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Dean, Chapman University School of Pharmacy (CUSP)
March 15, 2015

PREPARING FOR BIOSIMILARS

The Evolving Role of Pharmacists in the Age of Biologic Therapies

My Background

- Registered pharmacist, Fellow and Former President of the American Pharmacists Association (APhA)
- Founding Dean of Chapman University School of Pharmacy (CUSP) at its new multidisciplinary Rinker Health Sciences Campus in Irvine, CA
- Responsible for all aspects of the strategic direction and development of the new program.
- Former Dean, College of Pharmacy at the University of Rhode Island (URI)
- Board Member of American Association of Colleges of Pharmacy, Finance, Investment and Bylaws and Policy Development Committees
- Trustee and Standardization Chairman of the National Council for Prescription Drug Programs (NCPDP), which develops consensus standards for the prescription drug benefit industry.
- Twice cited as one of the 50 most influential pharmacists in the United States by *American Druggist*.
- Advisory Board Member of Alliance for Safe Biologic Medicines

CHAPMAN UNIVERSITY

APhA

THE UNIVERSITY OF RHODE ISLAND COLLEGE OF PHARMACY

SafeBiologics
ALLIANCE *for* SAFE BIOLOGIC MEDICINES

Involvement with the Alliance for Safe Biologic Medicines

- Member of Advisory Board
- Dec. 13, 2012: ASBM holds forum at University of Rhode Island College of Pharmacy, provides different perspectives, including biologic manufacturing facility tour
- ASBM is group of patients, physicians, pharmacists, researchers, manufacturers, and others who share goals of scientifically-sound standards of quality and safety for biosimilars.
- Brings pharmacists, physicians, patients together to work collaboratively on policy recommendations
- Education to stakeholders, lawmakers, and regulators about emerging policy concerns

Why Is Education on Biologics/Biosimilars Important?

- Biologic medicines and biosimilars are the future of medicine, including pharmacy
- More than 400 biologic medicines exist
- Expected to comprise 60% of the top ten selling drugs within the next few years, hundreds in development.
- The first biosimilars expected in the U.S. within a matter of months
- We owe it to the patients we serve to have deep familiarity with these therapies
- Developing a robust biologics curriculum is key for Colleges of Pharmacy and CE

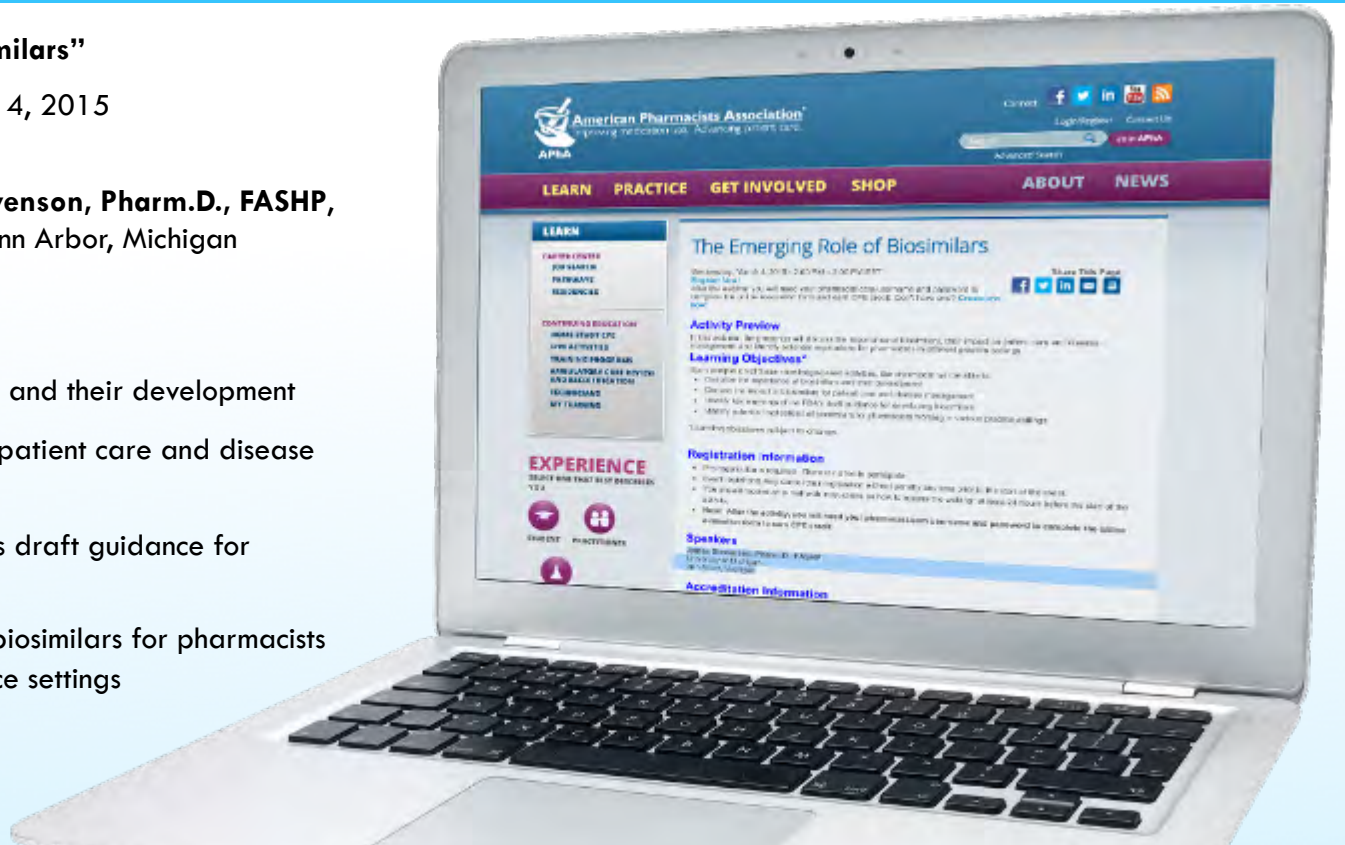
APhA Education: March 4 Biosimilars Webinar

"The Emerging Role of Biosimilars"

- Held Wednesday, March 4, 2015
  2:00 PM – 3:00 PM EST
- Presented by **James Stevenson, Pharm.D., FASHP,** University of Michigan, Ann Arbor, Michigan

Topics covered included:

- Importance of biosimilars and their development
- Impact of biosimilars for patient care and disease management
- Key elements of the FDA's draft guidance for developing biosimilars
- Potential implications of biosimilars for pharmacists working in various practice settings



Health Care: Transforming Toward the Triple Aim:

IMPROVING HEALTH

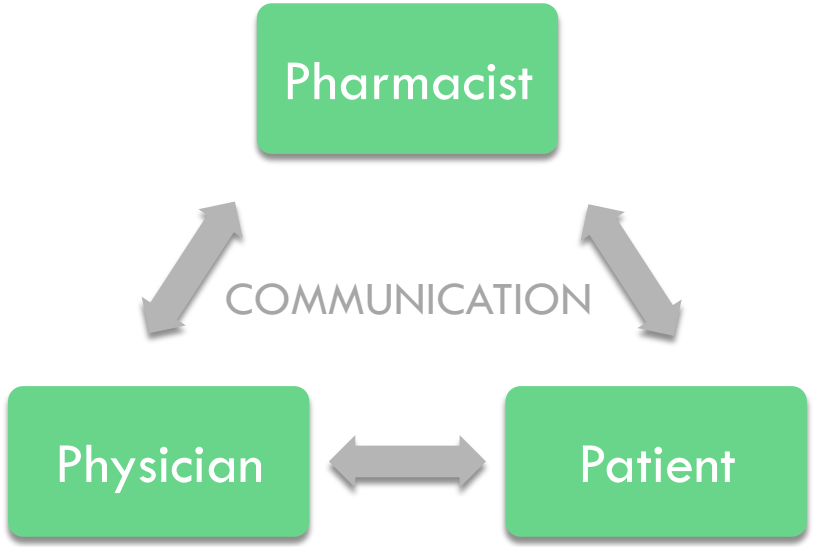
IMPROVING CARE

REDUCING COSTS

- Proposed by Berwick and Nolan in 2007 to re-vision healthcare around 3 core values

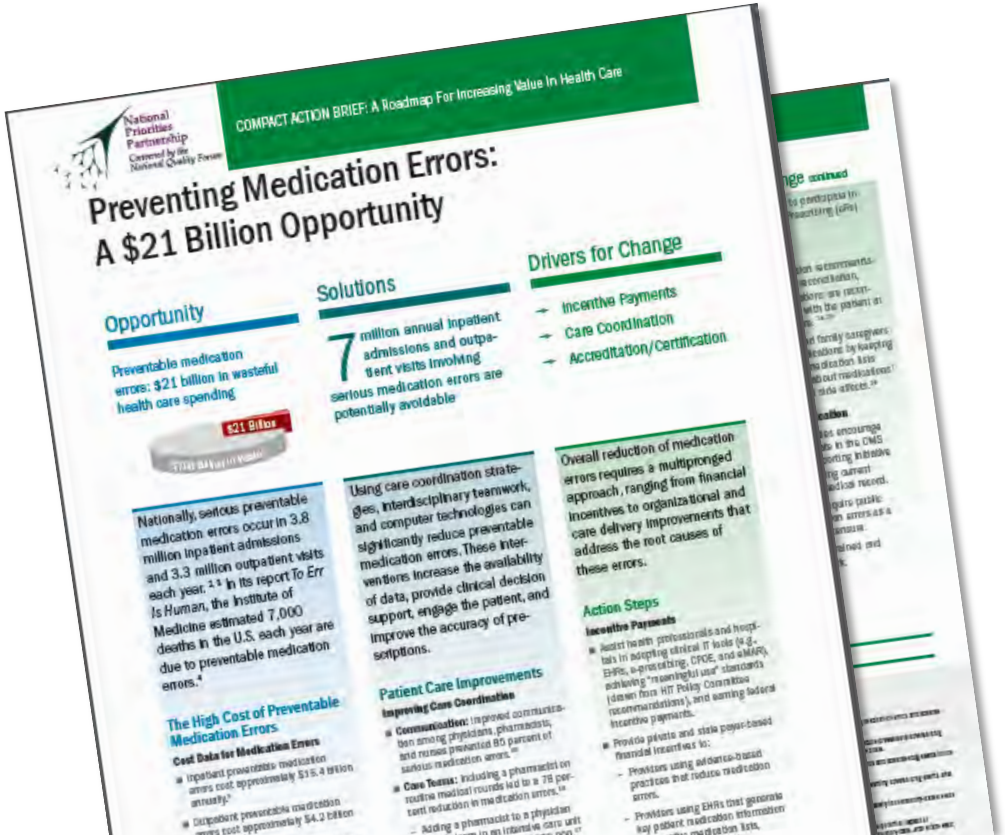
Why Is Collaboration on Biologics Important?

- Pharmacists are playing an increasingly important role as health care providers
- We are the last line of defense before the patient receives the medicine.
- Collaboration and communication with physicians and patients are key to good pharmacovigilance, and avoiding errors.
- As biosimilar policy is created at the Federal and State levels, it is important for pharmacists to lead on this issue by being educated and engaged.



NEHI and RWJF Work Lays Out Benefits of Collaboration Well. Let's Borrow!

- We are not the only stakeholders who think pharmacist engagement can bring savings to the system.
- This is particularly relevant with biologics because of their sensitivity, fragile structure, and inherent risk on immunogenicity
- Paper available at http://www.nehi.net/bendthecurve/sup/documents/Medication_Errors_%20Brief.pdf



Preventing Medication Errors:

A $21 Billion Opportunity

Made possible through support from:

WELLPOINT FOUNDATION

Learn more about ways to Bend the Curve in health care costs at: www.nehi.net/bendthecurve

A $21 Billion Opportunity

- Improve Care Coordination
- Facilitate Patient Engagement
- Require Pharmacist Follow-up
- Enhance Technology Interventions
- Increase Incentive Payments
- Update Accreditation/Certification

Notes

1. NEHI. (2008). How Many More Studies Will It Take? A Collection of Evidence That Our Health Care System Can Do Better. Retrieved from http://www.nehi.net/publications/30/how_many_more_studies_will_it_take. Last accessed October 2011.

Scope of Medication Errors

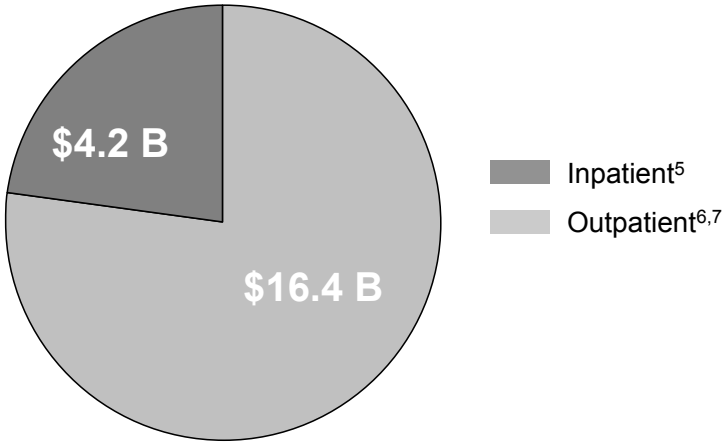
- Serious preventable medication errors occur in:
  - 3.8 million inpatient admissions[2]
  - 3.3 million outpatient visits[3]
- Mortality from preventable medication errors:
  - 7,000 deaths each year[4]

Notes

2. Massachusetts Technology Collaborative (MTC) and NEHI, 2008. *Saving Lives, Saving Money: The Imperative for CPOE in Massachusetts*. Updated to 2008 figures. Cambridge, MA: NEHI, 2008. Available at: http://www.nehi.net/publications/8/saving_lives_saving_money_the_imperative_for_computerized_physician_order_entry_in_massachusetts_hospitals.
3. Center of Information Technology Leadership (CITL), *The Value of Computerized Provider Order Entry in Ambulatory Settings*. Updated to 2007 figures. Available at: http://www.partners.org/cird/pdfs/CITL_ACPOE_Full.pdf. Last accessed October 2011.
4. Institute of Medicine (IOM). *To Err Is Human: Building a Safer Health System*. Washington, DC: National Academy Press; 1999.

Costs of Medication Errors

Annual Cost of Preventable Medication Errors by Setting



Notes

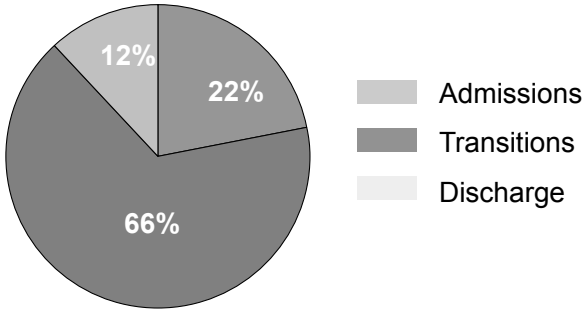
5. Massachusetts Technology Collaborative and NEHI. 2008.
6. Center of Information Technology Leadership. 2007.
7. Burton, M.M., Hope, C., Murray, M.D., et al. (2007). The cost of adverse drug events in ambulatory care. AMIA Annu Symp Proc, 90-93.

Driver: Prescription Errors

Types of Prescription Errors

- Dosing errors make up 37% of all preventable medication errors.[8]
- Drug allergies or harmful drug interactions account for 11% of preventable medication errors.[9]
- Approximately 100 undetected dispensing errors can occur each day as a result of the significant volume of medications dispensed.[11]

Settings for Medication Reconciliation Errors[10]



Preventable medication reconciliation errors occur in all phases of care.

Notes

8. Bobb, A., Gleason, K., Husch, M., et al. (2004). The epidemiology of prescribing errors. Arch Intern Med, 164(7), 785-792.
9. Bobb, Gleason, Husch, et al. 2004.
10. Santell, J.P. (2006). Reconciliation failures lead to medication errors. Jt Comm J Qual Patient Saf, 32(4), 225-229.
11. Cina, J.L., Gandhi, T.K., Churchill, W., et al. (2006). How many hospital pharmacy medication dispensing errors go undetected? Jt Comm J Qual Patient Saf, 32(2), 73-80.

Other Drivers

Fragmentation of Care

- Only 13% of primary care physicians reported that they communicated with a pharmacist regarding new prescriptions.[12]

Lack of Information Technology Infrastructure

- EMR systems that are described as fully functional and had a prescribing function were reported by only 4% of physicians.[13]
- E-prescribing is used by only 32% of physicians in ambulatory care settings.[14]

Notes

12. Ranelli, P.L., Biss, J. (2000). Physicians' perception of communication with and responsibilities of pharmacists. J Am Pharm Assoc, 40(5), 625-630.
13. Hsiao, C.J., Burt, C.W., Rechtsteiner, E., et al. (2008). Preliminary Estimates of Electronic Medical Records Use by Office-Based Physicians. Atlanta, GA: National Center for Health Statistics (NCHS). Retrieved from www.cdc.gov/nchs/data/hestat/physicians08/physicians08.pdf. Last accessed October 2011.
14. Grossman, J.M. (2006). Even When Physicians Adopt E-Prescribing, Use of Advanced Feature Lags. Washington, DC: Center for Studying Health System Change. Issue Brief No. 133. Retrieved from www.hschange.com/CONTENT/1133/1133.pdf. Last accessed October 2011.

Solution: Improve Care Coordination

- Communication:
  - Improved communication among physicians, pharmacists and nurses prevented 85% of serious medication errors.[15]
- Including a pharmacist on routine medical rounds led to a 78% reduction in medication errors.[16]
  - Adding a pharmacist to a physician rounds team in an intensive care unit led to annual savings of $270,000.[17]

Notes

15. Fortescue, E.B., Kaushal, R., Landrigan, C.P., et al. (2003). Prioritizing strategies for preventing medication errors and adverse drug events in pediatric inpatients. Pediatrics, 111(4 Pt 1), 722–729.
16. Kucukarslan, S.N., Peters, M., Mlynarek, M., et al. (2003). Pharmacists on rounding teams reduce preventable adverse drug events in hospital general medicine units. Arch Intern Med, 163(17), 2014-2018.
17. Leape, L.L., Cullen, D.J., Clapp, M.D., et al. (1999). Pharmacist participation on physician rounds and adverse drug events in the intensive care unit. JAMA, 282(3), 267-270.

Solution: Facilitate Patient Engagement

- Engagement of Patients and Families:
  - Active engagement of patients and family caregivers with the care team
  - Use of patient safety checklists
  - Increased awareness of publicly reported hospital safety records

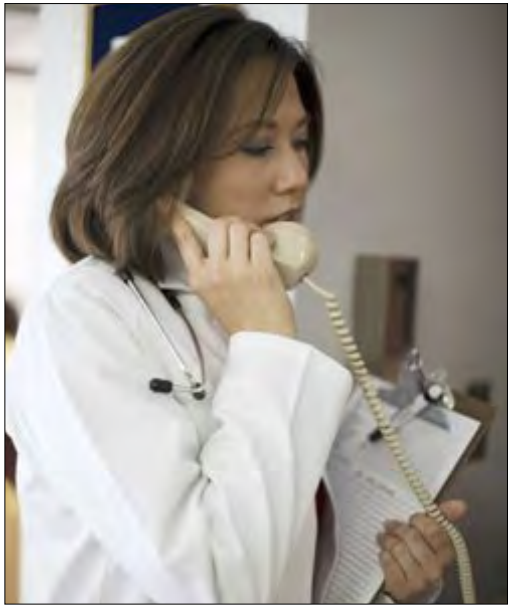
- Adopt Joint Commission recommendations for medication reconciliation, ensuring that medications are reconfirmed and reviewed with the patient at each transition in care.[18,19]
- Empower patients and family caregivers to manage their medications by keeping PHRs and personal medication lists and informing them about the purpose, effects and side effects of their medications.[20]

Notes

18. Joint Commission on Accreditation of Healthcare Organizations. (2006). Using medication reconciliation to prevent errors. Sentinel Event Alert, 35, 1-4.
19. National Priorities Partnership. (2008). National Priorities and Goals: Aligning Our Efforts to Transform America's Healthcare. Washington, DC: National Quality Forum.
20. Sabogal, F., Coots-Miyazaki, M., Lett, J.E. (2007). Ten effective care transitions interventions: improving patient safety and healthcare quality. CAHQ Journal, 31(2), 15-19.

Solution: Require Pharmacist Follow-up

- Patients who received pharmacist follow-up calls
  - 88% less likely to have a preventable medication error resulting in an ED visit or hospitalization.[21]



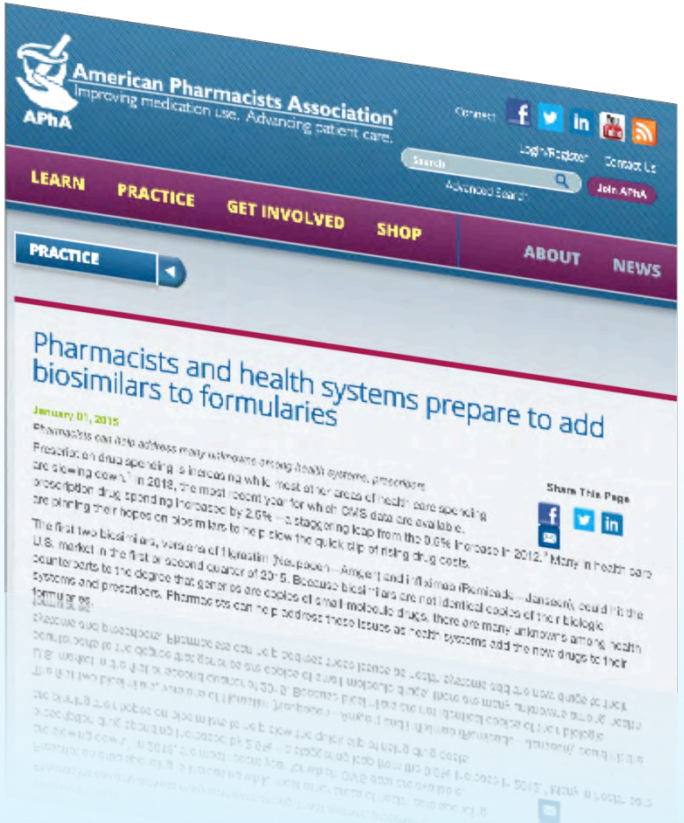
Notes

21. Schnipper, J.L., Kirwin, J.L., Cotugno, M.C., et al. (2006). Role of pharmacist counseling in preventing adverse drug events after hospitalization. Arch Intern Med, 166(5), 565-571.

Example: Distinguishable Naming as Aid to Pharmacovigilance

"Even if a drug is considered similar, it should be easily identified. There's been a longstanding principle in health care that pharmacists have used to avoid look-alike, sound-alike drug names, so the industry's been asked to change drug names so there aren't those kinds of mix-ups…Once a decision is made, it should be very clear what drug the patient's receiving."

-Philip Schneider, MS, FASHP,
Associate Dean at the University of Arizona College of Pharmacy ASBM Advisory Board member



Considerations in Developing a Biologics Curriculum

- Understanding the fundamental differences between biologic and chemical medicines:
  - Sensitivity of proteins to minor manufacturing differences/molecular modifications, heat, light
  - Clinical considerations- differences in patient response due to minor differences between similar medications
  - Unique PV challenges, tracking and tracing of adverse events of biosimilars
- Understanding biosimilarity– the FDA designation of "interchangeable" and how biosimilars are approved
- Keeping track of FDA policies (e.g., labeling and naming) that affect pharmacists
- Understanding development of regulations at state level (e.g.,) related to substitution and record-keeping, which differ from state to state

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