STATE SENATOR
Leah Vukmir

Senate Committee on Health and Human Services
Tuesday, December 12, 2017

Senate Bill 575

Committee members, thank you for hearing Rep. Rohrkaste's and my bill today. Senate Bill 575 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. I'd be happy to answer any questions you may have.

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MIKE ROHRKASTE

STATE REPRESENTATIVE • 55TH ASSEMBLY DISTRICT

Testimony on Senate Bill 575
December 12, 2017

Madam Chair and committee members, thank you for the opportunity to speak to you today on behalf of Senate Bill 575.

SB 575 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 adalimubab – 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 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. SB 575 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. SB 575 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.

Senate Bill 575 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.

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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.

Contact FDA

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Consumer Affairs Branch (CBER)
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December 12, 2017

Senator Leah Vukmir
Room 415 South
State Capitol
PO Box 7882
Madison, WI 53707

Dear Chairwoman Vukmir and members of the Senate Health and Human Services Committee,

We are writing to urge your support of Senate Bill 575 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 SB 575.

Sincerely,

HOMETOWN PHARMACY

Chair Vukmir and Senate Health and Human Services Committee Members, thank you for the opportunity to speak in support of Senate Bill 575 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 Senate Bill 575 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. SB575 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 SB575 and I would be gladly answer any question relating to my testimony.

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Arthritis Foundation℠

Testimony – State Biosimilar Substitution

Wisconsin State Senate
Senate HHS Committee
Speaker:
Deb Constien
Patient Advocate
Arthritis Foundation

Re: SUPPORT SB 575

Good Morning (Afternoon) Chair Vukmir, Vice-Chair Moulton and Members of the Senate Committee on Health and Human Services.

My name is Deb Constien and I am from Sun Prairie. I am here as a patient with arthritis and a volunteer with the Arthritis Foundation. I started my journey with Rheumatoid Arthritis at the young age of 13. I have had this disease for now 35 years. Life for me changed significantly, literally overnight. I went in for a benign foot surgery and came home a very different person, a person with Arthritis. I went from being 2nd chair flute, a competitive swimmer and cheerleader.....to being barely able to get through the day without fatigue, swelling of hands, feet, knees...too many joints to count and pain....constant pain. As a freshman in high school, I had my first Rheumatology appointment. I started an aggressive treatment plan almost immediately. This included countless pills, weekly shots, blood work, and countless Doctor appointments. Not only was I starting that awkward time in a teenager's life of making new friends and trying to keep up with the demand of homework..... I was battling Arthritis. I didn't want to appear different, so I always took the stairs to class, even though I had gotten special

permission to take the elevator. I never wore shorts because I didn't want anyone to see that my knees were 3x the size they should have been. It took 2 full years to achieve the diagnosis of Rheumatoid arthritis. It became clear quickly that my future would include serious destruction to my joints in a short amount of time. From that point forward, my family and I faced a constant barrage of changing medication and treatment strategies.

Fast-forward 20 years. The beginning of the Era of Biologics. These have been life changing. For the past 15 years, I have been on a total of 7 biologic medications- 2 lasted 6 years each, until they stopped working. I am being very serious when I say, my disease progression had literally stopped in those 15 years. My many surgeries, including a knee replacement, 2 cervical neck fusions and a right wrist fusion, are only from the first 20 years of destruction. I still have several surgeries front of me like reconstructive surgeries to both feet and further hand surgeries. But again, no new progression of RA.

I consider these medications come at a very high price; I am very hopeful that Biosimilars will lower that cost to patients making them more accessible to many more patients that could benefit from them like I have. But, I also think there needs to be definite communication between the Rheumatologist and patient if there are any changes to occur at the pharmacy level, especially if the patient is doing well on the Biologic they currently are on. The physician should have the ability to indicate N.S. or No Substitution on the prescription. If there is a substitution by the pharmacist of an interchangeable biologic product, both the patient and physician should be informed.

Also, having the pharmacist discuss the options with a patient if there is a less costly option, will empower the patient to be part of this decision-making process. Biosimilars being available in our healthcare system, opens doors for new options for the patients like me who have gone through most of the Biologics that are available at this time. It's a win - win in my book.

In addition to the Arthritis Foundation, the following organizations are also supporting the bill language.

- American Cancer Society Cancer Action Network
- American Lung Association
- Alzheimer's and Dementia Alliance
- NAMI Dane County
- National Psoriasis Foundation
- Susan G. Komen
- Wisconsin Academy of Family Physicians

Thank you for allowing me to provide the patient perspective on this bill.

WRA
Wisconsin Rheumatology Association

December 11th, 2017

Wisconsin Committee on Health and Human Services
Wisconsin Senate
P.O. Box 7882
Madison WI 53707

Re: Support for Senate Bill No. 575

Dear Members of the Senate Committee on Health and Human Services,

The Wisconsin Rheumatology Association (WRA) is a professional rheumatology society formed in order to advocate for excellence in rheumatologic care, and to ensure access to the highest quality care for patients with rheumatologic and musculoskeletal disease. Rheumatologists are entrusted with the safe care of patients with rheumatoid arthritis and other autoimmune diseases that require the careful choice of safe and effective pharmaceutical and biological therapies.

As you consider SB 575, WRA wishes to convey its qualified support. Importantly, the bill requires that: a pharmacist substituting an interchangeable biological product must, "Within 5 business days after the dispensing of a biological product… Make an entry of the specific product provided… to provide notice to the prescribing practitioner."

Biosimilar products, even those deemed interchangeable by the FDA, do not have the same active chemical ingredients as their reference products, presenting the potential for adverse consequences on a patient-by-patient basis that necessitates quick intervention by prescribers. Timely substitution communications for prescribing physicians are essential to ensure patient safety with these uniquely innovative, but uniquely challenging products. The agreed upon timeframe for the communication to occur within 5 days of the substitution is an important step in the right direction for protecting patients. However, WRA believes that the communication to prescribers should occur at least 5 days ***before*** the substitution occurs, and that the pharmacist must directly contact the prescribing physician to verbally inform them that a substitution has occurred. This specific time period offers physicians a safer and more consistent window to understand and counter any adverse effects of medications.

Physicians must be involved in decisions regarding their patient's use of a biosimilar. Allowing health systems to impose an automatic substitution for biologics, without informing the prescribing physician of the product dispensed, makes it harder to determine which product is responsible for adverse events and may not be safe for patients.

WRA recognizes that follow-on biologic products are a natural evolution of biotechnology and we welcome the introduction of these medications. Rheumatologists are keenly aware of the dramatic long-term, life changing clinical improvements that biological agents have on some of the most crippling and disabling conditions. These biologic response modifying agents are available for the treatment of autoimmune diseases and have a significant impact on improving our patients' quality of life, preventing disability and lowering mortality.

However, we must insist that physicians know what medicine their patient receives and that the prescribing physician is notified in a timely manner prior to any substitution of a patient's biologic medicine.

Biologics, and soon biosimilars, will continue to be an important treatment option for rheumatology patients. WRA appreciates that SB 575 supports steps towards safe introduction of biosimilars to the practice of medicine and urges its enactment with the aforementioned changes.

Respectfully,

Daniel G Malone MD, RMSK

Daniel G. Malone, MD, RMSK, FACR
President
Wisconsin Rhuematology Association