

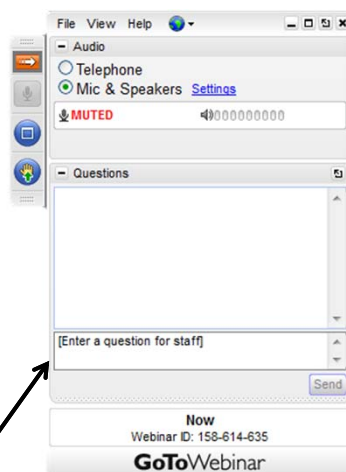
# AMCP Webinar Series

## Education for Health Care Providers The New Frontier for Biosimilars

August 24, 2016



## How to Ask A Question



Type your question in  
the 'Questions' area

[www.amcp.org](http://www.amcp.org)



## Education for Health Care Providers The New Frontier for Biosimilars



### Today's Speaker

#### **Brian Lehman**

Manager, Pharmacy Benefits & Policy

Ohio Public Employees Retirement System



- **Mr Lehman manages programs, services, and plan design for one of the U.S.'s largest public employee retiree systems**
- **Engaged with federal and state policy makers on issues related patient access to affordable medications**
- **Experience with plan management and retail pharmacy**
- **Former assistant professor of clinical pharmacy**

[www.amcp.org](http://www.amcp.org)



## Objectives

- Biosimilars and biologics basics
- Importance of education
- Opportunity to educate health care providers
- Overview and demonstration of the Biosimilars Resource Center

[www.amcp.org](http://www.amcp.org)

AMCP  
Academy of  
Managed Care  
Pharmacy®

©2015 Academy of Managed Care Pharmacy

## Definitions - Biologics

- Large molecule medications
- Product made from materials of living organisms, including human or animal cells, yeast, or bacteria
- Manufactured using biotechnology methods such as recombinant DNA
- More expensive to produce and manufacturer than conventional small molecule agents

42 U.S.C. § 262(i)(1)

[www.amcp.org](http://www.amcp.org)

AMCP  
Academy of  
Managed Care  
Pharmacy®

©2015 Academy of Managed Care Pharmacy

## Definitions - Biosimilars

- Product developed based on an originator biologic known as a reference product
- Similar but not an exact copy of a reference product
- May have a slightly different structure but active ingredients similar
  - No clinically meaningful differences between innovator and biosimilar

42 U.S.C. § 262(i)(2)

[www.amcp.org](http://www.amcp.org)

**AMCP** Academy of  
Managed Care  
Pharmacy®

©2015 Academy of Managed Care Pharmacy

## Definitions - Interchangeable Biologic Product

- No specific guidance on exact definition yet and no approvals yet
- Concept is unique to the U.S.
  - Interchangeability not in other countries
- Sponsor must provide additional evidence that product will produce the same clinical results as innovator in any patient
  - Must show that switching will not result in greater harm to patient than when using reference continuously

42 U.S.C. § 262(i)(3)

[www.amcp.org](http://www.amcp.org)

**AMCP** Academy of  
Managed Care  
Pharmacy®

©2015 Academy of Managed Care Pharmacy

## Why is Education important?

“Our initiative is to educate US health care providers about the benefits of biosimilars will be critical in ensuring that the therapies become widely adopted and utilized in a safe and effective manner. AMCP is proud to take the lead in this effort.”

Susan A. Cantrell, RPh, CAE  
AMCP CEO

[www.amcp.org](http://www.amcp.org)

AMCP  
Academy of  
Managed Care  
Pharmacy®

©2015 Academy of Managed Care Pharmacy

## Why is Education Important?

- Education is one of the keys to successful adoption –  
*IMS Delivering on the Potential of Biosimilar Medicines: The Role of Functioning Competitive Markets*
- “Stakeholder engagement is essential to success of the biosimilar program.”  
Janet Woodcock, MD, Director of FDA’s Center for Drug Evaluation and Research Before US House Energy & Commerce Committee (2016)

[www.amcp.org](http://www.amcp.org)

AMCP  
Academy of  
Managed Care  
Pharmacy®

©2015 Academy of Managed Care Pharmacy

## Why is Education Important?

What We Don't Know Will Hurt Us

Uncertainty about safety and efficacy among consumers and providers could stymie adoption

We've seen this before: Lack of understanding resulted in slow initial adoption of generics in the 1980s

[www.amcp.org](http://www.amcp.org)

AMCP  
Academy of  
Managed Care  
Pharmacy®

©2015 Academy of Managed Care Pharmacy

## Education Opportunity – Pharmacists

Majority of AMCP/HOPA Biosimilars survey respondents found that **additional education is needed regarding biologics, biosimilars, and interchangeable products**

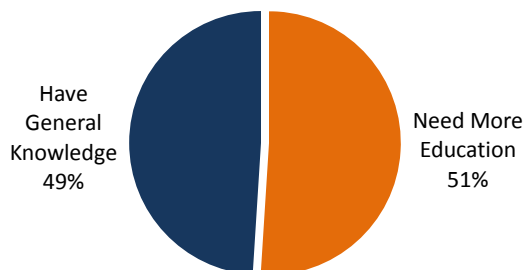
[www.amcp.org](http://www.amcp.org)

AMCP  
Academy of  
Managed Care  
Pharmacy®

©2015 Academy of Managed Care Pharmacy

## Education Opportunity – Providers

A 2015 survey of 180 gastroenterologists' views on biosimilars



Source National Survey Reveals  
Gastroenterologists' Views on Biosimilar Drugs.  
Am. Gastroenterologist Assn. July 29, 2015.

[www.amcp.org](http://www.amcp.org)

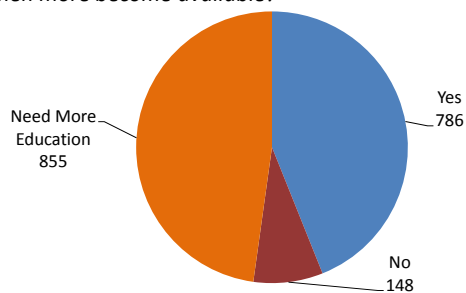
AMCP  
Academy of  
Managed Care  
Pharmacy®

©2015 Academy of Managed Care Pharmacy

## Education Opportunity - Providers

2016 survey of 1,789 physicians in the U.S.

Question: In general, do you feel biosimilars will be safe and effective enough for you to prescribe when more become available?



Source Medical Media & Marketing, June 2016.  
<http://www.mmm-online.com/commercial/what-do-physicians-think-about-biosimilars/article/498542/>

[www.amcp.org](http://www.amcp.org)

AMCP  
Academy of  
Managed Care  
Pharmacy®

©2016 Academy of Managed Care Pharmacy

## Biosimilars Resource Center

- The Biosimilars Resource Center (BRC) provides needed educational resources and information on biosimilars to health care providers and other stakeholders in a policy-neutral and non-promotional manner.
- Biosimilars have the potential to significantly decrease health care costs in the United States and improve access to treatment for patients. The need for education of health care providers on how to prescribe and dispense cost effective biosimilars is critical to driving adoption and maximizing their use in a safe and effective manner for patients

[www.amcp.org](http://www.amcp.org)

AMCP  
Academy of  
Managed Care  
Pharmacy®

©2015 Academy of Managed Care Pharmacy

## Now the live demonstration of the website!



### Follow the BRC on Twitter

Get the facts about [#biosimilars](https://twitter.com/Biosimfacts).

[@Biosimfacts](https://twitter.com/Biosimfacts)

Is the twitter feed for the new Biosimilars Resource Center - your first stop for unbiased, up-to-date information and education on biosimilars.

[BiosimilarsResourceCenter.org](http://BiosimilarsResourceCenter.org)



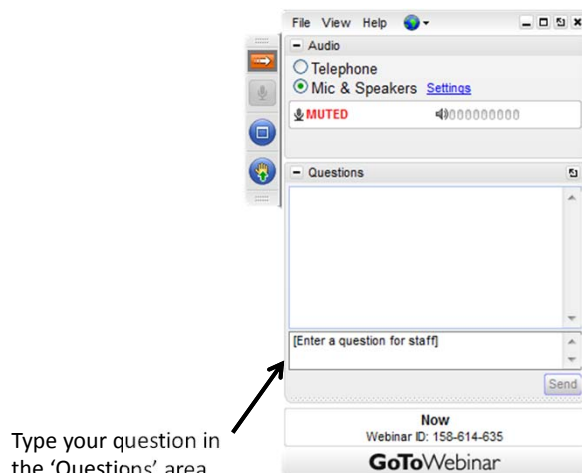
[www.amcp.org](http://www.amcp.org)

AMCP  
Academy of  
Managed Care  
Pharmacy®

©2015 Academy of Managed Care Pharmacy



## How to Ask A Question



[www.amcp.org](http://www.amcp.org)

AMCP Academy of Managed Care Pharmacy®

©2015 Academy of Managed Care Pharmacy

# THANK YOU!

upcoming webinars  
[www.amcp.org/calendar](http://www.amcp.org/calendar)

AMCP Academy of Managed Care Pharmacy®