SUBJECT: Allowing biologically similar products to be substituted for some drugs

COMMITTEE: Public Health — favorable, without amendment

VOTE: 9 ayes — Kolkhorst, Naishtat, Collier, Cortez, S. Davis, Guerra S. King, J.D. Sheffield, Zedler

0 nays

1 absent — Coleman

1 present, not voting — Laubenberg

SENATE VOTE: On final passage, April 22 — 29–2 (Deuell, Seliger)

WITNESSES: For — Fritz Bittenbender, Biotechnology Industry Organization; Dennis Borel, Coalition of Texans with Disabilities; Kimberly Greco, Amgen; Roxana Rhodes; Louis Tharp, Global Healthy Living Foundation; Allen Todd, Creaky Joints and Global Healthy Living Foundation; (*Registered, but did not testify*: Yvonne Barton, AbbVie; Chase Bearden, Coalition of Texans with Disabilities; Dan Finch, Texas Medical Association; Michael Floyd; Kathy Hutto, AstraZeneca; Matt Johnson, Takeda Pharmaceuticals, USA; Tom Kowalski, Texas Healthcare and Bioscience Institute; Gaspar Laca, GlaxoSmithKline; Anna Lozano; Shari Noonan, Texas Urological Society; Robert Peeler, UCB and Allergan; Bradley Westmoreland, Genentech; Richard White)

Against — Brynna Clark, GPhA; Cheyanne Cook, Boehringer-Ingelheim Pharmaceuticals; Allen Horne, CVS Caremark; Jerry Moore, Teva Pharmaceuticals; (*Registered, but did not testify*: Robert Culley, Generic Pharmaceutical Association; Michael Harrold, Express Scripts; John Heal, Texas TrueCare Pharmacies; Cheri Huddleston, Alliance of Independent Pharmacists; Don Stevens, Novartis; Mark Vane, Gardere Wynne Sewell; Kwame Walker, Boehringer-Ingelheim Pharmaceuticals)

On — Gabriel Hortobagyi, The University of Texas MD Anderson Cancer Center; (*Registered, but did not testify*: Kerstin Arnold, Texas State Board of Pharmacy)

BACKGROUND:

Occupations Code, ch. 562, regulates the prescription and dispensation of drugs that can be substituted for brand-name prescriptions, such as generic drugs.

DIGEST:

SB 190 would allow interchangeable biosimilar biological products to be substituted for brand-name biological products under certain circumstances, with the intent of saving money for consumers.

Substitution authorized. If the price of a generic drug or an interchangeable biosimilar biological product was lower than a patient's copayment, a pharmacist would have to allow the patient the option of paying for the lower-priced alternative. The pharmacist would have to record the name, strength, and manufacturer/ distributor of the biological product.

If a practitioner prescribed a specific brand, the pharmacist would have to dispense that particular drug or biological product and could not provide a substitute product. The Texas Board of Pharmacy would have to require that prescription forms prohibit interchangeable biosimilar biological product from being dispensed if a particular brand was specified. If no particular brand was specified, the pharmacist could dispense an interchangeable biosimilar biological product in place of a biological product.

Notification. The bill would contain a temporary provision expiring on December 31, 2015 requiring a pharmacist to notify the prescribing practitioner within three days if the pharmacist dispensed an interchangeable biosimilar biological product. The notification would have to be in writing and identify the name, strength, and manufacturer/ distributor of the product.

Labeling. Unless otherwise indicated, the prescription label would have to indicate the brand name, or the name, strength, and manufacturer/ distributer, of the biological product. If a different biological product was selected instead of the prescribed product, the label would have to indicate that it was a substitute. Retail and out-of-state pharmacies would have to comply with additional labeling requirements.

Before dispensing an interchangeable biosimilar biological product, the pharmacist would have to notify the patient (or agent) that an

interchangeable product was available and ask the patient or agent to choose between that product and the prescribed brand. This information could be provided on the prescription order form and, in certain circumstances, the pharmacy would not have to notify the patient that a less expensive alternative was available. The pharmacy would have to post a sign informing patients about this notification requirement.

Liability and limitations. A pharmacist who selected an interchangeable biosimilar biological product would assume the same responsibility when filling a prescription for a biological product, and the prescribing practitioner would not be liable for the decision. A pharmacist could select an interchangeable biosimilar biological product only if it was less expensive than the prescribed product, and a pharmacist could not charge a higher fee for dispensing interchangeable products than for the brand-name products. The bill would not apply to certain products, such as injectable medications, unless they were determined to be an interchangeable biosimilar biological product.

The bill would adopt federal definitions of biological product, biosimilar, interchangeable, and reference product. The Texas State Board of Pharmacy would have to adopt rules necessary to implement the bill by March 1, 2014.

This bill would take effect September 1, 2013.

SUPPORTERS SAY:

SB 190 would allow Texas patients to take full advantage of medical innovations, which could save them money on prescriptions. Biological products, and their biosimilar counterparts, represent exciting advances in medicine. Rather than being chemically synthesized, biological products are created by recombining or controlling the genes of living organisms. These products have been effective at treating breast cancer, rheumatoid arthritis, and Crohn's disease, among other conditions. Recently, scientists have started developing interchangeable biosimilar biological products (biosimilars), which are comparable to the generic versions of brand-name drugs and could offer less expensive alternatives to costly medications.

In 2010, the Patient Protection and Affordable Care Act recognized the importance of these new medications and authorized an abbreviated approval pathway for biosimilars, expediting the U.S. Food and Drug Administration's (FDA's) licensing process. Although several types of biosimilars will soon be available, Texas pharmacists need statutory

authorization to dispense these medications to patients. SB 190 would provide this framework by updating state pharmaceutical laws to include biosimilars. This would ensure that Texas patients had access to the newest advances in medicine.

The bill would not create onerous requirements or regulations. By creating a temporary practitioner notification system, SB 190 would strike a proper balance between patient safety and additional administrative burdens.

This bill would not be premature because it is likely that biosimilars will become available before the next legislative session. Several other states, including Florida and Virginia, are preparing for the approval of biosimilars by passing similar laws. SB 190 would be a forward-looking bill designed to keep on the cutting edge of medical technology.

OPPONENTS SAY:

SB 190 would be premature. Currently, there are no biosimilars that have earned FDA approval, and Texas should wait for guidance from that agency. Biosimilars are highly complex, sensitive molecules that are difficult to produce. In order to ensure patient safety, Texas should wait until the FDA has fully researched and vetted these medications before implementing a regulatory framework to make them available to patients.

In addition to being premature, this bill would be an example of "regulatory capture" by improperly advancing the commercial interests of large biopharmaceutical groups.

OTHER OPPONENTS SAY:

The bill would create an unnecessary and burdensome notification system. Pharmacies are a heavily regulated industry and an additional requirement could prompt pharmacies to limit the availability of biosimilars, reducing access to these medications.