

## Biosimilars are Coming. Are You Ready?

*The right message, to the right audience, at the right time, will increase adoption*

Biosimilars are coming to the US. Although the details on the pathway for biosimilars are still being finalized, the cost savings potential and the positive impacts on human health are too compelling for industry and regulators to not come to an agreement. In anticipation of the day when biosimilar medicines are available in the US, as they are in other parts of the world, there are two critical stakeholder groups whose perspectives must be understood – prescribers and patients.

Clarkston Consulting and Babson College teamed up to execute a Biosimilars Market Adoption Survey to better understand the knowledge level and perceptions of both prescribers and patients, with the intent of providing recommendations to biosimilars manufacturers on what they can do to achieve the greatest levels of adoption in the fastest amount of time.

### **Biosimilars: In Some Ways, the Next 'Generics,' But Not In All...**

Congress established an abbreviated approval pathway for biosimilars and interchangeable biologics as part of the Affordable Care Act, which became law in March, 2010. The Affordable Care Act authorized the FDA to develop regulations for the approval of less-costly biosimilar medicines. While biosimilar products are available in other highly regulated markets, like the EU, Canada, Australia and Japan, the FDA is now charged with, and is in the process of, developing the regulations and guidances for biosimilars here in the US.<sup>1</sup>

A recent study by Grant Thornton noted that over the next four years (by end of 2016), branded biologics with \$40 billion in U.S. sales will come off patent; with the more than \$20 billion in branded biologics already off patent, \$60 billion in annual spending in the U.S. is on the table. The most conservative estimates in the report show that biosimilars hold the potential to save \$20 billion annually<sup>2</sup>. Various other economic impact studies estimate the projected savings to be between \$42 billion and \$108 billion over the first 10 years of biosimilar market formation<sup>3</sup>.

These savings are clearly compelling, just as with generic drugs. However, this is where many of the similarities end. There are two very key differences between traditional generics and biosimilars that leading generics companies are focused on in anticipation of FDA approval for the US market. First is the science behind these drugs and the way they will need to be manufactured and brought to market.

Second, and the focus of this study, is on the sales and marketing side of the equation. One key difference between when generics were first introduced into the market and the environment in which biologics will enter the market is the





knowledge and awareness level of the typical patient, whose access to information is now infinitely greater. Companies that make branded biologics will certainly look to use this fact to impact the adoption of biosimilars. So conversely, biosimilar manufacturers need to be prepared for this and gain a deeper understanding of patient and prescriber preferences in order to best target education and factual information.

**Survey Approach and Methodology**

The Biosimilars Market Adoption Survey was conducted by Clarkston Consulting and the Babson College Management Consulting Field Experience (MCFE) Program. The survey included a focus group as well as online surveys targeted to both patients and physicians. The focus group included a diverse set of people with different backgrounds and education levels, ranging in age from 25 to 70 years old. Online surveys focused on an understanding of patient and physician confidence given demographics such as age and level of education, as well as their perceptions of generic medications. One hundred and thirty complete survey responses were collected (32 physicians and 98 patients).

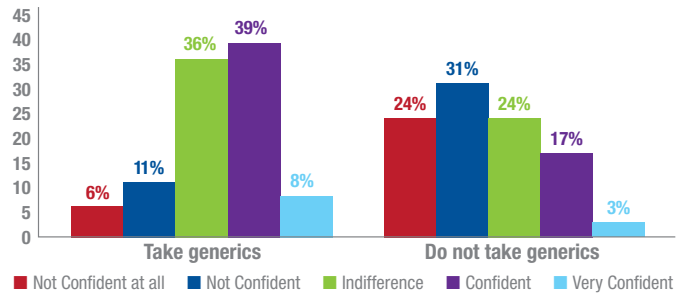
**Focus Group Results**

- Participants were confident in using generics and the price difference seemed to be the leading factor in why they liked using generics over their branded counterparts.
- None of the focus group participants had heard of the terms biologics or biosimilars.
- Once definitions were shared, the group was interested in learning more about each category of medication, and wanted to know more information before making a decision as to whether or not they would actually be confident to use one versus the other.
- Many participants said they would highly rely on the recommendation of their physician to determine if they should use biosimilars.
- Additional reasons that would influence their decision included the degree of price difference, what would be covered by insurance, their understanding of the effectiveness of the biosimilar substitute, and the severity of the condition for which they were being treated.

**Patient Survey Results**

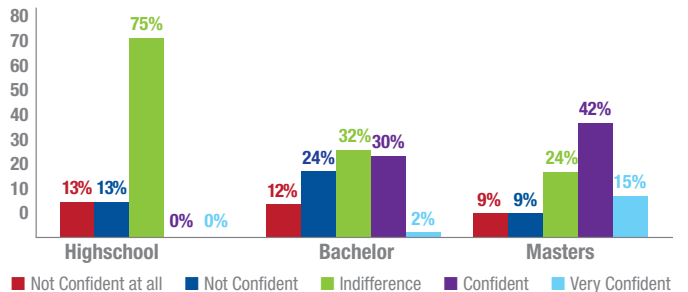
- Findings suggest that older populations tend to know more about biologics and biosimilars. Based on further analysis, this is likely due to the fact that older populations are more likely to need biologics and therefore may be more interested in a biosimilar alternative.

- Older populations cited that the underlying reason for their potential lack of confidence in using biosimilars was their concern about side effects and the effectiveness of the medication itself. They also showed variability based on severity of their condition (i.e., if their illness was severe, they would rather take the biologic).
- Younger populations cited a potential lack of confidence due to lack of knowledge about biosimilars. Many had never heard of either biologics or biosimilars.
- Out of the total surveyed patients, 67% said they typically take generic drugs. This group in turn showed a higher willingness to take biosimilars than those that do not typically take generics. The criterion of “typically takes generics” was determined as a very influential factor on whether or not patients will take biosimilars. See Exhibit 1.



**Exhibit 1: Experience with Generics Impacts Willingness to Consider Biosimilars**

- Findings suggest that those with higher levels of education would have a higher degree of confidence taking biosimilars. Based on further analysis, formal education did not specifically inform this group about biosimilars. Rather, the higher degree of confidence was attributed to general education impacting people’s perceptions and willingness to make informed decision about accepting new advances in science and technology. See Exhibit 2.



**Exhibit 2: Education Level Impacts Patient’s Confidence About Biosimilars**



### Physician Survey Results

- Physicians who prescribe generics will be more confident in prescribing biosimilars. 91% of physicians surveyed said that they typically prescribe the generic equivalent to branded pharmaceutical products. Additionally, the majority of this group use biologics in their respective fields.
- 59% of these physicians who typically prescribe generics said they would be confident in prescribing biosimilars with 34% saying they were undecided. Their uncertainty stemmed from their lack of knowledge and unfamiliarity with biosimilars. See Exhibit 3.

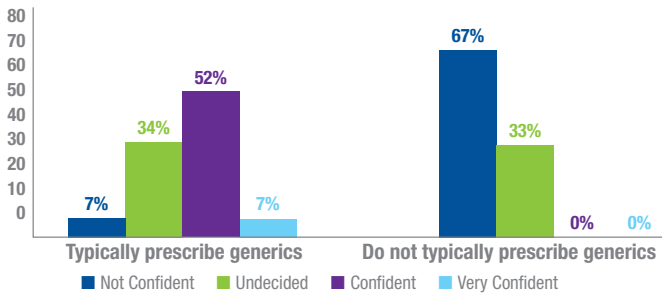


Exhibit 3: Physicians Who Prescribe Generics Typically Confident with Biosimilars

- Physicians who use biologics in their medical field have a higher level of confidence in biosimilars. Out of the physicians who typically prescribe biologics, 85% were confident or very confident in prescribing biosimilars and 15% were undecided. See Exhibit 4.

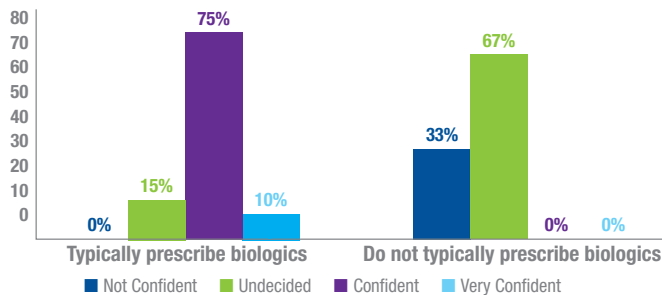


Exhibit 4: Physicians Who Use Biologics Have a Higher Level of Confidence in Biosimilars

- These findings suggest that physicians who typically use biologics are more knowledgeable about these types of medicines, therefore contributing to their higher level of confidence. This data also supports the recurring trend that physicians who know less about biologics have lower confidence.

- In addition, there seems to be a strong lack of understanding in biologics and biosimilars among general practitioners and physicians in internal medicine and pediatrics. These fields prescribe or use biologics, such as vaccines, but the majority of responses convey a lack of understanding in this type of medicine.

### Recommendations

Similar to other new medications, education through all channels of patient influence will be critical to promote adoption. Given the significant investment it appears will be required by biosimilar manufacturers to bring products to market, these drugs are perhaps best marketed not as a “low cost generic alternative,” but rather simply as another treatment option. It is the combination of three product attributes - “same science, same outcome, lower cost” - that will influence patient and physician perception and preferences.

Branding will be critical to biosimilar adoption. Branding will help to establish trust and confidence in the marketplace. Recommendations include the following:

**Develop Targeted Plans for “Receptive” versus “Non-Receptive.”** When physicians are presented with a new medicinal alternative, they will first offer it to a small group of patients willing to undergo the new treatment. This allows them to establish their own beta group of patients. It is only when they have enough data of their own to determine that the new treatment is more effective and safe to use that they fully commit to promoting it to their patients. Some physicians will also wait on the sidelines and observe other physicians’ use of the new treatment before making a commitment of their own.

It will be critical for biosimilar manufacturers to help physicians see biosimilars and interchangeable biologics not as an entirely new class of medicine, but rather emphasize the notion of “same science.” Capturing a high adoption group of physicians and patients out of the gate and sharing these success stories will help move the non-receptive base.

Highly receptive patients are between the ages of 25 and 35, have earned a bachelor’s degree or higher, and have used generic drugs in the past.

Taking this into account, the converse patient and physician set need to be addressed as well. Examples of ways to differentiate for these groups are outlined in the following sections.

**Differentiate the Product Design.** Based on the data, patients and physicians expressed desire for additional incentives to use biosimilars. Therefore, although biologics and biosimilars provide the same function, further innovation can be done on the non-clinical elements to differentiate biosimilars. For example, a biosimilar product could be designed to be produced as a pre-filled syringe or designed to need less refrigeration during storage. Instead of the only incentive being cost-savings, this would provide additional incentive for patients and physicians to use biosimilars.

**Educate the Market.** From our research, it can be inferred that a higher level of knowledge in biosimilars will lead to a greater chance of adoption by both patients and physicians. We believe that the most effective way to do this is to concentrate resources in educating the physician. It is clear from the focus group that physicians' opinions and recommendations are some of the most influential factors in the patient's decision making process. However, a two pronged educational approach is recommended:

EDUCATE THE PHYSICIAN	EDUCATE THE PATIENT
<ul style="list-style-type: none"> <li>• Sponsor seminars on biosimilars for physicians and medical students.</li> <li>• Co-host biosimilar events in highly ranked medical universities.</li> <li>• Sponsor panel discussions, conferences, and training programs for physicians on biosimilars.</li> <li>• Sponsor research to spread supporting data in medical papers, journals, and articles.</li> </ul>	<ul style="list-style-type: none"> <li>• Sponsor patient seminars and hospital events on biosimilars.</li> <li>• Post relevant information on patient forums.</li> <li>• Place brochures in hospitals and doctor's offices.</li> <li>• Sponsor articles in health magazines.</li> <li>• Place medical ads on TV / internet / magazines.</li> <li>• Continue to aggregate and demonstrate cost savings as well as the reach of affordable medications to larger patient populations. Groups such as the GPhA will continue to play a major role in this regard.</li> </ul>

Biosimilars are coming to the U.S. and many biosimilars manufacturers have already developed their business and operational plans for capitalizing on this opportunity. Reflecting on the findings in this survey, biosimilars have a considerable ways to go to gain the recognition and credibility among two key stakeholder groups – prescribers and physicians. However, by targeting the appropriate messaging to the appropriate audiences, as outlined above, biosimilars manufacturers can maximize and drive adoption.



#### About the Authors

Joe D'Ambrosio is a partner with Clarkston Consulting. He has over 20 years of experience working primarily with life sciences and consumer products companies.



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#### References

- 1 GPhA Web Site: <http://www.gphaonline.org/issues/biosimilars>
- 2 Reference Grant Thornton Press Release from GPhA Page: <http://www.gphaonline.org/media/press-releases/2013/statement-ralph-g-neas-president-and-ceo-generic-pharmaceutical-associati-0>
- 3 GPhA Web Site: <http://www.gphaonline.org/issues/biosimilars>

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