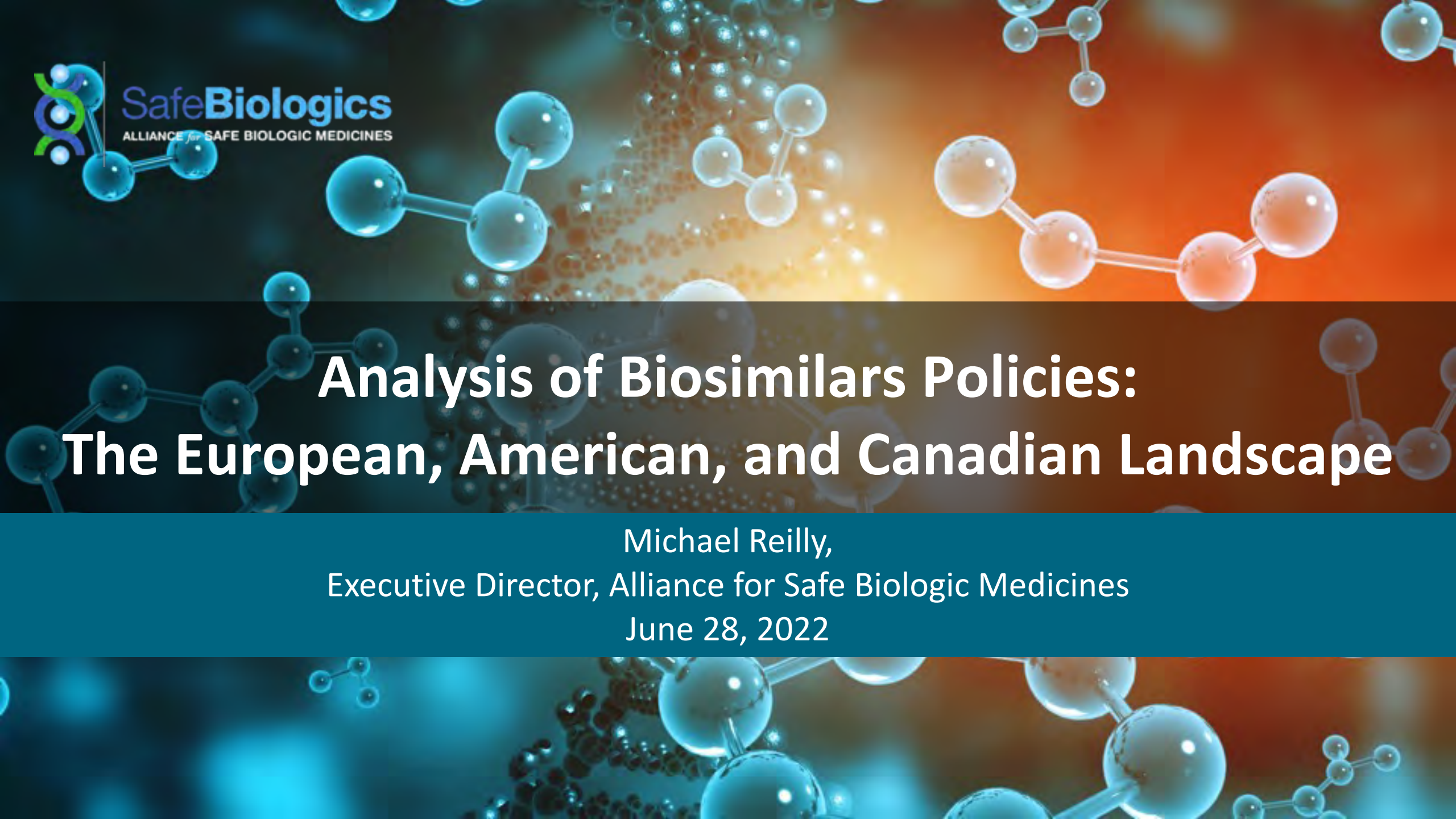


Analysis of Biosimilars Policies: The European, American, and Canadian Landscape

Michael Reilly,
Executive Director, Alliance for Safe Biologic Medicines

June 28, 2022

Introduction

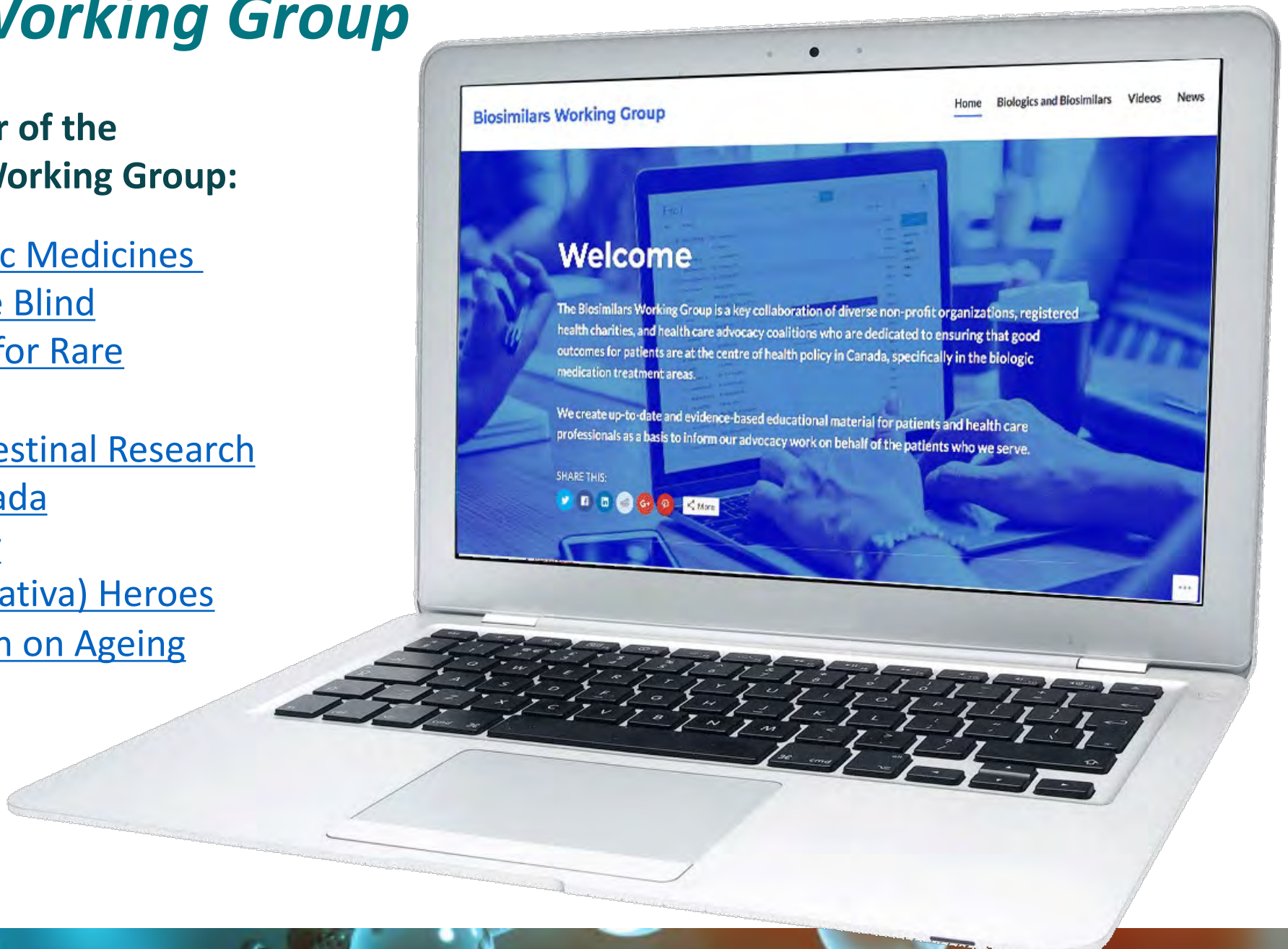
Michael Reilly, ESQ
Executive Director, Alliance for Safe Biologic Medicines
2010-Present

- Associate Deputy Secretary at the U.S. Department of Health and Human Services (HHS) from 2005-2008
- Responsible for policy development and implementation, regulatory oversight for issues involving CMS and the FDA.
- Senior Advisor to the Assistant Secretary for Public Affairs and the Assistant Secretary for Planning and Evaluation at HHS from 2002-2005

Biosimilars Working Group

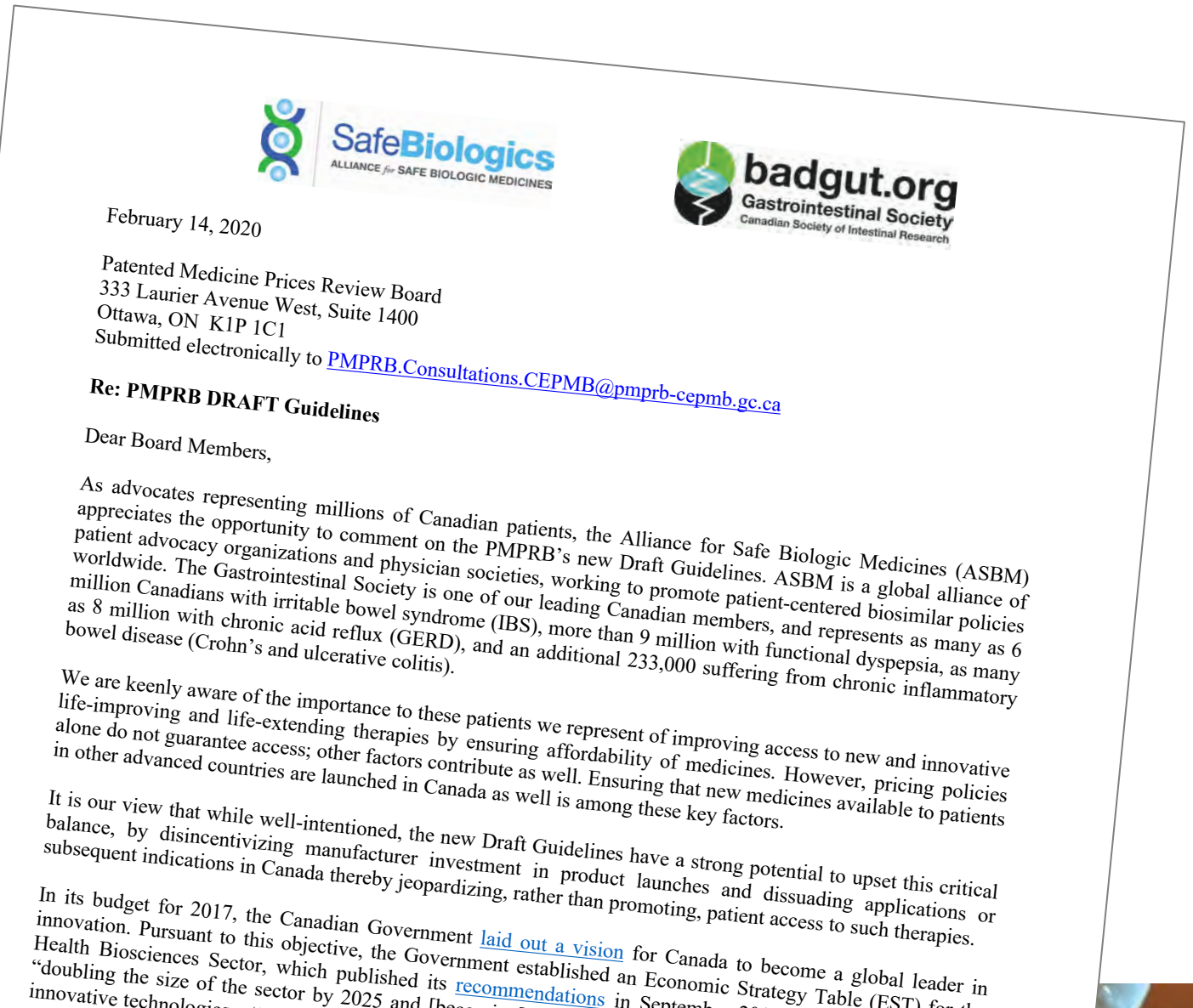
ASBM is also a member of the Canadian Biosimilars Working Group:

[Alliance for Safe Biologic Medicines](#)
[Canadian Council of the Blind](#)
[Canadian Organization for Rare Disorders](#)
[Canadian Society of Intestinal Research](#)
[Crohn's and Colitis Canada](#)
[Gastrointestinal Society](#)
[HS (hidradenitis suppurativa) Heroes](#)
[International Federation on Ageing](#)
[MedAccess BC](#)



biosimilaroptions.ca

Joint PMPRB Comments: February 14, 2020



SafeBiologics
ALLIANCE for SAFE BIOLOGIC MEDICINES

badgut.org
Gastrointestinal Society
Canadian Society of Intestinal Research

February 14, 2020

Patented Medicine Prices Review Board
333 Laurier Avenue West, Suite 1400
Ottawa, ON K1P 1C1
Submitted electronically to PMPRB.Consultations.CEPMB@pmprb-cepmb.gc.ca

Re: PMPRB DRAFT Guidelines

Dear Board Members,

As advocates representing millions of Canadian patients, the Alliance for Safe Biologic Medicines (ASBM) appreciates the opportunity to comment on the PMPRB's new Draft Guidelines. ASBM is a global alliance of patient advocacy organizations and physician societies, working to promote patient-centered biosimilar policies worldwide. The Gastrointestinal Society is one of our leading Canadian members, and represents as many as 6 million Canadians with irritable bowel syndrome (IBS), more than 9 million with functional dyspepsia, as many as 8 million with chronic acid reflux (GERD), and an additional 233,000 suffering from chronic inflammatory bowel disease (Crohn's and ulcerative colitis).

We are keenly aware of the importance to these patients we represent of improving access to new and innovative life-improving and life-extending therapies by ensuring affordability of medicines. However, pricing policies alone do not guarantee access; other factors contribute as well. Ensuring that new medicines available to patients in other advanced countries are launched in Canada as well is among these key factors.

It is our view that while well-intentioned, the new Draft Guidelines have a strong potential to upset this critical balance, by disincentivizing manufacturer investment in product launches and dissuading applications or subsequent indications in Canada thereby jeopardizing, rather than promoting, patient access to such therapies.

In its budget for 2017, the Canadian Government laid out a vision for Canada to become a global leader in innovation. Pursuant to this objective, the Government established an Economic Strategy Table (EST) for the Health Biosciences Sector, which published its recommendations in September [illegible] "doubling the size of the sector by 2025 and [illegible] innovative technologies

June 29 Webinar: “Key Factors for Successful Uptake of Biosimilars: Europe and US”

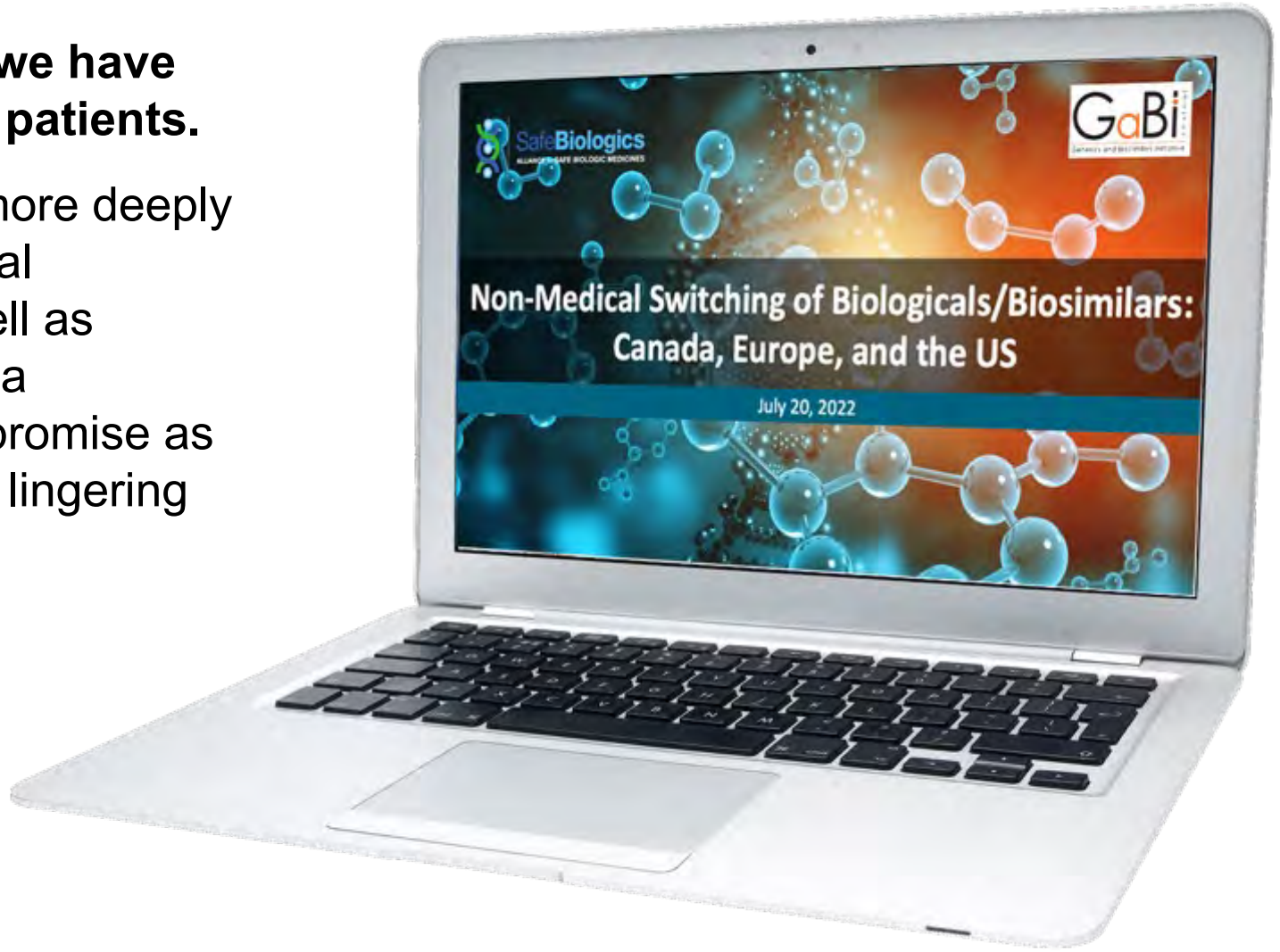
- Tomorrow ASBM & GaBI will present a webinar which discusses the factors contributing to the success of biosimilars in Europe and the U.S.
- This is the first in a series of webinars presented by ASBM and GaBI this year.

REGISTER

Non-Medical Switching Webinar: July 20th

Non-Medical Switching is a concern we have seen across our surveys and among patients.

Our next webinar (July 20th) will delve more deeply into physician concerns with non-medical switching and forced substitution- as well as discussing how the FDA designation of a biosimilar as "Interchangeable" shows promise as an effective means of addressing these lingering concerns for most physicians.



Europe Enjoys High Biosimilar Uptake Rates and Savings

Biosimilar Uptake Varies Throughout Europe by Country and Product (Usually 20-80% range):

Total Biosimilar Volume: Denmark: 63%; UK: 45%; Germany 40%; France 34%, Belgium and Switzerland tied at 14%.

Filgrastim/Pegfilgrastim: 16 European countries had > 90% biosimilar utilization in 2018, Ireland was just 27%.

Anti-TNF biosimilars (adalimumab, etanercept and infliximab): Norway and Denmark had 81% and 96% biosimilar uptake, respectively, while every other country's utilization was less than 50% .

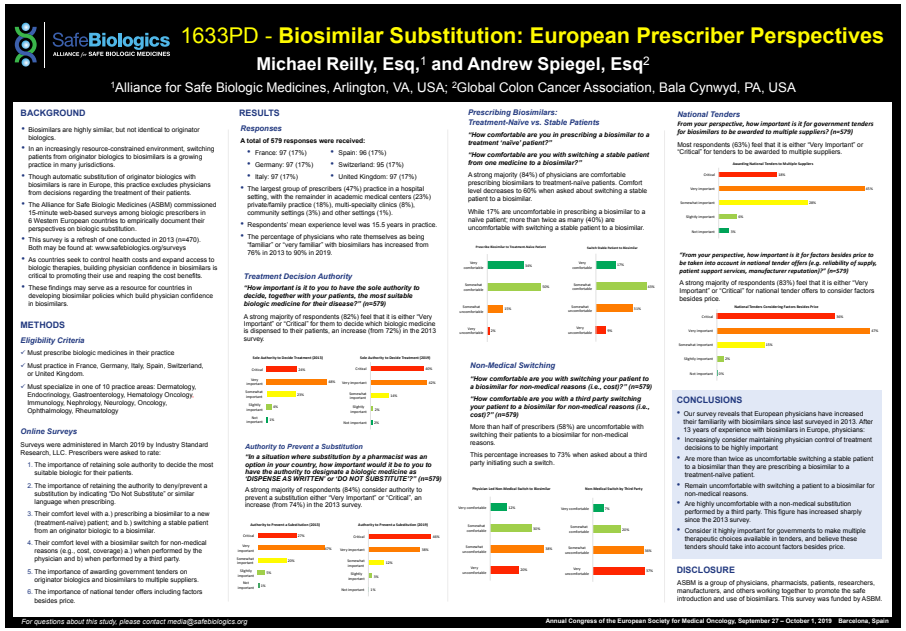
Variations are influenced by government involvement, reimbursement structures and tender procurement policies.

Biosimilar Policy in Europe: A Collaborative, Patient-Focused Approach

- **Regular multi-stakeholder consultations held by European Commission in Brussels.**
- Discussions about switching are made collaboratively between health care providers and patients.
- Education of patients to build trust in biosimilars has been a priority.
- Savings attributed to biosimilars are being visibly reinvested into the system- more healthcare workers, etc.

Survey Presented at ESMO Congress 2019

- An update of a prior survey in 2013
- The survey findings were presented at the European Society of Medical Oncology 2019 Congress in Barcelona, Spain.
- The European physicians took great pride in their approach, which is very patient-focused.
- ***Notably, as familiarity and comfort with biosimilars increased, so did the importance to physicians of maintaining control of treatment decision.***



SafeBiologics ALLIANCE for SAFE BIOLOGIC MEDICINES

1633PD - **Biosimilar Substitution: European Prescriber Perspectives**

Michael Reilly, Esq,[1] and Andrew Spiegel, Esq[2]

[1]Alliance for Safe Biologic Medicines, Arlington, VA, USA; [2]Global Colon Cancer Association, Bala Cynwyd, PA, USA

BACKGROUND

- Biosimilars are highly similar, but not identical to originator biologics.
- In an increasingly resource-constrained environment, switching patients from originator biologics to biosimilars is a growing practice in many jurisdictions.
- Though automatic substitution of originator biologics with biosimilars is rare in Europe, this practice excludes physicians from decisions regarding the treatment of their patients.
- The Alliance for Safe Biologic Medicines (ASBM) commissioned 15-minute web-based surveys among biologic prescribers in 6 Western European countries to empirically document their perspectives on biologic substitution.
- This survey is a refresh of one conducted in 2013 (n=470). Both may be found at: www.safebiologics.org/surveys
- As countries seek to control health costs and expand access to biologic therapies, building physician confidence in biosimilars is critical to promoting their use and reaping the cost benefits.
- These findings may serve as a resource for countries in developing biosimilar policies which build physician confidence in biosimilars.

METHODS

Eligibility Criteria

- ✓ Must prescribe biologic medicines in their practice
- ✓ Must practice in France, Germany, Italy, Spain, Switzerland, or United Kingdom.
- ✓ Must specialize in one of 10 practice areas: Dermatology, Endocrinology, Gastroenterology, Hematology Oncology, Immunology, Nephrology, Neurology, Oncology, Ophthalmology, Rheumatology

Online Surveys

Surveys were administered in March 2019 by Industry Standard Research, LLC. Prescribers were asked to rate:

1. The importance of retaining sole authority to decide the most suitable biologic for their patients.
2. The importance of retaining the authority to deny/prevent a substitution by indicating "Do Not Substitute" or similar language when prescribing.
3. Their comfort level with a.) prescribing a biosimilar to a new (treatment-naïve) patient; and b.) switching a stable patient from an originator biologic to a biosimilar.
4. Their comfort level with a biosimilar switch for non-medical reasons (e.g., cost, coverage) a.) when performed by the physician and b) when performed by a third party.
5. The importance of awarding government tenders on originator biologics and biosimilars to multiple suppliers.
6. The importance of national tender offers including factors besides price.

RESULTS

Responses

A total of 579 responses were received:

- France: 97 (17%)
- Germany: 97 (17%)
- Italy: 97 (17%)
- Spain: 96 (17%)
- Switzerland: 95 (17%)
- United Kingdom: 97 (17%)

- The largest group of prescribers (47%) practice in a hospital setting, with the remainder in academic medical centers (23%) private/family practice (18%), multi-specialty clinics (8%), community settings (3%) and other settings (1%).
- Respondents' mean experience level was 15.5 years in practice.
- The percentage of physicians who rate themselves as being "familiar" or "very familiar" with biosimilars has increased from 76% in 2013 to 90% in 2019.

Treatment Decision Authority

"How important is it to you to have the sole authority to decide, together with your patients, the most suitable biologic medicine for their disease?" (n=579)

A strong majority of respondents (82%) feel that it is either "Very Important" or "Critical" for them to decide which biologic medicine is dispensed to their patients, an increase (from 72%) in the 2013 survey.

Authority to Prevent a Substitution

"In a situation where substitution by a pharmacist was an option in your country, how important would it be to you to have the authority to designate a biologic medicine as 'DISPENSE AS WRITTEN' or 'DO NOT SUBSTITUTE'?" (n=579)

A strong majority of respondents (84%) consider authority to prevent a substitution either "Very Important" or "Critical", an increase (from 74%) in the 2013 survey.

Prescribing Biosimilars: Treatment-Naïve vs. Stable Patients

"How comfortable are you in prescribing a biosimilar to a treatment 'naïve' patient?"

"How comfortable are you with switching a stable patient from one medicine to a biosimilar?":

A strong majority (84%) of physicians are comfortable prescribing biosimilars to treatment-naïve patients. Comfort level decreases to 60% when asked about switching a stable patient to a biosimilar.

While 17% are uncomfortable in prescribing a biosimilar to a naïve patient, more than twice as many (40%) are uncomfortable with switching a stable patient to a biosimilar.

Non-Medical Switching

"How comfortable are you with switching your patient to a biosimilar for non-medical reasons (i.e., cost)?" (n=579)

"How comfortable are you with a third party switching your patient to a biosimilar for non-medical reasons (i.e., cost)?" (n=579)

More than half of prescribers (58%) are uncomfortable with switching their patients to a biosimilar for non-medical reasons.

This percentage increases to 73% when asked about a third party initiating such a switch.

National Tenders

From your perspective, how important is it for government tenders for biosimilars to be awarded to multiple suppliers? (n=579)

Most respondents (63%) feel that it is either "Very Important" or "Critical" for tenders to be awarded to multiple suppliers.

"From your perspective, how important is it for factors besides price to be taken into account in national tender offers (e.g. reliability of supply, patient support services, manufacturer reputation)?" (n=579)

A strong majority of respondents (83%) feel that it is either "Very Important" or "Critical" for national tender offers to consider factors besides price.

CONCLUSIONS

- Our survey reveals that European physicians have increased their familiarity with biosimilars since last surveyed in 2013. After 13 years of experience with biosimilars in Europe, physicians:
- Increasingly consider maintaining physician control of treatment decisions to be highly important
- Are more than twice as uncomfortable switching a stable patient to a biosimilar than they are prescribing a biosimilar to a treatment-naïve patient.
- Remain uncomfortable with switching a patient to a biosimilar for non-medical reasons.
- Are highly uncomfortable with a non-medical substitution performed by a third party. This figure has increased sharply since the 2013 survey.
- Consider it highly important for governments to make multiple therapeutic choices available in tenders, and believe these tenders should take into account factors besides price.

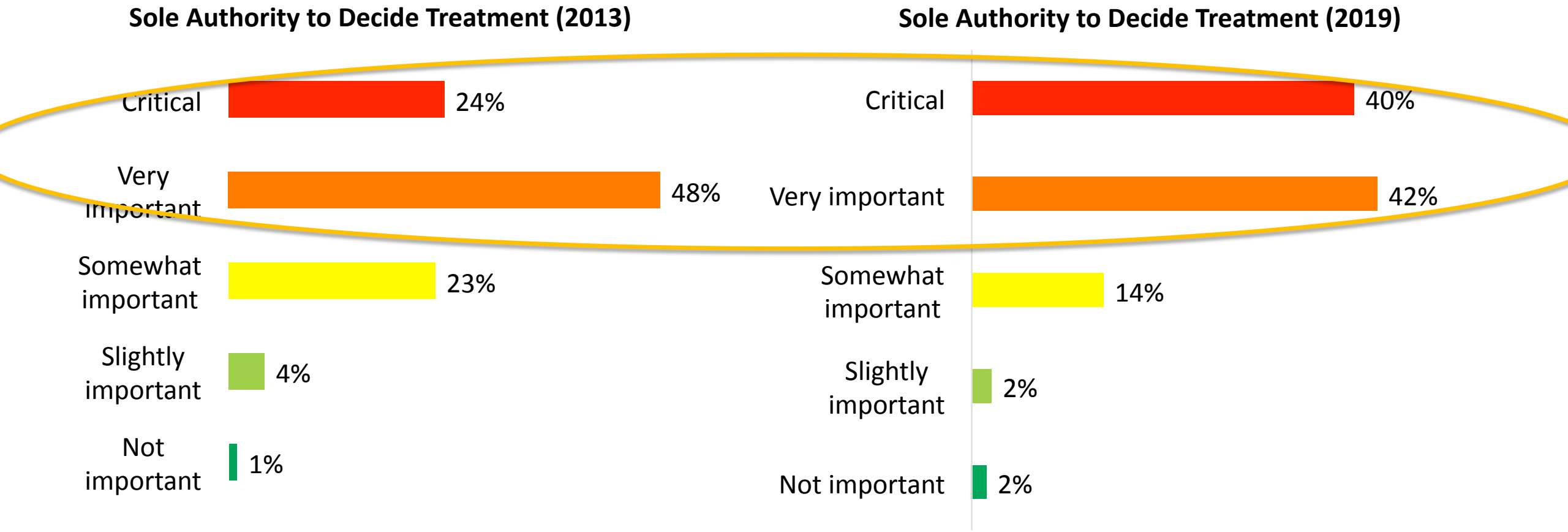
DISCLOSURE

ASBM is a group of physicians, pharmacists, patients, researchers, manufacturers, and others working together to promote the safe introduction and use of biosimilars. This survey was funded by ASBM.

For questions about this study, please contact media@safebiologics.org

Annual Congress of the European Society for Medical Oncology, September 27 – October 1, 2019 Barcelona, Spain

European Surveys (2013 vs. 2019): Importance of Physician/Patient Control of Treatment Decisions



82% feel that it is either "Very Important" or "Critical" for the physician & patient to decide which biologic medicine is used, **an increase (from 72%) since 2013**. **Those considering this "Critical" nearly doubled from 24% to 40%.**

“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 Whitepaper Identified "Must-Have" Principles, Critical for Countries to Achieve Biosimilar Success:

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.

Outliers: Norway and Denmark

- Even in Norway with a national tendering system, physicians retain the prescription choice among all available products but are strongly encouraged to choose the lowest priced product for new patients.
- Only Denmark, following a transparent process, will solely reimburse the winning product, except in rare substantiated circumstances.

- **Critically: No European country has stopped reimbursement of an originator product through an arbitrary government fiat as occurs in the Alberta and British Columbia forced-switching policies.**

While Europe is Viewed as the Leader in Biosimilar Adoption, the U.S. is Catching Up…

- **U.S. biosimilar market shares are catching up with European uptake rates:**
- 80% for filgrastim biosimilars, 70% for trastuzumab and bevacizumab biosimilars, and 55% for rituximab biosimilars.
- Infliximab biosimilars have had the most limited adoption, with approximately 20% market share.

2 https://accessiblemeds.org/resources/press-releases/study-finds-us-generic-and-biosimilar-savings-totaled-record-338-billion


And Then, There's Canada…