

# Structural Market Changes Needed in U.S. to Achieve Cost-Savings from Biosimilars

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Lessons from Europe's Biosimilars Successes:  
Payer, Physician, and Patient Alignment Will  
Lower Costs, Increase Access to Biosimilars

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**Biosimilars**  
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## EXECUTIVE SUMMARY

Biosimilars represent an equally safe and effective alternative to specialty biologics at lower cost, yet their uptake in the U.S. market has been disappointing, especially compared to the market in the EU. While the EU has had a biosimilar approval pathway for a few years longer than the U.S., anti-competitive behaviors in the U.S. and other market dynamics are discouraging biosimilar uptake and we currently show no signs of catching up.

With the ongoing debate on drug pricing in the U.S., this paper seeks to outline key lessons that U.S. policymakers can consider as they look to reduce healthcare costs and drive a robust and sustainable biosimilars market in the U.S.

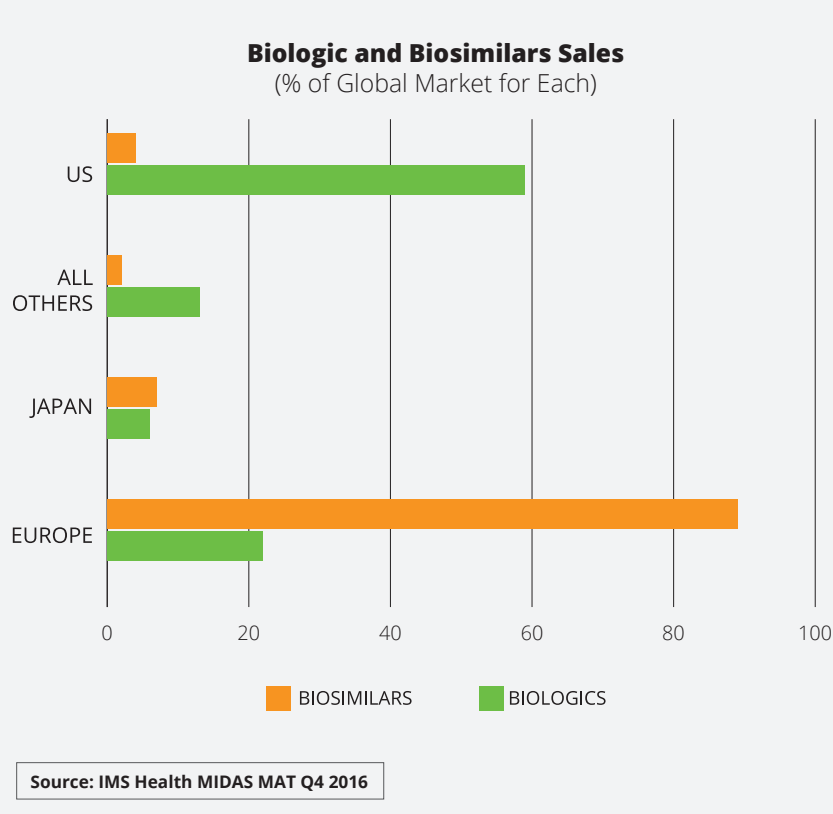
This paper includes a call to action for U.S. policy makers including, HHS, CMS and FDA, as well as commercial payers, to drive forth policies that will support a robust biosimilar market in the U.S.

# INTRODUCTION

## Competition and Innovation in Biosimilars Market: Lowers Costs, Increases Patient Access

Specialty biologic medicines offer dramatic improvements in treatment for complex and often life-threatening diseases such as arthritis and cancer. Biosimilars present an equally safe and lower cost option than their reference biologics. Yet in the United States, biologic medicines, including biosimilars, can be among the most expensive and difficult treatments for patients to access<sup>1,2,3</sup>. Anti-competitive behaviors and other market dynamics currently discourage market uptake of biosimilars in the U.S., preventing cost-savings and patient access. In fact, recent estimates suggest nearly \$60 billion in savings are possible over the next decade<sup>4</sup> – but only if policymakers help institute and cultivate a multisource biologics market that both prioritizes patient access and encourages multiple competitors to remain in the market for the longer term.

The U.S. need not reinvent the wheel, however. Europe has instituted a successful and sustainable biosimilars market that the U.S. can look to for guidance to increase market uptake of, and patient access to, biosimilars. Biosimilar use by millions of patients in Europe has shown their safety and efficacy in treating multiple diseases during regular clinical practice<sup>5</sup>.



Moreover, the European experience with biosimilars has proven that proactive measures to ensure market preparedness and ease administrative burdens for health care providers can help create a sustainable and vibrant biosimilars market.

Given that the European models for a successful biosimilars market was made possible by U.S.-led regulatory science and research<sup>6,7,8</sup>, the same competitive environment – and resulting increases in both access and costs savings – can and should happen in the U.S. The U.S. can learn from European successes<sup>9</sup> to balance the impact of incentives on long-term goals of sustainability versus short-term savings of winner-take-all markets.

Despite increasing familiarity of and trust in biosimilars by payers, physicians, and patients, simply waiting for the U.S. biosimilars market to naturally emerge is no longer an option.

It is incumbent upon those with the legal authority within the Food and Drug Administration (FDA), Centers for Medicare & Medicaid Services (CMS), Congress, as well as other stakeholders in the public and private sectors to help catalyze and sustain a vibrant U.S. biosimilars market.

Payers specifically have a unique and significant role to play in promoting a vibrant biosimilars market:

Full buy-in is needed from payers to sustain a competitive market that values the most cost-effective medicines. This includes proactive incentivizing of biosimilar prescriptions, educating stakeholders on the promise of biosimilars, and requiring commercial insurers to provide access to biosimilars.

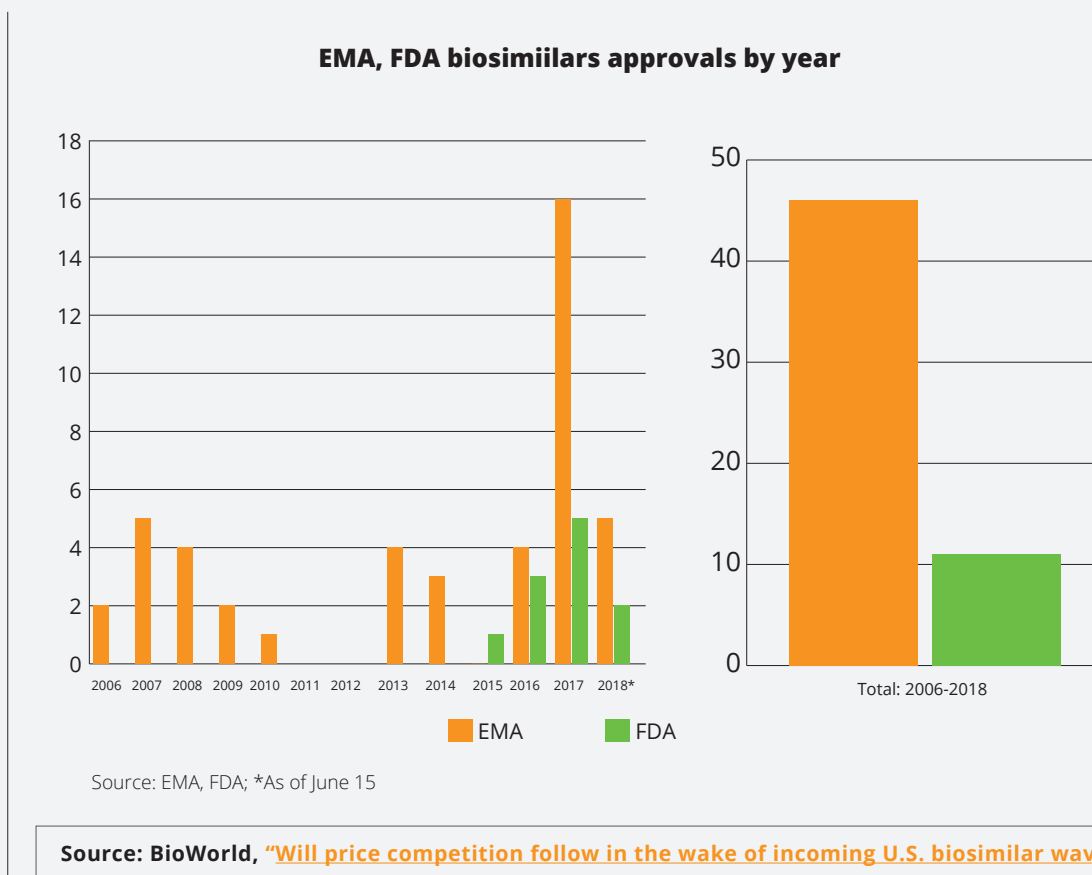
Leadership from HHS, CMS, and other payers is critical to actualizing the cost- and life-saving aspects of biosimilar treatments. A multi-stakeholder effort to align payers, physicians, and patients on a fair, efficient biologics market that includes biosimilars – as shown by the European experience – will help drive savings and lead to better patient outcomes in the U.S. too.

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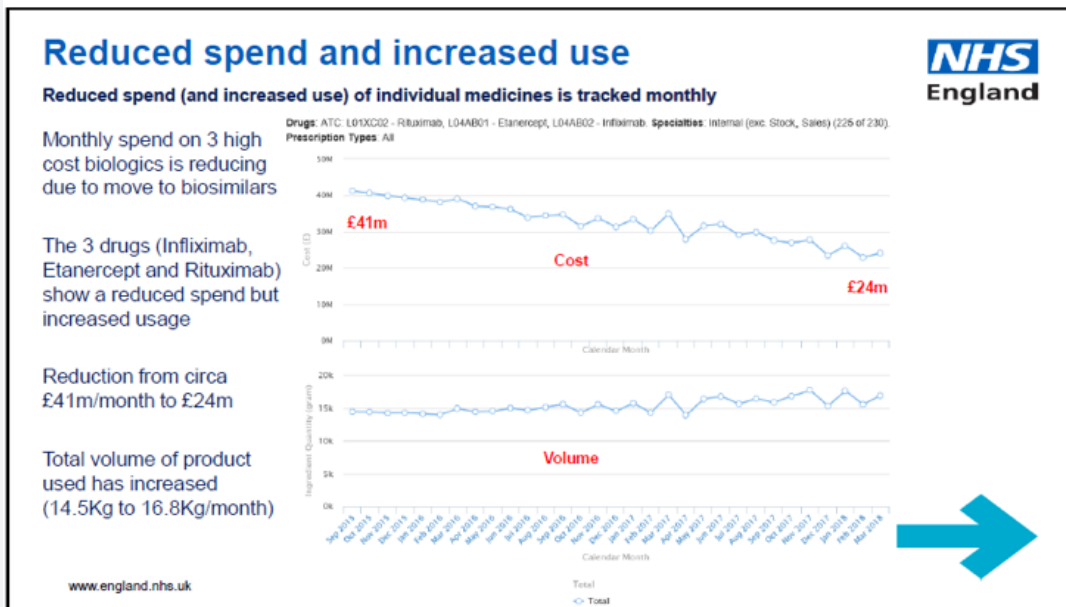
# THE EUROPEAN EXPERIENCE

## Lessons Learned From 10 Years of a Successful Biosimilars Market

As of early 2019, the U.S. has approved 17 biosimilars to 9 reference biologics<sup>10,11</sup>, although not all are yet commercially available. Meanwhile, since 2006, Europe has approved 53 biosimilars to 15 reference medicines<sup>12</sup>, reflecting extensive experience across a broader variety of therapeutic and treatment areas.



As biosimilars have become available across Europe, costs have gone down and patients' access has increased<sup>13</sup>. For example, in the U.K., three biologics – infliximab (Remicade®), etanercept (Enbrel®) and rituximab (Rituxan®) – show reduced spend but increased usage when biosimilars became available<sup>14</sup>. The reductions in price have averaged 40 percent, and the overall volume increased almost 16 percent<sup>15</sup>.



**Source: NHS England: Keith Ridge, Chief Pharmaceutical Officer April 2018 Biosimilars - the national view from NHS England**

Moreover, the European experience has shown that savings from an expansive biosimilars market benefit not only the health care system at-large, but also enable earlier and broader access to optimal care for individual patients, ultimately leading to individual cost-savings<sup>16</sup>. For example, enabling earlier treatment for degenerative diseases, such as rheumatoid arthritis before joint damage is irreversible, helps ensure that patients can be employed longer, heading off income losses due to disability and unemployment.

Currently 90 percent of global biosimilars sales take place in Europe<sup>17</sup>, despite 60 percent of overall biologic medicines sales occurring in U.S.<sup>18</sup>. This gap reflects both the failure of biosimilars uptake in the U.S. market and, accordingly, the considerable and increasing opportunities for biosimilars to offer savings in the U.S., should market changes encourage market uptake. Biosimilar sales globally are still under 1 percent of those of originator biologics worldwide, so the room for further savings remain large and apply well beyond the U.S. and Europe<sup>19</sup>.

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Some countries within Europe are more explicit than others in how they achieve savings and help sustain a successful biosimilars market<sup>20</sup>. But many countries – with the understanding that a truly competitive market will offer the industry and patients the most efficient treatments and best cost-savings – are increasingly and actively considering the need to ensure that multiple products remain on the market<sup>21</sup>, whether they be a reference biologic or a biosimilar.

This and other best practices from the European models offer a proven framework for instituting a successful biosimilars market. Broadly, Europe has shown that proactive measures are needed by policymakers and purchasers to drive uptake of biosimilars and that waiting for the natural progression of the market is not enough.

# KEY LESSON # 1: Biosimilars are Safe and Effective.

## Case Study: EU Safety Track Record for Biosimilar Utilization and Switching is Clear

Key to the biosimilars experience is that they don't have any meaningful difference in safety or efficacy from the reference biologic and accordingly that they perform the same in clinical practice<sup>22</sup>. Europe's decade-long experience with biosimilars confirms this: over 700 million patient days of treatment through 2016<sup>23</sup> has shown that clinical outcomes with biosimilars match the outcomes of the reference biologics.

Similarly, patient switching from the reference biologic to the biosimilar, as any physician can do today in the U.S., is not of concern. No change in clinical outcomes have been seen with the 14,255 switches from reference biologic to the biosimilar, as documented through July 2017<sup>24</sup>. If the U.S. is to commit to cultivating a successful biosimilars market, the proven track record of safety and efficacy need to be at the forefront of communications between physicians and patients.

In Europe, approval and switching of biosimilars is centralized, and then each country manages their own health budget, priorities, and implementation, separately<sup>25</sup>. In some countries, patients are rapidly switched to lower-cost treatments once they become available. In others, patients are prescribed biosimilars as a first step in treatment<sup>26</sup>. Regardless of when patients are able to access biosimilars in the course of their treatment, the European experience shows that safety and efficacy outcomes remain unchanged<sup>27,28</sup>, and consequently more patients are treated using biosimilars<sup>29</sup>.



## **KEY LESSON #2:** **Streamlining Administrative Processes is Critical**

### **Case Study (Sweden): Easing Administrative Burden for Physicians is Key to Successful Biosimilars Uptake**

The U.S. can also help encourage increased uptake of biosimilars by reducing the administrative burdens placed on physicians. In Sweden, before the biosimilar filgrastim became available, three physicians had to sign off on use of the reference product.

After biosimilars were available, the lower cost of treating febrile neutropenia made it possible to have sign off by a single physician with no further authorizations. Use increased five-fold in Southern Healthcare Region, showing that reducing prescriber burdens encourages greater use and better patient outcomes.

Similar policies can be adopted in the U.S., with associated reductions in cost of physician's time and that of others by reducing requirements for prior authorization for biologic treatments.

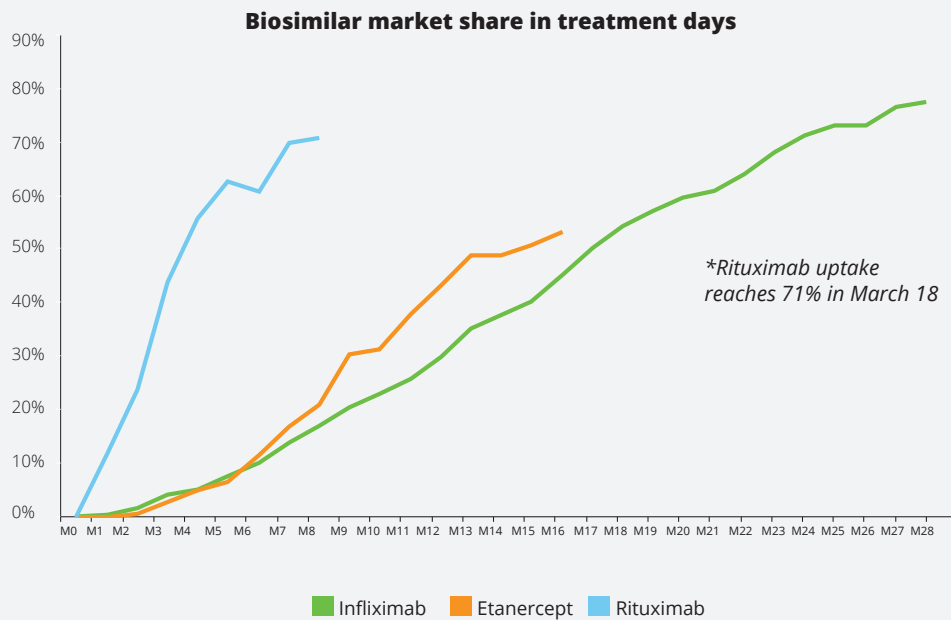
## KEY LESSON #3: Market Preparedness Matters

### Case Study (United Kingdom:) Proactive Measures to Prepare Markets for Biosimilars Help Facilitate Uptake, Confidence

The biosimilars experience in the U.K. has shown that instituting a framework for anticipating biosimilars approvals and then proactively engaging all relevant stakeholders helps encourage market readiness, leading to rapid adoption of biosimilars.

In September 2017, the National Health Service (NHS) in England released a detailed framework for achieving a successful biosimilars market<sup>30</sup>. The publication explicitly seeks to support and encourage various stakeholders to “act promptly to make the most of the opportunity presented by increased competition amongst biological medicines, including biosimilar medicines.” It also emphasizes “the importance of taking a collaborative approach to the commissioning of biological medicines, including biosimilar medicines, from the outset, as well as setting out how this can be achieved.” The framework also explicitly defined roles and responsibilities of patients, prescribers, providers and commissioners in a burgeoning biosimilars market. It also directly set a benchmark for “at least 90% of new patients [to] be prescribed the best value biological medicine within 3 months of launch of a biosimilar medicine, and at least 80% of existing patients within 12 months, or sooner if possible.”

This policy created predictability for biosimilar sponsors ahead of the actual product launches and allowed NHS England to benefit from multiple timely bids that optimized competition and access as soon as key patents expired<sup>31</sup>. The clear communication of roles, processes, and goals helped prime the market for successful biosimilars uptake, reflecting the proven premise that sound public policy and proactive preparation helps commercial policies succeed. Indeed, to underscore the extent to which the U.K.’s market preparedness helped institute a successful market, initial savings are of the order of 75 percent<sup>32</sup> across multiple biosimilars and the originator reference biologic.



Source: QI MIDAS Restricted MTH Jun 2017; Each product treatment day share calculated with respect to the individual, relevant accessible market

**Source: NHS England: Keith Ridge, Chief Pharmaceutical Officer April 2018 Biosimilars - the national view from NHS England**

Additionally, the U.K. experience shows that adequately engaging stakeholders helps lead to faster rates of adoption with subsequent biosimilars when they are approved, generating savings ever more quickly. Once stakeholders become familiar with the concept of biosimilars, they adopt subsequent ones as soon as they become available, showing how much the familiarity with and confidence in biosimilars, as well as the individual experiences of physicians and patients, matter<sup>33</sup>.

Based on this case study, it's clear that the U.S. should continue to encourage such familiarity with U.S. health care options, especially for providers and physicians, but in a manner that respects decision-makers and fits the country's health system's complex and diffuse needs. The U.S. needs to be proactive, for example with affirmative policies for each professional and patient community, as seen in the U.K.'s released framework that explicitly defines roles and responsibilities. For example, in the U.S., the Crohn's and Colitis Foundation has developed extensive resources on biosimilars for both physicians and patients to drive awareness<sup>34</sup>. The opportunities for savings and better treatment are significant both for acute care (for example, oncology) and for chronic conditions (for example, immunology).

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# A CALL TO ACTION FOR POLICYMAKERS IN THE U.S.

The same competitive environment seen in Europe and resulting increase in both access and cost-savings can occur in the U.S., too, but only if proactive steps are taken to ensure that the first cohort of biosimilars can succeed. Increased experience, familiarity, and market preparedness, complemented with sound public policy and proactive preparation can all help commercial policies succeed, as seen in Europe. Each subsequent cohort of biosimilars will ideally then have a better market infrastructure in place to encourage uptake and access. Importantly, experience taught Europe that seeking out the lowest price is not the sole priority, and indeed that market share can be at least as important<sup>35</sup>. We know market share is essential in the U.S. to being able to compete fairly<sup>36</sup>.

**For the U.S. biosimilars market to emerge, three structural market changes are needed:**

- 1. Commercialization:** A fair market that allows those products that initiate lower prices to gain market share. This will attract more biosimilar sponsors, as well as originator products, into the market and enable sustainability;
- 2. Authorization:** A strong biosimilars pipeline with scientifically-sound and efficient, well-resourced, and timely review by FDA;
- 3. Coordination:** A framework that aligns incentives across all stakeholders to ensure appropriate uptake.

Though challenges exist for each, these structural market changes are urgently needed to foster a successful biosimilars market in the U.S. Multi-stakeholder engagement support is essential immediately for market uptake to be successful in the U.S. Without alignment across the health care system on a framework for a biosimilars market, the other needs become irrelevant.

# Proposals for U.S. Policymakers

Ultimately for a competitive free market to emerge for specialty medicines in the U.S. that will drive down drug costs, the concurrent use of biosimilars alongside reference biologics is essential. If biosimilars cannot compete fairly, we will continue to have single-market entrants with no competition to drive down costs to all stakeholders. The following suggestions can all be implemented immediately and concurrently. While each alone may not be enough, they will help sustain the hope for a U.S. multisource biologics market that includes and promotes biosimilars.

## 1. What can HHS, CMS, and other payers do to support biosimilar-forward policies?

A biosimilar product that provides the same clinical outcomes for patients at a lower price must be rewarded with market share<sup>37</sup>. If rewards do not match investments, the U.S. pipelines for biosimilars will continue to be trimmed<sup>38</sup>.

Consequently, short-term savings, through rebates<sup>39</sup> and other market tactics, must be considered in the context of the damage to longer-term gains in health (access and affordability) for U.S. patients. Only by taking the long view towards competition will the U.S. patient benefit. Currently short-termism governs the biologics market, and that is death-on-the-vine for biosimilars.

Immediate actions for CMS, payers and others to drive the uptake of biosimilars in the U.S. include:

- Giving biosimilars, just like generics, automatic priority tiering in formularies and reduced or zero-dollar co-pays for patients;
- Banning fail-first policies with the reference product before a biosimilar can be prescribed because these are always contrary to the ethical practice of medicine and create dangers for patients<sup>40</sup>;
- Proactively encouraging and incentivizing switching to biosimilars by physicians in order to increase access and affordability and assessing shared savings models that can foster this;
- Educating stakeholders on the contribution that biosimilars can make to better healthcare for all, using the European successes as examples;
- Encouraging patient groups and professional societies to adopt a “train the trainer” model with FDA’s educational materials to stimulate their members to enable appropriate use of biosimilars [and interchangeable biologics];
- Requiring commercial insurers to provide access to biosimilars, with lower or zero co-pays, for all beneficiaries.

## 2. What can FDA do to support biosimilar-forward policies?

The FDA Biosimilars Development Program (BDP) pipeline is already showing a decline<sup>41,42</sup>, which suggests fewer future approvals. A highly visible defense of the quality of FDA's review and approval for all biologics is key to the public support of biosimilars and interchangeable biologics in the U.S.

The FDA can immediately do the following to help competition and innovation for all biologics:

- Resource and prioritize the biosimilars program within the Agency, including fulfilling Biosimilar User Fee Act (BsUFA) hiring commitments;
- Minimizing duplication or unnecessary studies during development, especially clinical studies;
- Seizing opportunities for harmonization across regulatory jurisdictions, using existing mechanisms<sup>43</sup>, and leading new ones;
- Providing clarity and direction to stakeholders on interchangeability;
- Encouraging use of real-world evidence on the experience with biosimilars already used in other highly-regulated markets such as, but not only, Europe, as a valued part of an U.S. application;
- Endorsing and creating educational materials, as the citable source<sup>44</sup>, such as downloadable brochures, that contain accessible information for each constituency interested in biosimilars, just as occurred in Europe<sup>45,46,47</sup>;
- Understanding the needs of each decision maker, and actively educating policy makers (for example CMS and Veterans Administration) about their options. For example, helping physicians understand that an interchangeability designation is not relevant to them and does not indicate a "better biosimilar" and that the same quality applies to all FDA-approved biologics; and
- Aggressively and immediately countering misinformation and fearmongering by a few vested interests apparently opposed to competition on the merits for their FDA-approved specialty products<sup>48</sup>. FDA can state that biosimilars are held to the same standards of safety and efficacy as their originator reference products with no compromise in quality. Indeed the trust we hold in FDA for originator products can be shared by biosimilars since it is the same reviewers applying the same standards to both.

## CONCLUSION

Significant savings to both the U.S. health care system and to patients is an achievable goal, should a vibrant biosimilars market be allowed to flourish.

Currently, however, market barriers are inhibiting the uptake of biosimilars. For the U.S. to create a sustainable, competitive biosimilars market, it will require actions that prepare the market by removing barriers that stifles successful uptake and that proactively engages industry-wide stakeholders to ensure alignment on policies and goals. The steps needed to ensure a vibrant market are within the purview of various U.S. decisionmakers, including the FDA, HHS, CMS, Congress, and other public and private sector stakeholders.

Cultivating a viable and sustainable multisource biosimilars market in the U.S. will only be possible by implementing a framework that emphasizes the safety and efficacy of biosimilars, ensures market readiness through proactive coordination, and reduces administrative burden.

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