormones
  - 11 unique trade names, but one INN
- Filled at 145 pharmacies
- Includes 7 different manufacturers

Pharmacy Systems in Practice – epoetin alfa

- 333 claims for epoetin alfa
- Filled at 285 pharmacies
- Includes 2 different manufacturers

Summary

- The US market place needs biosimilars
- Managed care pharmacist are crucial to bringing these products to the market
- We must work together to insure patient safety

An Opportunity for Working Together