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CLIENT ALERT

Virginia Becomes First State to Limit Substitution of Biosimilar Drugs

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This week Virginia became the first state in the nation to enact a law that limits the substitution of biosimilar drugs. On March 26, 2013, Virginia's Governor signed into law (SB 1285/HB 1422), codified as §*54.1-3408.04,* entitled *Dispensing of interchangeable biosimilars permitted.* By its terms, the law forbids pharmacists from dispensing a biosimilar substitution to a brand-name biologic drug if the prescribing physician specifies the prescription must be dispensed as written or if a patient wants the branded drug. Other extra administrative requirements for dispensing a biosimilar require pharmacists to inform patients before dispensing a biosimilar and require them to note the product name and manufacturer on the prescription label and dispensing record. Pharmacists also must give patients cost information on the branded and biosimilar products under the law, which as enacted will automatically expire in July, 2015.

Unlike traditional 'small molecule' pharmaceuticals, biologic drugs are made from living materials and are difficult to replicate with absolute precision. Biosimilars, like generic small molecule drug products already prevalent on the market, offer the prospect of reducing healthcare costs. The Congressional Budget Office has estimated that biosimilars could cut the country's total drug spending by $25 billion over 10 years and reduce government health care programs' direct spending by $7 billion

A biosimilars pathway was created in the Patient Protection and Affordable Care Act to foster generic competition in biologics. The FDA has issued draft guidelines that provide the first substantial description of the expected approval pathway. As a result, the FDA approval pathway for biosimilars allows for two categories: one for drugs that are "highly similar" to their brand-name counterparts and one for drugs that are deemed "interchangeable" because there is no difference in safety and effectiveness. Drugs that are determined to be interchangeable with the original biologic, rather than just highly similar, could be substituted more easily with the original under the FDA's proposed guidelines, and have the potential to substantially reduce healthcare costs.

The signing of the Virginia law is a win for branded companies in the ongoing battle between branded and generic pharmaceutical companies over biosimilars. Generic drug companies, the most likely manufacturers of biosimilars, are concerned that such laws will have a chilling effect on the market for biosimilars.

Commenting on the groundbreaking Virginia statute, the Biotechnology Industry Organization (BIO) commended the Virginia Governor for his action, saying that the "policies outlined in the new law align with all five of BIO's principles on biologic substitution." The Virginia law was described as "a model for legislation necessary in all 50 states to address this cutting-edge technology," according to BIO. In contrast, Ralph Neas, President of the US Generic Pharmaceutical Association (GPhA), was less enthusiastic, saying the law, "while well intentioned, is preemptive, and carries burdensome administrative red tape that threatens the positive impact biosimilars will have in Virginia." The only part of the law that its generic opponents like is the Virginia state legislature's understanding of the need to limit this legislation by including a two-year 'sunset' clause. This clause means that the bill will expire in 2015, likely before an interchangeable biologic is approved and available in the United States.

Similar laws have been working their way through the legislatures of other states, such as Indiana, North Dakota, Pennsylvania, Texas, Washington, Colorado and Florida, and could stand in the way of full implementation of the biosimilar approval pathway.

Biotech companies have supported state laws limiting biosimilar substitution as necessary to promote patient safety. They argue that unlike generic small molecule drugs, which are required to be identical to their branded counterparts, slight changes to a biologic drug, such as differences between the cell lines used by the creator of an original biologic and those used by the creator of a biosimilar, can change its properties and therefore its safety and efficacy profile. The generic drug companies, which strongly backed the abbreviated pathway for biosimilars, dispute the biotech industry's view. Generic manufacturers believe that the FDA's approval of a biosimilar as "interchangeable" under the statute should be sufficient for purposes of substitution for the brand biologic drug.

Caught in the middle are the pharmacists. Last year three pharmacy trade groups pushed the FDA to allow pharmacists to substitute biosimilars for their biologic counterparts without physician approval, saying substitution standards don't need another step before patients receive medication. In a letter to the FDA signed by the American Pharmacists Association, National Association of Chain Drug Stores and National Community Pharmacists Association, pharmacists requested additional guidance on the agency's standards for substituting the drugs, saying pharmacists need more information, but shouldn't require physician oversight when dispensing drugs to patients. The groups also urged the FDA not to require separate names for biosimilars and biologics, claiming it would cause undue confusion and cause issues with pharmacy systems.

The text of the new Virginia law is below:

§ 54.1-3408.04. Dispensing of interchangeable biosimilars permitted.

A. A pharmacist may dispense a biosimilar that has been licensed by the U.S. Food and Drug Administration as interchangeable with the prescribed product unless (i) the prescriber indicates such substitute is not authorized by specifying on the prescription "brand medically necessary" or (ii) the patient insists on the dispensing of the prescribed biological product. In the case of an oral prescription, the prescriber's oral dispensing instructions regarding dispensing of an interchangeable biosimilar shall be followed. No pharmacist shall dispense a biosimilar in place of a prescribed biological product unless the biosimilar has been licensed as interchangeable with the prescribed biological product by the U.S. Food and Drug Administration.

B. When a pharmacist dispenses an interchangeable biosimilar in the place of a prescribed biological product, the pharmacist or his designee shall inform the patient prior to dispensing the interchangeable biosimilar. The pharmacist or his designee shall also indicate, unless otherwise directed by the prescriber, on both the record of dispensing and the prescription label, the brand name or, in the case of an interchangeable biosimilar, the product name and the name of the manufacturer or distributor of the interchangeable biosimilar. Whenever a pharmacist substitutes an interchangeable biosimilar pursuant to a prescription written for a brand-name product, the pharmacist or his designee shall label the drug with the name of the interchangeable biosimilar followed by the words "Substituted for" and the name of the biological product for which the prescription was written. Records of substitutions of interchangeable biosimilars shall be maintained by the pharmacist and the prescriber for a period of not less than two years from the date of dispensing.

C. When a pharmacist dispenses an interchangeable biosimilar in the place of a prescribed biological product, the pharmacist or his designee shall provide electronic, written, or telephonic notification of the substitution to the prescriber or his staff within five business days of dispensing the interchangeable biosimilar or as set forth in a collaborative agreement as defined in § 54.1-3300.

D. Whenever a pharmacist or his designee dispenses an interchangeable biosimilar in the place of a prescribed biological product, the pharmacist or his designee shall provide the patient with retail cost information for both the prescribed biological product and the interchangeable biosimilar. For the purposes of this subsection, "retail cost" means the actual cost to be paid by a retail purchaser to a pharmacy for a drug at the prescribed dosage and amount.

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