ASBM/Ohio State University Biosimilars CE Course for Pharmacists
Spring 2022

OVERVIEW

The Alliance for Safe Biologic Medicines and Ohio State University College of Pharmacy are partnering to present a 7-hour Continuing Education (CE) Course for pharmacists on the topic of biosimilars and related policy concerns which affect pharmacy practice.

The course is open to pharmacists nationwide, including:

- OSU-Pharmacy students and alumni
- Practicing pharmacists within the State of Ohio
- National and regional/state pharmacy organizations

THE OHIO STATE UNIVERSITY
COLLEGE OF PHARMACY

SafeBiologics
ALLIANCE for SAFE BIOLOGIC MEDICINES

FACULTY LECTURERS

Philip Schneider, MS, FASHP, FFIP; Professor of Pharmacy at OSU College of Pharmacy. Professor Schneider leads the Biosimilars CE Course. He has served on the faculty at the College for 30 years and is past president of the American Society of Health-system Pharmacists (ASHP), the largest U.S. pharmacist organization. He recently completed a term as Vice President of the International Pharmaceutical Federation (FIP). Schneider has served Chair of ASBM's Advisory Board since 2014.

Ralph McKibbin, MD, FACP, FACG, AGAF; Chairman, Alliance for Safe Biologic Medicines
Dr. McKibbin is a practicing gastroenterologist at Blair Gastroenterology Associates in Altoona, PA. He is past president of both the Pennsylvania Society of Gastroenterology and of the Digestive Disease National Coalition (DDNC). He sits on the Member Advisory Panel of the Pennsylvania Medical Society; and is a member of the Pennsylvania State Cancer Control Consortium. Dr. McKibbin has written extensively on the issues of non-medical switching and insurance industry utilization management techniques including step therapy and copay accumulator adjustments.

Madelaine Feldman, MD, FACR; President, Coalition of State Rheumatology Organizations
Dr. Feldman is a rheumatologist in private practice and a national speaker on drug pricing and transparency in the drug supply chain in the United States. She is a clinical assistant professor of medicine at Tulane University Medical School and President of the Tulane Medical Alumni Association board of directors. She was awarded the Distinguished Service award by Tulane Medical School. She served as Chair of ASBM from 2014-2017.

Andrew Spiegel, Esq.; Executive Director, Global Colon Cancer Association
Mr. Spiegel co-founded the Colon Cancer Association and served as its Executive Director for 5 years before founding the Global Colon Cancer Association. Spiegel is currently co-chair of the DDNC. In 2012, Spiegel received the David Jagelman Award for Patient Advocacy from the American Society of Colon and Rectal Surgeons. He currently serves on the Board of the Digestive Disease National Coalition (DDNC) and is Chairman of the World Patients Alliance. Mr. Spiegel serves on the steering committee of the Alliance for Safe Biologic Medicines.

ACPE ACCREDITED

The College of Pharmacy at The Ohio State University is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. This program is approved for 3.0 contact hours (0.3 CEU) under the ACPE universal program numbers 0633-0000-22-019-H01-P, 0633-0000-22-020-H01-P and 0633-0000-22-021-H01-P. Participants must view the program content and complete the post presentation quiz and evaluation to receive CE credit for the program. Questions about pharmacists' participation in the program and continuing education credit should be addressed to: Ashley Knackstedt at: cop-cpd@osu.edu; (614)-688-4420.

ACPE

COURSE DESCRIPTION

The course currently consists of seven 1-hour modules; additional modules to follow on an ad hoc basis.

1) Intro to Biologics and Biosimilars (Schneider)

This module familiarizes students with the basic structure and function of biologic medicines, the benefits they bring to patients, and describes how biosimilars differ from generic versions of small molecules. Key policy challenges surrounding biosimilars (e.g. approval standards, accurate pharmacovigilance, concerns with substitution) are introduced. This module is a prerequisite for each subsequent module.

2) Biosimilar Substitution and Interchangeability (Schneider)

This module describes U.S. biosimilar substitution policy and practices, including those of private and public payers. It contrasts the U.S. approach to that of several other countries including Canada, Australia, and Western Europe. Physician and patient concerns with biosimilar switching are discussed and supported with survey data. This module, along with module 1 (Intro) are prerequisites for all subsequent entries.

3) Biosimilar Pharmacovigilance (Schneider)

This module examines the unique pharmacovigilance challenges that biosimilars pose due to having an abbreviated approval pathway sharing a non-proprietary name with their reference product and other biosimilars to that product. The importance of accurate attribution of adverse events is discussed, as are various approaches to addressing this challenge used by countries around the world to varying degrees of effectiveness. The U.S. biologic pharmacovigilance and nomenclature system is examined in detail. The WHO-proposed international nomenclature standard is also discussed.

4) The Biosimilar Market (Schneider)

This module examines the reasons for increasing biosimilar uptake, and various factors which contribute to their gaining market share. Among these are building physician confidence through data, robust post-market surveillance to address concerns about abbreviated pathways, the preservation of physician and patient choice, multiple payer-reimbursed products competing on a level playing field, and downward price pressure resulting from competition. The mature biosimilar markets of Europe are analyzed in great detail, and lessons regarding best practices are drawn. The current U.S. biosimilar market is also discussed, including an examination of biosimilars which have achieved significant, even dominant, market shares.

5) Physician Perspectives on Biosimilars (McKibbin)

In this module, Dr. McKibbin shares survey data from physicians in 13 countries, including U.S. (n=401, 2021) and Europe (n=579, 2019). Physician attitudes on a variety of aspects of biosimilars are examined including: confidence in their safety and efficacy, comfort level with prescribing biosimilars, physician-led switching of patients, third-party switching for cost/coverage reasons, implications of interchangeability designations and distinct suffixes, and payer coverage and reimbursement practices.

6) Patient Advocacy Perspectives on Biosimilars (Spiegel)

In this module, patient advocate Andrew Spiegel shares patient perspectives on biosimilars, drawn from his 12 years working on biosimilar policy in the U.S. and worldwide. Spiegel discusses the benefits that biologic medicines have given to patients with serious and chronic conditions including arthritis, psoriasis, Crohn's disease, and cancer. He also shares patient concerns with non-medical and/or forced switching, including policies which have raised backlash from patient organizations in the U.S., Canada, and Australia. Case studies of successful patient advocacy in the biosimilar space are shared, including a seven-year campaign to enact substitution legislation in 50 states.

7) Biosimilars: Payer and PBM Practices (Feldman)

In this module, Dr. Feldman explains unique features of the U.S. drug distribution system, with an emphasis on payer and pharmaceutical benefit manager (PBM) practices regarding biologic medicines and biosimilars. The bifurcated U.S. system (provider-administered vs. specialty pharmacy) is examined in detail and the differences in these two sub markets are highlighted: in particular, the degree to which savings can be achieved, and the role played by middlemen and manufacturer rebates in driving up rather than lowering costs. Utilization management tools used by payers (including non-medical switching and step therapy) are described, as are proposed regulations and legislation to restrict such practices.

Visit osupharmacy.catalog.instructure.com to access the course.