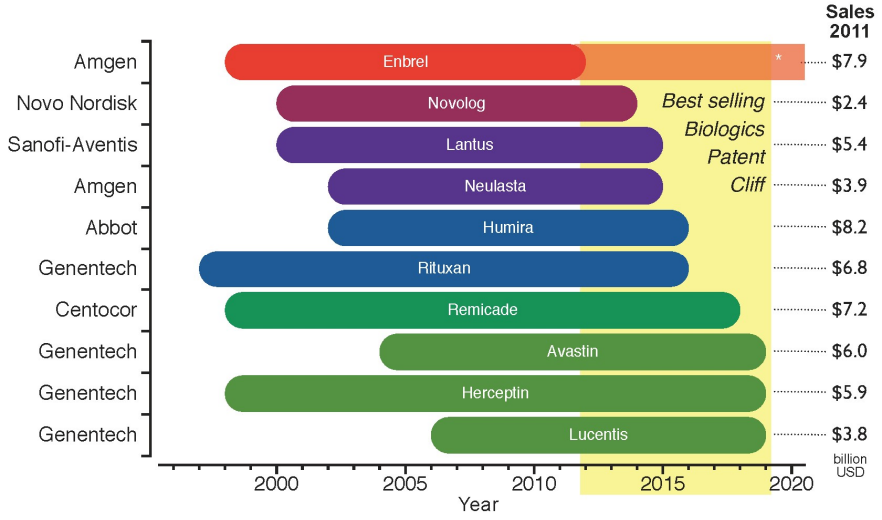
BIOSIMILARS AND THE NJ ECONOMY

MAY 2018 TECH BRIEF FOR LIFE SCIENCES TALENT NETWORK



http://www.mdpi.com/1424-8247/5/12/1393

Biosimilars replicate biopharmaceuticals

Biologics, as a class of medicine, are extremely expensive and profitable. Sadly, for the NJ economy, popular biologics are facing patent cliffs. Pharmaceutical companies have sought and sometimes have received patent extensions. One method is to develop a new delivery method for the therapeutic such as self-injectables. These medical devices can be shipped to customers through the mail using Styrofoam containers and ice-packs to prevent overheating. Humira and Enbrel may be the best-known examples due to prime-time advertising.

To get around the patents, competitors are developing **biosimilars**; i.e. a biologic with **no clinically meaningful differences** in terms of safety and effectiveness from the patented product. Theoretically, they are a 1:1 substitute for every therapy the original biologic was used for, at a fraction of the cost. The reality is more complex. Happily, marketplace complexity means jobs will be created as the use of biologics, generic biologics and biosimilars spreads beyond those with generous health insurance benefits.

Meanwhile, brace yourself for **biobetters**. These "superior" drugs are described as new *molecular* entities that are related to existing biologics by target, although they have been deliberately altered to improve disposition, safety, efficacy, or manufacturing attributes. More complexity as we approach the patent cliffs!

Labor Force Takeaway

Biologics are usually administered like chemotherapy. In addition to more jobs administering therapies, jobs will be created for designing new delivery systems. Hopefully the medical device positions will be in NJ.

Jobs will be created around the packaging and distribution of biologics and other biofabricated materials. Previous tech briefs have discussed how organs-for-transplant via courier is not scalable. Biofabricated skin and organ cells may not be able to be shipped by mail. In that case, they will be distributed through specialty pharmacies. As the use of self-injectable therapies expands, there may come a point where it is more efficient to distribute biosimilars through **specialty pharmacies** expanding those jobs as well. Upskilling class recommended.

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Biosimilars – bioequivalent therapeutics

Generic drugs and biosimilars are not the same. Biologic therapeutics, also known as targeted therapies or biological response modifiers, are derived from living material. Roughly speaking, they are a mixture of proteins and whatever-else the Creator put in the plant/animal/micro-organism that wasn't separated out during extraction. Biologics are designed to interfere with specific parts of the body's immune system to treat and prevent immune-mediated inflammatory disorders and cancers. Biosimilars aim to achieve a bioequivalence.

When small molecule drugs are replicated, they produce the identical molecule, with identical purity and equivalent additives to form the pill or caplet. The different requirements for approval and bioequivalence testing between generics and biosimilars puts them in an entirely different regime.

Will biosimilars stimulate the market for targeted therapies? If so, a whole different set of companies will be making money and a variety of new positions/jobs created.

Biosimilars only need to be tested against one treatment regime for one disease. The assumption is that the biosimilar will work identically in all other use cases. According to Dr. Tratenberg, a rheumatology specialist at Atlantic Health in Morristown, biosimilars are having a slow uptake. Currently they are not much lower in price than the biologics they aim to replace. Also, the clinical outcomes for (technically) off-label uses of the original therapy are not guaranteed to provide a similar outcome. Biologics are derived from nature and contain a bit of the wild.

That said, biologics have done wonders for patients with challenging diseases or who needed those who need growth factors during a bone marrow transplant. Disabling diseases that can be arrested by biologics include multiple sclerosis, rheumatoid arthritis, psoriatic arthritis, diabetes, kidney disease …. the list goes on.

Biologics are hard on the body. Liver function has to be monitored regularly via blood tests. The aim is to push the progress of the disease past the point of one's expected life expectancy. Meaning, you choose to die of something else other than the chronic disease you are fighting – a cancer, a respiratory disease or a rare disorder.

The choice *can* come down to the level of debilitation one will accept visa vie a marginally shortened life span. Many people would/do trade years of life in a wheel chair (or bedridden, for that matter) for a foreshortened life of work, activity and family dinners. Assuming biosimilars will wear down the liver, kidneys and the whole blood-purification system of the body, why risk it if the outcome is unsure? Well, perhaps money – trying that which is attainable.

Payers are sure to make their voice heard in this discussion. No doubt they are doing calculations involving the cost of biologic therapy with its known risks vs. biosimilar therapy with its less-well-known risks vs. accommodating the debilitated disease-sufferer. As a state, NJ needs to consider the lost tax revenue from a person not working or participating in society. That all gets very cold, but it needs to be done given the US health care system.

As mentioned before, the whole equation of treatment vs suffering is complex when dealing with difficult diseases. It is made more complex with the addition of choices and future pricing trends – downward presumably. Where there is growing complexity, there is an opportunity for upskilling.

Biosimilars should be part of any planned upskilling curriculum.

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