Vote NO on Wisconsin S.B. 354

S.B. 354 Unnecessary -- Prescriber Already Has the Primary Authority

- S.B. 354 would require a pharmacist to obtain and document additional consent from the prescriber and patient prior to dispensing an antiepileptic generic drug product that has already been approved for substitution by the FDA.
- **This mandate is unnecessary because the prescriber already has the primary authority, at the point of issuing a prescription order, to indicate whether a generic substitution is permitted.**
- In fact, according to Wisconsin law, a pharmacist may not make a generic substitution if the prescriber indicates on the prescription that he/she wishes for the patient to take the brand medication. The prescriber has the option to specify in writing, or if a prescription is transmitted electronically, by designating in electronic format, the phrase "No substitutions," "N.S.," or words of similar meaning on the prescription.[1]

S.B. 354 Would Create Barriers to Patient Access to Generic Drugs

- The mandates in this bill would have a negative impact on patient care because of the unnecessary and burdensome steps both pharmacists and prescribers would have to take before patients could obtain their medications. This would take time away from both the pharmacist's and the prescriber's ability to serve the needs of their patients.
- A patient may have to unnecessarily wait for hours or even days for additional substitution approval if the mandates of S.B. 354 were enacted. Such delays in the delivery of medications, particularly for patients with strict medication regimes, such as patients with epilepsy, can have harmful and possibly life-threatening results.
- The requirements of S.B. 354 would create major logistical challenges to generic substitution that, in order to avoid delay, could leave pharmacists with no choice but to dispense more expensive brand-name drugs even if the patient prefers the equivalent generic drug product.
- Generic substitution, as permitted by current Wisconsin law, is a well-established practice and any unnecessary mandates would inhibit access to prescription drugs that provide significant cost-savings to consumers, health plans, and employers.

AMA and FDA Support Generic Substitution

- The American Medical Association (AMA) recently restated its policy with regard to generic substitution and looked specifically at the substitution of narrow therapeutic index (NTI) drugs (such as anticonvulsants). After reviewing the scientific evidence, the AMA's Council on Science and Public Health determined that a more stringent generic substitution process for NTI drugs was not necessary. The AMA's House of Delegates concurred with this determination.
- The U.S. Food and Drug Administration (FDA) also recently restated its policy on bioequivalence and the use of generic substitution with drugs listed in the FDA's "Orange Book." Specifically, the FDA stated that:
    - "Additional clinical tests or examinations by the health care provider are not needed when a generic drug product is substituted for the brand-name product.
    - Special precautions are not needed when a formulation and/or manufacturing change occurs for a drug product provided that the change is approved according to applicable laws and regulations by the FDA.
    - As noted in the 'Orange Book,' in the judgment of the FDA, products evaluated as therapeutically equivalent can be expected to have equivalent clinical effect whether the product is a brand-name or generic drug product.
    - It is not necessary for the health care provider to approach any one therapeutic class of drug products differently from any other class, when there has been a determination of therapeutic equivalence by FDA for the drug products under consideration." [2]
- **The FDA's policy applies to all FDA-approved generic drugs, including generic drugs used to treat epilepsy.**

Academy of Managed Care Pharmacy, American Pharmacists Association, Generic Pharmaceutical Association, National Alliance of State Pharmacy Associations, National Association of Chain Drug Stores, Pharmaceutical Care Management Association

[1] Wis. Stat. § 450.13 (2009).
[2] Letter from the U.S. Food and Drug Administration (FDA) to National Association of Chain Drug Stores, (April 16, 2007); *see also* Letter from FDA to Iowa Pharmacy Association, (January 11, 2008).