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Should Patients Be Forced to Fail a Drug First?

By Josh Bloom — October 9, 2017

Some Old Photo: Pixelbay [1]

Have you ever been prescribed a drug by your doctor only to find that your insurance company won't pay for it until you try (and fail) an older, cheaper alternative first?

There's a pretty good chance you have, something that American Council friend Dr. Robert Popovian, the Vice President of US Government Relations at Pfizer discusses in his recent editorial in *Morning Consult* **(1,2).** Popovian maintains that the answer is "yes," and that this practice comes at the expense of patient health? He is not alone.

Dr. Paul Barton Brown writing earlier this year in the *Seattle Times* certainly agrees. Barton makes his feelings known before you read even one word of his editorial: "Insurance companies' 'fail-first' policy enough to make you sick."

> *"As a doctor, I am forced by insurance-company requirements to let many of my patients fail on older, ineffective medicines before they become eligible for the treatments I know will make them better."*

Paul Barton Brown, M.D. Seattle Times, April 28, 2017

Brown, a rheumatologist elaborates [emphasis mine]: *"This is a process called step therapy or, more accurately, **fail first**. As in, my patients must fail first on older, cheaper drugs before **insurance companies determine they have earned the right** to take modern, effective medicine."*

David Charles, MD, writing for AOL News [2] back in 2013 wasn't having any of this either:

> *"This attitude [fail first] was starkly summed up by a quote from the head of one of the country's biggest pharmacy benefit manager companies. In a recent article published by the St. Louis Post-Dispatch, Express Scripts CEO George Paz said, "Our whole model is switching people to lower cost drugs. The more money my shareholders make, the more money I make."*

What is going on here? Are insurance companies really shoving inferior drugs down patients' throats simply in the interest of saving money? In his editorial, Popovian says yes, "first-fail" mandates are real and they can cause considerable harm. He puts the blame squarely on insurance companies [emphasis mine]:

> *"Medical professionals make it their life's work to make sure patients have access to medicines that will improve their lives. Traditionally, this means diagnosing and treating a medical condition. B**ut sometimes this means battling insurance company policies that run contrary to sound medical practice and have the potential to harm patients."***

Dr. Robert Popovian, October 2017

This issue is not new. When Zofran, the miracle drug for chemotherapy-induced nausea and vomiting, was approved in 1991, it was prohibitively expensive **(3)**, and many chemo patients were forced to first endure older, less effective drugs before insurance companies would allow them to have Zofran. Talk about cruel.

Now, this ongoing war between patients and provides has taken a strange twist because more than ever before, drug companies are churning out scores of biological drugs - large, complex, molecules, such as proteins, antibodies, and vaccines. Biological drugs are derived from living organisms; they are more difficult to make and purify and this makes them expensive. This latest battle involves biosimilars, which are "copies" of the brand version of a biological drug, and there is an awful lot of money at stake.

Although the biosimilar-brand name issue may sound just like generic drug substitution for brand drugs, there are some similarities, but even more differences. Popovian explains: "Biosimilars are like generic drugs in a sense that they offer affordable options for comparable care. To be approved, a biosimilar must demonstrate that it is highly similar to its original drug with no clinically meaningful differences in terms of safety, purity, and potency."

But with biosimilars, the rules are upside down. Now, some insurance companies are requiring that patients try the more expensive brand-name drug first, something that Popovian calls "nonsensical." Although the concept may sound screwy, it's (again) all about money, but reasons behind this conflict are very different. Pharmacy benefit management companies have signed

exclusive agreements with drug companies - an anti-competitive measure by any definition.

Although this may sound obscure and rare - a practice that will affect very few of us - the issue of biosimilar drugs is anything but. As pharmaceutical companies continue to move away from small molecules (pills) toward biological drugs, it is inevitable that many of us will face this situation at some point during our lives **(4)**. The war of patients against insurance companies has emerged on a different front. But the result is the same. Lost in the noise is what should be the primary concern—the health of the patient.

You can read Dr. Popovian's editorial in its entirety here [3].

NOTES:

(1) The editorial was co-authored by Dr. Sam Azoulay, a senior vice president and the chief medical officer of Pfizer's Essential Health Business Unit.

(2) Morning Consult is a nonpartisan digital media and survey research company established in 2013 in Washington, D.C. (Wikipedia)

(3) "Expensive" meant something very different in 1991. A Zofran pill originally cost about $20. Compare that with the hepatitis C cure Sovaldi, which original was priced at 100-times that. Generic Zofran (ondansetron) is now $50 for a one month supply.

(4) I am one of them. (See: The Arsenal Against Asthma Grows: Biologics [4])
