



MIKE ROHRKASTE

STATE REPRESENTATIVE • 55TH ASSEMBLY DISTRICT

Testimony on Assembly Bill 679 December 13, 2017

Mr. Chair and committee members, thank you for the opportunity to speak to you today on behalf of Assembly Bill 679.

AB 679 recognizes the growing importance of biologically developed medications, also known as biologics. These products are being used to treat patients suffering from diseases such as arthritis, cancer, diabetes, and epilepsy, to name only a few. One well-known example of a biologic is adalimumab – better known by its brand name, Humira – which is used to treat inflammatory conditions such as arthritis and Crohn's disease.

Biologics differ from traditional prescription drugs in that they are created from biological materials, not through chemical means. While a brand-name drug and its generic version are chemically identical, the nature of biologics means that products may not necessarily be identical. However, the federal Food and Drug Administration does regulate biologics, and it also determines whether a given set of biologics are therapeutically equivalent or otherwise interchangeable.

State law currently permits a pharmacist to substitute cheaper generic medications for brand-name medications if the prescribing practitioner has not forbidden substitutions in the prescription order. AB 679 extends that treatment to biologics that have met the FDA's standards for therapeutic equivalence or interchangeability. This will allow consumers who are prescribed biologics to save money: If an interchangeable version of a prescribed brand-name biologic exists, a pharmacist will be allowed to make the substitution under the same conditions as non-biologics. AB 679 also requires pharmacists who make these substitutions to notify the prescribing practitioner by making an entry into an electronic records system or by other means, so that a record exists of the exact biologic dispensed.

Assembly Bill 679 is a commonsense bill that recognizes developments in biotechnology and gives people with serious diseases additional opportunities to access safe, affordable medications.

Thank you for your consideration. I will be happy to answer any questions you may have.

What Are "Biologics" Questions and Answers

What is a biological product?

Biological products include a wide range of products such as vaccines, blood and blood components, allergenics, somatic cells, gene therapy, tissues, and recombinant therapeutic proteins. Biologics can be composed of sugars, proteins, or nucleic acids or complex combinations of these substances, or may be living entities such as cells and tissues. Biologics are isolated from a variety of natural sources - human, animal, or microorganism - and may be produced by biotechnology methods and other cutting-edge technologies. Gene-based and cellular biologics, for example, often are at the forefront of biomedical research, and may be used to treat a variety of medical conditions for which no other treatments are available.

How do biological products differ from conventional drugs?

In contrast to most drugs that are chemically synthesized and their structure is known, most biologics are complex mixtures that are not easily identified or characterized. Biological products, including those manufactured by biotechnology, tend to be heat sensitive and susceptible to microbial contamination. Therefore, it is necessary to use aseptic principles from initial manufacturing steps, which is also in contrast to most conventional drugs.

Biological products often represent the cutting-edge of biomedical research and, in time, may offer the most effective means to treat a variety of medical illnesses and conditions that presently have no other treatments available.

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STATE SENATOR
Leah Vukmir

Assembly Committee on Health

Wednesday, December 13, 2017

Assembly Bill 679

Chairman Sanfelippo and committee members, thank you for hearing Rep. Rohrkaste's and my bill today. Assembly Bill 679 is a commonsense, free-market bill that allows pharmacists to dispense cheaper drug equivalents of brand-name drugs to save patients their hard-earned money.

Under current Wisconsin law, pharmacists may dispense a generic version of a prescribed drug if the generic is cheaper than the brand-name version. These generic drugs have been determined to be equivalent to the prescribed drug by the Food and Drug Administration because their chemical makeups are the same.

Thanks to new biotechnology, biologic drugs have become commonplace on the market and now we are able to create biosimilar versions of biologics. These drugs are different from chemical drugs because they are replicated using processes using plant cells or other proteins, not just copying the chemical formula.

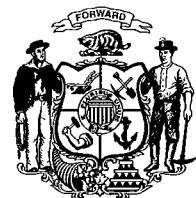
The FDA has recently created its approval process for interchangeable biosimilars. Because of that, it's time for Wisconsin to update our statutes so pharmacists can substitute these biosimilars the same way they currently can swap brand-name drugs for their generic alternative. Senate Bill 575 allows pharmacists to dispense biosimilars, unless the prescribing authority specifically prohibits substitutions.

This bill will result in the lowering of prescription drug prices for Wisconsin families and seniors. Per conversations I've had with drug manufacturers and pharmacists, purchasing a biosimilar instead of a brand-name drug could result in up to a 20% savings. Those are real dollars that will have a great impact on families' budgets.

Currently, 36 states (including Illinois, Iowa and Minnesota) have laws that address biological products and biosimilars. This bill will give Wisconsin consumers the chance and the choice to save money on their medications.

Thank you for your time.

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December 13, 2017

Rep. Joe Sanfelippo
Room 306 North
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Madison, WI 53708

Dear Chairman Sanfelippo and members of the Assembly Health Committee,

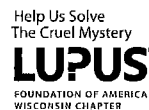
We are writing to urge your support of Assembly Bill 679, related to interchangeable prescription biologic products. The development of biologic drugs has provided patients and their physicians with access to improved therapeutic options. Biologic drugs are some of the most expensive drugs on the market today. However, as generics have done for small-molecule drugs, interchangeable biosimilars have the potential to increase price competition on older biologic drugs, and result in lower cost burdens for patients.

In order for biosimilars to provide increased access and affordability through competition, state pharmacy laws have to be amended to create the ability for biosimilar substitution at pharmacies. As biosimilar policies are developed, they must focus on ensuring the safety and efficacy of all biologic drugs, whether the original innovator or biosimilar, and policies must also ensure access and affordability of biosimilars for cancer patients.

We appreciate that this bill limits biosimilar substitution to products that the Food and Drug Administration (FDA) has designated as an interchangeable biologic product. We agree that pharmacy substitution should only happen under the circumstance where the FDA has deemed a product to be interchangeable. We further agree with the proposal to allow physicians the ability to prevent substitution via prescription instructions. In addition, we support the language to require that when there is an interchangeable biosimilar, the prescribing physician must be notified of the actual biologic dispensed within five business days to ensure an accurate and enduring patient medical record.

As interchangeable biologics are approved by the FDA, patients and their providers need a safe and transparent process by which they can receive access to these medications. By creating a new pathway for biologic substitution where none currently exists in Wisconsin, this legislation enhances patient access to new and potentially less costly medications. We urge you to support AB 679.

Sincerely,



HOMETOWN PHARMACY

Hometown Pharmacy testimony in support of Assembly Bill 679

Chair Sanfelippo and Assembly Health Committee Members, thank you for the opportunity to speak in support of Assembly Bill 679 on behalf of Hometown Pharmacy Partnerships. My name is Janet Fritsch and I am a pharmacist and owner of Hometown Pharmacy's Baraboo Corner Drug Store.

Hometown Pharmacy is a locally owned, leading pharmacy and complementary health care services provider in Wisconsin. We have 40+ locations in Wisconsin and are continuing to grow. We offer unparalleled services in pharmacy, clinical and long term care, as well as personal service, health education and convenience. Hometown Pharmacies are committed to our customers and our communities.

Our mission for the Hometown Pharmacies is to be a leading edge pharmacy and complementary health care services provider. We value our customers and are committed to providing them with personal service, education, and convenience. Affordable drug costs are crucial to providing top service to our customers.

Hometown Pharmacy supports Assembly Bill 679 bill, as it supports the benefit to the patient relating to scientific advancements in medicine and the reduction of costs at the counter through the dispensing of generic interchangeable biological products meeting FDA interchangeability standards. Any time an opportunity exists to reduce the cost of medicine and healthcare to patients while maintaining the same quality outcomes we all win. AB679 puts the decision of brand vs. interchangeable biological product in the hands of the pharmacist to make the decision and educate the patient of the change.

While biological products are most commonly dispensed through Specialty Pharmacies and not retail pharmacies like Hometown, the intent of this bill to increase drug options while promoting lower healthcare costs is a priority issue fitting Hometown's mission.

Again, thank you for the opportunity to speak in support of AB679 and I would be gladly answer any question relating to my testimony.