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February 23, 2020

PHARMACISTS & BIOSIMILARS

The Role of Pharmacists in Managing Biosimilar Use

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Daniel Tomaszewski, Pharm.D., PhD

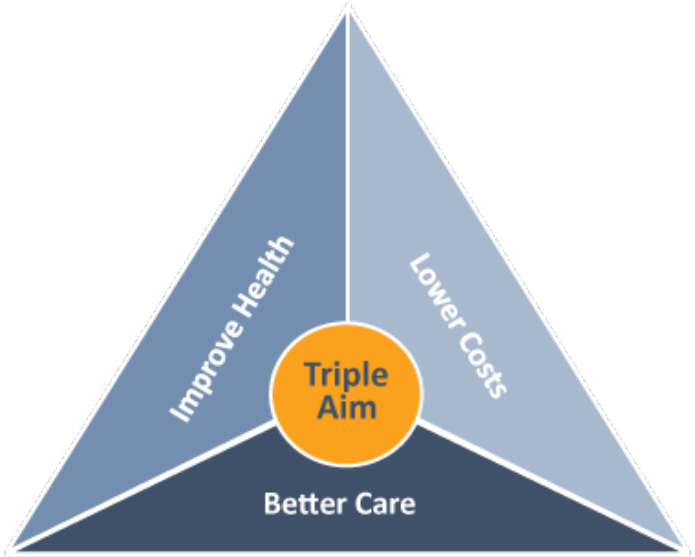
Assistant Professor in Pharmacy Administration, Chapman University

EDUCATION:

- Sept. 2009 - Sept. 2014 Ph.D. in Social and Administrative Pharmacy, University of Minnesota, College of Pharmacy
- Sept. 2005 - May 2009 Pharm.D., University of Minnesota, College of Pharmacy
- Sept. 2002 - May 2005 Pre-Pharmacy (No degree earned), University of Wisconsin – Madison, College of Liberal Arts
- Member, Public Policy Committee Member, Academy of Managed Care 2012-present.
- Board member, Minnesota Pharmacists Association, serving as a board member since May of 2014.

RESEARCH AREAS:
Measuring pharmacists involvement in clinical services, including biosimilars, evaluation of trends in pediatric opioid use, and medication adherence across multiple chronic conditions.

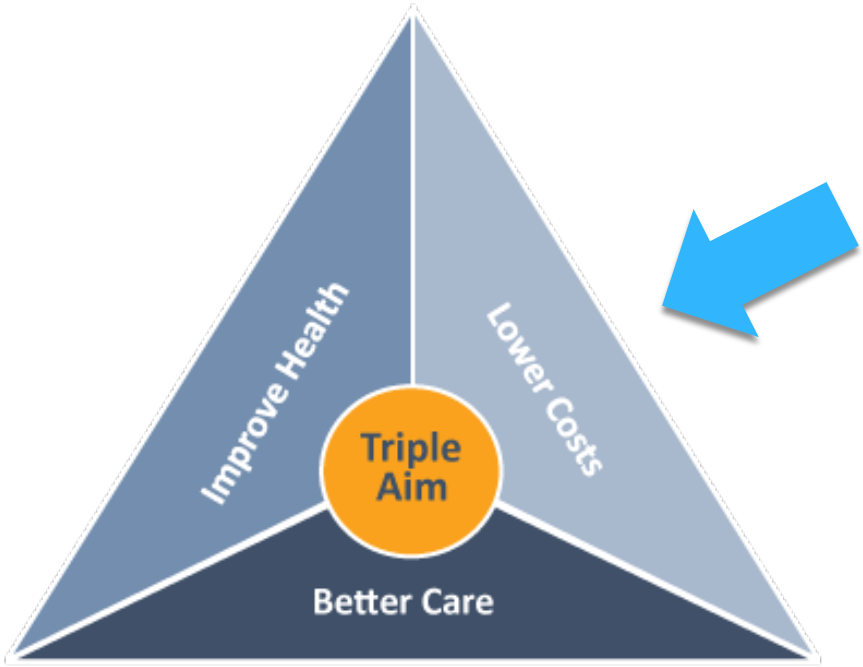
Health Care: Transforming Toward the Triple Aim:



- Proposed by Berwick and Nolan in 2007 to re-vision healthcare around 3 core values[1]

http://content.healthaffairs.org/content/27/3/759.full

Biosimilars and the Triple Aim



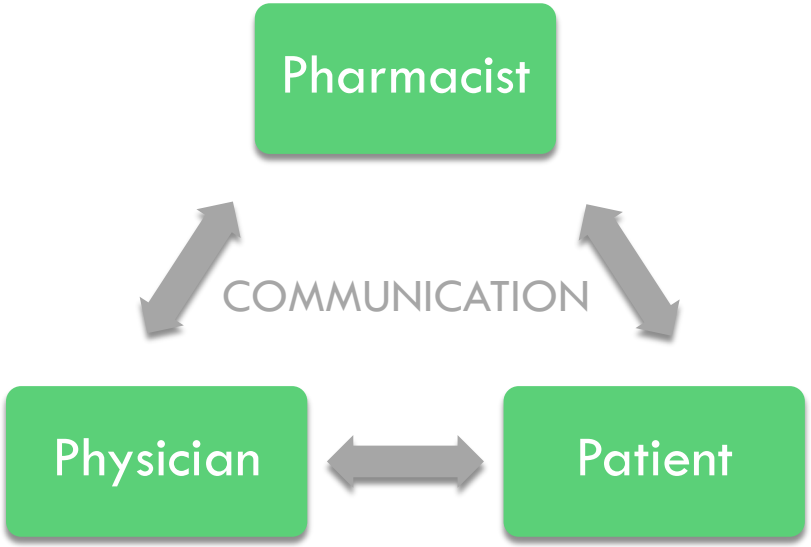
Why We Need Biosimilars: Price Inflation Example (Biologic "Drug A")

Date Reported	AWP Pricing	Total Cost Per Dose (AWP)	Percent Raise	Percent Raise Since Approval
2020	3334.180	6668.39	7.4	510.4
2019	3104.45	6208.90	6.2	475.2
2018	2923.22	5846.44	9.7	447.5
2017	2664.74	5329.48	8.4	407.9
2016	2278.26	4556.52	9.9	348.7
2015	2073.04	4146.07	28.0	317.3
2014	1620.19	3240.38	15.3	248.0
2013	1404.65	2809.3	14.3	215.0
2012	1229.17	2458.34	14.3	188.1
2011	1075.62	2151.23	6.9	164.6
2010	1006.19	2012.38	10.0	154.0
2009	914.38	1828.76	10.0	140.0
2008	830.96	1661.92	4.9	127.2
2007	792.14	1584.28	4.9	121.3
2006	755.14	1510.27	4.9	115.6
2005	719.86	1439.71	4.3	110.2
2004	690.15	1380.29	5.6	105.6
2003	653.3	1306.6	0	100.0

Cost is the Elephant in the Room

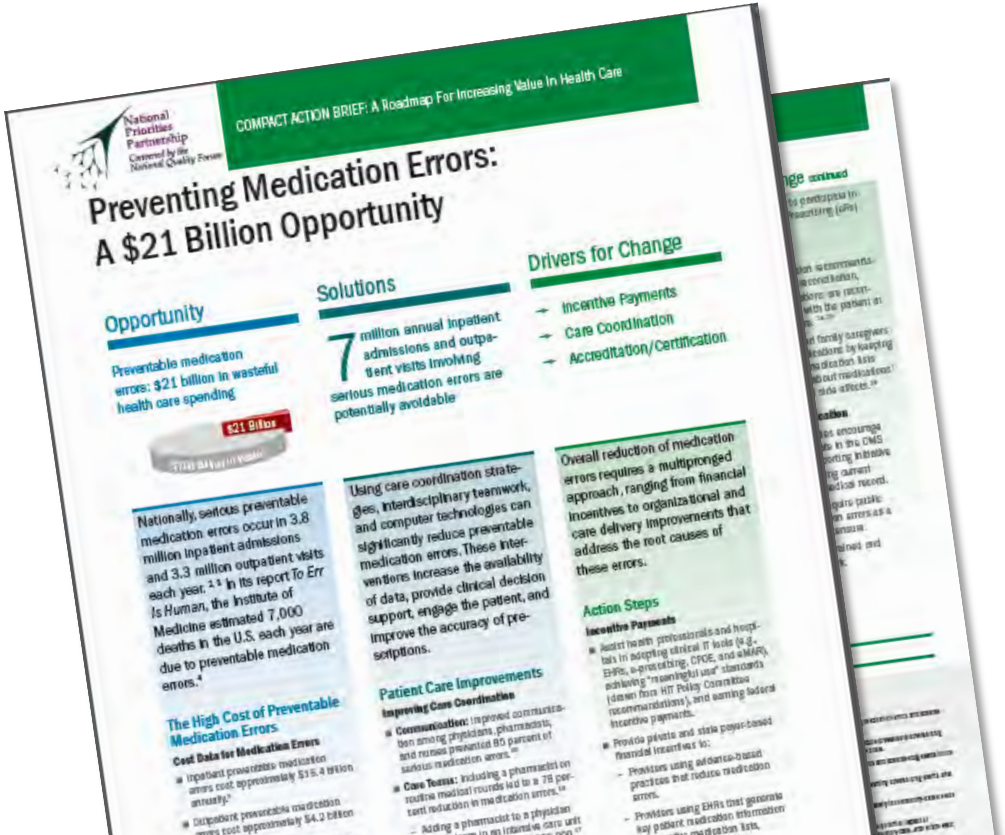
Why Is Collaboration on Biologics Important?

- Pharmacists are playing an increasingly important role as health care providers
- We are the last line of defense before the patient receives the medicine.
- Interprofessional communication are key to good pharmacovigilance, and error prevention.
- Pharmacists must engage as more biosimilars become available and state/federal regulations change



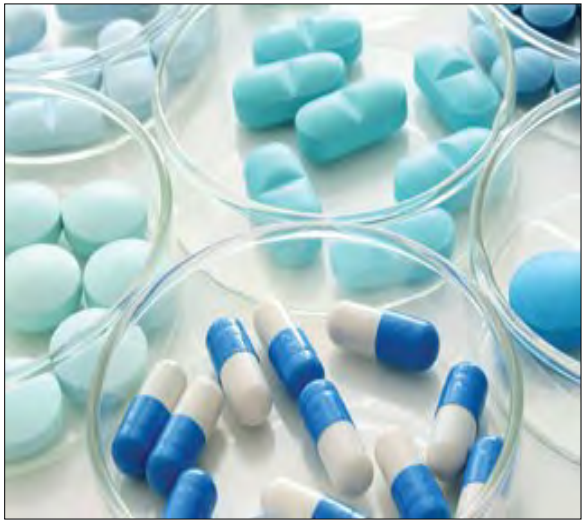
Benefits of Collaboration

- We are not the only stakeholders who think pharmacist engagement can bring savings to the system.
- This is particularly relevant with biologics:
  - Sensitivity
  - Fragile structure
  - Immunogenicity
- Confusion can result in non-adherence



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.

Clinical 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 70% of physicians.[13]
  - EMRs are not typically 2-way in nature
- E-Prescribing is extensive, however, communication remains 1-way in nature

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 ONC Data Brief. E-Prescribing Trends in the United States. Available at https://www.healthit.gov/sites/default/files/oncdatabriefe-prescribingincreases2014.pdf. Last Accessed 2016

Pharmacists' Role: Improve Care Coordination

- Communication:
  - Improved communication among physicians, pharmacists and nurses prevented 85% of serious medication errors.[15]
  - Communication between pharmacists and prescribers remain extremely limited
- 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.

Pharmacists' Role: Facilitate Patient Engagement

- Engagement of Patients and Families:
  - Informs the patient of what to monitor
    - Safety parameters
    - Effectiveness parameters
    - Medication's place in therapy
    - How to report any issues that may arise
  - Enhances patient's understanding of disease being treated
    - Are relapses common/likely
    - How to handle periodic worsening symptoms
    - What might suggest treatment failure

Pharmacists' Role: Pharmacovigilence

- Pharmacists have the ability to report adverse events
  - Historically low rates of engagement
  - Has potential to improve accuracy of reporting
    - What specific product used
    - Better define ADR being reported
    - Improve likelihood of ADR being reported

Overall Pharmacist Engagement with Biologics

- Complex medications to treat complex diseases
- Increased PBM oversight
  - Need to manage Prior Authorizations
  - Keep patients engaged
  - Ensure proper use and adherence
- Pharmacists may recognize patient use concerns
- Pharmacists can be ideal source of follow-up between clinic visits

The Pharmacists Role in Biosimilars Specifically

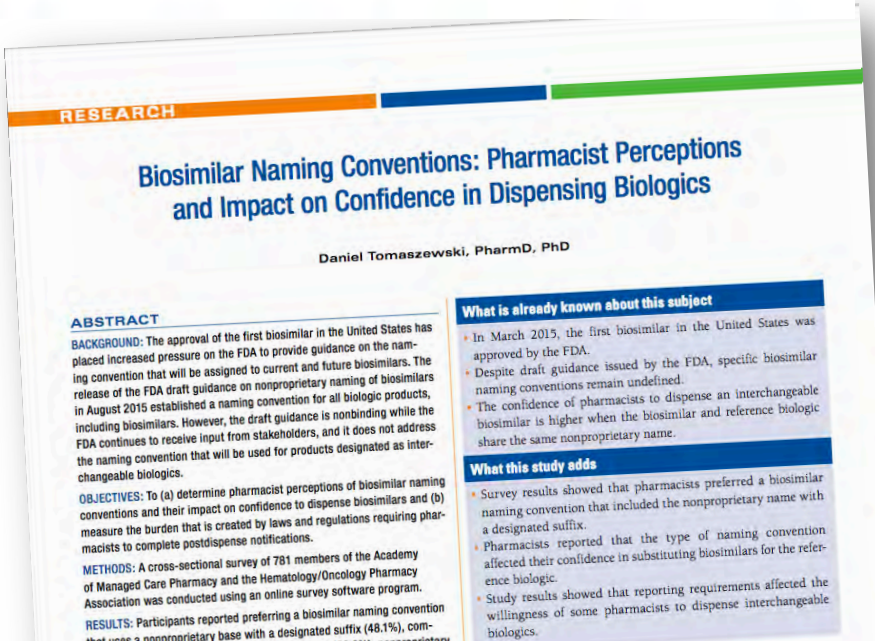
- Potential for confusion
  - What product is required by PBM
  - What product was dispensed and when
    - Help ensure adherence isn't causing apparent non-response
  - Potential product overlap with care transitions
  - Help patients navigate specialty pharmacy requirements
- Manage patient-specific needs

Whitepaper: Biosimilar Naming Conventions

JMCP Journal of Managed Care & Specialty Pharmacy
A Peer-Reviewed Journal of the Academy of Managed Care Pharmacy

PUBLISHED August 2016 (J Manag Care Spec Pharm, 2016 Aug;22(8):919-926.)

OBJECTIVE: Determine to what extent BIOSIMILAR NAMING CONVENTIONS impact PHARMACIST PERCEPTIONS, CONFIDENCE in DISPENSING BIOLOGICS…



RESEARCH

Biosimilar Naming Conventions: Pharmacist Perceptions and Impact on Confidence in Dispensing Biologics

Daniel Tomaszewski, PharmD, PhD

ABSTRACT

BACKGROUND: The approval of the first biosimilar in the United States has placed increased pressure on the FDA to provide guidance on the naming convention that will be assigned to current and future biosimilars. The release of the FDA draft guidance on nonproprietary naming of biosimilars in August 2015 established a naming convention for all biologic products, including biosimilars. However, the draft guidance is nonbinding while the FDA continues to receive input from stakeholders, and it does not address the naming convention that will be used for products designated as interchangeable biologics.

OBJECTIVES: To (a) determine pharmacist perceptions of biosimilar naming conventions and their impact on confidence to dispense biosimilars and (b) measure the burden that is created by laws and regulations requiring pharmacists to complete postdispense notifications.

METHODS: A cross-sectional survey of 781 members of the Academy of Managed Care Pharmacy and the Hematology/Oncology Pharmacy Association was conducted using an online survey software program.

RESULTS: Participants reported preferring a biosimilar naming convention

What is already known about this subject

- In March 2015, the first biosimilar in the United States was approved by the FDA.
- Despite draft guidance issued by the FDA, specific biosimilar naming conventions remain undefined.
- The confidence of pharmacists to dispense an interchangeable biosimilar is higher when the biosimilar and reference biologic share the same nonproprietary name.

What this study adds

- Survey results showed that pharmacists preferred a biosimilar naming convention that included the nonproprietary name with a designated suffix.
- Pharmacists reported that the type of naming convention affected their confidence in substituting biosimilars for the reference biologic.
- Study results showed that reporting requirements affected the willingness of some pharmacists to dispense interchangeable biologics.

Study in Context: FDA Naming of Biosimilars

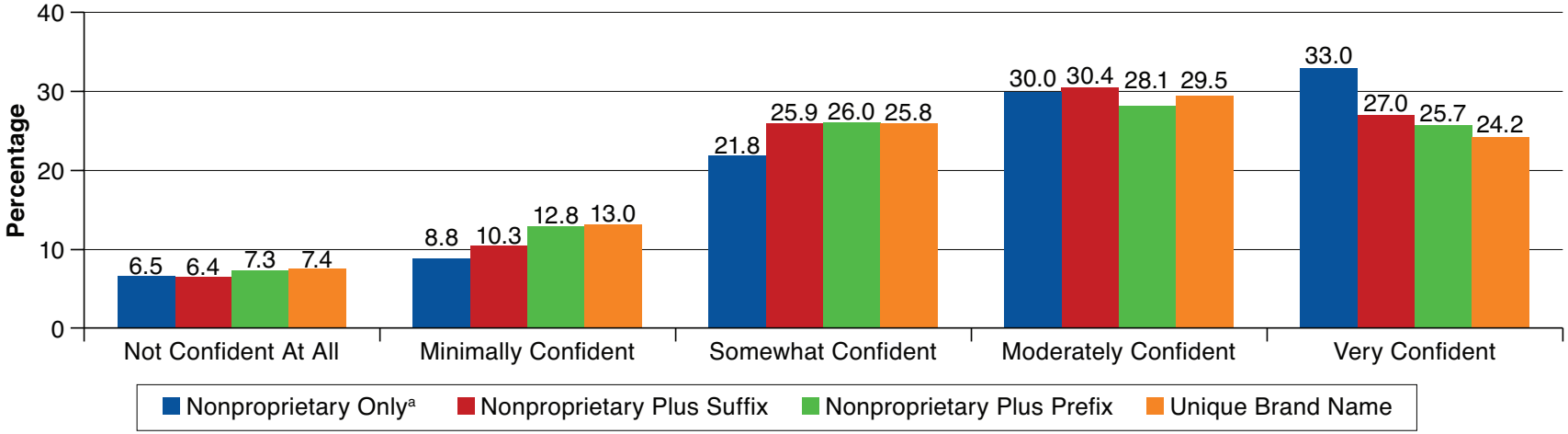
- **May-June 2015:** Data collection for study.
- **August 2015:** FDA releases Draft Guidance on Biologic Naming
  - Proposes to use random suffixes, proposes to change name of several current biologics (including "filgrastim-sndz" to "filgrastim-bflm").
  - FDA solicits feedback from stakeholders on naming preference.
- **April-September 2016:** FDA approves three more biosimilars, all with random suffixes.
- **August 2016:** Study published.
- **January 2017**: FDA Publishes Recommendations on naming

Primary Take Away From the Study

- Overall pharmacists support FDA naming requirements
- The use of a suffix did result in lower pharmacist reported confidence in dispensing the biosimilar
- Requiring post dispense prescriber reporting increases pharmacist burden (likely due to lack of IP communication)
- Naming convention adds further complexity
- **All biosimilars to date have used a proprietary name:**
  - Does a name really matter?

Impact on Confidence Level

FIGURE 2 Confidence of Pharmacists in Dispensing an Interchangeable Biologic Based on Naming Convention Use (N =619)

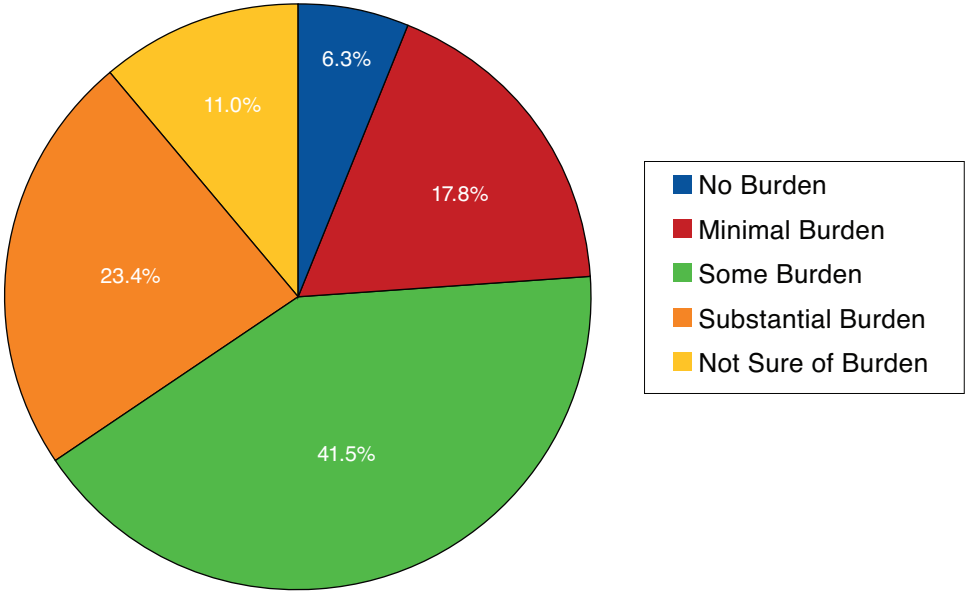


While expressing a preference for Nonproprietary name + suffix, respondents did not demonstrate increased confidence when dispensing an interchangeable biologic using this naming convention.

Burden of Prescriber Notification

- Most popular response was “some burden” (41.5%)
- 23.4% considered this burden “substantial”.
- A similar percentage (24.1) considered there to be “no burden”(6.3%) or “minimal burden”(17.8%)
- 11% were unsure of the burden.

FIGURE 3 Pharmacist-Reported Level of Burden Associated with Postdispensing Notification Requirements When Dispensing a Biosimilar (N =381)



Changing Landscape

- To date, approved agents primarily delivered inpatient or at clinic/office
- Focus is shifting to outpatient delivered medications
  - Acute drugs beginning to be released
  - Chronic self-injectables are current focus
- Enbrel is anticipated to be the first true outpatient biosimilar; however, release has been delayed
- New impact of pay for delay and confusion of available products grows

Delays in Availability of Biosimilars

- Enbrel biosimilar delays:
  - Involved in patent challenges
  - Patent challenge include:
    - Secondary patent on protein
    - Patent on production process
- Humira biosimilars have been delayed
  - Also led to patent challenges and pay for delay
    - Current reports are biosimilar entrance in 2021

Impact of Biosimilar Delays

- Creating additional confusion for all
- Prescribers expect biosimilars to be available
- Pharmacists unsure when approved biosimilars will be commercially available
- Managed Care Organizations having difficulty to plan for potential biosimilars

Poor Biosimilar Utilization in the US to Date

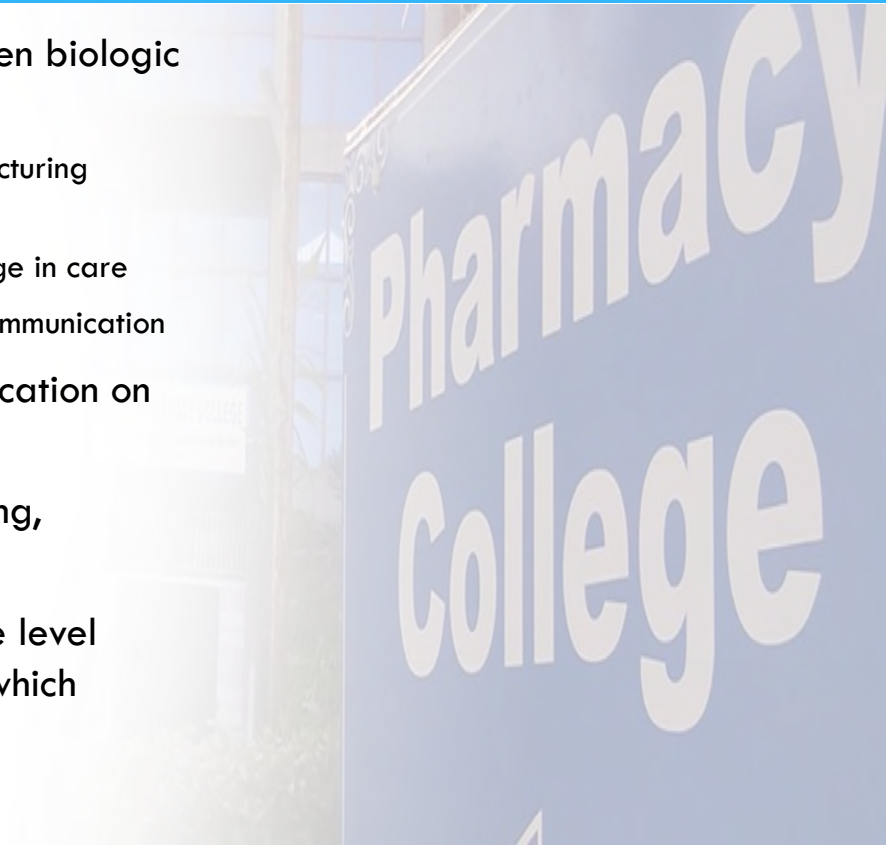
- Prescriber comfort?
- Availability concerns
- PBM decisions
  - Do they force the biosimilar?
  - Are there competing factors influencing access

Impact on Patient Communication

"So when is a generic going to be available for my…?"
&
"Will my PBM pay for it?"

Considerations in Enhancing Biosimilar Education

- Understanding the fundamental differences between biologic and chemical medicines:
  - Complexity of proteins potential to lead to minor manufacturing differences/molecular modifications
  - Clinical considerations- Pharmacists need to further engage in care
  - Need to describe the importance of two-way provider communication
- Provide a balanced, unbiased scientific based education on biosimilars
- Keeping track of FDA policies (e.g., labeling, naming, indication extrapolation, interchangeability, etc.)
- Understanding development of regulations at state level (e.g.,) related to substitution and record-keeping, which differ from state to state



Enhanced Biosimilar Education (cont.)

- Need to focus on providing fact driven data
- Help to eliminate confusion about current policies
- Encourage better pharmacist engagement in specialty drug utilization
- Engage in discussions about misinformation that is being spread
- Ensure appropriate medicinal chemistry, pharmacologic, and therapeutic understanding of biologic agents
- Incorporate coverage/formulary/utilization management strategies likely to be put in place by PBMs around biologics/biosimilars

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September 30, 2018

THANK YOU FOR YOUR ATTENTION

PHARMACISTS & BIOSIMILARS

The Impact of Naming Conventions and Notification on Biosimilar Substitution