Close But No Cigar

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Biosimilars have received a lot of attention and “buzz” lately. And, as the FDA continues to hold meetings and put out documents for comment as it decides just how to eventually approve and regulate these biopharm generics there is one question that needs to be addressed.

What if doctors won’t prescribe them?

I pose this question in light of a recent survey that asked U.S. and European endocrinologists if they would feel comfortable prescribing biosimilar analogue insulins. The survey found that these doctors would need extensive efficacy data from multiple Phase III trials, involving in excess of 1,000 patients to feel comfortable enough to prescribe biosimilar insulin.

The survey also revealed that if endocrinologists had to choose between multiple biosimilars of the same reference product, the most influential factors on their prescribing decision would be any non-significant differences in the safety and efficacy, as well as the robustness and number of clinical trials.

Granted this is just one group of doctors and one type of treatment – but this does not bode well for the biosimilars industry. As their goal is to produce biopharmaceuticals that are cheaper than the brand-name product – the possible future need to conduct numerous Phase III trials to convince doctors (and patients) that biosimilars are just as safe and effective as the original drug will most certainly eat into profit margins – that are probably already fairly thin.
The established generics industry has had this same problem for years – and although many doctors are now prescribing generics – I still see reminders in my local pharmacy that generics are just like brand-name pharmaceuticals – just less expensive.

So what should the biosimilar industry do? Educate, inform, remind and reach out to doctors and patients at every opportunity.

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