Biosimilars – A pharmacist's view

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Background

- Responsible use of medicines is complicated
  - Efficacy/effectiveness gap
  - Safety/preventable adverse drug events
  - Innovation/affordability conflicts
- Medication-use is a team effort
  - The greatest value from an investment in pharmacotherapy results from collaboration among health care professionals and patients
- Accountability
  - Health care professionals -> their patient

    Regulated by the States
  - Pharma -> innovations for patients
    - Regulated by the Federal Government
  - Insurance companies/PBMs -> Saving money
    - Regulated???

ASBM Platform: Physician/Pharmacist Collaboration is Key

- Physicians have the authority to specify “do not substitute” for biological products and that specification overrides any policy – e.g. by payers or state law – that would have substitution be the standard or default practice.
- Physicians and pharmacists should work collaboratively to ensure that the treating physician is aware of the exact biologic – by manufacturer – given to a patient in order to facilitate patient care and accurate attribution of any adverse events that may occurs.

Common Ground Between Physicians and Pharmacists

- Both healthcare providers, who share concern for our patients
- Both experienced with and knowledgable about medications
- Both incentivized to perform good pharamacovigilance
- Both want a good track-and-trace system for adverse events
- Both support good record keeping.

Why Disagreement Between Physicians and Pharmacists on Substitution of Biosimilars?

- Pharmacist often seen as playing a secondary role
- Notification requirements in some biosimilar substitution legislation have been viewed by some as too burdensome:
  - How many days will pharmacist have to notify physician?
  - What information must be recorded?
  - For how long must these records be retained?
- Health system pharmacists and retain chain pharmacists may view regulations differently.

ASBM Platform: Timing of Notification

- The timing of the notification process must not impose an undue burden on the pharmacist
- Notification need not be in advance of a substitution being made

- Must be timely enough to facilitate accurate record keeping and attribution of adverse events by the physician.

Medication-use system

- Prescribing
- Preparation
- Dispensing
- Administration
- Monitoring

Strategies for improving prescribing

- Collaborative practice that includes a pharmacist
- The formulary system
- Therapeutic interchange (NOT substitution)
- Evidence-based clinical practice guidelines
- Clinical decision support systems
- Metrics and performance management
  - Effectiveness
  - Safety
  - Cost

Added value of pharmacists

- Prudent purchasing
- Inventory control
- Managing waste
- Managing utilization
- “Balanced scorecard” (pharmacoeconomics)
- Proactive awareness