CE PRN

PHARMACY CONTINUING EDUCATION FROM WF PROFESSIONAL ASSOCIATES

"Generics, Biosimilars & Product Selection Laws"

March 2015

For hundreds of years product selection has been a significant consideration. First with generics, and now with biosimilars. Our goal in this lesson is to update the concepts of generics, biosimilars & product selecton laws.

Pharmacists will be able to:

1. Discuss FDA standards for equivalence of generic products.
2. List factors regulating drug product selection by pharmacists under state pharmacy practice acts.
3. Discuss the implications of the Biologics Price Competition & Innovation Act.
4. Describe how state legislatures are establishing the authority of pharmacists to engage in the substitution of biosimilars.

Technicians will be able to:

1. Define "generic equivalence."
2. Describe drug product selection.
3. State the main portions of the Biologics Price Competition & Innovation Act.
4. Define "biosimilars."

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Introduction

From colonial times through the mid-20th century, product selection was a key pharmacist function. Throughout those many decades, patients had the choice either to seek medical assistance from a physician, and have a prescription issued based on the physician's diagnosis, or patients could go directly to a pharmacy to acquire virtually any non-narcotic medication. Patients often relied on pharmacist judgment to guide them in the selection of an appropriate drug product.

In 1952, the Durham-Humphrey Amendment to the Food, Drug and Cosmetic Act changed that approach to control over medication acquisition. Through that amendment, a prescription requirement was formalized into law for medications that the FDA determined could not be adequately labeled for safe use without medical supervision. This federal legislation worked in parallel with state anti-substitution laws that were adopted in the late 1940s and early 1950s to prevent pharmacist substitution of a different drug than had been prescribed (the laws were not originally intended to prevent dispensing of a different product containing the same drug).

By the mid-1950s, federal and state laws coincided to require that a pharmacist dispense prescription drugs only pursuant to a physician's prescription, and that the exact product specified by the physician's prescription be dispensed, if an exact product was specified in the prescription.

Within twenty years following this legal development, consumers and legislators recognized the costs savings to be gained by allowing, or even requiring, generic substitution through product selection by a pharmacist. The traditional pharmacist authority for product selection was restored to pharmacists by law, with some limits. Standards for generic equivalence were adopted by the FDA, and guidelines for pharmacist product selection were incorporated into state pharmacy practice acts.

Generic substitution as authorized by state laws applies to small, synthetic molecules. While not completely without controversy, generic substitution has become a central and common activity within pharmacy practice. The same cannot be said for biosimilars, which are large and relatively complex molecules. The same economic forces that led to the legalization of generic substitution are now pushing regulators to find ways to legalize the substitution of biosimilars. Many of the same concerns that were voiced in opposition to generic substitution are being expressed with regard to biosimilars. The regulatory challenge with biosimilars is in some ways similar to that of generic products, but the solutions will necessarily be somewhat different.

FDA Generic Equivalence Standards

To be considered as a generic equivalent product by the FDA, a product must be of the same molecular entity, the same dosage form, and the same strength as the reference listed drug. The reference listed drug has usually been approved through a New Drug Application (NDA) that relies on results from years of clinical trials that have shown the drug to be safe and effective under the conditions listed in the drug's proposed labeling. It is an expensive and lengthy process, and it results in a term of market exclusivity through patent protection. Once the patent for the drug has expired, competitors have the opportunity to market the same molecular entity through approval of an Abbreviated New Drug Application (ANDA). The ANDA rests on an assumption that if the reference listed drug has been shown to be safe

and effective, and if the generic product is equivalent to the reference listed drug, then the generic product will also be considered safe and effective. While some people may make the point that generic products are approved through bioequivalence studies and not through clinical trials, the counterpoint is that clinical trials are not necessary for generic products that are equivalent to drugs approved through an NDA.

The FDA does not require absolute equivalence between generic products and the reference listed drug. This would be an unreachable standard. The FDA requires that bioequivalence studies show no significant difference between the generic product and the reference listed drug. The agency provides a summary of available information on therapeutic equivalence in a publication called the "*Orange Book.*" This reference is so-named because when it was available as a printed book, the cover was the color orange. Now the *Orange Book* is accessed online, and it is updated at least monthly. Within the online Orange Book there are drug listings (same molecular entity, same dosage form, same strength), and the FDA has assigned a two-letter code to each multi-source drug within the listing. When the two-letter code begins with the letter "A," the products to which the code applies are considered therapeutically equivalent. When the two-letter code begins with the letter "B," the products to which the code applies are not considered therapeutically equivalent.

The specific approach taken with generic products would not be possible with biosimilars, because biosimilars as large and complex molecules, are not the same molecular entity. On the other hand, the general policy of requiring therapeutic equivalence, but not exact sameness, can be applied to biosimilars. While the general FDA approach to biosimilar equivalence may be very much like that of generic equivalence, the details will be different.

Drug Product Selection By Pharmacists

The FDA does not regulate the practice of pharmacy. While FDA therapeutic equivalence evaluations are important and welcome information for pharmacists, they do not authorize generic substitution. It is state pharmacy practice laws, and the regulations of state boards of pharmacy, that establish rules for substitution of a generic product when a branded product has been prescribed. These rules do not apply when a prescription is written using a drug's generic name, because without a specific prescribed product designated in a prescription, there can be no substitution. Pharmacists decide which product to dispense when a prescription has been issued using a generic drug name, but this decision is not covered by state generic substitution laws, which apply only if one product is substituted when another product has been specified by trade name in a prescription.

States vary in their approach to the regulation of generic substitution by pharmacists. Some states mandate that substitution must be done when a prescription permits substitution, while other states merely allow pharmacists to substitute a generic product if they wish to do so. Most states have a formal mechanism through which prescribers can forbid substitution of a prescribed drug. This mechanism usually requires that the prescriber write a notation such as "brand necessary" or "no substitution" on the prescription, or that the prescriber sign a signature line below which is printed language such as "no substitution." A state may choose to restrict generic substitution by using a positive formulary, that lists those products that are available for substitution, or a negative formulary, that lists drugs for which substitution is forbidden. States may also defer to the "Orange Book" as authority for decisions about substitutable products.

States may require notification to the patient of a proposed substitution, and consent of the patient to the substitution. In some states there is a requirement that the full savings from generic substitution be passed on to the patient.

As a model for regulation of biosimilar substitution, state generic substitution laws provide a number of restrictions and limitations that have become relatively easy to manage for substitution of generics. These requirements, modified to reflect the character of biological products, could serve as a general framework for the substitution of biosimilars.

PBM Rules And Generics

Fortunately or unfortunately, depending on one's perspective, the conditions of payment established by prescription benefit management companies (PBMs) have largely superseded state laws for generic substitution. Although technically a patient is always free to personally pay for medication and thus avoid the restrictions established by the patient's PBM, the reality is that most patients have no choice but to have their pharmacists adhere to PBM rules or go without the medication.

A PBM may establish a rule that requires a pharmacist to contact a prescriber to obtain permission to substitute a generic when otherwise the law would not allow substitution. This rule may result in a conversation where the pharmacist says to the prescriber something like "I can give your patient a generic under the patient's drug plan, or the patient will go without the drug if you refuse to allow this." A faxed or computerized communication may convey the same message. If the prescriber allows the dispensing of a generic after such a conversation, then the original prescription becomes irrelevant and a new prescription has been issued under the drug's generic name. At that point, state product selection laws are inapplicable because they do not refer to prescriptions written using a drug's generic name.

It is highly likely that PBMs will promote the use of less expensive biosimilar products, if the PBM's pharmacy & therapeutics committees conclude that the alternate products are as safe and effective as the reference products. This may put pharmacists in the familiar position of requesting an alternate prescription from the prescriber, so that the biosimilar product will be covered by the patient's plan.

Generics and Litigation

As familiar and frequent as generic substitution has become within health care and pharmacy, this common practice is not without significant legal controversy. One point of legal controversy relates to the content of labeling that accompanies generic products. The traditional FDA approach has been to view the approved labeling as part of the approved reference product. Under this approach, when a generic manufacturer markets an equivalent product to that of the NDA holder, the labeling that accompanies the generic product must contain exactly the same safety information as the labeling of the innovator product. Several court cases have challenged this traditional view, and the FDA is considering a new rule that would permit generic manufacturers to independently update labeling information in response to the discovery of a new risk.

A second significant body of litigation relates to the practice of forced switching. A forced switch usually occurs when a product approved through a NDA is facing the end of its patent term. In order to extend the patent life of the drug, the manufacturer will obtain approval of

a new dosage form, often an extended release formulation. By discontinuing availability of the product that is soon to lose patent protection, and forcing a switch by patients to the new patented version, the manufacturer can preserve its market exclusivity. The absence in the market of the original version is a barrier to approval of a generic equivalent, because there is no marketed product with which to show equivalence. At least one court has recently ordered a manufacturer to continue availability of the original off-patient product to allow for generic equivalents to be approved. This continues to be a volatile area of litigation and is by no means well settled.

A third major area of generic drug litigation is often referred to as "pay for delay." This litigation stems from a relatively common practice in which the NDA holder enters into a settlement with one or more potential generic manufacturers. The settlement results in delayed marketing of a competitive generic product by the generic manufacturers, in return for a payment made to the generic manufacturers by the NDA holder. The value to the NDA holder is that the delayed entry into the market by the generic manufacturers leads to an extension of market exclusivity. A recent decision by the United States Supreme Court allows the Federal Trade Commission to sue pharmaceutical manufacturers that enter into pay for delay agreements. The importance of these generic drug cases, and others similar to them, is that even years after generic substitution has become a commonplace event in pharmacy, significant legal issues continue to be litigated. It can be expected that litigation will similarly affect the practice of biosimilars substitution for years after it becomes commonplace.

Generic Prices

The purpose of federal regulations that encourage the development of generic drug products, and of state regulations that allow or require substitution of generic products when a brand product has been prescribed, is to save money for patients and third-party payers. Recently, generic inflation has threatened to negate the purpose of federal and state regulatory policy with regard to generics. Reduced competition among generic manufacturers, short-term market exclusivity for some new generic products, rising costs for manufacturing, and the costs of regulatory compliance, have led to dramatic increases in the prices charged for some generic products.

The United States Congress is well aware of the problem with generic inflation. Solutions at a federal level are being considered. State attorneys general are also aware that a problem exists, and they are considering options as well. Senator Herb Kohl of Wisconsin has recently introduced a bill called the "Prescription Drug Cost Reduction Act" that, if passed, would lead to policy shifts to reduce the price of generics and other pharmaceutical products. One important message of this legislation, introduced over 30 years after passage of the law that expanded availability of generic drug products, is that dramatic pharmaceutical price escalation is an ongoing challenge for regulators. Simply allowing the production of generic products, and permitting or requiring substitution of them, does not necessarily guarantee low prices for patients and third-party payers. The same will undoubtedly be true with biosimilars.

The Promise Of Biosimilars

The broad access that patients currently have to generic products does not extend to biosimilars, which are more complicated and more expensive to produce than traditional drugs. The therapeutic equivalence standards used for generic products are limited to

small molecule drugs that are chemically synthesized, so they do not apply to biosimilars. In 2010, to address this challenge as part of the "Affordable Care Act", Congress passed the "Biologics Price Competition and Innovation Act." This legislation creates an abbreviated licensure process for biological products that are demonstrated to be biosimilar to, and interchangeable with, previously approved biological products. The financial significance of this legislation is enormous. Because biologic products are so complex and so costly to develop, the prices charged for them are very high. Projections by various agencies and groups suggest that the advent of biosimilars could save tens of billions of dollars over the coming decade.

Under the new law, "biosimilarity" means that a biological product is highly similar to the already licensed reference biological product, notwithstanding minor differences in clinically inactive components. For there to be biosimilarity, there can be no clinically meaningful differences between the biologic product and the reference product in terms of safety, purity, and potency. The term "interchangeable" means that a biologic product is biosimilar to the reference product and can be expected to produce the same clinical result as the reference product in any given patient. For a biological product that is administered more than once to a patient, the risk of adverse events or reduced efficacy from switching products cannot be greater than the risk of using the same product multiple times. Under the new law, a finding of biosimilarity is intended to provide assurance to pharmacists that an interchangeable product may be substituted for a prescribed reference product.

Implementation of the standards of the new law has been appropriately deliberate. In January, 2015, an advisory panel convened by the FDA recommended that the first biosimilar product be approved by the agency. The practicality of having few biosimilars available for consideration will allow for a deliberate approach to the development of standards for licensing of biosimilars.

FDA Practice For Biosimilars

Following the precedent set for publishing standards of therapeutic equivalence for generic products in the *Orange Book*, the FDA has announced that a list of biosimilar and interchangeable biological products will be published in what they call the "*Purple Book*." Biosimilar and interchangeable products will be listed in the *Purple Book* under the reference product to which biosimilarity and interchangeability has been demonstrated. Pharmacists who are accustomed to using the *Orange Book* will find the *Purple Book* to be in a familiar format, and it will be a user-friendly resource. Although the basic approach of equivalence listings will be similar, there will be differences based on the inherent nature of large biological molecules as opposed to small synthetic molecules.

The specifics for FDA standards are evolving, and the agency has provided guidance on their current thinking for the recognition of biosimilarity and listing in the *Purple Book*. Biosimilars need not contain exactly the same clinically active ingredients as the reference product. However, a sponsor would need to show that there are no clinically meaningful differences. For example, it may be possible for a proposed product formulated without human serum albumin to demonstrate biosimilarity with a reference product that has been formulated with human serum albumin.

Some design differences in the delivery device or container closure system used with a proposed

biosimilar product may be acceptable by the agency. It may be possible, for example, for an applicant to obtain licensure of a proposed biosimilar product in a pre-filled syringe or in an auto-injector device, even if the reference product is licensed in a vial. However, a biosimilar applicant would not be able to obtain approval of a product if the proposal were for a different route of administration, different dosage form, or different condition of use than what has been approved in licensing of the reference product.

A sponsor of a proposed biosimilar product need not request approval for all routes of administration for which a reference product has been licensed. Likewise, a biosimilar need not be licensed for all strengths, delivery devices, or container closure systems for which the reference product has been licensed. And a biosimilar product can be licensed for fewer than all conditions for use for which the reference product is licensed.

FDA standards require that the strength of a proposed biosimilar product be the same as that of the reference product. The agency recognizes that there may be a need to take into account different factors and approaches in determining the strength of biological products. In general, injectable biological products must have the same total content of drug substance and the same concentration of drug substance as the reference product, although for certain complex biological products, a modified approach may be used.

The total content of drug substances generally must be expressed using the same measure as the reference product. If the strength of the reference product is expressed in mg per total volume in a container, for example mg/5 mls, then the proposed biosimilar product generally must describe its strength in mg/5 mls. Sometimes the total content of drug substance is expressed in units of activity (e.g., international units or units per total volume in a container). When this occurs, the units of the proposed biosimilar product must be the same as the reference product.

Many other details have yet to be worked out with biosimilars and their *Purple Book* listings, as was the case with generic products when they were first approved by the agency and incorporated into the *Orange Book*. There is likely to be controversy regarding the equivalence ratings in the *Purple Book*, as there initially was with the ratings in the *Orange Book*. Cost savings for patients and third party payers can also be seen as profit losses by companies that distribute reference products with which biosimilars have been listed as interchangeable. Pharmacists will need to sort through the positions and arguments of those who promote biosimilars and those who question the appropriateness of biosimilars.

State Biosimilar Substitution Laws

Determinations of interchangeability by the FDA will not automatically allow pharmacists to select biosimilars to dispense in place of a prescribed reference drug, even if interchangeability is supported in the *Purple Book*. State laws must be changed to permit the substitution of biosimilar products, just as they were changed to allow substitution of generic products. State laws will vary with regard to biosimilars, just as they vary with regard to generics. The discussion of how to enact state laws for biosimilar substitution has been as deliberate as has the discussion on the federal level of how to develop standards for interchangeability.

Only a handful of states have enacted laws for biosimilar substitution by pharmacists. These states include Delaware, Florida, Indiana, Massachusetts, North Dakota, Oregon, Utah, and Virginia. A dozen or so additional states are considering the enactment of biosimilar

substitution laws. As should be expected, the biosimilar substitution laws follow the general format of generic substitution laws, with variations that reflect the nature of biosimilar products as opposed to generic products.

All of the existing biosimilar laws are permissive as opposed to mandatory, even in states where generic substitution is mandatory. The current laws defer to the FDA for a determination of interchangeability, rather than adopting positive or negative formularies as some states did when they passed their generic substitution law. One key difference with biosimilar substitution laws is that they tend to require specific authority from the prescriber. As opposed to state generic substitution laws, where the default position is usually one of substitutability unless specifically forbidden by the prescriber, biosimilar substitution laws tend to adopt a default position of non-substitutability unless specifically allowed by the prescriber. This position is not universally the case, but it is a core characteristic of many state biosimilar substitution laws.

Notification to the prescriber is a key aspect of state biosimilar substitution laws. Even though a prescription may permit the substitution of a biosimilar, a pharmacist may opt not to engage in substitution, and the law provides a requirement of notification to the prescriber when substitution has actually occurred. The requirement is usually a post-dispensing requirement, mandating that the prescriber be notified within a period of time (perhaps one to three days) after a biosimilar substitution has occurred. Usually an electronic communication through a shared medical record will suffice for the notification requirement.

Other requirements that are included within existing or proposed state biosimilar substitution laws mandate that patients be informed when a biosimilar substitution occurs, that records of a substitution be maintained for at least two years, and that a substitution be done only if the price of the substituted product is less than that of the prescribed product. As was the case with generic substitution laws, it can be anticipated that later states to enact biosimilar substitution laws will incorporate additional requirements that were not considered at all, or were not considered necessary, by the early states.

Conclusion

Pharmacists who practiced during the days when generic substitution was evolving into a common activity will remember the uncertainty of those times and the pressures brought by the need to assure scientific validity as well as cost savings. These same pressures will exist with biosimilar substitution, and pharmacists will face a new challenge to provide patients with safe and effective products at a reasonable price. Many of the lessons learned from generic substitution will influence decisions related to biosimilar substitution. The traditional and familiar pharmacist role of product selection will be guided by concern for patient outcomes and the responsibility for efficient product use.

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Please fill out this section as a means of evaluating this lesson. The information will aid us in improving future efforts. Either circle the appropriate evaluation answer, or rate the item from 1 to 7 (1 is the lowest rating; 7 is the highest).

1. Does the program meet the learning objectives?
   - Discuss FDA standards for equivalence of generics. YES NO
   - List factors regulating drug product selection. YES NO
   - Discuss the Biologics Price Competition & Innovation Act YES NO
   - Describe pharmacist involvement in substitution of biosimilars YES NO

2. Was the program independent & non-commercial YES NO

	Low Relevance						Very Relevant
3. Relevance of topic	1	2	3	4	5	6	7

4. What did you like most about this lesson?_____
5. What did you like least about this lesson?_____

Please Mark the Correct Answer(s)

1. **During what 2 decades were state anti-substitution laws adopted to prevent pharmacist substitution of a different drug than had been prescribed?**
   A. 1920s & early 1930s B. 1940s & early 1950s
   C. 1960s & early 1970s D. 1980s & early 1990s

2. **The *Orange Book* assigned a 2-letter code to products that are considered therapeutically equivalent. What is the first letter of this 2-letter code?**
   A. A B. B
   C. C. D. D.

3. **FDA standards require that the strength of a proposed biosimilar product be the same as that of the reference product.**
   A. True B. False

4. **Assume that a prescription is issued by a prescriber using a generic drug name. No particular product has been specified within the prescription. In this situation, state generic substitution laws do not apply.**
   A. True B. False

5. **To what activity does "pay for delay" apply?**
   A. PBM payments to pharmacists for withholding medications from patients.
   B. Pharmacist salaries that increase with age.
   C. A settlement between an NDA holder & a potential generic manufacturer.
   D. Expansion of Medicaid benefits under the Affordable Care Act.

6. **Under the Biologics Price Competition & Innovation Act, a term is used for a biologic product that is highly similar to an already licensed reference product, notwithstanding minor differences in clinically inactive component. What is that term?**
   A. Generic B. Reference
   C. Equivalent D. Biosimilar

7. **Under the Biologics Price Competition & Innovation Act, a term is used for a biologic product that is biosimilar to the reference product and can be expected to produce the same clinical result as the reference product in any given patient. What is that term?**
   A. Copy B. Substitute
   C. Interchangeable D. Twin

8. **The FDA has announced that it will list biosimilar and interchangeable biological products in a book. What is that book called?**
   A. *Orange Book* B. *Blue Book*
   C. *Purple Book* D. *Red Book*

9. **Through what approval mechanism is a generic product usually approved by the FDA?**
   A. NDA B. ANDA
   C. IRB D. DEA

10. **Notification to the prescriber is a key aspect of state biosimilar substitution laws.**
    A. True B. False

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