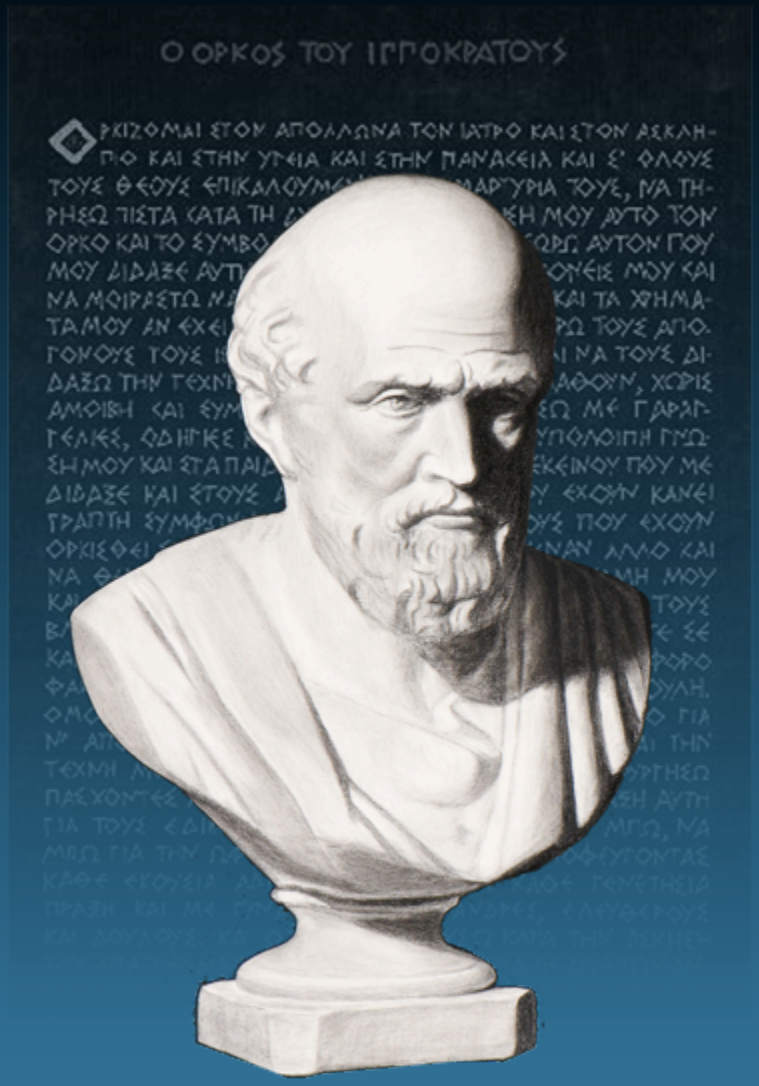
# *Naming of Biosimilars*

Richard Dolinar, MD
Endocrinologist, Chairman of the Alliance for Safe Biologic Medicines
Presented to the FDA/DIA Biosimilars Conference
September 13, 2012

# *Guiding Principles*

- The safety of my patients is paramount.
- Information is power: the more I know, the better for my patients.
- Manufacturers must be transparent for me to have confidence in the product.

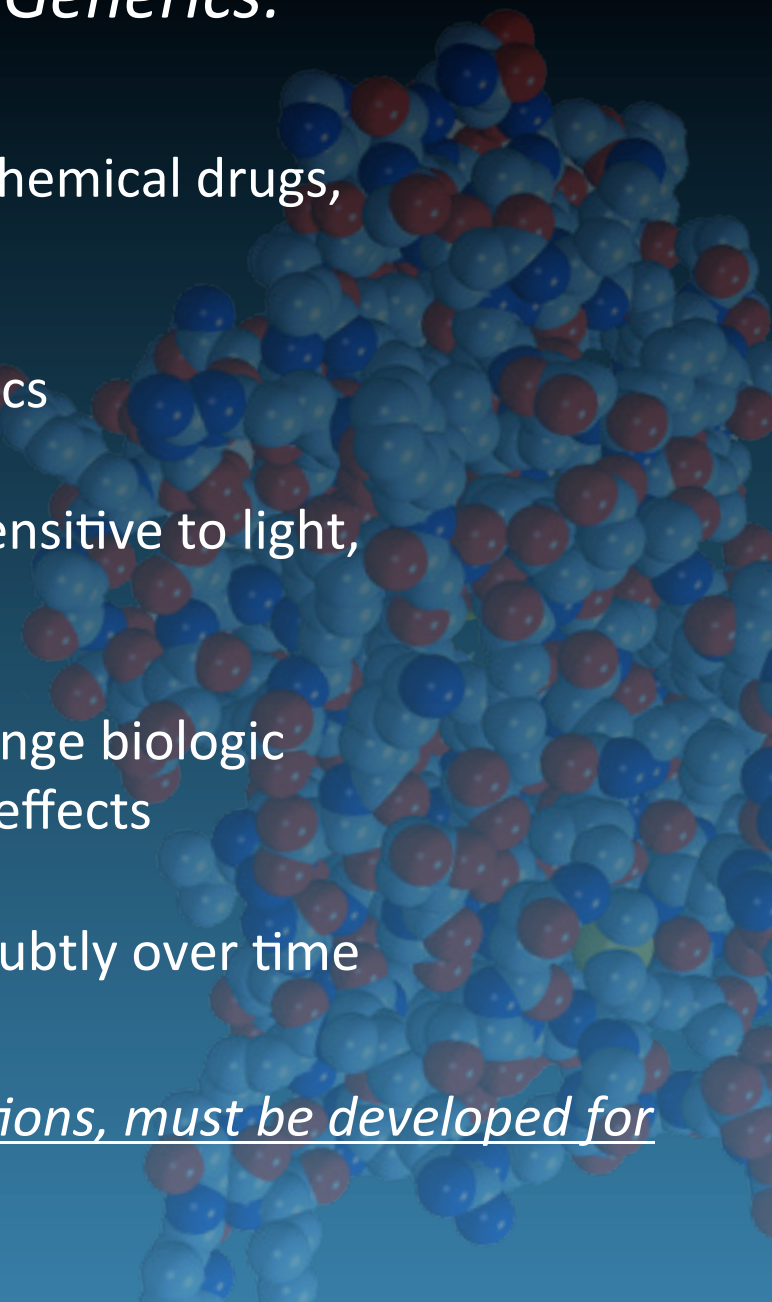



*Hippocratic Oath: "first, do no harm"*

## *Biosimilars are very different from Generics:*

- Larger size and greater complexity than chemical drugs, resulting in increased immunogenicity
- "Similar" is not "identical", as with generics
- Biologic medicines are often extremely sensitive to light, heat, and being denatured by agitation.
- Minor manufacturing differences can change biologic medicines and potentially cause adverse effects
- Biologic medicines can "drift", changing subtly over time

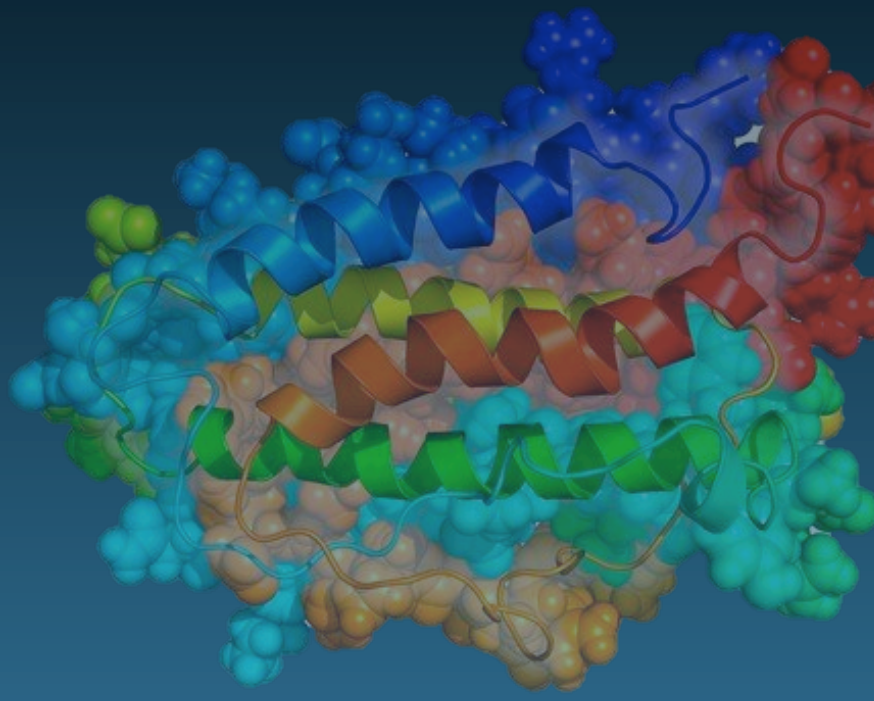
*New Standards, including naming conventions, must be developed for Biosimilars.*



*Patient safety is paramount: Biologics are highly sensitive; slight differences can have unexpected results.*

In 2001 an increase in life threatening adverse events associated with an innovative biologic in Europe was recognized.

At the time there were three products on the market with different scientific names. It took many months to determine the responsible product



- epoetin alfa
- epoetin beta
- darbepoetin alfa

**Imagine if these products had the same scientific name**

*Confusion can result with identical naming…*

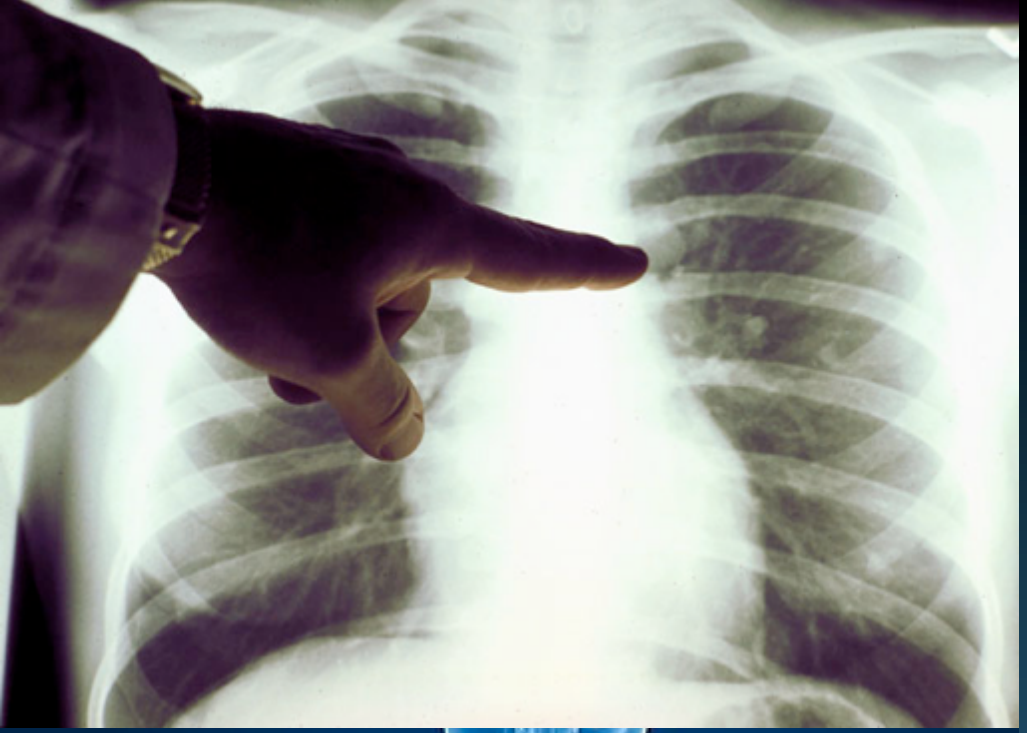
Eprex® (**epoetin alfa**)

Binocrit™ (**epoetin alfa**)

Abseamed (**epoetin alfa**)

Epoetin alfa Hexal (**epoetin alfa**)

*IF ONE OF THESE GENERATES AN ADVERSE EFFECT IN THE PATIENT, WILL THE DOCTOR KNOW WHICH ONE?*



*Ground lost is GROUND LOST.*

*-Dr. Robert Yapundich, practicing neurologist*

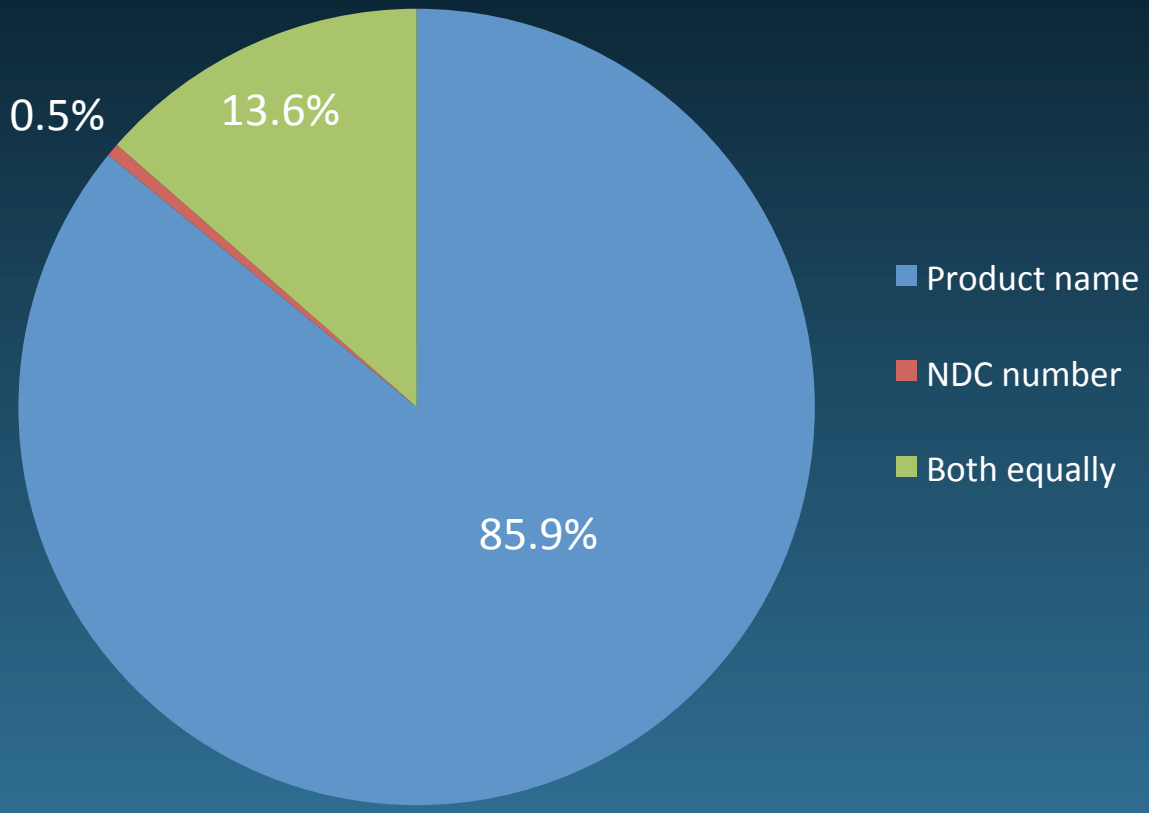
*We need to know as quickly as possible when and which product is associated with an unexpected outcome.*

*Unique names help physicians quickly and accurately identify and report adverse events.*

- Reliably distinguish between medicines
- Enable clearer communication with patient, medical staff and pharmacists

***Physicians overwhelmingly remember and refer to medicines by name***

# *Names or numbers? A strong majority of physicians prefer using product names for identifying adverse events*



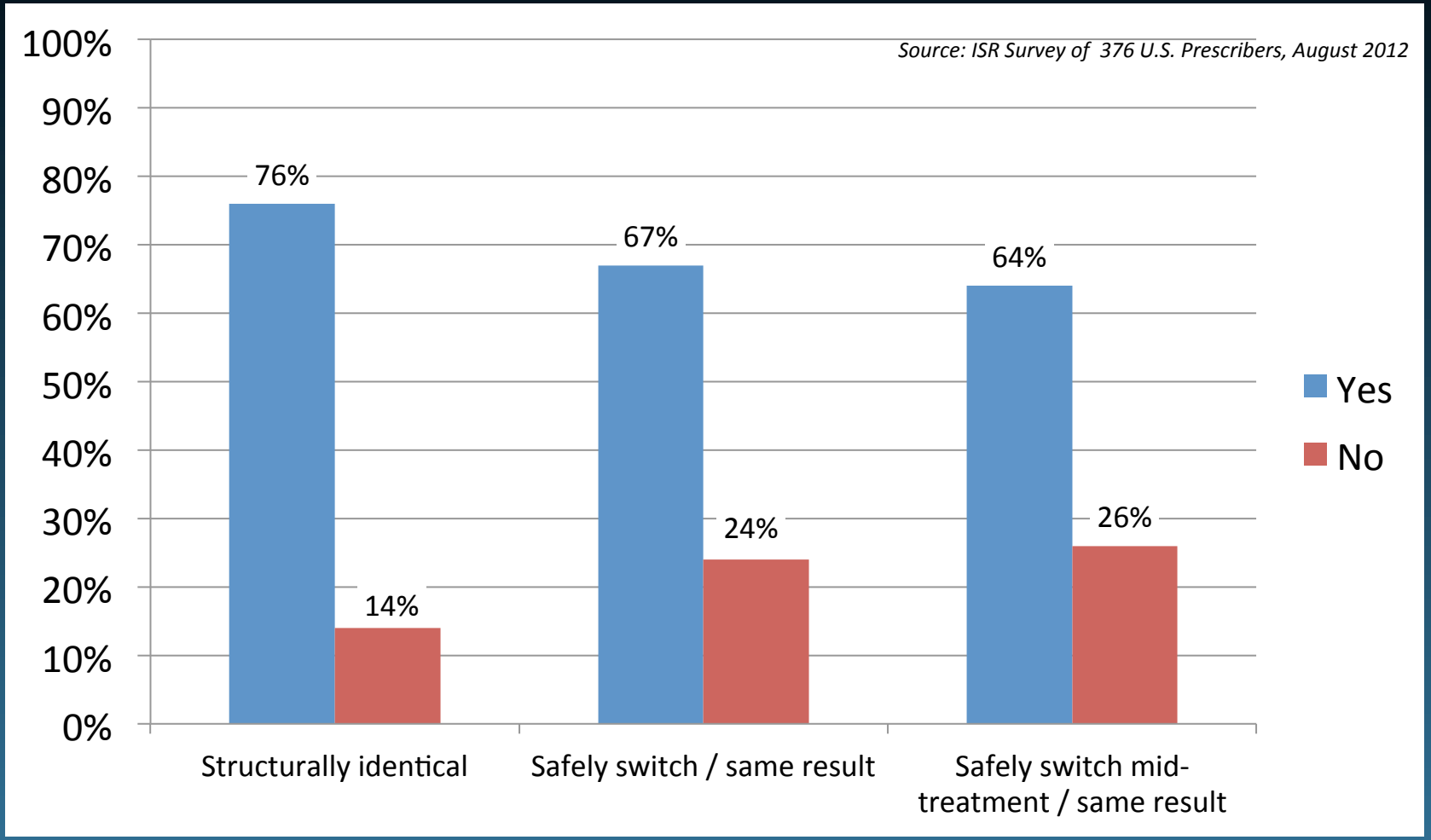

*Source: ISR Survey of 376 U.S. Prescribers, August 2012*

*Information is power…for patients and physicians*
*Transparency and accuracy are essential*

IDENTICAL NAMES imply IDENTICAL PRODUCTS…

…which will NOT be the case when biologics are made using different manufacturing processes and/or cell line.

# *What Physicians think Identical Naming means…*




***Identical names, even with extensive patient and physician education, would result in inappropriate substitution.***

# *Manufacturers must be transparent*

- Patient response must be traced to the correct manufacturer's product.
- Multiple means of product identification avoid a single point of information failure.
- Unique naming provides transparency and helps differentiate **products for observing and reporting adverse events.**
- **Patients and their caregivers are the last line of defense - unique names ensure that they can accurately identify the product.**

# *Summary: Unique Names Are Essential*

- The safety of my patients is paramount.
- Information is power: the more I know, the better for my patients.
- Manufacturers must be transparent for me to have confidence in the product.