

# **BIOSIMILARS ACTION PLAN:** Balancing Innovation and Competition

July 2018



# FDA's Biosimilar Action Plan (BAP)

## Introduction and Overview: Balancing Innovation and Competition

Congress has given the U.S. Food and Drug Administration (FDA), as part of the agency's mission to promote and protect the public health, responsibility for implementing laws intended to strike a balance between encouraging and rewarding innovation in drug development and facilitating robust and timely market competition.

Maintaining this balance between innovation and access requires a mix of statutory and regulatory measures, such as creating incentives for innovation in the form of exclusivity periods; modernizing regulatory requirements to maintain efficient, predictable and science-based pathways for drug review with the aim of reducing the time, uncertainty, and cost of drug development; and supporting a competitive marketplace through the efficient approval of lower-cost generic and biosimilar alternatives.

As the frontier of innovation evolves, the development of safe and effective new products can expand therapeutic options and address unmet medical needs. Similarly, the kinds of innovations that are advancing patient care are also changing. More and more some of the most significant advances are being made using biological products, including antibody drugs and other therapeutic proteins. After patents or other exclusivities expire on these novel products, prices can fall dramatically once follow-on products are available, potentially lowering costs for patients and payors and expanding access to these innovations.

At the FDA, we recognize both our important role in helping to ensure that the U.S. remains a driving force in medical innovation, as well as the importance of robust and timely competition to enhance patient access and reduce cost burdens on patients and our health care system.

Furthermore, it is important that we ensure that this balance between innovation and competition exists across the spectrum of pharmaceutical products – from traditional small molecules to complex products to biologics – given each of their critical roles in advancing the health of patients.

Patients are the primary beneficiaries of this virtuous cycle of innovation and competition.

Generic drugs, for instance, represent 90 percent of all prescriptions in the U.S.<sup>1</sup> Generic competition facilitated by the 1984 Hatch Waxman Act provided savings of more than \$1 trillion to the U.S. health care system over a decade and generated \$265 billion in savings in 2017 alone.<sup>2</sup> However, until relatively recently, the FDA lacked a statutory pathway to approve follow-on versions of biological products.

Biologic medicines play a critical role in the treatment of many serious illnesses, such as cancer and genetic disorders. They are, in many cases, the only treatments available. While these products offer much therapeutic promise and benefit, they often come at great expense. In fact, biologics represent almost 40 percent of all prescription drug spending. And, they accounted for 70 percent of growth in drug spending from 2010 to 2015.<sup>3</sup>

Against the backdrop of these high costs to our nation's health care system and the need to enhance access to these important products for patients, Congress passed the Biologics Price Competition and Innovation Act (BPCI Act), which established an abbreviated pathway for biologics, called biosimilars, in 2010. The BPCI Act was intended to strike a balance between access and innovation, providing a period of exclusivity for originator biologics and enabling

1 AAM 2018 Generic Drug Access and Savings in the U.S. Report.

2 *Id.*

3 Source: Biosimilar cost savings in the United States. RAND, <https://www.rand.org/pubs/perspectives/PE264.html> "biologics alone accounted for 38 percent of U.S. prescription drug spending in 2015 due to their high cost per dose, and for 70 percent of drug spending growth between 2010 and 2015."

a pathway for competitive biosimilars once exclusivity periods have lapsed. This is similar to the way the Hatch-Waxman amendments sought to establish balance between innovation for brand products and availability of generic competition. There are notable differences between the framework for follow-on biologics subject to the BPCI Act and small-molecule drugs subject to the Hatch-Waxman amendments, including issues related to product complexity and pharmacy substitution. These differences may result in different market dynamics. Nonetheless, the new legal framework for biosimilars is similar to the framework created under the Hatch-Waxman amendments in that it provides a pathway under which increased competition has the potential to emerge.

The approval pathway for biosimilars allows sponsors to leverage FDA's finding of safety and effectiveness for the reference product to support approval of the biosimilar at a potentially lower cost to sponsors than the development program for the originator reference product, provided the sponsor can demonstrate that the biosimilar meets the statutory standards for biosimilar approval. When it comes to the development of a biosimilar, some clinical studies may remain necessary because current analytical technologies, in most cases, may not be sufficient alone to demonstrate that a product meets the standards for biosimilar approval. Still, the reduced need for multiple large clinical outcomes studies as a part of biosimilar product development can significantly lower development costs. This could result in significantly lower prices for patients and payors. While the U.S. market for biosimilars is still maturing, FDA research suggests that after market entry, biosimilars have the potential to offer significant savings. This is especially true after two or more biosimilars for the same reference product are approved.

To date, the FDA has approved 11 products under BPCI Act authority, including five in 2017 and the first biosimilars approved for the treatment of cancer. As the U.S. market continues to expand and evolve, economies of scale should allow biosimilars to pass on more savings to payors and, in turn, patients. Prices should continue to fall as markets become more competitive.

The FDA will continue to play a critical role in facilitating increased access to biosimilars. The agency is taking steps to more efficiently manage our review and licensure pathways to facilitate biosimilar competition. We are modernizing our policies that govern the development of biosimilars to make it more efficient. We are also educating clinicians, payors and patients about biosimilar products and the rigorous evaluation they must go through. And, we are modernizing regulatory policies to accommodate new scientific tools that can better enable comparison between biosimilars and reference products that may reduce the need for clinical studies.

These actions will help create a more competitive market today, while creating greater incentives for sponsors to make the investments required to support future products that deliver greater benefits to patients and public health after statutory exclusivities have expired.

The FDA is committed to encouraging innovation and competition among biologics and the development of biosimilars. We are taking the following key actions:

1. Developing and implementing new FDA review tools, such as standardized review templates that are tailored to marketing applications for biosimilar and interchangeable products, to improve the efficiency of FDA review and enhance the public information about FDA's evaluation of these products.
2. Creating information resources and development tools for sponsors of biosimilar applications. This includes tools such as *in silico* models and simulations to correlate pharmacokinetic and pharmacodynamic responses with clinical performance. Such tools can make biosimilar drug development more efficient.
3. Enhancing the Purple Book to include more information about approved biological products, including information relating to reference product exclusivity determinations.

4. Actively exploring the potential for entering into new data sharing agreements with foreign regulators to facilitate the increased use of non-U.S.-licensed comparator products in certain studies to support a biosimilar application.
5. Establishing a new Office of Therapeutic Biologics and Biosimilars (OTBB) to improve coordination and support of activities under the Biosimilar User Fee Act (BsUFA) program, accelerate responses to stakeholders and support efficient operations and policy development.
6. Building on the FDA's Biosimilar Education and Outreach Campaign, continue providing critical education to health care professionals, including releasing a series of videos that explain key concepts about biosimilar and interchangeable products.
7. Publishing final or revised draft guidance on biosimilar product labeling to assist sponsors in determining what data and information should be included in the labeling.
8. Providing additional clarity for product developers on demonstrating interchangeability, including by publishing final or revised draft guidance.
9. Providing additional clarity and flexibility for product developers on analytical approaches to evaluating product structure and function to support a demonstration of biosimilarity, including by publishing revised draft guidance on the use of data analysis methods, including statistical approaches.
10. Providing additional support for product developers regarding product quality and manufacturing process, including by identifying physical product quality attributes that are most critical to evaluate, and by exploring ways to reduce the number of lots of the reference product required for testing.
11. Engaging in a public dialogue through a Part 15 hearing and opening a docket to request additional information from the public on what additional policy steps the FDA should consider as we seek to enhance our biosimilar program.

We also recognize that there are some significant factors affecting biosimilar competition and access outside of the FDA's direct control. These include payor reimbursement practices, which may affect sponsors' ability to successfully market new products even after FDA approval.

When we see practices that we believe create an imbalance between innovation and competition that is contrary to statutory intent, we will use our leadership to highlight these issues, encourage market participants to seek solutions that ensure timely access to biosimilar products and work with our partners across the government to take corrective action where necessary and appropriate.

## **Biologics and Biosimilars: Ensuring Access to Safe and Effective Options**

Like non-biologic drugs, biological products are regulated by the FDA and are used to diagnose, prevent, treat, mitigate and cure diseases and medical conditions. Since 1982, when the FDA approved the first humanized insulin developed through recombinant DNA technology, biological products have become increasingly important therapeutic options for patients with many serious ailments. These include, for example, many cancers, rheumatoid arthritis, diabetes and multiple sclerosis.

Advances in our ability to modulate the mechanistic causes of complex chronic diseases and reduce some of the most serious side effects from the first generation of biologics has enabled biological products to deliver increasingly safe and

effective treatments to patients. One of these advances was the ability to humanize modern antibodies. At the same time, however, the costs of these products have continued to increase, as has their share of U.S. drug spending.

The BPCI Act was enacted in 2010 with the intent of “balancing innovation and consumer interests”<sup>4</sup> by creating an abbreviated pathway for the approval of biological products demonstrated to be biosimilar<sup>5</sup> to, or interchangeable<sup>6</sup> with, an FDA-licensed reference product. However, in contrast to most drugs that are chemically synthesized and their structure is well-characterized, most biological products are complex proteins or other by-products of living cells. Their safety and effectiveness can be affected by small changes in manufacturing, packaging or storage (i.e., temperature changes).

FDA standards for evaluating a proposed biosimilar continue to incorporate new tools for assessing a biosimilar’s structural and functional properties relative to the reference product. The agency also continues to look for ways to ensure that manufacturers of reference products are not using FDA requirements to unfairly delay the entry of biosimilars.

While many factors affect the availability of biosimilars and interchangeable products, and while the FDA does not have a direct role in drug pricing, the FDA plays an important role in minimizing the time and cost to develop these products and in promoting effective competition. Through the agency’s application of the latest science and efficient review processes, the FDA can enhance patient and clinician confidence in this relatively new category of products. By advancing these efforts, we can help strike the proper balance between innovation, access and competition.

Availability of biosimilar and interchangeable products that meet the FDA’s robust approval standards will improve access to biological products through lower treatment costs and enable greater economies of scale in biosimilar manufacturing. By increasing treatment options, biosimilars can enhance competition in the market for biological products without reducing incentives to innovate.

## Demonstrating Biosimilarity Under the BPCI Act

Under the BPCI Act, the FDA implemented an abbreviated pathway for approval of biosimilar and interchangeable products. This abbreviated pathway allows a manufacturer to rely in part on the FDA’s previous determination of safety and effectiveness for a reference product for the approval of a biosimilar or interchangeable product. Instead of independently demonstrating safety and effectiveness, the manufacturer must demonstrate that its proposed product is biosimilar to, or interchangeable with, an FDA-approved reference product. As a result, manufacturers of biosimilar or interchangeable products typically do not need to conduct as many costly and lengthy clinical trials as is typical with development of a novel biological product.

To balance this abbreviated pathway for development and approval of biosimilar and interchangeable products with incentives to develop innovative new products, the BPCI Act also provides exclusivity to manufacturers of certain biological products. The FDA may not approve an application for a biosimilar or interchangeable product until 12 years after the date on which the reference product was first licensed. In the time since the enactment of the BPCI Act, the FDA has made substantial progress in developing the scientific and regulatory policies needed to implement this new approval pathway. Among the steps that the agency has already taken, the FDA:

4 Public Law 111-148, sec. 7001(b).

5 A biosimilar is defined as a biological product that is highly similar to the reference product notwithstanding minor differences in clinically inactive components and that has no clinically meaningful differences in terms of safety purity or potency from an existing FDA-approved reference product.

6 An interchangeable product is a biosimilar for which the sponsor has demonstrated that the biosimilar can be expected to produce the same clinical result as the reference product in any given patient. Also, for an interchangeable product administered to a patient more than once, the sponsor has also demonstrated that the risk in terms of safety and diminished efficacy of switching between use of the interchangeable product and a reference product will not be greater than the risk of using the reference product without such switching. As defined in the BPCI Act, an interchangeable may be substituted for the reference product without the involvement of the health care provider who prescribed the reference product.

- Established the Therapeutic Biologics and Biosimilars Staff (TBBS) under the Office of New Drugs (OND) in the Center for Drug Evaluation and Research (CDER) to support consistent review and policy development efforts for biosimilar and interchangeable product development and approval. TBBS coordinates with other offices and divisions in CDER through an integrated matrix to manage the development and approval of biosimilar and interchangeable products.
- Created the Biosimilar Product Development (BPD) Program to facilitate the rapid development of biosimilar and interchangeable products. Through enrollment in this program, the FDA provides detailed, product-specific advice to manufacturers. As of July 1, 2018, 68 programs were enrolled in the BPD Program.<sup>7</sup> CDER has meeting requests to discuss the development of biosimilars for 31 different reference products.
- Prioritizes efforts to share regulatory information broadly to stakeholders. The FDA has published policies and recommendations in a number of guidance documents.<sup>8</sup> In addition, the FDA publishes the Purple Book<sup>9</sup> to provide information on approved biological products, including information on exclusivity and whether a product has been demonstrated to be biosimilar to, or interchangeable with, a reference product.

This is a crucial time in the emergence of the marketplace of biosimilar and interchangeable products. The FDA expects continued expansion in the number of approved biosimilar and interchangeable products in the coming years. Although there are barriers to marketing a biosimilar or interchangeable product that are outside of the FDA's purview, we understand the importance of advancing policies to facilitate the efficient development and approval of these products. With this objective, the FDA has created the BAP.

## Key Elements of the BAP:

The BAP is focused on four key areas: (1) improving the efficiency of the biosimilar and interchangeable product development and approval process; (2) maximizing scientific and regulatory clarity for the biosimilar product development community; (3) developing effective communications to improve understanding of biosimilars among patients, clinicians, and payors; and (4) supporting market competition by reducing gaming of FDA requirements or other attempts to unfairly delay competition.

### **1. Improving the efficiency of the biosimilar and interchangeable product development and approval process.**

The FDA is currently examining the best way to improve efficiency and predictability of the biosimilar development and review process.

#### **Priority deliverables:**

- To increase the efficiency of the review of biosimilar and interchangeable biological products, the FDA is developing application review templates specifically for 351(k) Biologics License Applications (BLAs). The templates will be formatted specifically to the data and information inherent to a 351(k) BLA and approval standards specific to biosimilar and interchangeable products. The development of these templates is intended to streamline the FDA review process and enhance the public information about FDA's evaluation of biosimilar and interchangeable products.

<sup>7</sup> These numbers reflect ongoing development programs and do not include development programs that have resulted in an application submitted to the FDA.

<sup>8</sup> A current listing of FDA guidance documents related to biosimilar and interchangeable products can be found at: <https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm290967.htm>

<sup>9</sup> Available at: <https://www.fda.gov/drugs/developmentapprovalprocess/howdrugsaredevelopedandapproved/approvalapplications/therapeuticbiologicapplications/biosimilars/ucm411418.htm>

- To further improve coordination and support of all activities related to biosimilar and interchangeable product development and approval, the FDA is in the process of transitioning the TBBS to the Office of Therapeutic Biologics and Biosimilars (OTBB).

The transition to OTBB will:

- ◊ Improve coordination and support of all activities under the BsUFA program, as well as address any additional biosimilar or overlapping biological product issues;
  - ◊ Accelerate response time to internal and external stakeholders;
  - ◊ Improve the agency's efficiency in providing development-phase advice to product developers and reviewing application materials, including enhanced pre- and post-submission communication with individual applicants; and
  - ◊ Support efficient policy development and implementation through the creation of additional guidance documents for product developers.
- To continue to improve coordination within CDER and in support of a matrix review process, CDER developed and implemented Associate Director for Biosimilar positions in key scientific review discipline organizations. These positions provide targeted points of contact within the respective review disciplines to improve the efficiency and consistency of biosimilar and interchangeable product development and approval.
  - The FDA will also develop information resources and development tools that can assist biosimilar sponsors in developing high quality biosimilar and interchangeable products using state of the art techniques. For example, the FDA plans to develop an index of critical quality attributes for use in comparing proposed biosimilars to certain reference products. The elucidation of these features can allow sponsors to better understand how the FDA evaluates data from comparative analytical studies performed to support a demonstration of biosimilarity. The FDA's goals in this area also include the development and validation of pharmacodynamic biomarkers tailored to biosimilar development and *in silico* modeling and simulation to evaluate pharmacokinetic and pharmacodynamic response versus clinical response relationships using existing clinical data. The development and validation of these tools, alongside others, can allow development programs to be more efficient and can reduce the size of clinical studies. These smaller clinical studies, in turn, can enable more biosimilars to reach the market in a much more cost-effective and timely manner.

## **2. Maximizing scientific and regulatory clarity for the biosimilar product development community.**

The FDA is increasing stakeholder communications related to biosimilars, including timely guidance for sponsors in order to provide scientific and regulatory predictability, as well as more efficient structures to support the development and review of biosimilar and interchangeable products. This includes efforts to harmonize international regulation of biosimilars and the acceptance of non-U.S. comparator products, as well as greater use of real-world data supporting regulatory decision making related to biosimilars.

### **Priority Deliverables:**

Prior to the publication of this plan, the FDA issued six final and four draft guidance documents related to the development and approval of biosimilar and interchangeable products.

- To increase regulatory certainty for stakeholders, the FDA will focus efforts on the rapid development of additional guidance to provide further clarification of the regulatory pathway for biosimilar and interchangeable

products. The agency will also hold public meetings and hearings to seek additional input on possible alternative approaches. As outlined in the BsUFA II goals letter, the FDA is prioritizing the development of guidance on the following topics, which will add to the existing body of published FDA guidance on biosimilars, interchangeables and other aspects of the BPCI Act:

- ◇ Final or Revised Draft Guidance: *Reference Product Exclusivity for Biological Products Filed Under Section 351(a) of the PHS Act*
  - ◇ Final or Revised Draft Guidance: *Implementation of the “Deemed to be a License” Provision of the Biologics Price Competition and Innovation Act of 2009*
  - ◇ Final or Revised Draft Guidance: *Considerations in Demonstrating Interchangeability with a Reference Product*
  - ◇ Final or Revised Draft Guidance: *Statistical Approaches to Evaluate Analytical Similarity*
  - ◇ Draft Guidance: *Processes and further considerations related to post-approval manufacturing changes for biosimilar biological products*
- The FDA is developing updated guidance to provide additional clarity to biosimilar applicants who seek approval for fewer than all conditions of use for which the reference product is licensed because, for example, one of the licensed conditions of use of the reference product is protected by a patent.
  - The FDA is developing a proposed rule on the interpretation of the definition of “biological product” in the BPCI Act which would provide additional clarity and predictability for sponsors regarding the appropriate review pathway for such products.<sup>10</sup>
  - To improve regulatory clarity, the FDA is evaluating its regulations regarding the submission and review of BLAs to ensure that they account for current practices and authorities.
  - As part of the agency’s efforts to provide timely, easy-to-use information about approved biological products, including biosimilar and interchangeable products, the FDA is developing an enhanced Purple Book. The enhanced Purple Book will include more information about approved biological products and will provide a modernized, interactive user experience. As part of the Purple Book enhancements, the FDA will also continue its commitment under the BsUFA II goals letter to publish information about newly approved or withdrawn BLAs and about reference product exclusivity determinations.
  - Supporting an efficient global market for biosimilars also entails harmonizing requirements for their development as well as sharing regulatory experience across national boundaries. As part of this effort, the FDA is strengthening its partnerships with regulatory authorities in Europe, Japan and Canada. These partnerships can facilitate greater efficiency in developing safe and effective biosimilars. We are also exploring data sharing agreements that can give us better insights into biosimilars’ real world safety and efficacy and, in some circumstances, facilitate the increased use of non-U.S.-licensed comparator products in certain studies to support an application under section 351(k).
  - Real-world evidence can be used to support safety assessments and appropriate prescribing of biosimilars. We will advance these efforts by gathering data across a number of the FDA’s current data sources, including information gathered from FAERS, Sentinel and through partnerships with private insurers and the Centers for Medicare and Medicaid Services.

<sup>10</sup> <https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=201710&RIN=0910-AH57>



### **3. Developing effective communications to improve understanding of biosimilars among patients, clinicians, and payors.**

Given the relative newness of biosimilars, the FDA is taking a proactive role towards educating clinicians, patients and payors about biosimilar and interchangeable products by developing audience-appropriate, innovative educational materials, including videos, that can explain important scientific concepts the FDA uses to evaluate biosimilars.

#### **Priority Deliverables:**

- In October 2017, the FDA released the Biosimilar Education and Outreach Campaign and updated the FDA Biosimilars website<sup>11</sup>. The goal of the educational materials is to increase understanding about biosimilar and interchangeable medications among health care professionals and other stakeholders. The FDA also developed tools to help professional societies and stakeholder organizations share information about biosimilars with their colleagues and members. To continue to provide critical information to health care professionals and to build on the momentum gained from the initial launch of the Biosimilar Education and Outreach Campaign materials, we plan to develop additional resources.. For instance, the FDA recently released a series of five videos that explain key concepts about biosimilar and interchangeable products in spring 2018.
- FDA held a webinar, "Overview of the Regulatory Framework and the Development and Approval of Biosimilar Products in the U.S.," for health care professionals on December 5, 2017. This webinar provided an overview of the regulatory framework for biosimilar products, including information on the general requirements of the approval pathway for biosimilars, and the scientific concepts used in the development of biosimilar products. The goal was to emphasize the rigor of the development and approval process. To further build on the success of the December 2017 webinar, the FDA is planning to host a second webinar for Continuing Education credit that covers information related to the labeling for and prescribing of biosimilar and interchangeable products. The FDA plans to host additional webinars on topics of interest identified by stakeholders and the FDA.
- To further engage stakeholders, address knowledge gaps and encourage stakeholder use of the FDA Biosimilars webpage and resources, the FDA also conducted a Reddit AMA (Ask Me Anything) forum in April 2018. The focus of this AMA was to specifically engage pharmacists through the Reddit r/Pharmacy forum to address their questions on biosimilar and interchangeable products. To engage with patient stakeholders directly, the FDA is planning to develop a one-pager for patient audiences and pursue video-format communications that can be used on social media for patient and other key audiences. This is targeted to begin in fall 2018.

### **4. Supporting market competition by reducing gaming of FDA requirements or other attempts to unfairly delay competition.**

The FDA will continue to evaluate whether firms are using FDA statutory or regulatory requirements to inappropriately delay approval of biosimilar or interchangeable competitors.

#### **Priority Deliverables:**

- The FDA will clarify our position on issues affecting reference product exclusivity to better effectuate balance between innovation and competition. We will also take action, whenever necessary, to reduce gaming of current FDA requirements, and coordinate with the Federal Trade Commission to address anti-competitive behavior. Additionally, we will work with legislators, as needed, to close any loopholes that may effectively delay biosimilar competition beyond the exclusivity periods envisioned by Congress.

<sup>11</sup> Available at: [www.fda.gov/biosimilars](http://www.fda.gov/biosimilars)

- As part of our Drug Competition Action Plan (DCAP), which focuses on generic drugs, we made it a priority to address practices that delay or block competition from entering the market, including the refusal to sell the samples necessary for developing generic drugs [a practice we've seen with products under limited distribution, whether the drug maker limits distribution voluntarily or does so in connection with a Risk Evaluation and Mitigation Strategy (REMS) program]. We will apply the same principles used in DCAP to our BAP to address circumstances in which drug makers refuse to sell samples, or use any other anticompetitive strategies, to delay the entry of biosimilar or interchangeable development and competition.

## Conclusion

The FDA anticipates that the marketplace for biosimilar and interchangeable products will continue to evolve. Our biosimilars program will continue to put in place the foundational regulations and guidance, including as part of BsUFA II implementation, to provide regulatory certainty with respect to the approval pathway for biosimilar and interchangeable products.

Therefore, the FDA considers this BAP to be dynamic. The agency will continue to identify activities that can be added to this program to advance regulatory science and better inform regulatory decision making to successfully address new issues and challenges.

Efforts will be informed by ongoing engagement with stakeholders. For example, early interaction with sponsors during product development, through the BPD Program, is a key element to the FDA's identification of policy issues to address through the guidance process.

In addition, the FDA continues to consider comments related to biosimilars and interchangeable products that were submitted in the public docket established as part of the July 2017 public meeting, *Administering the Hatch-Waxman Amendments: Ensuring a Balance Between Innovation and Access*. The FDA will continue to further engage health care professional and patient stakeholders through participation in conferences and meetings, providing technical support for communications materials, when appropriate, and engaging in direct dialogue to seek input on identifying knowledge gaps and communication tools.

The FDA is committed to transparent, science-based regulation of biosimilar and interchangeable products that maintains the dynamic balance between innovation and timely access, as Congress intended. Appropriate market exclusivities allow innovators to recoup their investments, and compensate them for the time, risk and uncertainty that make the cost of capital to undertake these endeavors high. These rewards provide incentives for research and development of new treatment options, as well as help advance medical innovation and improve outcomes.

After exclusivities expire, the BPCI Act envisions the market entry of biosimilar and interchangeable products that can expand access to affordable treatment options and encourage developers to focus on novel product development, including for unmet medical needs. The FDA will balance these critical goals and ensure that the fruits of timely access to innovation and lower-cost alternative products continue to benefit patients for generations to come.



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