

Biologics and Biosimilars: *Reflections on the Past, Present, and Future*

GRx&Biosims

November 4, 2019

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Director (Acting)

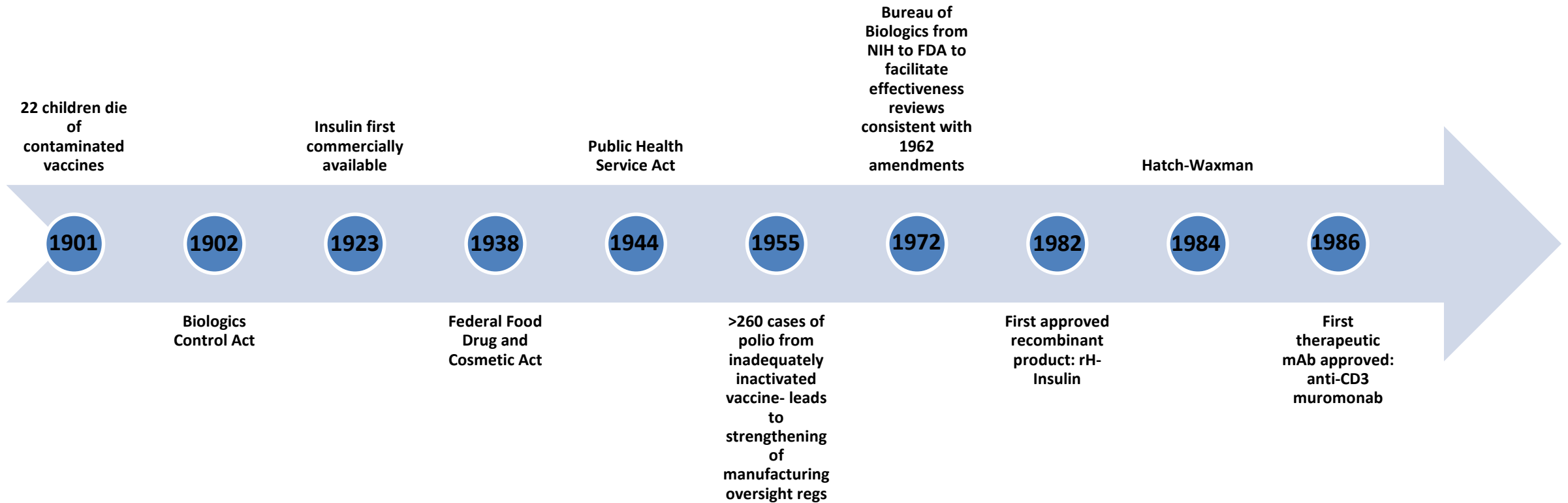
Office of Therapeutic Biologics and Biosimilars

OND/CDER/FDA/DHHS



U.S. FOOD & DRUG
ADMINISTRATION

Brief History of Biologics Regulation



Brief History of Biologics Regulation



22 children die of contaminated vaccines

1901



President Franklin D. Roosevelt and three polio patients in Warm Springs, Georgia, 1925

Courtesy of National Archives and Records Administration

Courtesy of Pfizer, Inc.

1955

>260 cases of polio from inadequately inactivated vaccine- leads to strengthening of manufacturing oversight regs

1972

Bureau of Biologics from NIH to FDA to facilitate effectiveness reviews consistent with 1962 amendments

1982

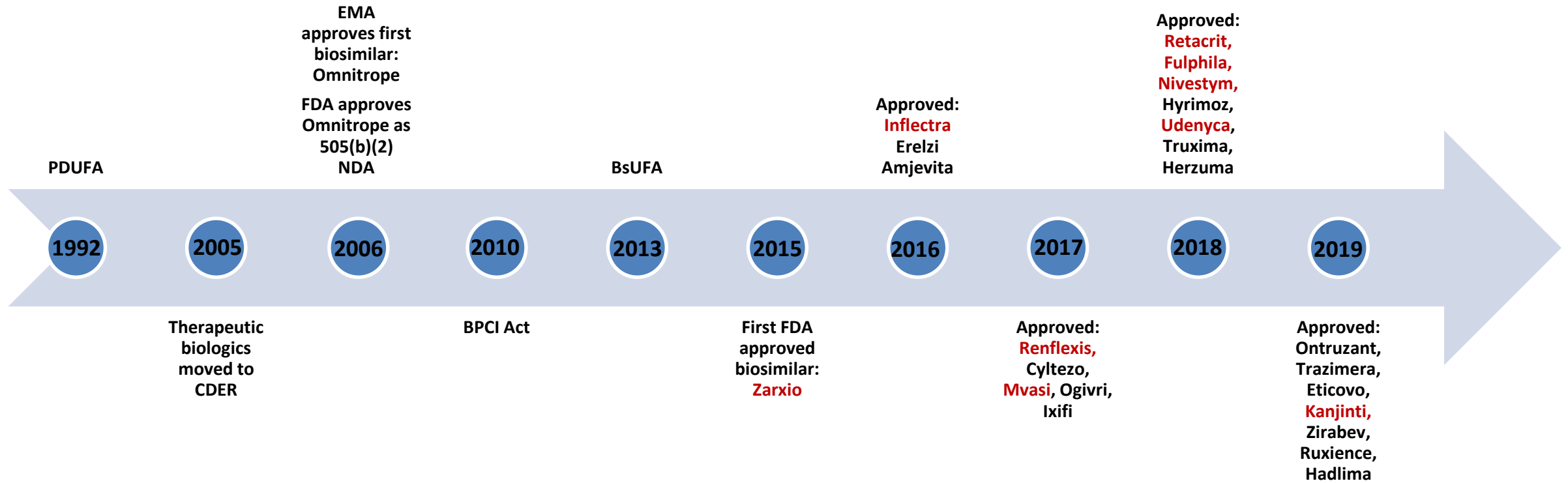
First approved recombinant product: rH-Insulin



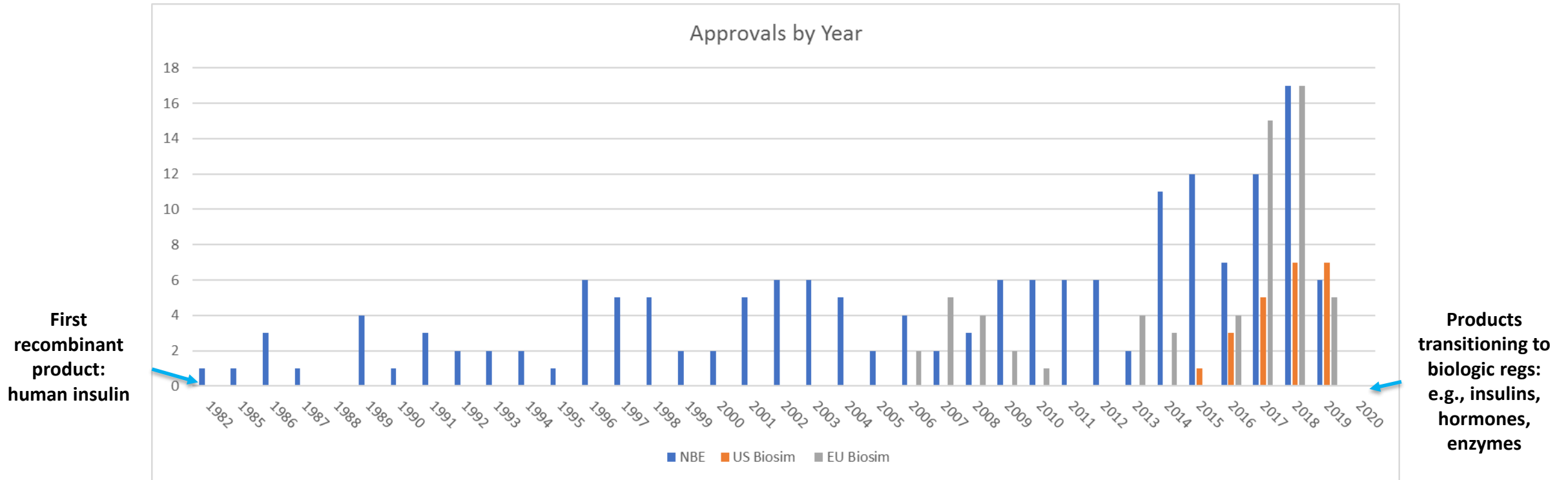
Generic drugs and brand name drugs - your body can't tell the difference. But your pocket will know... because generics **COST LESS!**

LEARN MORE: Write: GENERICS, Box 2000-P, Albany, NY 12220

Brief History of Biologics Regulation

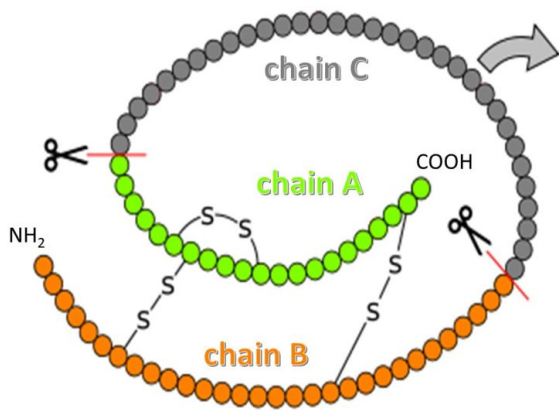


Biologics and Biosimilars: Looking Forward

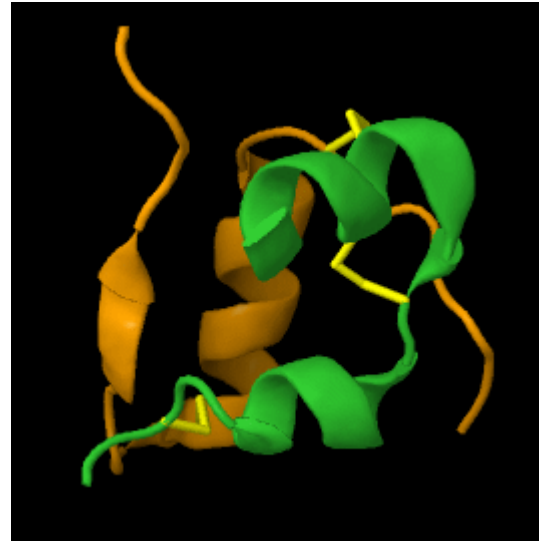


- Per BPCI Act, March 23, 2020: Biologics approved under the drug regulations will begin to be regulated as biologics

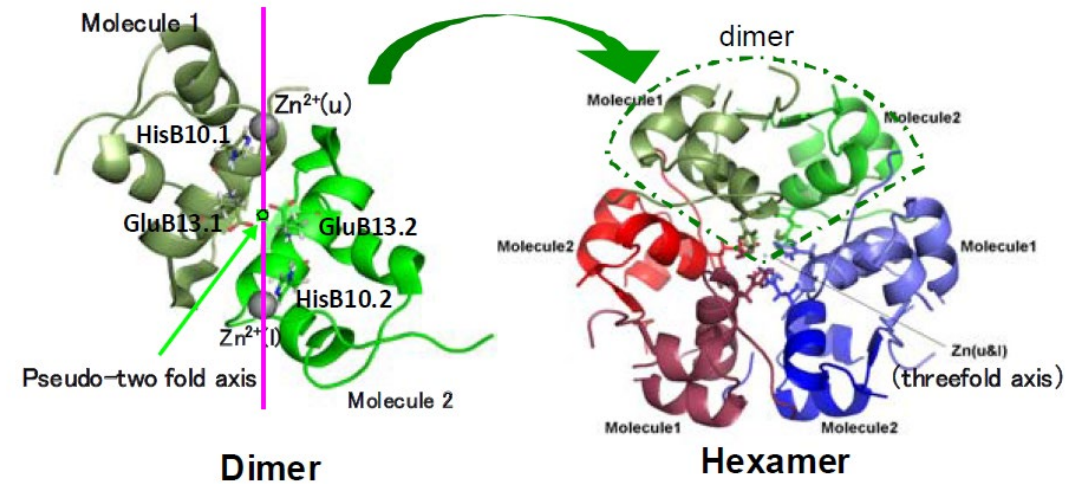
The Spectrum of Biologic Complexity: Insulin



Pro-Insulin
 Chain A=Green;
 Chain B=Orange
 S-S = disulfide bridges

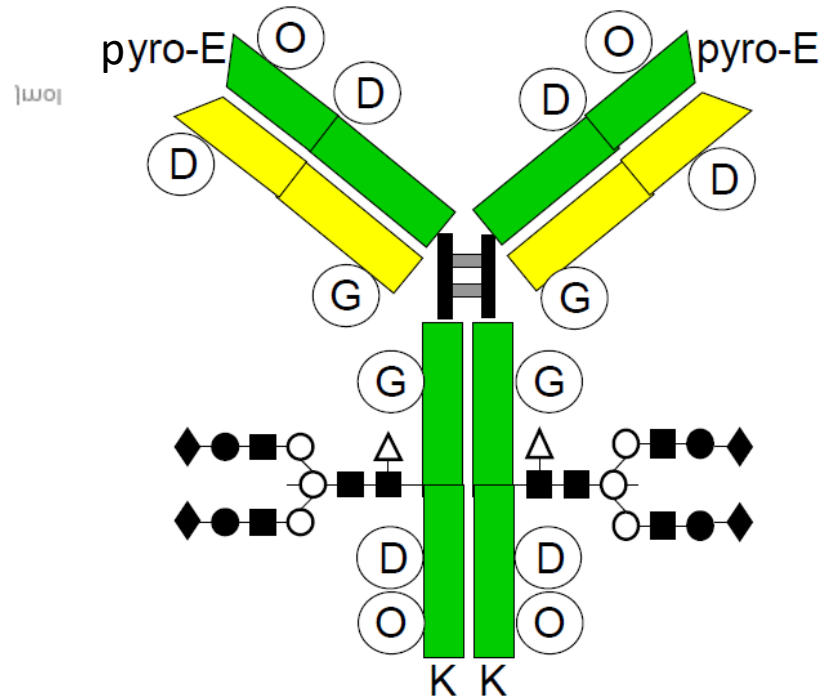
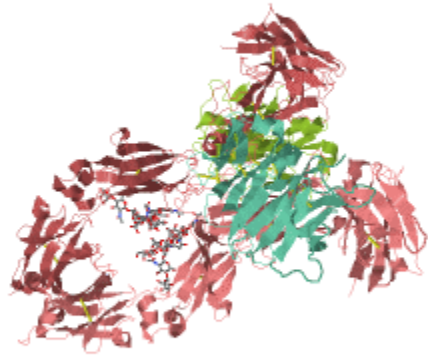


Insulin
 Chain A=Green (21 aa);
 Chain B=Orange (30 aa)
 Yellow=disulfide bridges
 Nonglycosylated



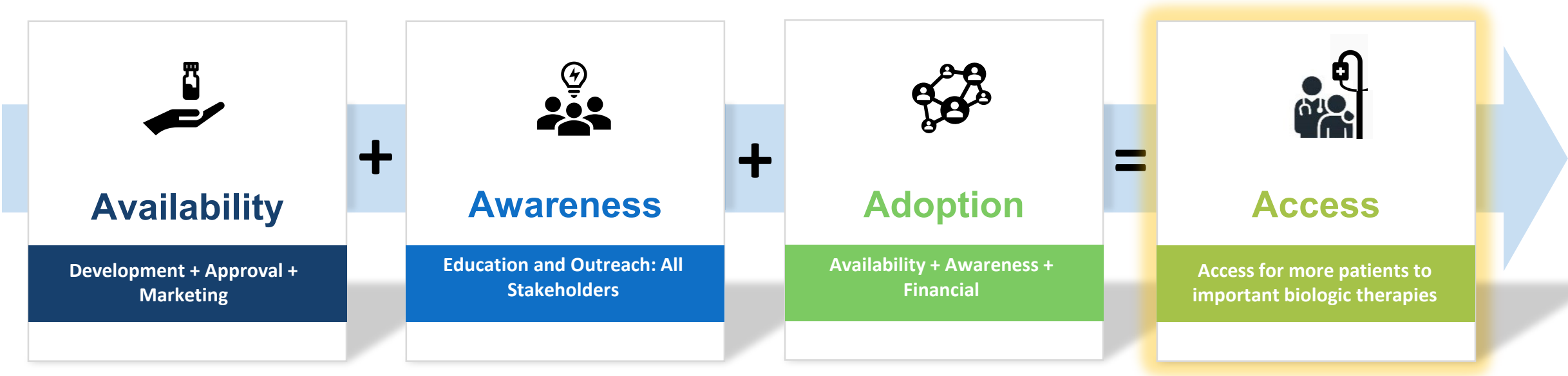
Structure: Simple
 Complexity: tendency to aggregate and immunogenicity

The Spectrum of Biologic Complexity: mAbs



- Structure: Complex
- Additional Complexity: “add-ons” and modifications to certain amino acids
- Result: Millions of slightly different versions of the same antibody per dose or batch
- Biosimilars try to match the patterns and variations of the reference product

Solving The Equation for Patient Access



Biosimilars Action Plan (BAP)

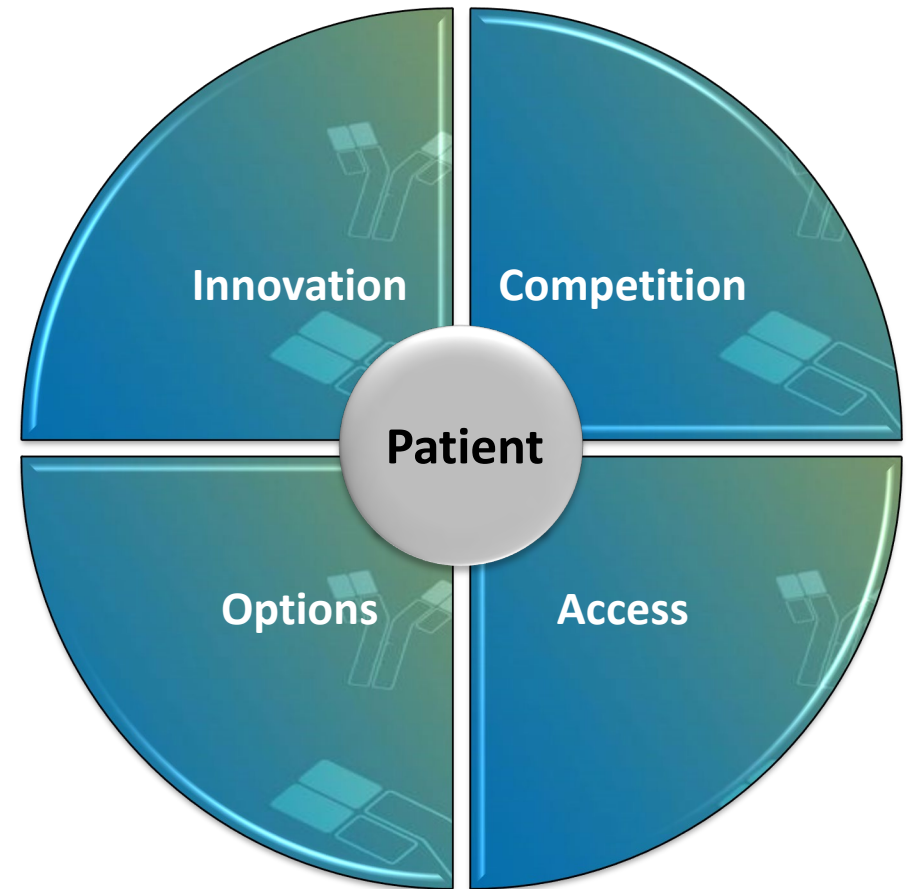
1. Improving the efficiency of the biosimilar and interchangeable product development and approval process
2. Maximizing scientific and regulatory clarity for the biosimilar product development community
3. Developing effective communications to improve understanding of biosimilars among patients, clinicians and payors
4. Supporting market competition by reducing gaming of FDA requirements or other attempts to unfairly delay competition

BIOSIMILARS ACTION PLAN:
Balancing Innovation
and Competition

July 2018

The Promise of Biosimilars

- More treatment options for patients
- Greater access to life-saving drugs
- Potential increases in market competition that will drive down cost



References/Sources



- Slide 2:
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 - <https://discoverysedge.mayo.edu/2015/06/17/a-line-in-the-sand-mayo-clinics-role-in-insulin-research-2/>
- Slide 6:
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 - Antibody Figure: C. Downey, FDA