Biosimilars play a critical role in lowering drug prices. Kaiser Permanente successfully uses biosimilars to improve affordability for our members. We are eager to share best practices and work with policymakers to help facilitate a more competitive market for biologic drugs in the United States.

A quick primer on biosimilars

- Biologics are drugs derived from living organisms, and they are used to treat conditions such as rheumatoid arthritis, multiple sclerosis, and some cancers.
- Biosimilars are highly similar versions of the original “reference” biologic that have been proven to show no meaningful clinical differences in safety, purity, and potency.¹
- Fostering a robust market for biosimilars to compete with pricier reference biologics could result in significant savings – up to $54 billion over 10 years² — to patients, taxpayers, and the health care system.
- The United States has been slow to approve and adopt biosimilars. As of July 2020, the U.S. Food and Drug Administration (FDA) had licensed 28 biosimilars, but only 18 are available to patients.³ In Europe, more than 60 biosimilars have been approved – and nearly all of them are available.⁴
- Even when biosimilars are available, adoption and uptake in the United States has proven challenging. For example, despite gaining FDA approval in 2016, the biosimilar Inflectra had only reached 3.2% market share in the United States compared to 96.4% for reference biologic Remicade as of January 2019.⁵ By comparison, two European countries – Norway and Denmark – had 81% and 96% uptake of the Remicade biosimilar, respectively.

Kaiser Permanente’s success story

Leveraging our integrated model†, Kaiser Permanente successfully uses biosimilars to improve affordability for patients while saving our system millions of dollars in the process. Contributing factors to our success include:

- Strong prescriber confidence in our formulary, which is evidence-based and developed in partnership by our expert pharmacists and Permanente Medical Group physicians
- A commitment to disseminating and generating unbiased information and data about biosimilars to educate clinicians and support treatment decisions instead of relying on pharmaceutical industry sales representatives as the primary source of information

† Kaiser Permanente is recognized as one of America’s leading health care providers and nonprofit health plans. Our integrated model combines coverage and care delivery. We also operate pharmacies that dispense drugs prescribed by Permanente Medical Group physicians, who contract exclusively with our health plans.
Biosimilars at Kaiser Permanente

- Clinician decision-making that is not influenced by drug reimbursement, facilitating financially neutral prescribing based on available evidence
- Close partnerships and communication between physicians, care teams, and patients in making treatment decisions
- A culture of sharing biosimilar success stories across our organization

Timeline of biosimilar adoption

The biosimilars pathway in the United States is relatively new. In March 2010 the Biologics Price Competition and Innovation Act was signed into law, creating the biosimilars approval pathway. Since then, Kaiser Permanente has led the way in adopting biosimilars.

<table>
<thead>
<tr>
<th>Biosimilar</th>
<th>Approval Date</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Zarxio™</td>
<td>March 2015</td>
<td>Biosimilar to Neupogen, which reduces risk of infection in chemotherapy patients</td>
</tr>
<tr>
<td>Inflectra®</td>
<td>April 2016</td>
<td>Biosimilar to Remicade, which treats rheumatic diseases and ulcerative colitis</td>
</tr>
<tr>
<td>Mvasi®</td>
<td>September 2017</td>
<td>Biosimilar to Avastin, which treats cancer</td>
</tr>
<tr>
<td>Truxima®</td>
<td>November 2018</td>
<td>Biosimilar to Rituxan, which treats rheumatoid arthritis</td>
</tr>
<tr>
<td>Kanjinti®</td>
<td>June 2019</td>
<td>Biosimilar to Herceptin, which treats breast cancer</td>
</tr>
</tbody>
</table>

How policymakers can address ongoing barriers

Kaiser Permanente’s experience demonstrates the potential value biosimilars can deliver to patients and the health care system. But, many barriers still exist that prevent a fully functional biosimilars market in the United States. Policymakers have an important role to play in helping the health care system overcome these barriers and fostering a more competitive market for biologic drugs. Some of the barriers include:

- **Over-patenting:** Patents are important catalysts for innovation. However, manufacturers use hundreds of patents to block biosimilar competition and maintain high prices far longer than our patent laws intend. These anticompetitive practices should be examined and addressed.

- **Lack of access to unbiased information:** Some manufacturers engage in marketing campaigns that suggest biosimilars are inferior to reference products. There are few unbiased resources about biosimilars that are readily available to prescribers to counter this misleading narrative. Policymakers can help increase access to clinical data about biosimilars and unbiased educational resources that will help instill confidence in both clinicians and patients.

* KP adoption rates each exceed 90%
**Insufficient incentives for adoption and uptake:** Converting patients from reference products and overcoming other operational barriers to using biosimilars can be resource intensive. Policymakers may need to provide temporary support to encourage providers to take these steps until a greater level of expertise with biosimilars is achieved.

**Misaligned payment incentives:** Potentially insufficient or perverse payment incentives that encourage providers and health plans to prefer more expensive reference biologics over biosimilars should be examined and addressed.

**References**

6. See note 5
7. Zarxio (filgrastim-sndz), U.S. Food and Drug Administration, April 20, 2015, [https://www.accessdata.fda.gov/drugsatfda_docs/nda/2015/125553Orig1s000TOC.cfm](https://www.accessdata.fda.gov/drugsatfda_docs/nda/2015/125553Orig1s000TOC.cfm).
11. Drug Approval Package: Kanjinti, U.S. Food and Drug Administration, July 18, 2019, [https://www.accessdata.fda.gov/drugsatfda_docs/nda/2019/761073Orig1s000TOC.cfm](https://www.accessdata.fda.gov/drugsatfda_docs/nda/2019/761073Orig1s000TOC.cfm).