Fix SB 1285

Ensure Patient Protections when Substituting Biosimilars

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Dear Members of the Virginia Senate:

For many of the more than two million Virginia patients—including our seniors, children and veterans—who suffer from one or more chronic illnesses, biologic medicines represent life-changing, and often lifesaving, therapies. They have improved quality of life, mitigated symptoms and reduced both disability and mortality rates.

As important as these therapies are, it is just as important that public officials take special care to ensure the safety of the patients who rely upon them. Biologics are made from living cells and, unlike conventional chemical therapies, their unique, complex structures cannot be easily replicated. Creating an interchangeable biosimilar product is extraordinarily difficult because the slightest variation from the original biologic medicine can cause a patient to have a severe adverse reaction.

That is why we strongly urge adoption by the Senate of all patient protections contained in House Bill 1422. This measure will bring Virginia state law in line with advances in modern medicine while also providing the essential safeguards that will ensure that Virginia patients receive exactly the medicines they need and will not be subject to potentially harmful substitutions.

Our support for HB 1422 is grounded in three paramount principles that are embodied in the House legislation. First, although we are not opposed to biosimilars, it is essential that substitutions for biologic medicines only be allowed in cases in which the Food and Drug Administration has certified that a biosimilar product is interchangeable. Because of the nature of these medicines, any biosimilar will never be exactly the same as the biologic original, so it is essential that only FDA-approved interchangeable biosimilars be allowed to be substituted.

HB 1422 also requires that physicians and patients be notified whenever a substitution occurs. We can't stress strongly enough the importance of this provision. In chronic disease cases, patients and physicians work closely in managing the illness. Often they have tried different medications before finding the therapy, or combination of therapies, that has the most beneficial effect. It is essential that both doctors and patients know if a substitution to a biologic medicine has been made.

Finally, we support the provision in HB 1422 to require that records of biosimilar substitutions be kept for a period of no less than two years from the dispensing date. Should a patient have an adverse reaction or a change in their condition, it is imperative that a historical record of the patient's medications be readily available.

Unfortunately, the recently-introduced Senate Bill on this issue, SB 1285, provides a significantly lesser degree of safety for patients. SB 1285 does not require that a health care provider be notified whenever a pharmacy or insurance company substitutes a biosimilar for the prescribed biologic medicine. This is a significant omission of a simple, sensible requirement that would ensure that doctors are informed of what medications their patients are receiving. The Senate Bill also does not require that records of biosimilar substitutions be maintained, meaning that critical documentation may not be available in the event of a problem with a biosimilar. Again, this would create an unnecessary health risk for Virginia patients.

That is why we encourage full support of all patient protections included in HB1422 by the Virginia House and Senate.

There is no aspect of HB 1422 that will be overly burdensome to any health care professional or any entity involved in health care payment or delivery. To the contrary, this is common-sense legislation that recognizes the benefits of biologic medicines and the potential safety risks when substitutions are made to those medicines. On behalf of Virginia patients who depend upon safe, effective medications for their health and well-being, we urge passage of these protections.