SafeBiologics
ALLIANCE for SAFE BIOLOGIC MEDICINES

Why Should Pharmacists Care About Biosimilars?

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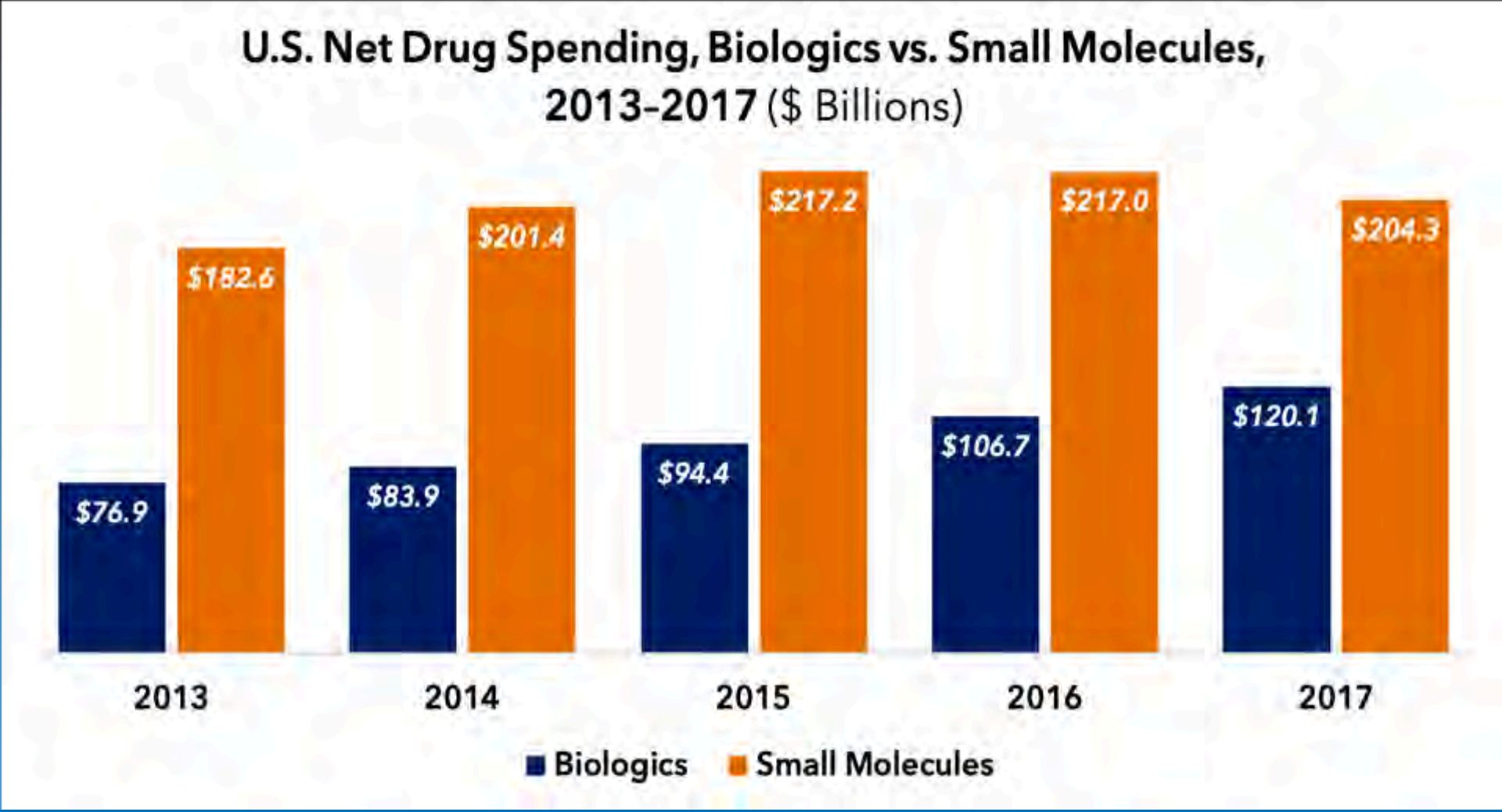
1. Concern About Rising Drug Costs

Spending on Biologics is a Major Driver of Rising Drug Costs

- In 2017, according to data from the IQVIA Institute, biologic drugs represented 2 percent of all U.S. prescriptions, but 37 percent of net drug spending.
- Since 2014, biologic drugs account for nearly all (93%) of the growth in net drug spending.



Source: https://www.forbes.com/sites/theapothecary/2019/03/08/biologic-medicines-the-biggest-driver-of-rising-drug-prices/#4eb0164b18b0

2. Promise of Savings from Biosimilars

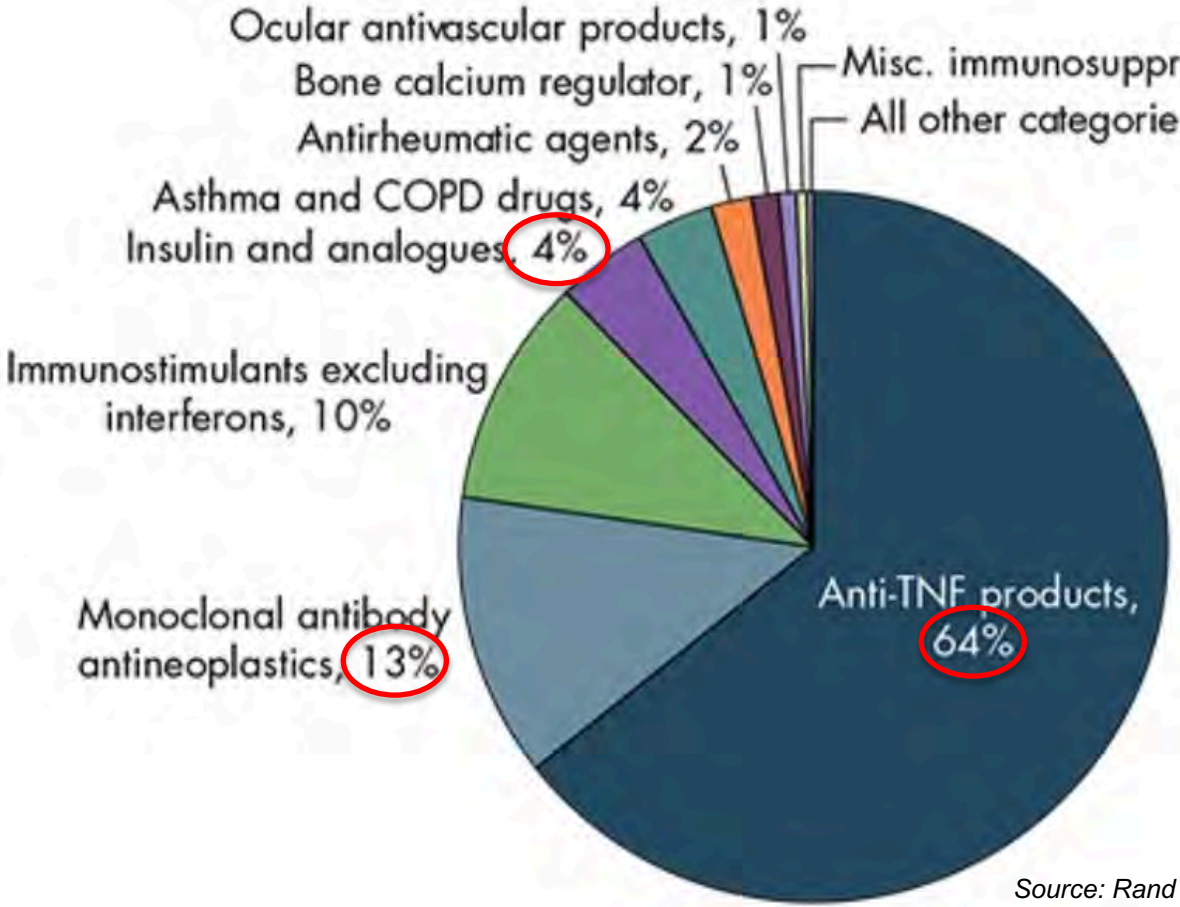
RAND Corporation Estimate, March 2018

"We estimate that biosimilars will reduce direct spending on biologic drugs by $54 billion from 2017 to 2026, or about 3 percent of total estimated biologic spending over the same period."

"…actual savings will hinge on industry and regulatory decisions as well as potential policy changes to strengthen the biosimilar market."

Source: Rand Health Q. 2018 Mar; 7(4): 3; Published online 2018 Mar 30.

RAND Savings Estimates Vary Widely by Product Category:



Anti-TNF: 64% savings

Cancer MAbs: 13% savings

Insulins: 4%

Source: Rand Health Q. 2018 Mar; 7(4): 3; Published online 2018 Mar 30.

3. Generic Drug Fallacy

Biosimilar Discounts are Lower than Generic Discounts

- Typically biosimilars in the U.S. have a discount of 15-20% off the price of the reference product.
- By contrast, generic versions of small molecule drugs typically launch with an 80%-90% discount over the originator.
- In Europe, biosimilar discounts can be somewhat higher (30-50%) after **availability of multiple products** drive prices down.

Note: In the case of a sole tender, however, this price competition can favor the originator manufacturer at the expense of biosimilar market (Norway example)

“Biosimilars are not generics, and there are important differences between biosimilars and generic drugs.”

Source: https://www.fda.gov/drugs/biosimilars/biosimilar-and-interchangeable-products

FDA: Differences Between Biosimilars and Generics

- "the active ingredients of generic drugs are the same as those of brand name drugs. In addition, the manufacturer of a generic drug must demonstrate that the generic is bioequivalent to the brand name drug."
- "By contrast, biosimilar manufacturers must demonstrate that the biosimilar is highly similar to the reference product, except for minor differences in clinically inactive components."
- "Biosimilar manufacturers must also demonstrate that there are no clinically meaningful differences between the biosimilar and the reference product in terms of safety and effectiveness."

Source: https://www.fda.gov/drugs/biosimilars/biosimilar-and-interchangeable-products

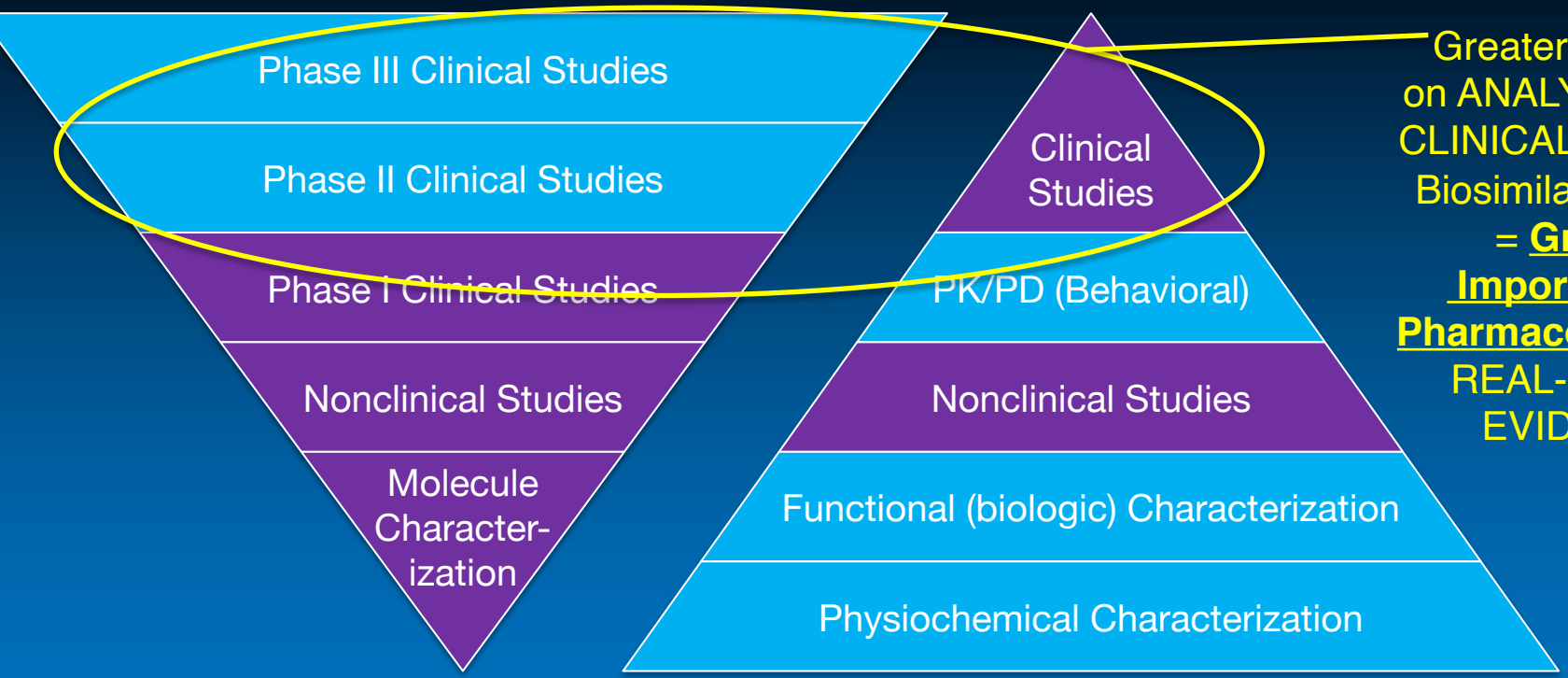
4. Abbreviated Approval Pathway

"[An abbreviated approval pathway] allows for a potentially shorter and less costly drug development program for a biosimilar."

- INDICATION EXTRAPOLATION
  "a biosimilar product may be approved for an indication without direct studies of the biosimilar in that indication. "
- If the total evidence in the biosimilar application supports a demonstration of biosimilarity for at least one of the reference product's indications, then it is possible for the biosimilar manufacturer to use data and information to scientifically justify approval for other indications that were not directly studied by the biosimilar manufacturer.
- [Indication Extrapolation] "is critical to the goals of an abbreviated pathway—improving access and options at a potentially lower cost."

Source: https://www.fda.gov/drugs/biosimilars/biosimilar-and-interchangeable-products

Approval Process for Biosimilars (US and EU)



Greater Reliance on ANALYTICS over CLINICAL TRIALS in Biosimilar Pathway = **Greater Importance of Pharmacovigilance**, REAL-WORLD EVIDENCE

Size of Pyramid = "Quantity" of Effort

Greater Regulatory Emphasis

Less Regulatory Emphasis

5. Declining Autonomy of Health Professionals

Challenges to Autonomy of Health Professionals

- Third parties, e.g., PBMs, insurers, P&T committees, governments dictating medication choice rather than clinicians working with patient
- Distortions to treatment-decision making processes:
  - Gag orders
  - Preferential treatment of one product over others
  - Financial incentives, Gain-sharing

6. Impact on Pharmacy

Declining Autonomy of Pharmacists

Professional Autonomy (FIP Definition):

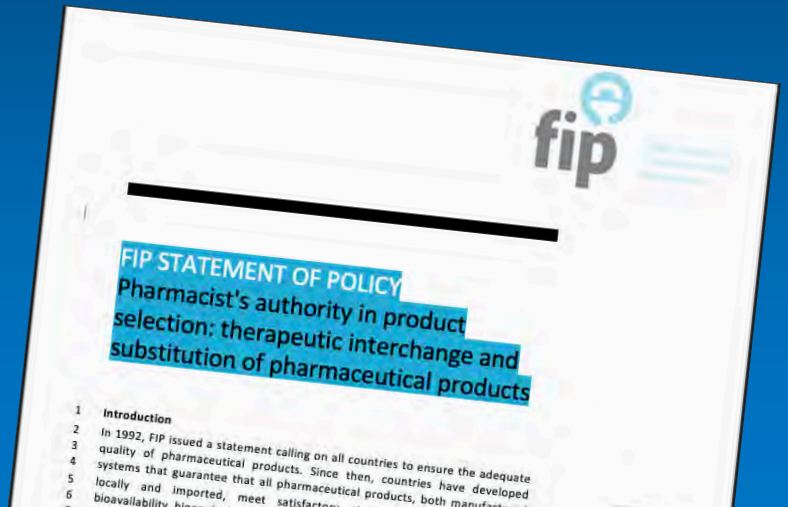
The right and privilege granted by a governmental authority to a class of professionals, and to each licensed individual within that profession, to exercise independent, expert judgment within a legally defined scope of practice, to provide services in the best interests of the client.

FIP Statement of Policy: Pharmacist Authority in Product Selection

"It is time for truth-telling in pharmacy with respect to:

1. the **limited professional role** of most pharmacists
2. the **conflict in mission** between corporations (which are accountable to stockholders) and the profession of pharmacy (which is accountable to society)
3. pharmacist-owned pharmacies that **do not put the needs of patients first**.

As a profession, pharmacy has a covenant with society, and its practitioners must behave appropriately to preserve the public's trust and to preserve their autonomy. "



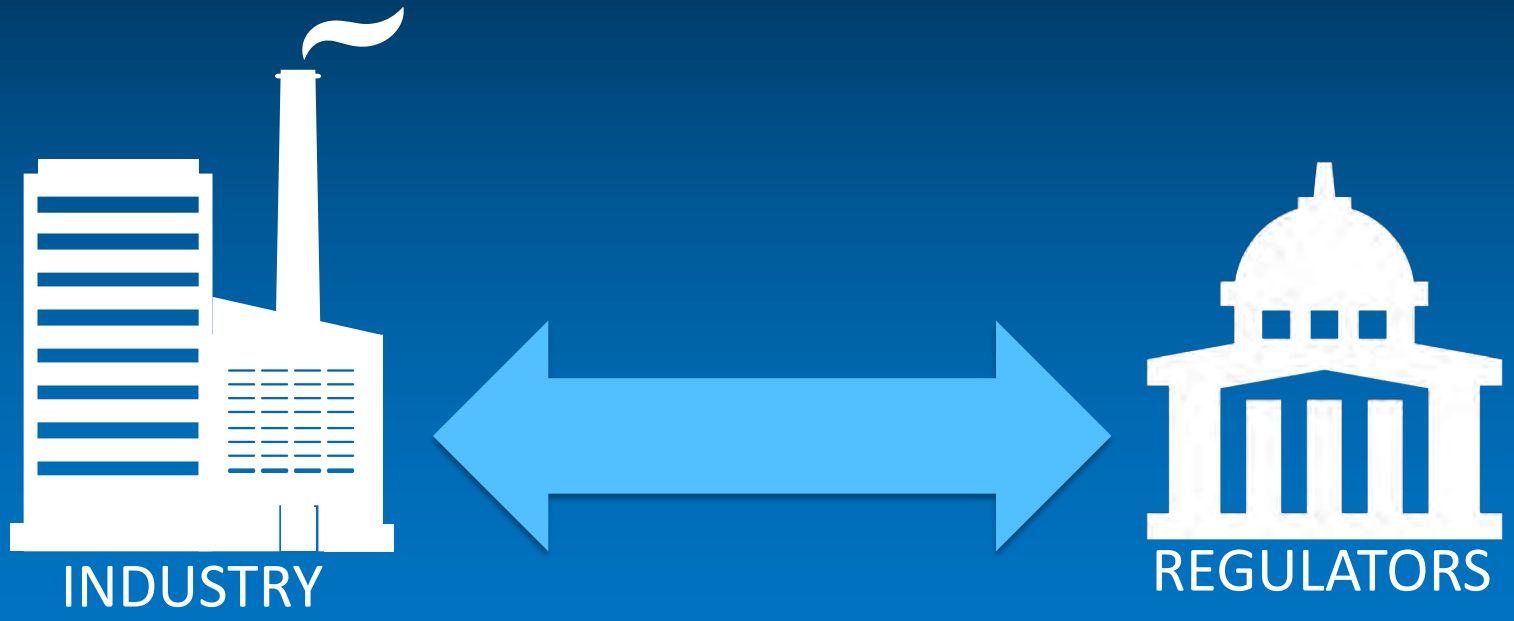
7. Strategic Issues for Health Professionals

Domains of Selecting a Medicine

The Role of Health Care Professionals

- There are PATIENT- SPECIFIC SITUATIONS that cannot be competently made for large populations of patients, which is the only approach a REGULATOR can take.
- HEALTH CARE PROFESSIONALS (including prescriber and pharmacists) acting on behalf of their patient can more competently evaluate issues of effectiveness and safety, while duly considering the responsible use of limited resources (i.e., cost).

As it stands now, it is a standoff between the industry and regulators, with the healthcare professionals and patients being left out of the discussion.



A better model might be:

8. Policy Implications Related to Biosimilars

Biosimilar Markets in Europe

- A leader in biosimilar approvals, Europe has 80% of the worlds biosimilars, and relatively high uptake rates compared to the rest of the world.
- Market share in Europe for biosimilars varies by country and product class.
- For those approved after 2013 it ranges between 0% and 43%, and from 5% to 91% with older products.
- The vast majority of countries leave the decision on what biologic medicine to use with the prescriber, in consultation with their patient.
- **Competition and prescriber choice** are cited by many analyses to be key factors in Europe's success.

Creating Conditions for a Healthy Biologics and Biosimilars Market:

- Cost control resulting from **competition in the marketplace.**
- **Innovation** that requires investment and a return on investment.

A Need for Alternative and more Innovative Payment Models?

Alternatives to the “cost/pill” price point tendering model

- Louisiana HIV treatment model where **income security for the industry** for the total cost of care is used instead of the traditional price point tendering system
- ”Value-based” contracts where reimbursement depends on response to therapy
- Annual ”installment” payments over time (e.g., 5 years)

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Thank You For Your Attention