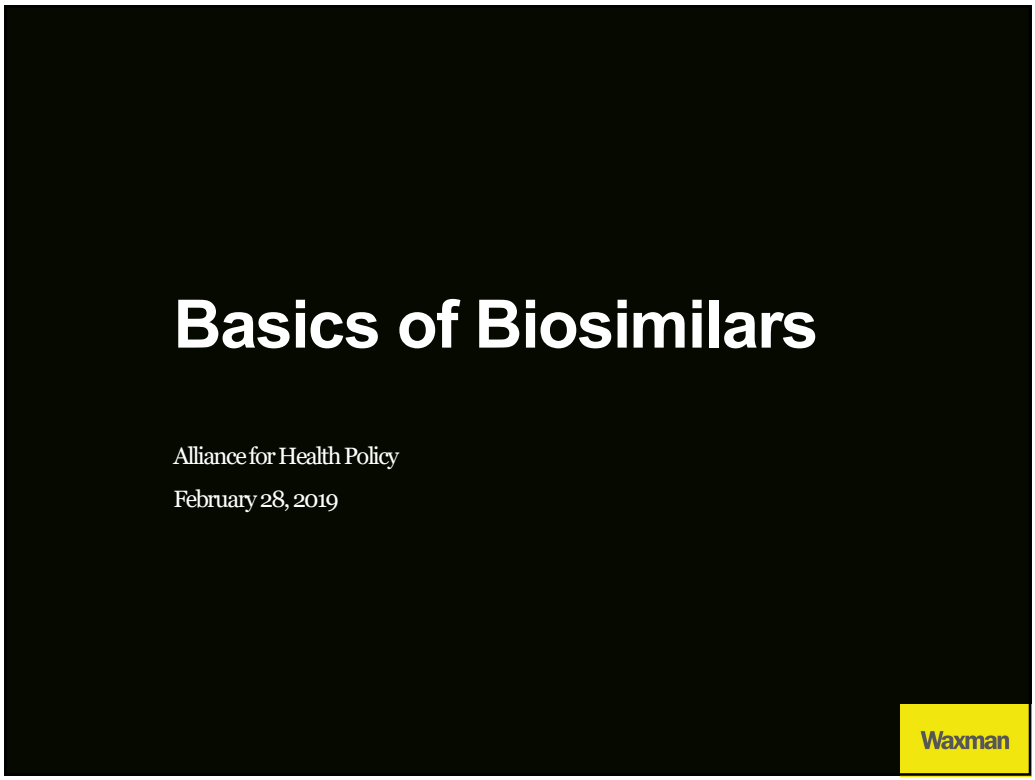
Basics of Biosimilars
Alliance for Health Policy
February 28, 2019
Waxman

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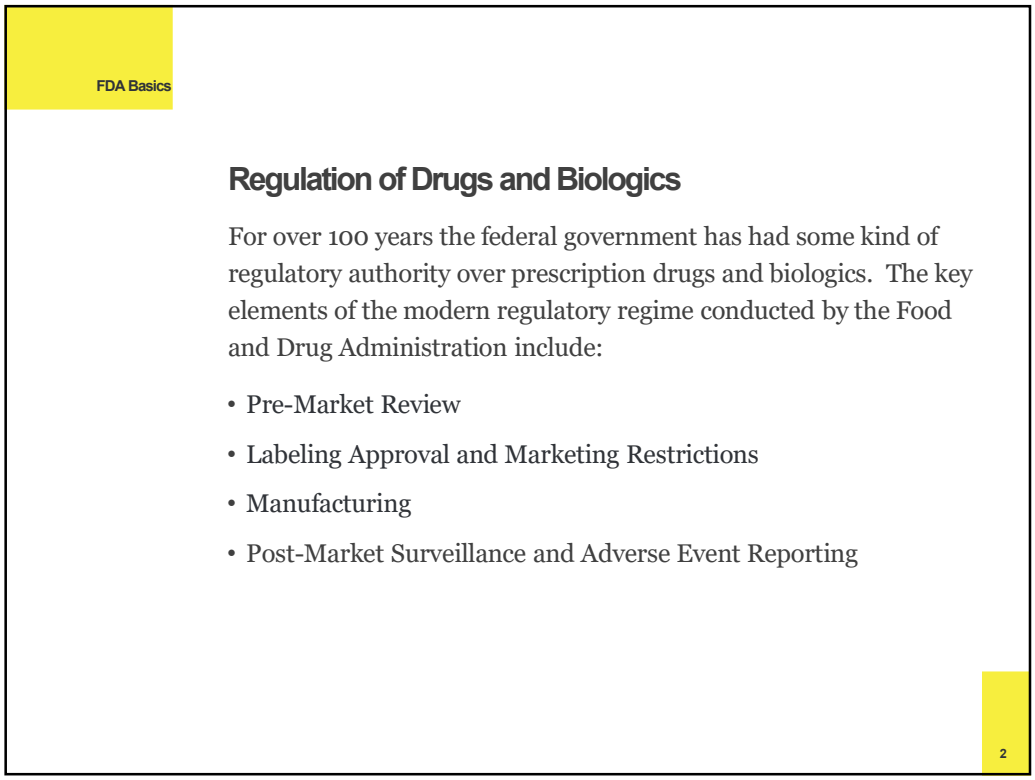
FDA Basics
Regulation of Drugs and Biologics
For over 100 years the federal government has had some kind of regulatory authority over prescription drugs and biologics. The key elements of the modern regulatory regime conducted by the Food and Drug Administration include:
• Pre-Market Review
• Labeling Approval and Marketing Restrictions
• Manufacturing
• Post-Market Surveillance and Adverse Event Reporting
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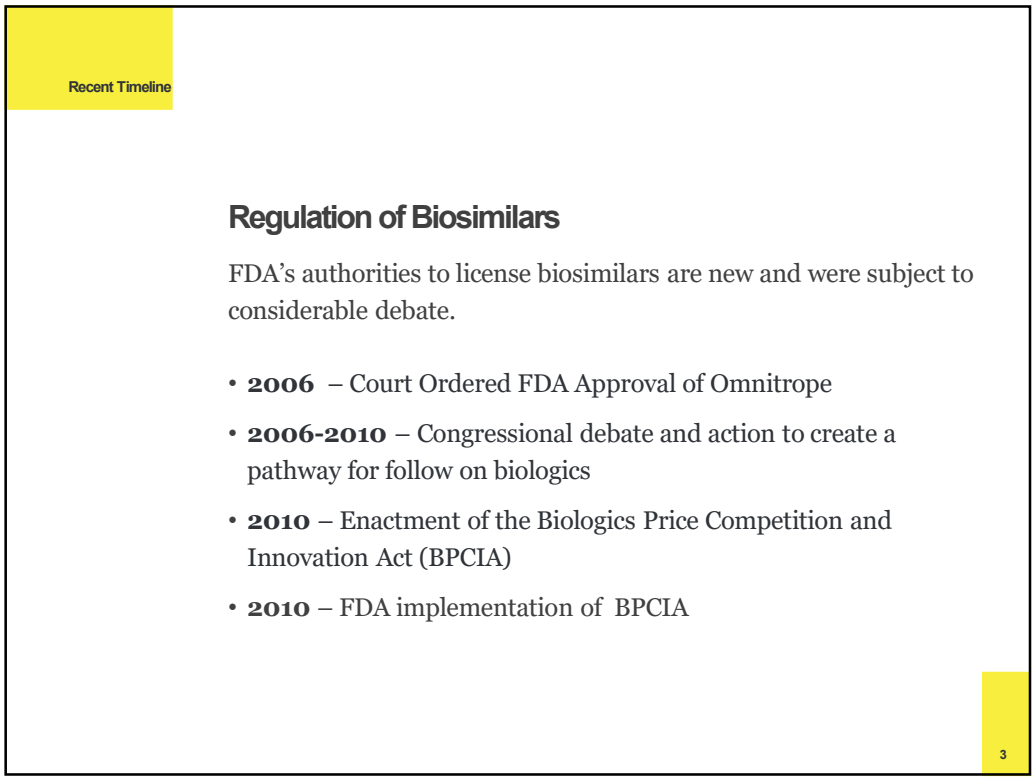
Recent Timeline
Regulation of Biosimilars
FDA's authorities to license biosimilars are new and were subject to considerable debate.
• 2006 – Court Ordered FDA Approval of Omnitrope
• 2006-2010 – Congressional debate and action to create a pathway for follow on biologics
• 2010 – Enactment of the Biologics Price Competition and Innovation Act (BPCIA)
• 2010 – FDA implementation of BPCIA
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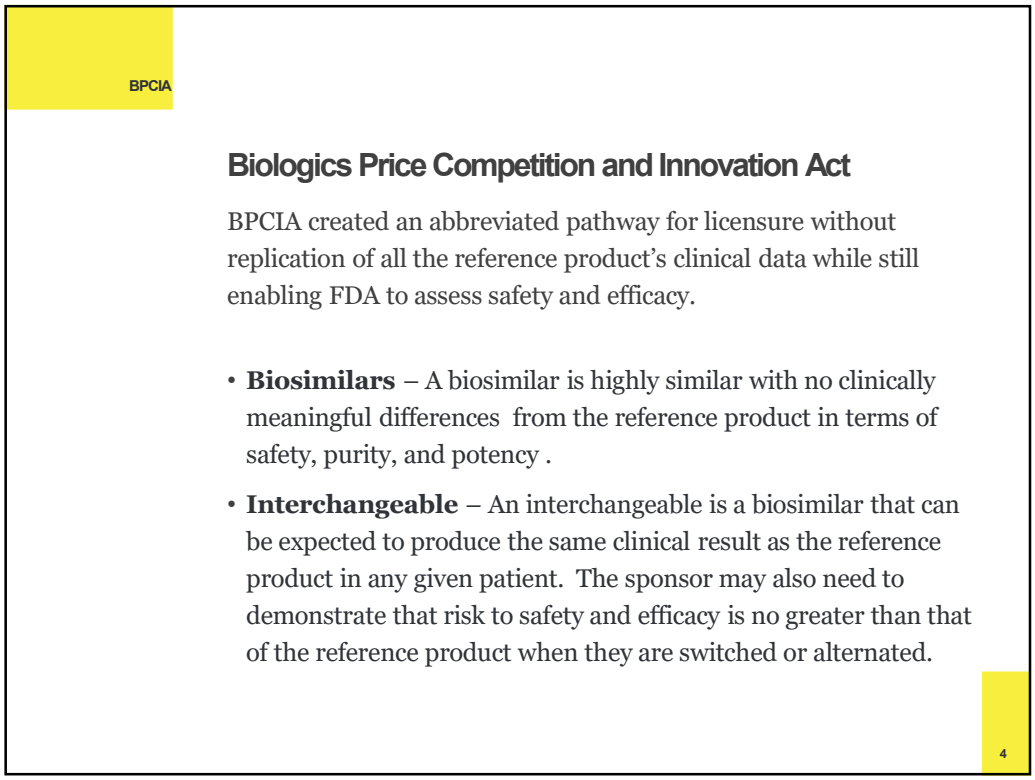
BPCIA
Biologics Price Competition and Innovation Act
BPCIA created an abbreviated pathway for licensure without replication of all the reference product's clinical data while still enabling FDA to assess safety and efficacy.
• Biosimilars – A biosimilar is highly similar with no clinically meaningful differences from the reference product in terms of safety, purity, and potency .
• Interchangeable – An interchangeable is a biosimilar that can be expected to produce the same clinical result as the reference product in any given patient. The sponsor may also need to demonstrate that risk to safety and efficacy is no greater than that of the reference product when they are switched or alternated.
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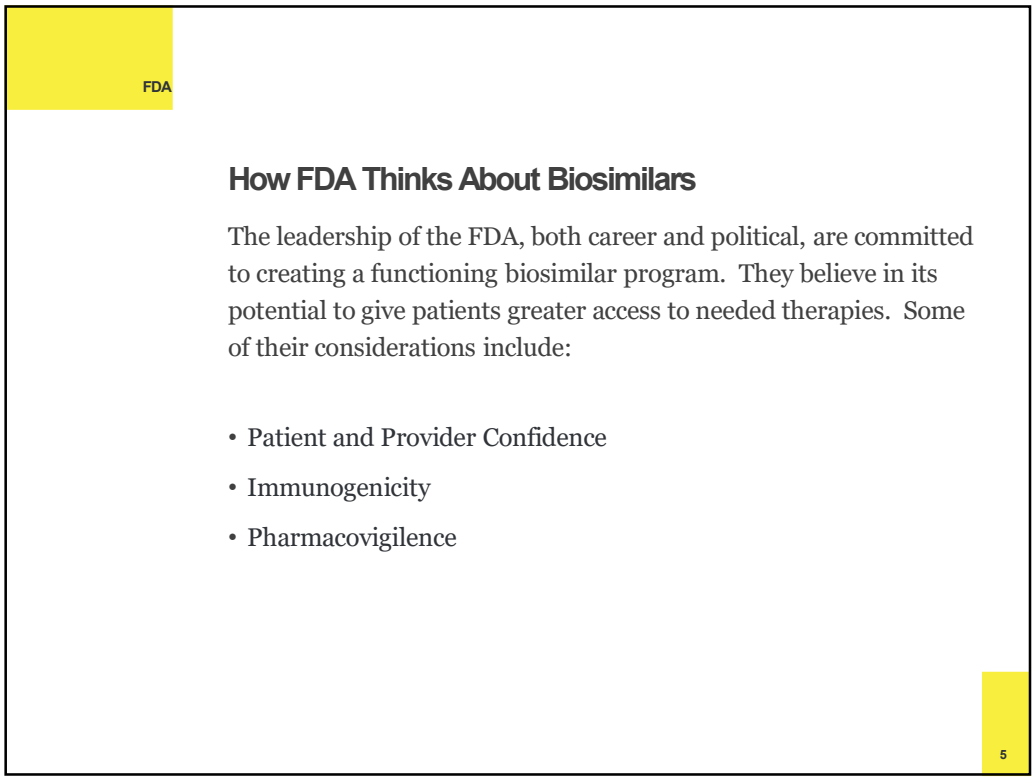
FDA
How FDA Thinks About Biosimilars
The leadership of the FDA, both career and political, are committed to creating a functioning biosimilar program. They believe in its potential to give patients greater access to needed therapies. Some of their considerations include:
• Patient and Provider Confidence
• Immunogenicity
• Pharmacovigilence
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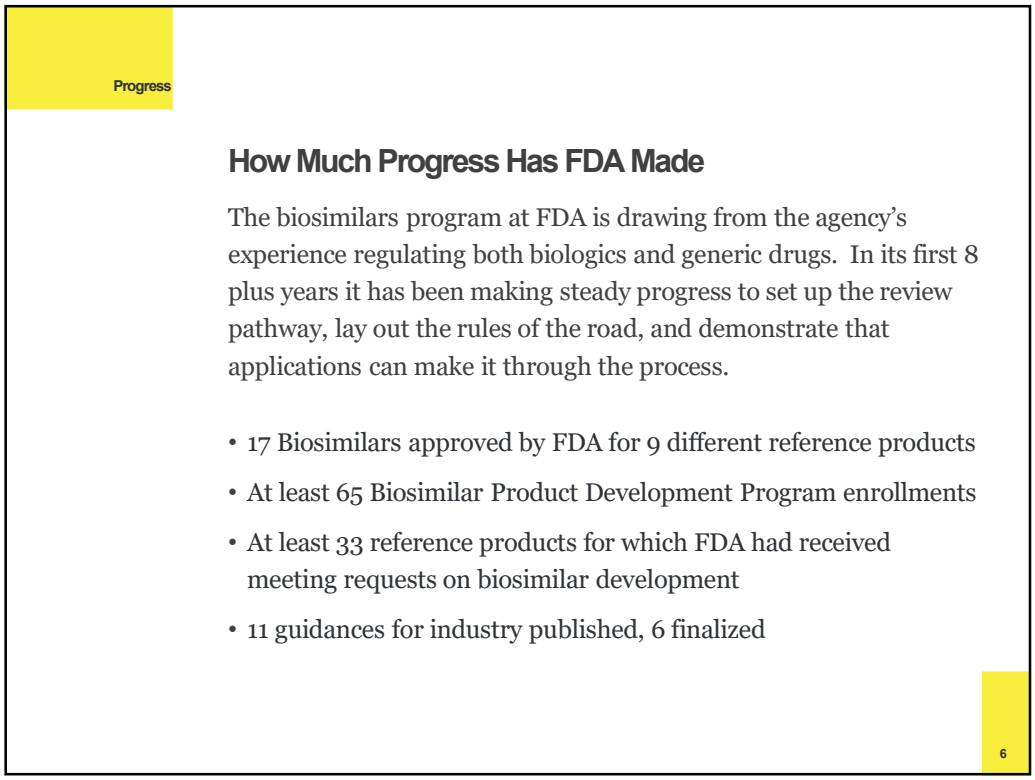
Progress
How Much Progress Has FDA Made
The biosimilars program at FDA is drawing from the agency's experience regulating both biologics and generic drugs. In its first 8 plus years it has been making steady progress to set up the review pathway, lay out the rules of the road, and demonstrate that applications can make it through the process.
• 17 Biosimilars approved by FDA for 9 different reference products
• At least 65 Biosimilar Product Development Program enrollments
• At least 33 reference products for which FDA had received meeting requests on biosimilar development
• 11 guidances for industry published, 6 finalized
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BAP

The Biosimilar Action Plan

In July of 2018, Commissioner Scott Gottlieb announced his Biosimilars Action Plan (BAP) to "help create a more competitive market…" This follows on the Drug Competition Action Plan unveiled the year before.

- Making product development and approval more efficient
- Increasing scientific and regulatory clarity
- Developing effective communications with patients, providers, and payors
- Reducing gaming of FDA requirements to delay competion

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Questions

Questions Policy Makers Should Be Thinking About

As Congress and the Administration consider how to address high drug prices and explore how to increase the availability and uptake of biosimilars and interchangeables there some questions they should seek the answers to:

- What is the biggest obstacle to the marketing of biosimilars? Regulation? Litigation? Reimbursement?
- Has FDA correctly assessed the risk profile of these products?
- Has FDA established the the correct review standards?
- What are the scientific uncertainties that stand most in the way of efficient review of product applications?

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