A Science-Based Naming Policy for Biologics:

FTC Public Meeting on Biosimilar Policy

Gino Grampp, PhD
R&D Policy Director
Amgen, Inc.

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Nonproprietary names for biologics are science based*

- Biologics are very large, complex molecules designed and manufactured using living cells and recombinant DNA technology
- Historically, products have been named in a manner that accounts for the complexity of the structure and the possibility of differences
  - Cell expression system or method of manufacture
  - Glycosylation or other modifications
  - Altered amino acid sequences
  - Secondary, tertiary, quaternary structure
  - Immunochemical attributes (e.g., effector functions of antibodies)
- Differences in any of the above can impact safety, purity or potency; clinical result could differ for any given patient

Sources: * United States Adopted Name (USAN) or proper name in the US; International Nonproprietary Name (INN) as issued by the World Health Organization

Distinguishable names can help biologics manufacturers accurately report adverse events

- FDA is dependent upon manufacturers to investigate, mitigate and address problems identified through adverse events
  - Only manufacturers are legally obligated to report adverse events
  - "The *licensed manufacturer* shall report to FDA adverse experience information, as described in this section"[1]
  - More than 90% of AERs come to FDA through manufacturers[2]
- Attending physicians are in the best position to identify adverse events
  - 70-75% of adverse event reports are submitted either directly or indirectly by health care professionals as voluntary reports[3]
- As use of electronic order entry and health records expands, the use of nonproprietary name is increasingly important
  - The nomenclature standard designed by the National Library of Medicine (USAN + dosage form + strength) to ease electronic systems interoperability relies on nonproprietary names[4,5]

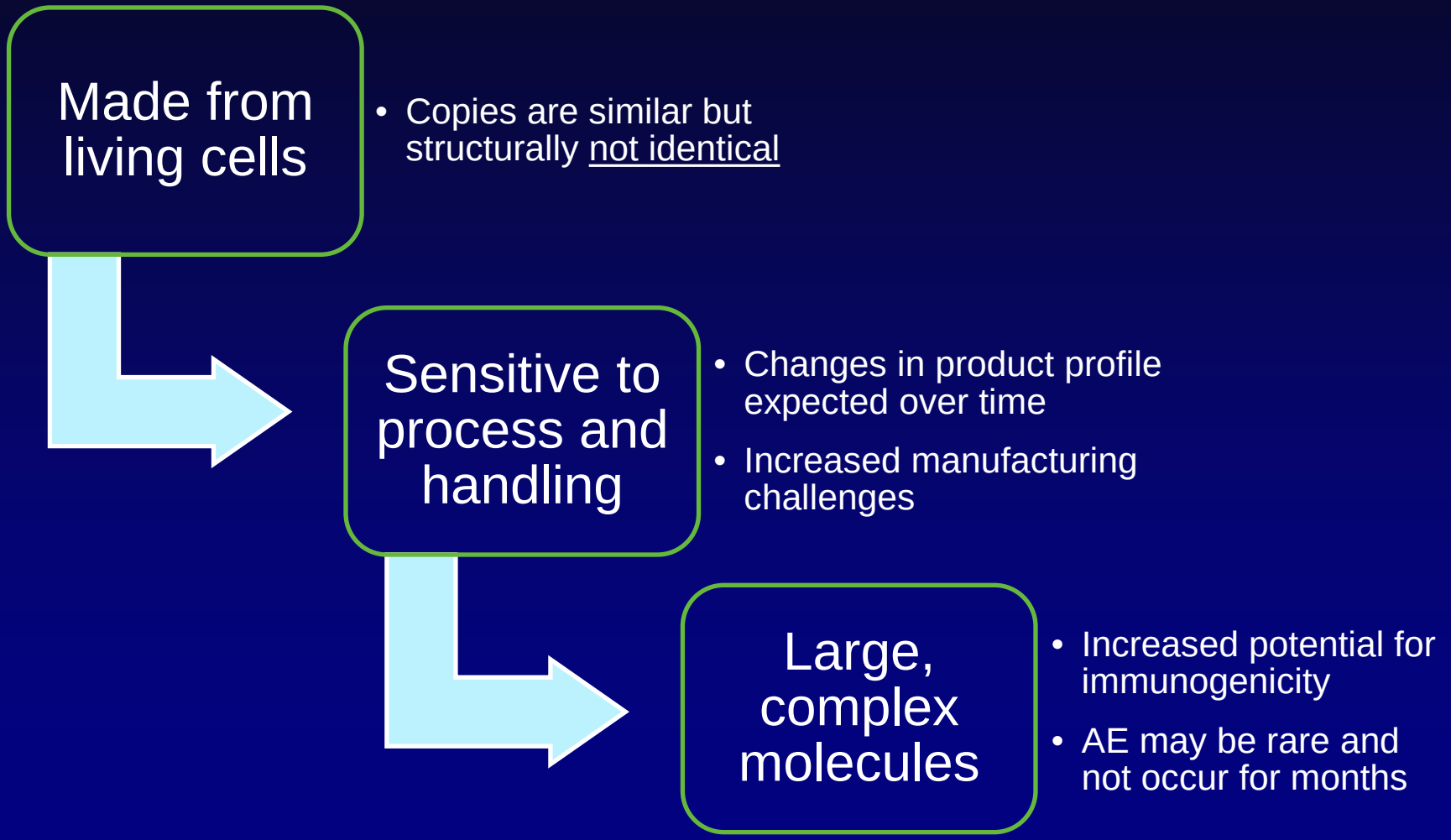
Sources: [1] 21 CFR 600.80 (emphasis added); [2] Strom, B, JAMA. 2004;292(21):2643-2646. doi:10.1001/jama.292.21.2643 (accessed at: http://jama.jamanetwork.com/article.aspx?articleid=199878); [3] Ahmad S, et al. Spontaneous Reporting in the United States. Pharmacoepidemiology. 4th ed. John Wiley and Sons; 2005:135–159; [4] Liu et al., RxNorm: Prescription for Electronic Drug Information Exchange, IT Pro. Sept–Oct. 2005, at 17 (2005); [5] Nelson et al., Normalized Names for Clinical Drugs: RxNorm at 6 years, 18 J. Am. Med. Inform. Assoc. 441 (2008).

The naming convention for generic drugs is not applicable to biologic medicines

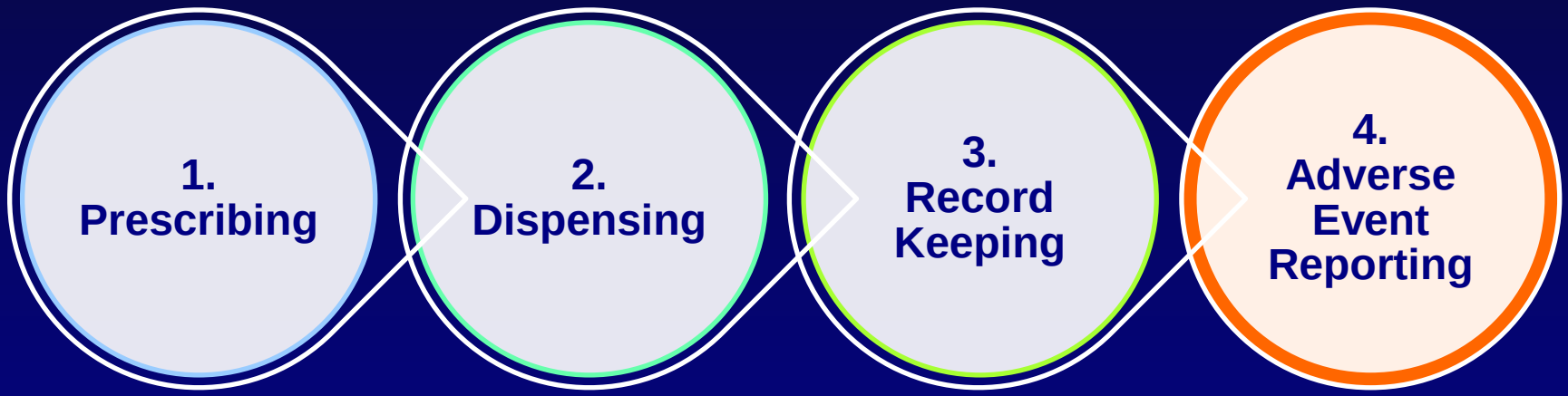
- Biosimilars are ‘similar’ but not identical to either the originator biologic or other biosimilars
- Differences are both expected and allowed; there is no requirement for biosimilars to be evaluated against one another or for safety in switching
- Biosimilars can be produced in different expression systems that also result in distinguishable differences

Source:[1] Section 7002(b)(3) of the Affordable Care Act, adding section 351(i)(2) of the PHS Act.

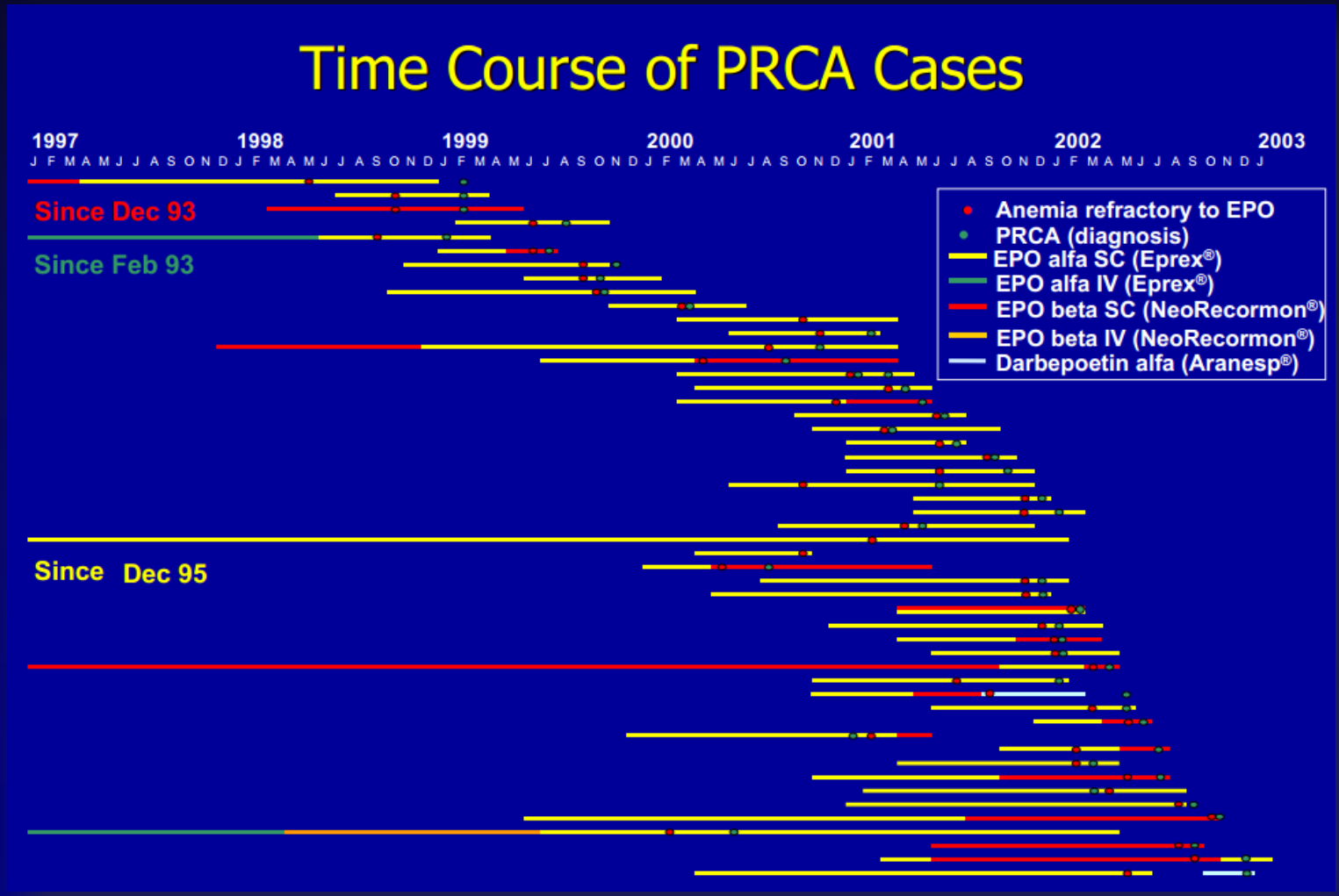
Biotechnology presents unique manufacturing and lifecycle challenges



Nonproprietary names play an important role in product identification and thus patient safety

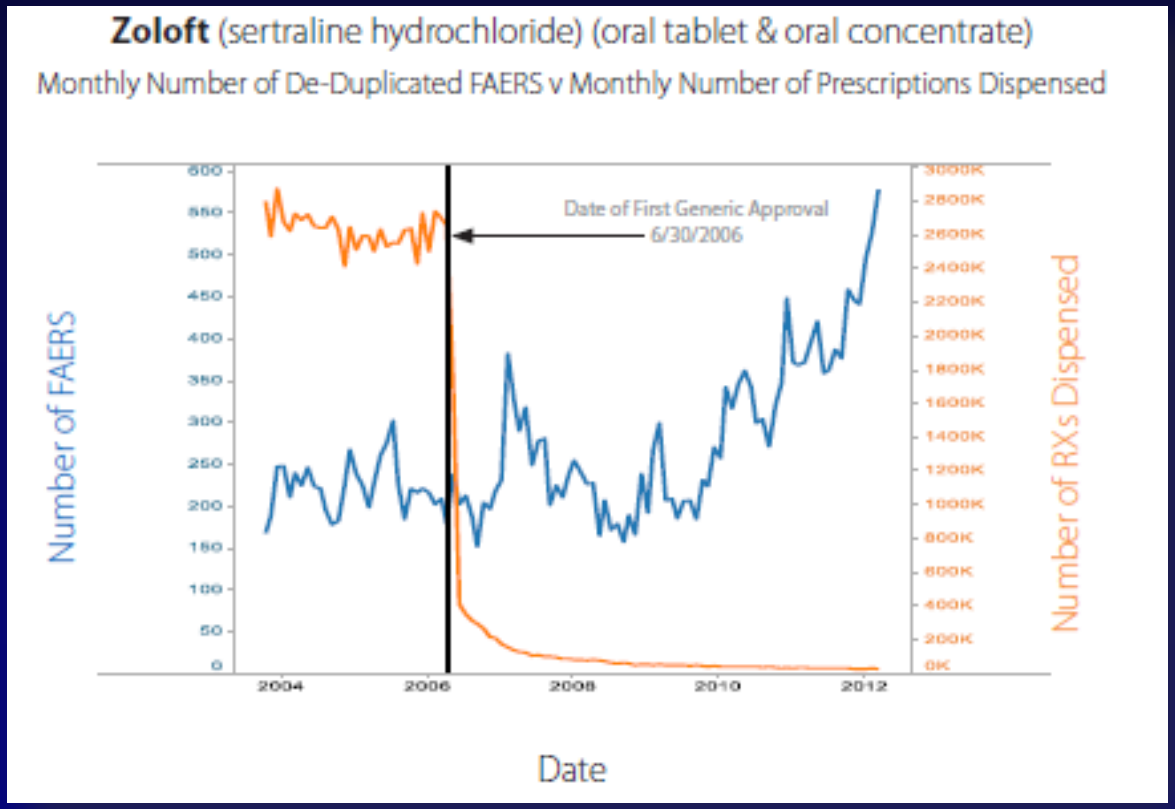


The proximal agent is not always the causal agent with biologics; longitudinal records are critical



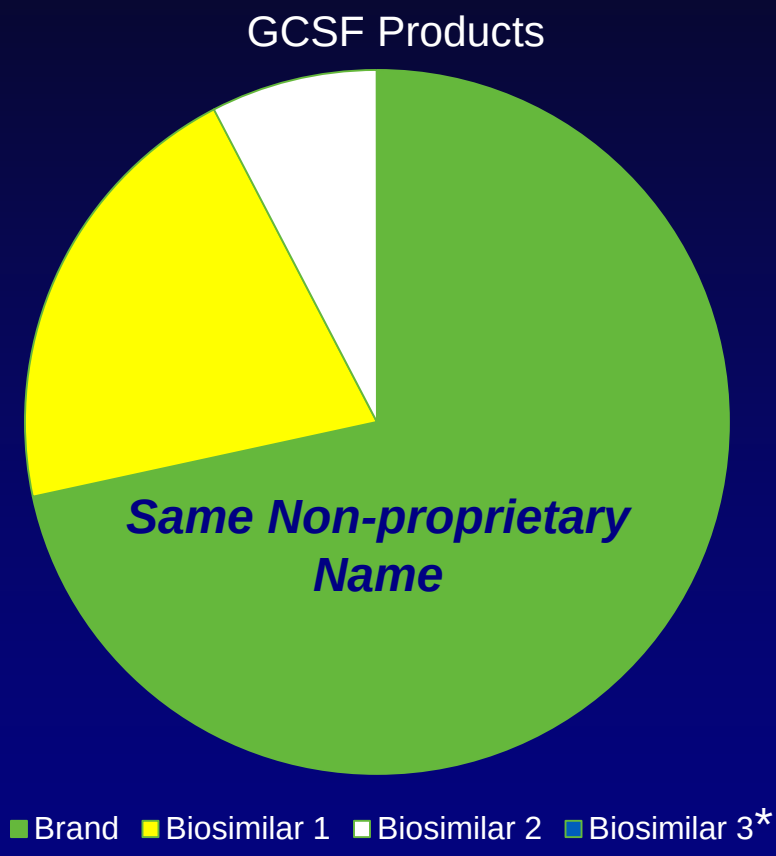
Source: Casadevall Nicole, Immune-response and adverse reactions: PRCA case example. Presentation to EMA Nov, 2009. Available at http://www.ema.europa.eu/docs/en_GB/document_library/Presentation/2009/11/WC500011064.pdf

Data from the US adverse event reporting system suggests events can be misattributed



Source: Lietzan EA, et al. Food and Drug Policy Forum. 2013;3(6).

Data show no major effect of names on current uptake in Australia



Source: Amgen analysis based on IMS data, showing Q3 2013 unit volumes
* Biosimilar 3 has no market share yet

Support for and interest in distinguishable nonproprietary names is broad and diverse

Doctors

- 80% of US and EU doctors surveyed believe a biosimilar should not have the same name as the reference product[1]

Payers

- 93% of US payers surveyed believe a biosimilar should not have the same name as the reference product[1]

Ex-US Regulators

- Japan has adopted distinguishable names for biosimilars
- Australia has adopted distinguishable names for biosimilars

World Health Organization

WHO is actively considering distinguishable nonproprietary naming of biologics in the INN Expert Committee

Source: [1] BioTrends Research Group, Biosimilars Advisory Service 2013

Distinguishable nonproprietary names for biologics are sound, science-based policy

- Nonproprietary names are based on scientific principles that reflect the complexity of both the molecules and the manufacturing processes
- Distinguishable names for all biologics are scientifically appropriate, justified by global experience and necessary for tracking adverse events
- Policy measures that are transparent, scientifically consistent and that engender accountability will earn the trust and confidence of physicians and patients, resulting in a successful U.S. biosimilars program

Questions