AMCP Webinar Series

Biosimilars in the United States
Ready, Set, Launch

29 April 2015

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Reginia Benjamin, JD
Director, Legislative Affairs, AMCP

Elizabeth Jex, JD
Attorney Advisor, Federal Trade Commission

Sara Fernandez-Lopez, PhD, MBA
Director, Reimbursement Strategy, Xcenda

Denise Kazaz, BA
Director, Scientific Client Strategies, Xcenda

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Presentation Overview

- Review AMCP activity on biosimilars with a focus on state activity
- Predictions for biosimilar activity from FTC
- Review of survey assessing pharmacists' views on biosimilar naming conventions

AMCP Biosimilars Position

- **Pathway** – expedited FDA approval process
- **Naming** – same government-approved name/INN as reference product
- **Interchangeability** – FDA should implement a 2-step process that determines:
  - (1) biosimilarity
  - (2) interchangeability
- **Clinical Trials** – FDA case-by-case determination

AMCP Advocacy

Federal:

- Coalescing with other stakeholders with aligned interests to convince key federal agencies and Congress about importance of common naming
- Providing direct input to FTC, FDA, HHS, and Congress
- Letter to World Health Organization on the need for common naming

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Reginia Benjamin, JD

Director, Legislative Affairs

AMCP

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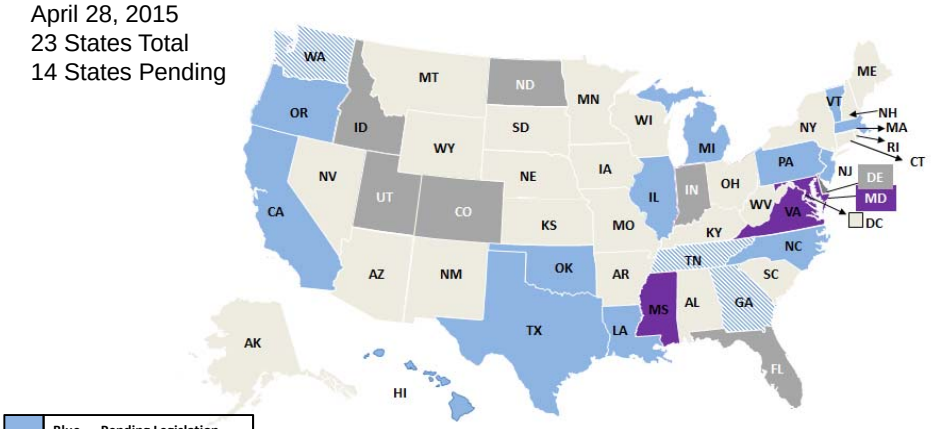
Current State Activity on Biosimilars

Biosimilar Legislation
April 28, 2015
23 States Total
14 States Pending



Blue – Pending Legislation
Purple – Failed in 2015
Blue Lines – Pending Governor Action
Gray – Enacted Since 2013
Beige – No Activity

Overview of Laws & Legislation

2013
Notification, labeling, record keeping requirements

Original legislation basically required notification by pharmacist to prescriber/patient within specified time period (facsimile, telephone, in writing) and required additional labeling and record keeping.

2014
EMR notification requirement added

2015
PBM record system added

Entry into a PBM system accessible to prescriber and entry into other electronic systems deemed notification by pharmacist; however if pharmacist or prescriber do not have access to electronic methods, then facsimile, telephone or writing required.

Issues with State Actions on Biosimilars

- 2013 and 2014 legislation was premature – especially 2013 -- there were no biosimilar applications
- 2015 legislation still premature – No FDA decision on product naming and no guidance on criteria for interchangeability
- Legislation poorly drafted and often confuses biosimilar products with interchangeable products
- Legislation ignores federal law that clearly states the pharmacist can substitute an interchangeable without intervention of the prescriber
- Legislation refers to Orange Book rather than Purple Book
- No requirement for prescribers to maintain records

Elizabeth A. Jex, JD

Attorney Advisor

Office of Policy Planning

Federal Trade Commission

AMCP Academy of Managed Care Pharmacy®

Disclaimer

- The views I express are mine alone, and do not necessarily represent the views of the Federal Trade Commission or any individual Commissioner
- These views are also not necessarily those of AMCP

Background

FTC attorney in biopharmaceutical mergers (1990-2008) staff/author of 2008 FOB workshop and 2009 Report (BPCIA), 2014 FOB workshop on naming and state laws.

Overview

- Importance of Competition for Biologics
- Recent and expected future developments
- Overview of last year's workshop:

  Substitution laws and Naming Conventions
- My predictions on the Biosimilar market

Biologics Price Competition and Innovations Act

- Passed in 2009, incorporated into the ACA in March 2010
- Sought similar balance as Hatch-Waxman Act between innovation/ROI and competition/access
- BPCIA established:
  - 12.5 years data exclusivity for biologics

    FTC's economic analysis concludes that there is no economic justification for this 12 year period of exclusivity, even considering R&D costs, including failures

Biologics Price Competition and Innovations Act

- Two abbreviated pathways for low priced biologic competition
  - Biosimilars –comparable to B-rated generics
  - Interchangeable biologics – comparable to A-rated generics
    - –Automatic substitution OK unless DAW
- Patent resolution mechanism

  Mechanism seems obscure, poorly considered and risks patent holdup – not an efficient patent resolution method

Benefits of Competition in Biologics

Patent and Data exclusivity expiry triggers competition

Spur Innovation

- Technological improvements, such as reduced side effects, extend half life of proteins, humanized Mabs, pegylated, fusion proteins and Mabs
- Biosimilar improvements: processes updated and improved, less expensive and time-consuming development

Spurs Price Competition

- Reduces per unit/per therapy prices
- Increases access – e.g. 30% increase in EU units for filgrastim at same time as per unit price decreased with biosimilar entry (Sandoz presentation)

Whether biosimilars are financially viable and will maximize competition in a comparable manner to the way in which generic drugs revolutionized drug competition in the US remains to be seen

US spending Increasing for Biologics (2013)

- Biologics: Per patient/Per year $10,000 to $250,000
- Biologics account for ~25% of the $320 Bn in US spent on pharmaceuticals annually
- Annual growth 15-20%
- New, more expensive biologics and drugs (Specialty) are putting unprecedented pressure on health care spending;
- Impact on federal, private, and state spending is significant e.g., Hep C

Older Adults Are More Likely to Be at Risk for High Cost-Sharing

- Older adults use more prescription drugs than any other segment of the population
  - 36% of seniors are on 5 prescription drugs or more
- Biologics are often used to treat conditions that are more commonly found in older adults (e.g., multiple sclerosis, cancer, rheumatoid arthritis)
- Eight of the ten highest-expenditure Medicare Part B drugs in 2010 were biologics[11]

Drug Name	Indication	Spending
Epogen, Procrit	Anemia (ESRD)	$2.0B
Rituxan	Cancer, rheumatoid arthritis	$1.3B
Lucentis	Wet AMD	$1.2B
Avastin	Cancer, wet AMD	$1.1B
Remicade	Autoimmune disorders	$0.9B
Neulasta	Infection prevention	$0.9B
Aranesp	Anemia	$0.5B
Epogen/Procrit	Anemia (non-ESRD)	$0.4B

- Part B beneficiaries are responsible for 20% of their prescription drug costs without any cap

Source: AARP

FTC Perspective: Patient Access Is About Patient Health

Harm to patients does not just run in one direction

- Patients will be harmed if they cannot afford to pay for treatment
- Studies show patients' compliance with their treatment regimen falls off as patient cost-sharing for that treatment rises
- Increased pre-auth and tiered access to reduce access to Hep C drugs because of their costs of $84,000 pp/pt

FDA Commissioner Hamburg

"Biosimilars will provide access to important therapies for patients who need them," said FDA Commissioner Margaret A. Hamburg, M.D. "Patients and the health care community can be confident that biosimilar products approved by the FDA meet the agency's rigorous safety, efficacy and quality standards."

http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm436648.htm.

Status of FOBs in 2015

First 351 (k) Biosimilar approved in the United States

- Novartis (Sandoz) Zarxio (filgrastim-sndz).
- Based on analytic tests and one small confirmatory clinical trial in 260 breast cancer patients the product was approved (14-0) for all five indications extrapolated from the current reference Amgen's Neupogen (filgrastim).
- Amgen's Neupogen has U.S. sales of $1.9 billion, approved 1991 (24 yrs exclusivity)

Labeling: Name, Indications, etc.

- The placeholder nonproprietary name for Zarxio is "filgrastim-sndz."
- Label matches that of the reference brand like generic drug labels

  http://www.accessdata.fda.gov/drugsatfda_docs/label/2015/125553lbl.pdf
- Indications based on extrapolation
- Evidence presented at 1/7/15 ODAC meeting that in 7.5 million patients days in Europe safe substitution with no adverse events from immunogenicity.
- Biosimilar approval only, but raises the question about future upgrade to interchangeable, and USAN/INN naming changes

FDA Press Release for Zarxio

"The BPCI Act created an abbreviated licensure pathway for biological products shown to be "biosimilar" to or "interchangeable" with an FDA-licensed biological product, called the "reference product." This abbreviated licensure pathway under section 351(k) of the Public Health Service Act permits reliance on certain existing scientific knowledge about the safety and effectiveness of the reference product, and enables a biosimilar biological product to be licensed based on less than a full complement of product-specific preclinical and clinical data.

A biosimilar product can only be approved by the FDA if it has the same mechanism(s) of action, route(s) of administration, dosage form(s) and strength(s) as the reference product, and only for the indication(s) and condition(s) of use that have been approved for the reference product. The facilities where biosimilars are manufactured must also meet the FDA's standards."

FTC Staff estimates for Biosimilar Development in the U.S.

- Sandoz Zarxio approved March 2015, once the patent litigation is resolved in the Fed Cir. marketing may begin in May 2015
- Celltrion's biosimilar to Remicade 3/17/15 AdComm postponed (Hospira partner is subject to acquisition by Pfizer) – patent litigation and many other variables.
- Apotex biosimilar to Neulasta BDUFA date: ~Mid-August 2015
- Hospira's biosimilar to Epogen BDUFA date: ~October 2015
- Apotex' biosimilar to Neupogen ~October 2015

Purpose of 2014 FTC Workshop

Examine Potential Regulatory Barriers

- How new proposals for state laws may help or hinder competition from biosimilars
- How new proposals for naming conventions may help or hinder competition from biosimilars

Proper answers require balancing appropriate concerns about patient safety with expanded patient access and reduced spending that can be achieved with competition

The Role of Pharmacists Under State Laws

What is the role of pharmacists controlling or reducing escalating medical costs and stagnant medical quality?

- Historically had a critically important role to play in generic drug competition.
- States generally allow pharmacists automatically to substitute generic for a branded drug, unless a doctor has indicated otherwise, DAW.
- These laws typically do not permit substitution of even an interchangeable biologic, because they don't apply to biologics

Proposed Naming Conventions for Biosimilars

Convention for Generics:
Non-proprietary Name (USAN/INN) SAME for generic and branded drug

Proposed Conventions for Biosimilars:

Different Names
- Supported by brand name pharma and biotech companies

Same Names
- Supported by most participants: AARP, CVS, Express Scripts, Aetna, America's Health Insurance Plans, the AMA, American Pharmacists' Association, Academy of Managed Care Pharmacy, National Association of Chain Drug Stores, Hospira, Novartis (Sandoz), and Professor Kesselheim (Harvard Medical School/Brigham and Women's Hospital and FTC

Competitive Effects of Biosimilars Naming

- Conference presentations from actual market experiences in the many countries that have biosimilars approved suggest that different non-proprietary names can reduce biosimilars' market penetration and consumer access
- These are not without controversy; correlation does not equal causation
- But they are consistent with economic theory

Competitive Effects: EPO Markets

Europe:
Epoetin biosimilars with different INN (epoetin zeta) trails the penetration of biosimilars with the same INN as the brand (e.g., Sandoz's Binocrit epoetin-alpha) because of legal challenges and other impediments associated with the different INN

Australia:
Epoetin products all have different (local) non-proprietary names, and biosimilar epoetin accounts for **only 2%** of the epoetin dispensed

Teva and Hospira filgrastim biosimilars (same INN as reference Amgen product) account for 24% of the filgrastam dispensed.

Naming: Necessary for Pharmacovigilance?

Better Pharmacovigilance Is Available

- NDC Codes Used by Many Pharmacies for Each Patient
- Even Hospitals Track Pharmaceutical Inventory by NDC Code
- Surescripts Is Available to Any Pharmacy or Physician

The Medical Community Perspective

American Medical Association

- Any change in current nomenclature rules or standards should be informed by a better, and more complete, understanding of how such changes, including a unique identifier for biologic INNs, would impact prescriber attitudes and patient access, and affect postmarketing surveillance.
- Actions that solely enhance product identification during surveillance activities but act as barriers to clinical uptake are counterproductive."

Pharmacists

- Warned of confusion and potential for medication errors. Some expressed concern that patient safety could be compromised if FDA followed through with reported plans to used prefixes. E.g. ado-trastuzumab and trastuzumab
- Use of distinct non-proprietary names could undermine product safety data collection
- Use of common INN only commonality among pharmaceutical names

What if the biosimilars market never develops?

- The costs associated with biologics are not sustainable for patients or payers
- Many patients will be unable to afford biologics if competition does not provide some level of price relief
- Medical advances are meaningless if no one can afford to use them

Conclusion: Predictions

- Biosimilars entry likely in markets with > $500M annual sales
- 2-3 entrants per reference biologic product;
- If products do not have same name, Biosimilars will have less market penetration and greater entry costs.
- 10-40% price discounts likely for biosimilars; 50% or greater for interchangeables.
- Market share constrained by different USANs (suffixes), entry costs increased for marketing
- Reference brand likely to retain 70-90% market share 1-2 years after launch of first biosimilar, which demonstrates the reason the 12 year period of exclusivity is economically unjustified
- NRx dominated markets will have greater penetration by lowered price Biosimilars than TRx dominated markets. Markets with predictive assays of efficacy also have greater market penetration.

Thank You

FTC.gov webpage for Biosimilars

http://www.ftc.gov/news-events/events-calendar/2014/02/follow-biologics-workshop-impact-recent-legislative-regulatory

Staff:

Ejex@ftc.gov
(202)326-3273

Sdesanti@ftc.gov
(202)326-2210

Review of Pharmacists' Views on Biosimilar Naming Conventions

Sara Fernandez-Lopez, PhD, MBA
Director, Reimbursement Strategy, Xcenda

Denise Kazaz, BA
Director, Scientific Client Strategies, Xcenda

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Overview and Objectives

- As the date for introduction of biosimilars in the United States approaches, questions remain regarding the naming, coding and approval process for these agents
- Xcenda, in collaboration with AMCP, American Pharmacists Association, (APhA), and the American Society of Heath System Pharmacists (ASHP) designed and fielded a 15 minute survey to pharmacists to gain insight into the impact of identical or different non-proprietary names on pharmacists' confidence in substituting interchangeable biologics
- The survey consisted of two main sections: 1) current processes for reporting biologics and 2) familiarity and preferences regarding biosimilars naming options
- A combined total of 93 respondents participated in the survey

Topline Summary

Current practices for sharing information

Pharmacists reported sharing information mainly with payers and PBMs (78.5%), and prescribers (66.7%). The methods used to share information included interoperable health information technology (HIT, 51.6%), e-prescribing software (46.2%), fax or telephone (35.5%), paper copy (31.2%) or email (25.8%)

Methods used to record dispensed products

Pharmacists selected scanning a barcode that links to and populates a patient health record (24.7%), typing the information into an electronic patient record (23.4%), and selecting the product from a drop-down menu (23.4%)

Familiarity with biosimilars

66.2% of respondents identified a level 4 or 5 of familiarity with biosimilars. The percentage of respondents indicating the same level of familiarity with interchangeable biosimilars fell to 50.6%. 72.7% of respondents indicated a level 4 or 5 of awareness on whether other biosimilars were being sold in other countries

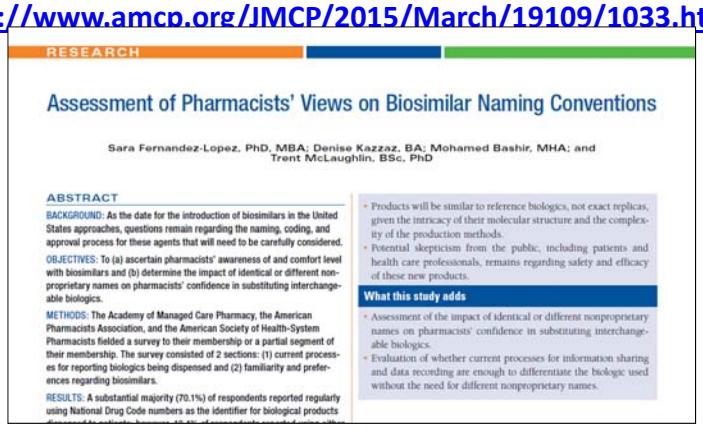
Confidence in substituting

Pharmacists felt most comfortable with biosimilar substitution when under a scenario where both the reference product and biosimilar shared the same non-proprietary name, with 74.6% being confident or very confident. Under the scenario of different non-proprietary names, 25.3% indicated a level 4 or 5 of confidence. Under a scenario in which reference products and biosimilars would not share a non-proprietary name because of a prefix or suffix, 37.3% indicated a level 4 or 5 of confidence.

Detailed Findings Available at JMCP

Journal of Managed Care & Specialty Pharmacy *JMCP* March 2015 Vol. 21, No. 3, 188-195

http://www.amcp.org/JMCP/2015/March/19109/1033.html



RESEARCH

Assessment of Pharmacists' Views on Biosimilar Naming Conventions

Sara Fernandez-Lopez, PhD, MBA; Denise Kazzaz, BA; Mohamed Bashir, MHA; and Trent McLaughlin, BSc, PhD

ABSTRACT

BACKGROUND: As the date for the introduction of biosimilars in the United States approaches, questions remain regarding the naming, coding, and approval process for these agents that will need to be carefully considered.

OBJECTIVES: To (a) ascertain pharmacists' awareness of and comfort level with biosimilars and (b) determine the impact of identical or different non-proprietary names on pharmacists' confidence in substituting interchangeable biologics.

METHODS: The Academy of Managed Care Pharmacy, the American Pharmacists Association, and the American Society of Health-System Pharmacists fielded a survey to their membership or a partial segment of their membership. The survey consisted of 2 sections: (1) current processes for reporting biologics being dispensed and (2) familiarity and preferences regarding biosimilars.

RESULTS: A substantial majority (70.1%) of respondents reported regularly using National Drug Code numbers as the identifier for biological products

- Products will be similar to reference biologics, not exact replicas, given the intricacy of their molecular structure and the complexity of the production methods.
- Potential skepticism from the public, including patients and health care professionals, remains regarding safety and efficacy of these new products.

What this study adds

- Assessment of the impact of identical or different nonproprietary names on pharmacists' confidence in substituting interchangeable biologics.
- Evaluation of whether current processes for information sharing and data recording are enough to differentiate the biologic used without the need for different nonproprietary names.

Detailed Survey Findings

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Survey Participant Classifications

Type of Pharmacy or Organization	Percent (%)	Classification
Managed Care	45	Managed Care/PBM/Consultant
Hospital	14	Dispensing organization
Manufacturer	13	Manufacturer
Specialty	3	Dispensing organization
Clinic	1	Dispensing organization
Independent	1	Dispensing organization
Pharmacy Small Chain	1	Dispensing organization
Pharmacy Large Chain	1	Dispensing organization
Other: Retail and Hospital (1), VA (1), Federal Facility (1), IDN (1), ACO (1), LTC (1), Home Infusion (1)	8	Dispensing organization
Other: Consultant/vendor (9), PBM (2)	12	Managed Care/PBM/Consultant
Other: Pharmaceuticals	1	Manufacturer

ACO = accountable care organization; IDN = integrated delivery network; LTC = long term care; PBM = pharmacy benefit manager; VA = Veterans Administration

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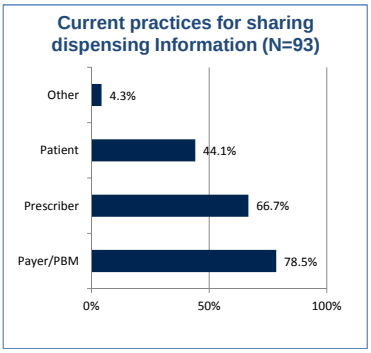
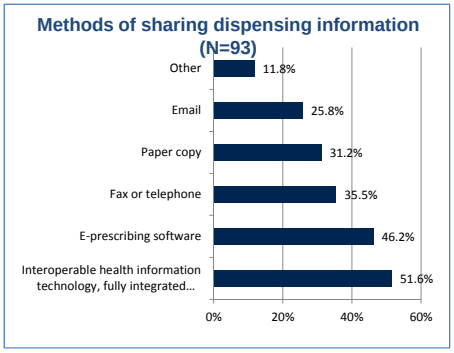
Dispensing Information Mostly Shared with Payers/PBMs

Majority of respondents (78%) reported sharing dispensing information to Payers/PBMs.
A Majority of respondents (78%) reported sharing dispensing information to Payers/PBMs.
A variety of communication methods are used to disseminate this information such as interoperable health technology (52%), e-prescribing software (46%) and fax/telephone (36%) variety of communication methods are used to disseminate this information such as interoperable health technology (52%), e-prescribing software (46%) and fax/telephone (36%)

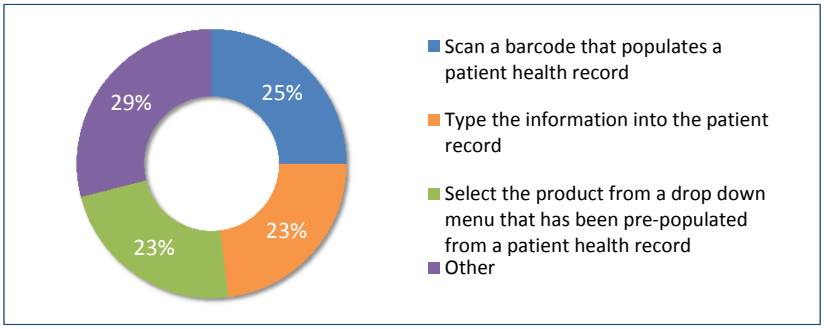




With whom is the general dispensing information regularly shared? (Mark all that apply.) (N=93)
How is the dispensing information shared? (Mark all that apply.) (N=93)

Variety of Methods Used to Record Dispensing Biologics

A variety of methods are used fairly equally to record dispensed biologics such as scanning a barcode that can populate a patient's record (25%), typing the information in the electronic medical record (23%), and selecting a drop-down menu from pre-populated information into the patient record (23%)



How do you typically record which biologic product was dispensed to a patient? (N=77)

NDC Reported Most of the Time to Identify Biologics

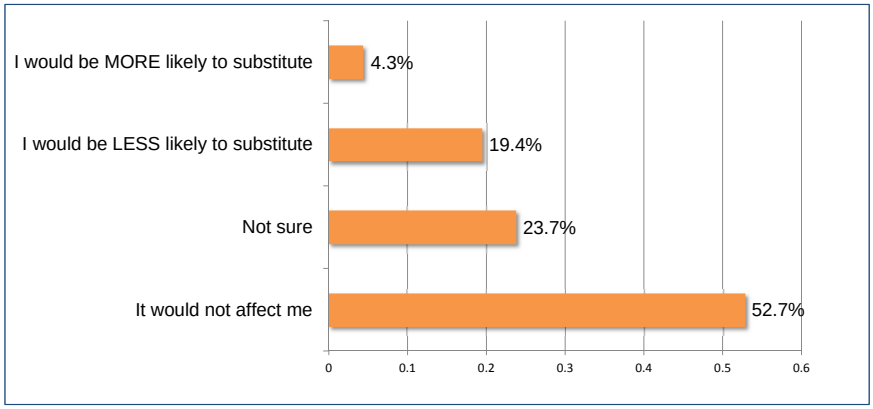
NDC code is reported 70% of the times, but 10% of respondents use HCPCS code or non-proprietary name only to identify dispensed biologics

	NDC recorded	NDC not recorded		Not dispensing
		Non-proprietary name or HCPCS code with either manufacturer or brand name	Non-proprietary name or HCPCS code with no manufacturer or brand name	
Type of Respondent	% (n)	% (n)	% (n)	% (n)
All respondents (N=77)	70.1 (54)	6.5 (5)	10.4 (8)	13.0 (10)
Dispensing organizations (N=25)	72.0 (18)	16.0 (4)	5.5 (3)	0
Managed Care/ PBM/ Consultant (N=42)	69.0 (29)	2.4 (1)	9.5 (4)	19.0 (8)
Manufacturers (N=10)	70.0 (7)	0	10.0 (1)	20.0 (2)

What information is typically recorded when a biologic product is dispensed to a patient? (Mark all that apply.) (N=77)

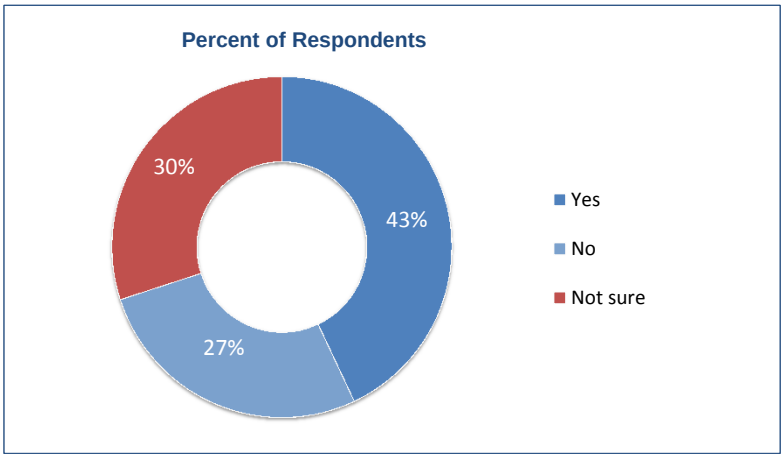
Impact of Notification Requirements

Most pharmacists do not perceive that notification requirements on dispensing interchangeable biosimilars will affect their substitution practices



Some states may require post-dispensing notification / communication to the prescriber when an interchangeable biosimilar would be substituted for the respective reference biologic product. Would such a notification requirement affect your willingness to dispense an interchangeable biosimilar? (N=93)

Awareness of Regulations



Are there any U.S. state or federal regulations that you are aware of related to dispensing biosimilars (regardless of interchangeability considerations)? (N=77)

Familiarity with Biosimilars

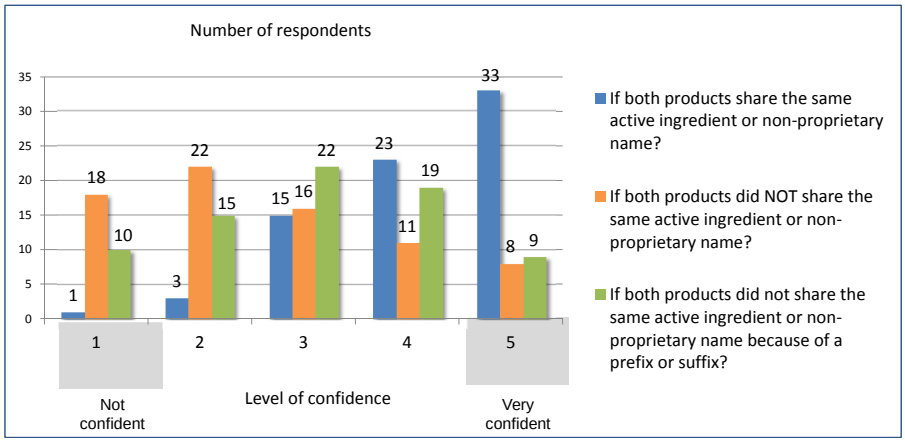
Majority of respondents across all stakeholder types report a high level of familiarity with biosimilars in general and in other countries; familiarity with interchangeable biosimilars is not as high indicating a need for education in this area

Respondent Type	Familiarity with Biosimilars (level 4 or 5)	Familiarity with Interchangeable Biosimilars (level 4 or 5)	Awareness of Biosimilars being sold outside the US(level 4 or 5)
	% (n)	% (n)	% (n)
All respondents (N=77)	66 (51)	51 (39)	73 (56)
Dispensing organizations (N=25)	68 (17)	60 (15)	76 (19)
Managed Care/PBM/ Consultant (N=42)	69 (29)	52 (22)	76 (32)
Manufacturers (N=10)	50 (5)	20 (2)	50 (5)

Please indicate your level of familiarity on a scale of 1-5, with 1 being the least familiar and 5 being the most familiar: How familiar are you with biosimilars? (N=77)
Please indicate your level of familiarity on a scale of 1-5, with 1 being the least familiar and 5 being the most familiar: How familiar are you with interchangeable biosimilars? (N=77)
Please indicate your level of familiarity on a scale of 1-5, with 1 being the least familiar and 5 being the most familiar: Are you aware whether biosimilars are already being sold in other countries; i.e., European countries, Australia, or Japan? (N=77)

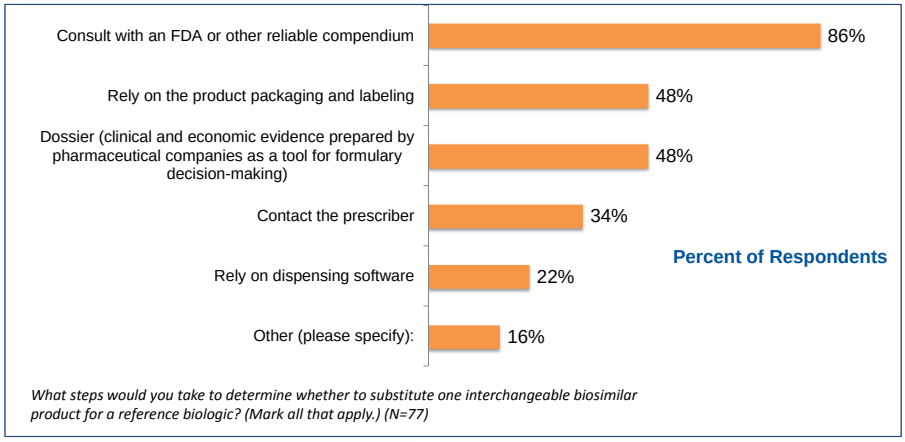
Level of Confidence in Substitutions

Confidence in substituting an interchangeable biosimilar is highest when both products share the same active ingredient or non-proprietary name



FDA Most Frequent Source for Consultation on Interchangeability

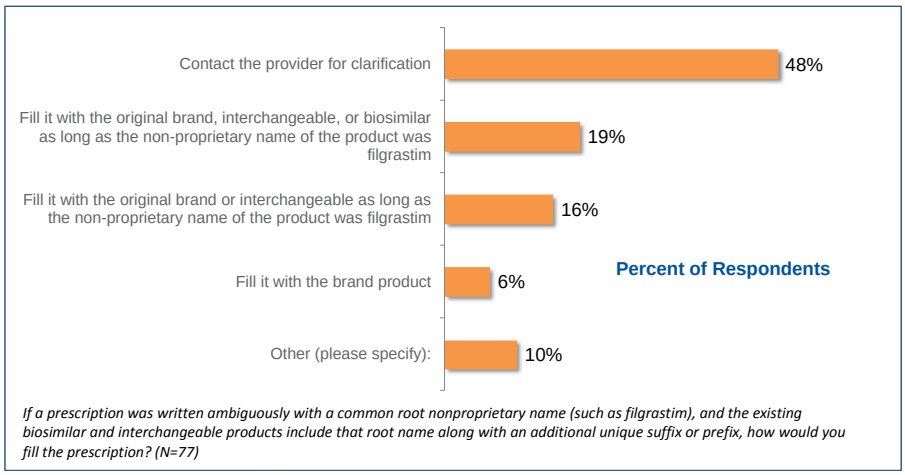
Majority of pharmacists (86%) would consult with the FDA or review compendia to determine whether to substitute an interchangeable biosimilar for a reference biologic



What steps would you take to determine whether to substitute one interchangeable biosimilar product for a reference biologic? (Mark all that apply.) (N=77)

Clarification from Prescribers for Ambiguous Prescriptions

Pharmacists would seek clarification from prescribers if a prescription was written ambiguously



If a prescription was written ambiguously with a common root nonproprietary name (such as filgrastim), and the existing biosimilar and interchangeable products include that root name along with an additional unique suffix or prefix, how would you fill the prescription? (N=77)

Considerations for Naming of Biosimilars

While 66% of respondents indicated a high level of familiarity with biosimilars, only 51% of pharmacists reported the same level of familiarity with interchangeable biosimilars. The naming convention selected for biosimilars will play a pivotal role in the substitution practices of interchangeable biosimilars, given that most pharmacists have the highest level of confidence of substitution only when the interchangeable biosimilar and reference products share the same active ingredient or non-proprietary name

Based on the lower levels of familiarity with interchangeable biologics and how naming of biosimilars may influence their behavior, this study indicates that pharmacists will require substantial education on biosimilars and interchangeable biosimilars prior to the launch of the first agent in the United States

This education should focus on: 1) instances where substitution is allowed according to FDA approval (as a biosimilar or interchangeable biologic); 2) appropriate recording of biologic dispensed for pharmacovigilance efforts; and 3) notification requirements driven by specific state laws

Policy Issue Groups

Sign up for late-breaking info. and the opportunity to be in the conversation: www.amcp.org/list

- Specialty/Biosimilars
- Health Care Reform Implementation
- Medicare Part D
- HIT
- Quality initiatives

Staff Contacts

Lauren Fuller, J.D. VP, Government Affairs 703-684-2625 lfuller@amcp.org	**Mary Jo Carden, RPh, J.D.** Sr. Director of Regulatory Affairs 703-684-2603 mcarden@amcp.org
Reginia Benjamin, J.D. Director of Legislative Affairs 703-684-2620 rbenjamin@amcp.org	**Dana Whitley, IOM** Grassroots Advocacy Coordinator 703-684-2636 dwhitley@amcp.org

Thank you.

Questions?

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