Testimony on Biologics, Biosimilars, and Interchangeables

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My name is Abigail Nobel. I am a bachelors-prepared nurse with a masters in politics. My interest here today as a health policy nurse is in state-level policy that impacts patient access and healthcare costs. Biologics constitute one third of drugs dispensed nationwide. Thousands in MI are currently using them; many more could benefit if they were more readily available and affordable. That time is on the horizon, and the bill under consideration today prepares Michigan for the day it arrives.

However, having read HB 4812, I believe Sec. 17755 (5) does not best represent patients' wishes, or their best interests, and I request it be stricken before the bill is reported to the Senate.

Background

Access problems related to price are well known and have been addressed in previous testimony. In context, Healthcare inflation has risen faster than the US Consumer Price Index for nine of the past ten years, exceeding it by 3.2% for the first five months of this year. This is due primarily to high regulation and low levels of competition, according to Forbes.

The committee has heard about FDA guidelines for pharmacists to be able to substitute Interchangeables, their safety, and the likely dramatic savings from the generic effect of substitution.

Specific to this bill is a brief FTC [Federal Trade Commission] quote from the Commerce Committee hearings for the original Biologics Act, showing the Congressional information available at the time, which assumed there would be **no** substitution in the Biosimilar market:

"… market dynamics will contrast sharply with the market dynamics of generic drug competition, where lower-cost generic entry **plus automatic substitution** lead to rapid erosion of the branded drug's market share. When the first generic drug enters the market, it generally offers a 25 percent discount off the branded drug's price. As additional generic firms enter, and often there are 8 or more of them, the price discounts reach as high as 80 percent."

That's a lot of savings. Of course, most do not expect the percent to be as high with Interchangeables. However, early this year, upon the first FDA panel's approval of an Interchangeable, some predicted up to 90% savings with biosimilars **if** pharmacists are allowed to substitute. A 2011 Rand study predicted that biosimilars would lead to a $44.2 billion

reduction in direct spending on biologic drugs from 2014 to 2024 **with the caution** that actual savings will hinge on the level of competition.

Patient Perspective

The second area of access is where I believe I have new testimony for you today; that is, access problems related to the regulatory burden. There are two ways to approach health policy that have been called fortress and frontier. We are used to thinking of the bad things that can happen, and making laws, rules, and regulations to guard against them. That is the fortress mentality. The problem is that not all the solutions are inside the fortress.

Every day, hundreds of MI residents awake to face symptoms for which they have no effective treatment. Treatment can be complicated by individual patient variation in metabolism, blood type, genetic makeup, and other physical characteristics. Especially in the area of Biologic drugs, trial and error are the norm in the quest for the ideal plan of care for individual patients.

It is impossible to centrally master the immense quantity of data needed to determine what is best for each of these thousands of individual patients, while eliminating all risk of failure or unintended effect. The good news is, patients do a pretty good job of figuring out what does and does not help them. The difficulty these days is for them to convey their feedback to the prescribing physician, who spends up to 70% of his time meeting regulatory requirements.

I'd like to conclude by reading into the record testimony from a patient remarkable both for the severity of her disease, and for her spirit in fighting for her right to access the medications that allow her to live as normal a life as possible. Diana Brown had hoped to be here today to speak for herself, but is instead honoring a work commitment—itself a tribute to the effectiveness of this class of medications. I hope you can hear the passion of her words as she speaks for the many other patients who will benefit from an open-door health policy in MI, to free competition and reduce health cost inflation.

To whom it may concern:

My name is Diana Brown and I am 33 years old. I was diagnosed with rheumatoid arthritis in 2010. The next 5 years would be a revolving door of pain, medications, and doctors offices. I started taking biologics in October of 2011 after all other treatments had failed miserably. I fully understood the side effects and possible things that are all associated with taking a biologic medicine. The first biologic took me over 2 months to finally get; due to all the paperwork that my rheumatologist had to fill out just so that my insurance would allow me to take the drug.

That was Humira. A drug that most people have heard of due to the commercials on television. I was losing hair and throwing up for hours daily the first 2 weeks that I took the medicine. Then, came the time to give myself another shot. Now I know that many of you are asking why I would even take a drug that caused these side effects. My life was a day to day thing. I couldn't work and most days were great if I even could walk when I went to get out of bed. My children had to help me get dressed and do things around the house. My husband was having to do more things and even help me bathe.

Biologics were my only hope. After the first biologic did nothing but make me sick we went to the next, and the next, and the next. Each with its own side effects, and most not helping me at all. Now when I say side effects I don't mean throwing up each time. In fact, I have gone into anaphylactic shock 2 different times when receiving an infusion, and had to quit 2 other biologics because my system decided that it could have me develop issues breathing on 2 others. Yes, side effects are a part of life for me. All 3 different biologics that caused breathing issues for me worked though. That's the saddest part. I could plan things, do activities with family and friends. Start working again even!

So, now I am on Orencia. Again, a drug most people have seen commercials for. It doesn't work quite as well as a couple others, but I can work and live a pretty normal life. Except for every 6 months when my insurance company wants my doctor to spend 30-45 minutes on the phone with him to make sure that I "really still need this biologic medication." This can delay me being able to get my biologic for 2 months. So, for 2 months I slowly have the medicine leave my body and the excruciating pain start again. All because of restrictions on this medication.

I understand the risks. I know the side effects too well. I have to give myself a shot into my stomach every week. Not because it is fun or I enjoy it. I do it so that I can be a mom, wife, and friend. So that I can have a life that most people take for granted. PLEASE, please do not make it harder than it already is to get these drugs. Without them I have a life, yes; but not one that anyone should have to live!

Thank You for listening to my story.

Diana M. Brown

Disease seems likely to keep researchers, physicians, and patients guessing well into the future. The greatest health for the greatest number of patients lies in the greatest number of treatment choices available. I believe the best role of regulators is to get out of the way and maximize patient and clinician autonomy. What may seem a minor regulation and reasonable safety precaution in Lansing can be harmful when its effect is multiplied upon hundreds of physicians and pharmacists and thousands of patients across our state.

Section 17755 (5)

Why is the "simple" notification of sub-section 5 such a problem? Today's clinicians are swamped in documentation requirements under Meaningful Use and other provisions of the ACA, Medicare, and other third party payers. Some studies indicate up to 70% of clinical time is spent meeting non-care tasks, and mindless documentation is one of the major factors listed in recent studies of medical depression and early retirement. Medical office busyness has a major downside for patients: visits take longer to schedule, and calls to clarify or correct prescription problems are delayed or even lost in the blizzard of data. Far more important than every biologic interchangeable medication having a back-check "just in case," is that a patient with a real prescription problem can actually reach the doctor for resolution in a timely manner.

Summary

I ask the committee to reject any burden of time, documentation, or data-collection that is not absolutely required under current federal law. Notification requirements, by adding even more unnecessary data communication and filing to the pharmacy and prescriber roles, disrupt the flow of care by competing for valuable time. As such, I strongly oppose this provision and request that it be stricken. Let's allow healthcare to get back to the point of it all: patient care.

Please take Section 5, the extra documentation mandate, out of HB 4812 before reporting this otherwise excellent bill to the floor of the Senate.

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