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# Editorial

## Creating a workable biogenerics pathway for patients

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The issue of bringing safe and affordable generic versions of biopharmaceuticals — biogenerics — has been the subject of great debate over the past several months in the United States Congress. While residents in the European Union and Australia have been able to obtain biogenerics, the United States lags behind because the US Food and Drug Administration does not have legal authority to create an approval pathway. The legislation before Congress would give the FDA the authority and flexibility it needs to approve biogenerics for safety and efficacy.

Biogenerics would provide equally safe and effective, but more affordable treatments for devastating conditions such as cancer, heart disease, AIDS, diabetes and rheumatoid arthritis. The need for these medicines in the United States is critical with more than 21 million Americans grappling with diabetes, 79 million suffering from cardiovascular disease and more than 1.3 million diagnosed with cancer last year alone. Many of these patients are currently being treated with a biopharmaceutical medicine.

Unfortunately, the costs of brand biopharmaceuticals are putting these life-saving medicines out of reach for countless Americans. Some biopharmaceuticals can cost up to \$200,000 per patient, per year. Treatment with the colon cancer drug Avastin costs \$100,000 per year, and Cerezyme, used to treat Gaucher disease, a potentially life-threatening enzyme deficiency caused by a genetic mutation, costs an average of \$200,000 per patient, per year — with some adult patients paying more than \$500,000 a year.

According to a study by Express Scripts, biogenerics could save American consumers more than \$71bn over ten years. Another study released by the Pharmaceutical Care Management Association revealed that biogenerics would save the Medicare Part B programme alone \$14bn over ten years. It is clear that biogenerics will provide patients and payers substantial relief compared to the cost of brand products.

Biogenerics also would bring much needed competition into the US healthcare system. While brand companies like to argue that biogeneric competition would stifle innovation, the fact is that indefinite drug monopolies actually chill incentives for innovation. As the US healthcare system has witnessed in the past 20 years since the introduction of generic drugs into the marketplace, the proper balance between pharmaceutical innovation and access spurs research and development of novel medicines and reduces healthcare costs. If there was competition from biogenerics, brand biotech companies would not only have more pressure to innovate, but many are expected to become producers of biogenerics themselves. Simply put, biogenerics would reduce costs to consumers and businesses through greater competition and choice, while also generating new incentives to develop innovative treatments and cures for patients.

While it would seem that biogeneric legislation that balances innovation and access should be a pretty easy lift in Congress given the FDA's scientific expertise and the urgent need to reduce healthcare costs in the US, brand PhRMA and BIO are powerful forces when it comes to

lobbying Congress. For months, they have been making false claims about safety. Fortunately, FDA has stated publicly that it has the scientific ability to approve biogenerics for safety and efficacy for products of low to moderate complexity.

In fact, the supporting science for the review of biogenerics is not new — it has existed for over a decade. The FDA has already been using a science-based, case-by-case approach to approve biopharmaceuticals — and, more importantly, changes in biopharmaceuticals. It is abundantly clear there is just one FDA safety standard. And that standard has been, and will continue to be, applied in the review and approval of each and every biologic — whether it be a brand or generic.

As Dr William Schwieterman, a former FDA official noted in his testimony before Congress, ‘A critical, but not often publicized fact in the biopharmaceutical industry, is that FDA does not require brand companies to perform large clinical outcome studies to “re-test” the product generated by new manufacturing processes. This is because such an approach would not only be infeasible, but more importantly, would ignore the utility of existing sophisticated scientific analytic tools and techniques for this purpose.’

Schwieterman went on to note that in reviewing biopharmaceuticals, ‘FDA starts with an assessment of extensive analytical comparability data. With these data, and keeping in mind the nature of the drug, the tests used and the disease being studied, FDA decides how to proceed. The agency can give a thumbs up or a thumbs down regarding each post-approval brand manufacturer change; and, if thumbs up, have that change be supported by: analytical data alone; analytical data coupled with pharmacokinetic and/or pharmacodynamic studies; or analytical data, the studies just mentioned, plus data from a large clinical outcome study.’

Experience has shown that the vast majority of brand manufacturing changes need no further studies when data from the analytic tests show the products to be comparable. And for the small number that do reveal small differences, the FDA has the ability to require additional analytic tests. It is rare for the FDA to require a full-scale clinical outcome study after a brand company makes a manufacturing change. Of all the hundreds of brand biologic products changes, the vast majority were approved without large clinical outcome trials.

In fact, when FDA Deputy Commissioner Janet Woodcock was asked at a Congressional hearing whether clinical trials are always the most sensitive studies for detecting changes in safety or effectiveness due to process changes, Dr Woodcock answered, ‘No. Now that’s a common misconception.’ Clinical trials may be insensitive to certain types of changes — adverse effects, for example, that are rare or uncommon — and we really need to use this scientific tool to assess the change in the product that is appropriate.

The US Congress has heard testimony from FDA and other scientific experts on the issue of safety and is currently trying to pass legislation that would give FDA the authority it needs to ensure safety. However, while it is good news that Congress is moving forward to give FDA the legal authority to create a workable approval pathway, problems remain on ensuring timely patient access.

Specifically, the new legislation, ‘The Biologics Price Competition and Innovation Act of 2007,’ contains an extension of 12 years of market exclusivity to brand biotechnology companies. Such an arbitrary and excessive period of time is not only unprecedented and unwarranted, but more importantly, would unjustifiably delay access to affordable competition and choice for consumers and businesses alike.

There is also the ongoing issue of ‘evergreening.’ This practice permits brand companies to make a minor change to their product and receive additional years of market exclusivity — in effect, maintaining their monopolies in perpetuity. Evergreening essentially prevents safe and affordable life-saving biogenerics from ever reaching patients.

The generic industry is working hard to educate Congress on the true harm that needlessly extending market exclusivity can have on consumers. After all, biogenerics are only useful to patients if they can access them.

I am reminded of testimony from a patient with multiple sclerosis who appeared before Congress earlier this year to discuss her first-hand experience with trying to afford brand biopharmaceutical medicines for her debilitating disease. She concluded her emotional testimony by stating, 'if I can leave this committee with one thought it is that no matter how good a drug is supposed to be, it has no chance of being effective if it is not affordable to those who need it. For a long time, no treatments were available for MS. Now there are. The sad thing is, it doesn't matter. Some people just can't afford them. They cost too much. We have to change that.'

The generic pharmaceutical companies, millions of employers, workers, consumers and patient groups and older Americans are working hard to change just that by educating Congress on the 'fact versus fiction' of biogenerics. The fact is that it is time for the United States to catch up with other nations who recognise the true benefits of biogenerics. The science exists to ensure safety. Now, the US Congress must get it right for the countless patients who are in need of safe and affordable life-saving medicines.

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