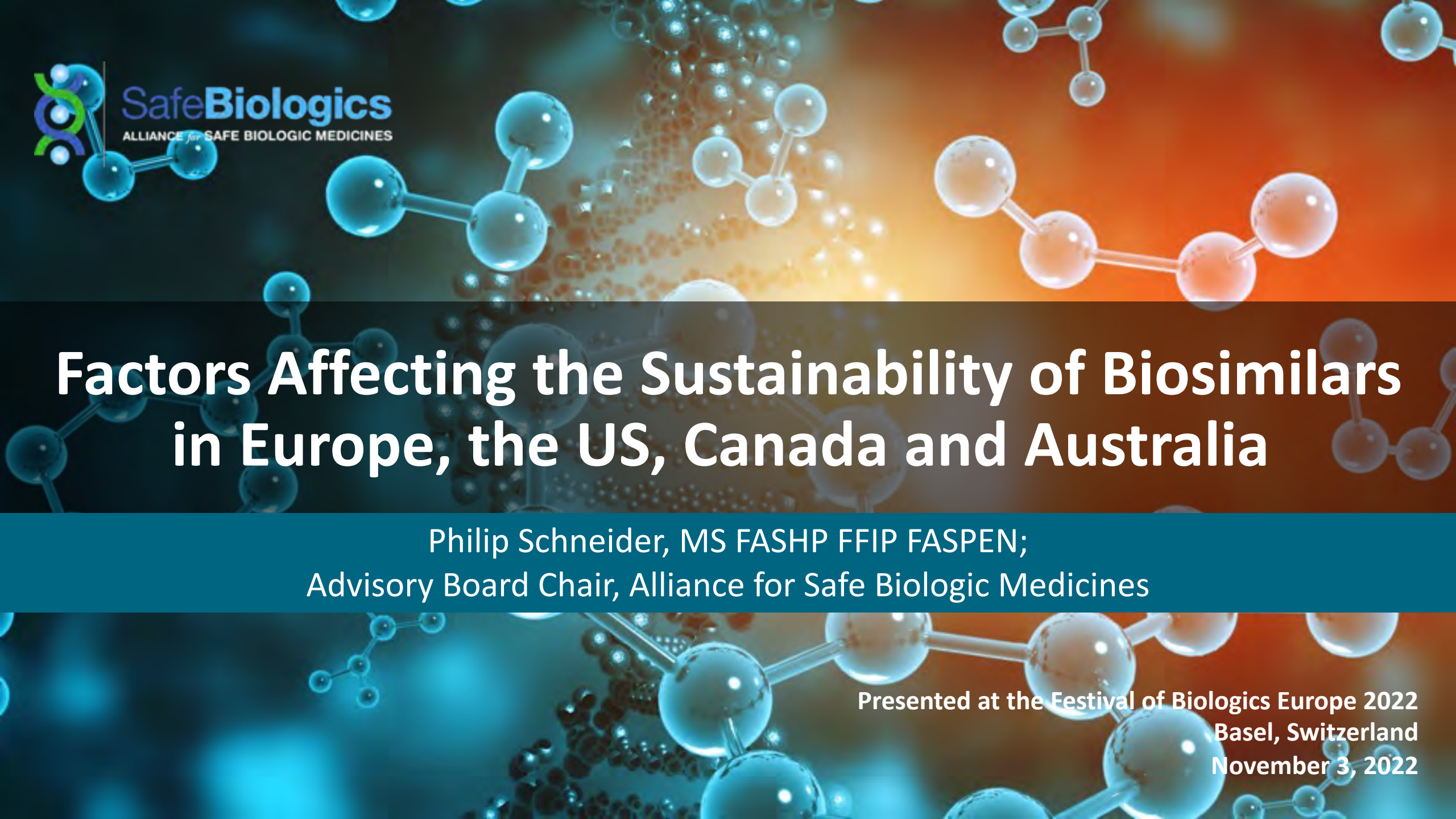


Factors Affecting the Sustainability of Biosimilars in Europe, the US, Canada and Australia

Philip Schneider, MS FASHP FFIP FASPEN;
Advisory Board Chair, Alliance for Safe Biologic Medicines

Presented at the Festival of Biologics Europe 2022
Basel, Switzerland
November 3, 2022

Introduction

- **Philip Schneider, MS, FASHP, FFIP**
- Advisory Board Chair, Alliance for Safe Biologic Medicines
- Past Vice President, International Pharmaceutical Federation (FIP)
- Past-President, American Society of Health-system Pharmacists
- Professor of Pharmacy, Ohio State University

Components of Sustainable Biosimilar Markets: Learning from Europe

Learning from European Biosimilar Markets

- **Largest biosimilar market in the world, about 60% of the global biosimilar market. As of June 2022, 70 biosimilars of 15 originator biological medicines have marketing authorization in Europe. (~50 unique products, under different brands)**
- **Biosimilar market share as high as 91% for older products (before the approval of the first monoclonal antibody biosimilar in 2013) and as high as 43% for newer products (approved post-2013)**
- **European countries, with their large biosimilar markets and diverse healthcare systems, serve as valuable examples of different approaches to biosimilar policy.**

Whitepaper: "Policy Recommendations for a Sustainable Biosimilars Market: Lessons from Europe"

- Generics and Biosimilars Initiative Journal (GaBI Journal). Published in: Volume 9 / Year 2020 / Issue 2
- Authors: Michael S Reilly, Esq, Professor Philip J Schneider, MS, FASHP, FASPEN, FFIP
- Analyzed the different approaches to biosimilar policy across Europe
- <u>OBJECTIVE: identify principles which can be applied to develop an efficient and sustainable biosimilar market.</u>

The European Paper examined findings and recommendations of five previous studies and reports on biosimilar sustainability in Europe.

2014: *GfK Market Access/European Generics Association (EGA) (now Medicines for Europe)*

2015: *European Federation of Pharmaceutical Industries and Associations (EFPIA)*

2016: *Simon & Kucher/ Medicines for Europe report: "Payers' price & market access policies supporting a sustainable biosimilar medicines market."*

2018*: IQVIA; Advancing Biosimilar Sustainability in Europe; commissioned and funded by Pfizer.*

2019*: Patch Consilium study "Towards a sustainable European market for off-patent biologics", commissioned and funded by EFPIA.*

medicines for europe
better access. better health.

efpia
European Federation of Pharmaceutical Industries and Associations

IQVIA


There are differences in biosimilar policy within the 28 EU Member States and the three European Economic Area (EEA) countries…

- Different supply and/or demand-side incentives
- Different degrees of competition
- Determined either at the national, regional or hospital level, or a mixture of these.
- Independent of the kind of policy which is pursued, data suggest that biosimilar price and use also depends on therapeutic area and the time the biosimilar has been on the market.

National Tender Markets

NORWAY and DENMARK are the only European countries to pursue a national tender policy for biosimilar products such as adalimumab, etanercept, or infliximab.

- DENMARK will only reimburse the manufacturer with the lowest bidding price for a particular molecule, for a 12-month period. This potentially requires physicians to switch patients every 12 months.
- NORWAY also engages in a tender process. However, the choice is ultimately left to the physician and all lower ranked products are still reimbursed if prescribed, i.e. switching is not explicitly mandated as it is in Denmark. Tenders in Norway tend to be in effect for one year.

Across All European Markets, Biosimilars Have:

1. **Increased competition**
2. **Reduced unit cost of both originator and biosimilars** compared to price levels prior to the arrival of biosimilars
3. Increased volume consumption of molecules with biosimilar competition thus **expanding market access** and optimizing patient dosing
4. **Alleviated budget pressures** by providing headroom to fund novel treatment solutions.

Common Principles Across European Markets:

While the policies by which this has been achieved vary between countries, all major European markets share the following principles:

1. Automatic substitution for biologicals is forbidden.
2. All approved biologicals, i.e. originators and their biosimilars, are available on the market and are reimbursed when prescribed.
3. Reimbursement decisions on novel treatment solutions are independent from biosimilar use and uptake.
4. The time from market approval to first product sales for biosimilars is shorter than the time to first sales of novel medicines

The "Gold Standard": Six Principles

1. Policies should be designed to **incentivize and reward innovation** in all types of biologicals.
2. Healthcare financing must take into account **societal benefits derived from biological medicines,** as well as the **unique characteristics of biologicals**.
3. Procurement practices **must provide for multiple suppliers** and a minimum term of 12 months.
4. **Physicians must have autonomy to choose the most appropriate medicine for their patient, including making decisions on switching, which must also be consented to by the patient; no automatic substitution.**
5. Mandatory **brand- name prescribing** to avoid unintended switches and a **robust pharmacovigilance system** to report adverse drug reactions (ADRs).
6. **Policies with potential to undermine sustainability, such as measures which induce biosimilar uptake or promote preferential treatment, thereby limiting physician choice, should be avoided.**

Identified Three "Must-Have" Principles:

1. Physicians should have the **freedom to choose between off-patent originator biologicals and available biosimilars** and to act in the best interest of their patients based on scientific evidence and clinical experience.
2. Tenders should be designed to include **multiple value-based criteria beyond price**, e.g. education, services, available dose strengths, and **provide a sufficient broad choice** (multi-winner tenders versus single-winner tenders) to ensure continuity of supply and healthy competition.
3. A **level playing field** between all participating manufacturers is the best way to foster competition; mandatory discounts which place artificial downward pressure on manufacturers do not engender a sustainable market environment.

Potential Threats to Sustainable Markets

What Could Jeopardize A Market's Sustainability?

- **Prioritizing short-term savings at the expense of long-term savings resulting from competition**
- **Shortages due to an insufficient number of suppliers**
- **Undermining physician and patient confidence in biosimilars**

While countries seek to replicate Europe's success with biosimilars, some are ignoring the principles which made it possible…

FORCED-SWITCHING: CANADA

Some Canadian provinces (Alberta, British Columbia, Quebec, and New Brunswick, have begun to **forcibly switch** patients to the government-chosen biosimilar.

FORCED-SWITCHING: AUSTRALIA

The Australian government has also force-switched patients, including stage IV cancer patients. Reimbursement practices have caused manufacturers to cancel planned launches and even remove their products from the country.

In addition to raising concerns among patients and physicians, this may jeopardize the long-term sustainability of these countries' biosimilar markets.

Little Similarity to the Successful Policies of Europe…

- **While the European biosimilar experience was cited extensively by forced-switching proponents, These European governments achieved their success by:**
  - **AVOIDING automatic substitution**
  - **Preserving and EXPANDING rather than RESTRICTING patient/physician choice**
  - **Achieving savings through COMPETITION between MANY reimbursed products**

…the direct opposite of what is happening in Forced-Switching provinces.

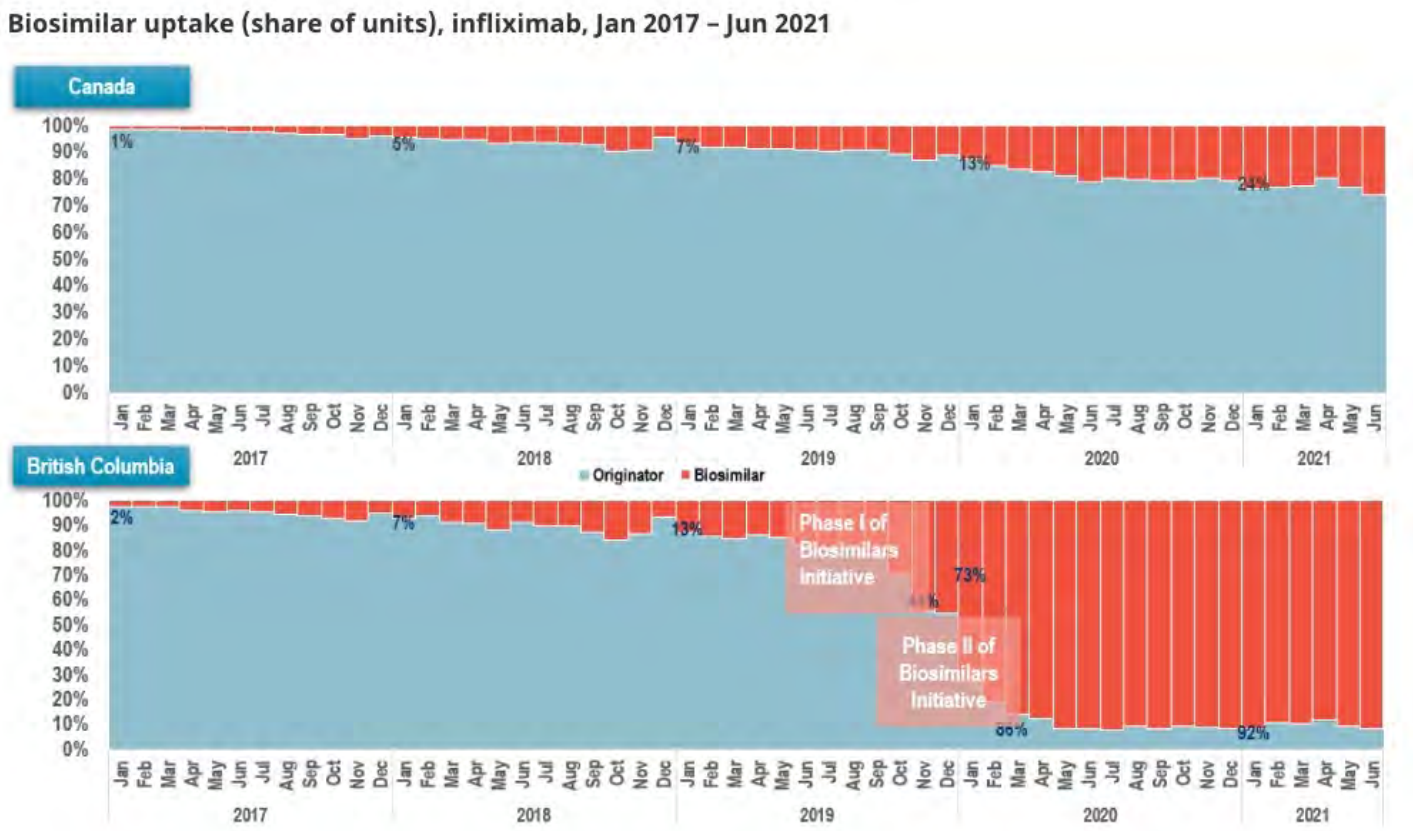
"B.C. is leading the country by promoting the widespread use of biosimilars, which have been proven to work just as safely and effectively as higher priced biologics. To date, Canada is far behind European jurisdictions."

-Adrian Dix, British Columbia Minister of Health, May 17, 2019

Sacrificing Long-Term Savings for Short-Term Savings

- **Little transparency (compared to tender systems in Norway, Denmark).**
- **Much of the savings biosimilars bring come from innovator products and additional biosimilars cutting prices to compete.**
- **Forced-switching artificially achieves high market share but loses any savings which would occur from competition.**
- **Substituting one monopoly for another?**

Organic growth of biosimilar infliximab uptake (Canada) vs. forced switching (BC)



https://www.canada.ca/en/patented-medicine-prices-review/services/npduis/analytical-studies/slide-presentations/biosimilars-cadth-2021.html

U.S. Biosimilar Market: A Snapshot

According to the FDA's Janet Woodcock, the savings from biosimilars was $2.5 billion in 2019, and **more than three times that much in 2020**.

- 38 Approved in the past 7 years, about 25 are on the market. At least 6 more arriving in 2023.
- Biosimilars launch at wholesale acquisition cost (WAC) 15% to 37% lower than their reference products and up to 40% below the reference product's average sales price (ASP).
- **In the US, biosimilars have gained significant share in the majority of therapeutic areas in which they have been introduced:**
- 80% for filgrastim biosimilars, 70% for trastuzumab and bevacizumab biosimilars, and 60% for rituximab biosimilars. 40% for pegfilgrastim and infliximab biosimilars.
- As more become available, the increased competition has **driven down prices of both biosimilars and innovator biologics.**

Price Competition: A Key Factor in Boosting Biosimilar Uptake

As in Europe, as more and more biosimilars launch in a given product class, competition drives prices downward, discounts increase, and biosimilar market share goes up:

- First U.S. filgrastim biosimilar launched with 15% discount over its reference product. Today, with increased competition, **its discount has increased to 35% and it has now attained a majority market share (55%).**
- First U.S. rituximab biosimilar launched at a 10% discount over its reference product. **A few months later the second launched at a larger, 24% discount to compete.**
- As it becomes routine to have 3, 4, or 5 biosimilars approved for a reference product we expect this trend- and savings- to continue.

https://www.pacificresearch.org/wp-content/uploads/2019/07/BiosimilarsCompetition_F.pdf
https://pharmaintelligence.informa.com/resources/product-content/teva-debuts-us-rituximab-at-a-10-discount
https://generics.pharmaintelligence.informa.com/GB149550/Pfizers-US-Rituximab-Launched-At-A-24-Discount

RAND 2022 Study: Most of Savings Will Come from Originators Dropping Prices

- Savings estimated to be $38.4 billion or 5.9% of projected total U.S. spending on biologics from 2021 to 2025, according to a new RAND Corporation study.

- More aggressive biosimilar uptake and competition could trigger larger cuts, with **savings estimated to be as large as $124.5 billion from 2021 to 2025 under the most-optimistic scenario**.

- **The study estimates that most of the expected savings from biosimilars would be caused by downward pressure on the brand-name biologics they compete with, rather than lower biosimilar prices**.

Chain Drug Review

Biosimilars could generate $38.4 billion in savings over five years

January 10, 2022 by Chain Drug Review

PRINT PDF EMAIL

NEW YORK — Biosimilar drugs could drive down prices for expensive medicines used to treat illnesses such as cancer and rheumatoid arthritis, with savings estimated to be $38.4 billion or 5.9% of projected total U.S. spending on biologics from 2021 to 2025, according to a new RAND Corporation study.

Switching in the US Biosimilar Market

- Biosimilars are attaining significant market share, and competition is creating savings.
- Physician and patient confidence in biosimilars is high, although there are **concerns about non-medical switching by third parties** (such as private health insurers or pharmacy benefit managers).
- Substitution laws at the state level, supported by patients, have attempted to address these concerns. Only “interchangeable” biosimilars can be automatically-substituted at the pharmacy level. These have provided additional data to the FDA demonstrating safe switching.
- State law also ensures that the prescribing physician is aware of any substitution that occurs, and only permit interchangeable biosimilars- which have provided more data- to be automatically substituted.
- The federal government- and many state governments- are working on legislation to restrict how and how often patients may be switched by private insurers (step therapy, etc.)

FDA Task Force on Drug Shortages

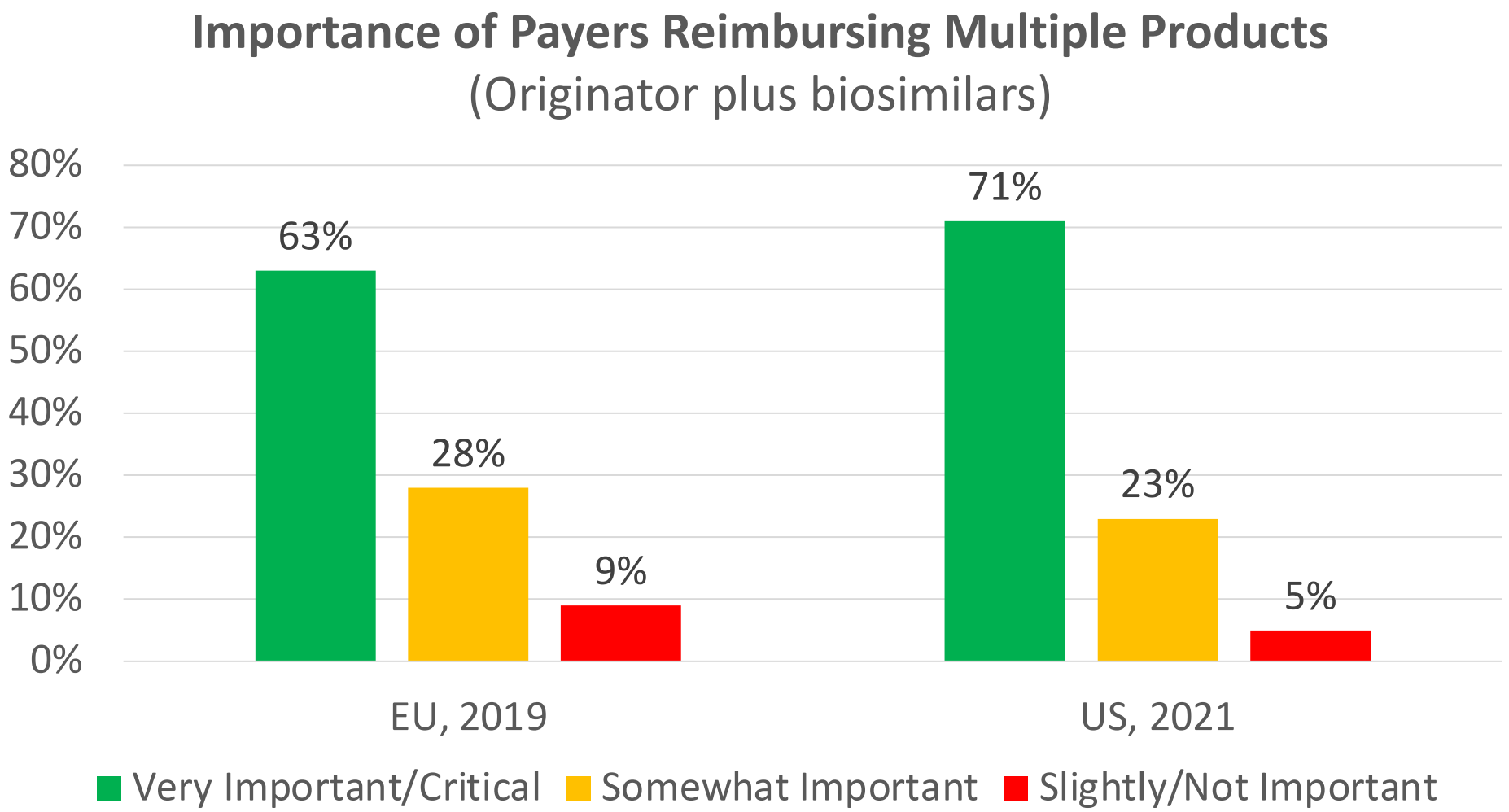
The 2019 report identifies three root causes for drug shortages:

1. Lack of incentives for manufacturers to produce less profitable drugs
2. The market does not recognize and reward manufacturers for "mature quality systems" that focus on continuous improvement and early detection of supply chain issues; and
3. Logistical and regulatory

<u>One proposed solution:</u>

"**Promoting sustainable private sector contracts** (e.g., with payers, purchasers, and group purchasing organizations) to **<u>make sure there is a reliable supply of medically important drugs.</u>**"

Physicians Agree: Choice Between Multiple Products is Critical



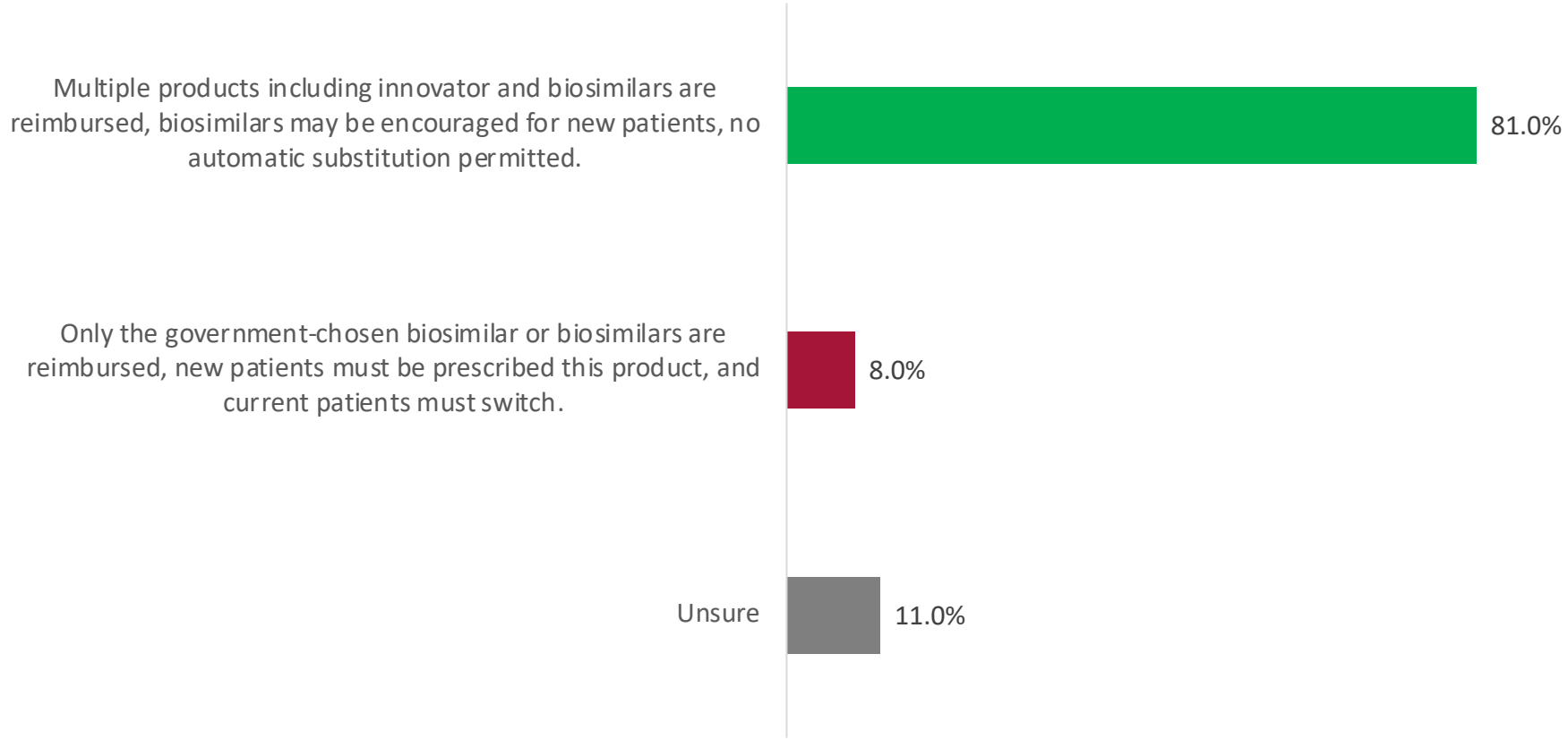
European and US physicians agree- it is **VERY IMPORTANT or CRITICAL that payers (public and private) reimburse/cover multiple products-** including the originator biologic as well as the different biosimilars.

Preferred Biosimilar Access Scenario

81% of U.S. physicians believe that their patients would be best served in an access scenario under which:

- biosimilars were encouraged for new patients
- multiple products reimbursed
- No automatic substitution

- Q20. From your perspective, which type of access scenario would better serve your patients? (n=401)



Switching in the Australian Market

- In 2015, Australia broke with other advanced nations and allowed automatic substitution of biosimilars, over the objection of patients and physicians. Physicians often blocked these forced substitutions, leading to very low uptake/market share.
- Several manufacturers have pulled their products- one for liability reasons, after the government began automatic substitution, another after an unexpected, deeper-than normal price cut.
- **Forced-switching is now occurring with stage IV cancer patients. No grandfathering of current patients.**
- Patients are disappointed and bitter: biosimilars were sold to patients as a way to expand choice, with many products listed alongside each other to choose from- this has not happened. “they have replaced one monopoly with another…was this by design?”

IMPACT

- **1 Jun 2021 –Company removed Avastin from PBS as a result of local price reduction that makes availability unsustainable in the market**
- **30 Jun 2021 – 100mg/4mL dose removed from Australian market**
- **3 Dec 2021 – 400mg/16mL dose removed from Australian market**

Supply Chain Issues

For me, the underlying piece of all of this is **market consolidation**," she said."

THE WALL STREET JOURNAL.

Baby-Formula Supply Woes Persist

BY JESSE NEWMAN AND KRISTINA PETERSON

Many U.S. households are still struggling to find baby formula, almost a year since supplies thinned on store shelves and eight months after a nationwide recall.

Adults in roughly one-third of households with infant children who typically use formula had trouble obtaining it last month, according to a recent survey by the U.S. Census Bureau. Nearly 1 in 5 of affected households has less than a week of formula on hand, the survey showed.

The survey offers one of the most detailed views yet into the nationwide formula shortage, and it comes as lawmakers are taking steps to address ongoing supply issues.

The census findings came from its Household Pulse Survey, launched in 2020 to assess how the Covid-19 pandemic has affected people's lives and livelihoods. The challenges were most acute for lower-income families, according to the survey, which had responses from nearly 51,000 households between Sept. 14 and Sept. 26.

On average, 40% of adults with household incomes less than $75,000 reported difficulty finding formula the previous week, twice the rate of those whose household incomes topped $75,000.

IMPACT

- 30,247 PBS scripts (Mar 20-21) were written for Avastin for the treatment of metastatic bowel cancer
- When were metastatic bowel cancer patients to be informed?
- No grandfather provision for existing patients being treated with Avastin
- Forced switched
- How will the decision increase competition?
  - Biologic removed from market
  - Will the deeper than normal price cut apply to all Avastin biosimilars?
  - Will other biosimilars apply for PBS-listing or become inactive?

Summary

- The goal of biosimilars is not biosimilar uptake for its own sake- but for the savings it will bring to our health systems worldwide. **This savings results not only from an initial discount, but from competition between an ever-increasing number of products, over time.** For example, as we have seen in the U.S., much of the savings come from downward pressure as innovator products are forced to slash prices to remain competitive.
- **Long-term savings and sustainability should not be sacrificed for short term savings.**
- **Physicians, regulators and other healthcare stakeholders have all emphasized the importance of having multiple reimbursed products available.** This brings both health benefits for patients (e.g. avoiding unnecessary switching for patients, less likelihood of drug shortages) as well as economic benefits (increased competition, greater savings).
- Europe has led the world in biosimilar approval and commercialization. It has built numerous thriving and sustainable biosimilar markets and achieved immense savings for its health systems. **The rest of the world can learn much from Europe about how to this without sacrificing patient & physician choice, undermining confidence in biosimilars, or simply replacing one monopoly with another.**
- **Ignoring these lessons risks undermining the long-term success of a biosimilar market.**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