Coalition of Texas Pharmacy Organizations

Texas Pharmacy Coalition Position on Biological Products and Biosimilars

Pharmacy supports updating state laws to recognize and allow for substitution of interchangeable biosimilars consistent with the federal law and standards under development by FDA. Doing so will improve access to lifesaving medications, and is consistent with the standards established for biosimilars in the Biologics Price Competition and Innovation Act developed to ensure that any product deemed interchangeable by FDA would be suitable for substitution without the prescriber's intervention. **However, pharmacy has serious concerns with proposals that would further enact unwarranted prescriber notification requirements for biologic and biosimilar drugs in particular.** We caution state policymakers against enacting any special notification requirements for these drugs for the following reasons:

- Proponents of special notification requirements for biologic and biosimilar drugs have suggested that prescriber notification of the name and manufacturer of the product dispensed is necessary for patient safety reasons. *That is highly disputable given FDA's approach for evaluation and approval of these products, as well as the current systems used to identify and report adverse drug events.*

- The FDA approval and interchangeability standards for biosimilars will be rigorous. In an article published in the *New England Journal of Medicine*, agency leadership made clear that FDA is cognizant of the complexities inherent to biologic products and that the approval standards will ensure that FDA can perform an overall assessment that a biologic is biosimilar to an approved reference product. Only biosimilar products that meet FDA's standards for interchangeability will be designated as interchangeable.

- FDA has further indicated that the Agency will look to Europe, where biosimilar products have been approved for use and on the market without any safety issues since 2006. Drawing from the experience of the European Medicine Agency, as well as the nearly 30 years of experience that FDA has in approving generic drugs, we are confident that FDA will develop approval and interchangeability standards for biosimilars that will be appropriate to protect patient safety.

- Ostensibly, the proposed special prescriber notification requirements for biologic and biosimilar products are meant to provide prescribers with information to aid in reporting any adverse drug reactions to drug manufacturers, FDA, and other stakeholders when there is a quality problem with a particular product. However, the necessary information is already available to prescribers who, under current practices, can obtain this information from patients' prescription labels or contact pharmacies directly to obtain patients' medication histories when patients experience an adverse drug reaction. In fact, pharmacies maintain robust and extensive dispensing records that can, through the national drug code ("NDC") identify for each prescription dispensed the specific manufacturer, product, and even information about the specific dosage form, strength, and packaging of the drug. When requested by prescribers, pharmacists can and provide information to aid prescribers reporting adverse drug events. The current system of reporting can accommodate reporting of adverse drug events with any prescription drug product, including biologic and biosimilar products; there is no need to augment this process for biologic and biosimilar products in particular.

- Special notification requirements for biosimilar drugs would create otherwise unnecessary distractions from the important communications already initiated by pharmacists when there are pressing healthcare issues to address. For example, pharmacists commonly reach out to physicians regarding potential drug interactions, patient allergies to medications, and formulary issues. These additional communications would increase the volume of information flowing from pharmacies to physicians' offices, detracting focus from important patient care issues that need resolution and inundating physicians with information that is likely irrelevant for the overwhelming majority of patients.

- As an alternative to the special prescriber notification requirements for biosimilar products discussed above, some proposals have emerged that instead require the use of special recordkeeping systems for all biologic medications (including innovator biologic and biosimilar products). These proposals would require that pharmacies either notify the physician of the manufacturer and product name for any dispensed biologic medication, or record this information in an interoperable electronic health record system that both the physician and the pharmacy have access to. While advances in health information technology continue, the thousands of physicians and pharmacies in Texas do not commonly share access to interoperable health records. Thus, to comply with the requirements of these proposals, those pharmacies without access would need to follow the physician notification alternative discussed above as highly problematic.

Ultimately, there is no sound reason to impose any special requirements on biologic and biosimilar medications. These products should be subject to the same substitution and recordkeeping requirements that apply to other prescription drugs.

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