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Canadian Non-Medical Switching Policies on Biologicals & Biosimilars: Implications for Physicians and Patients

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Introduction

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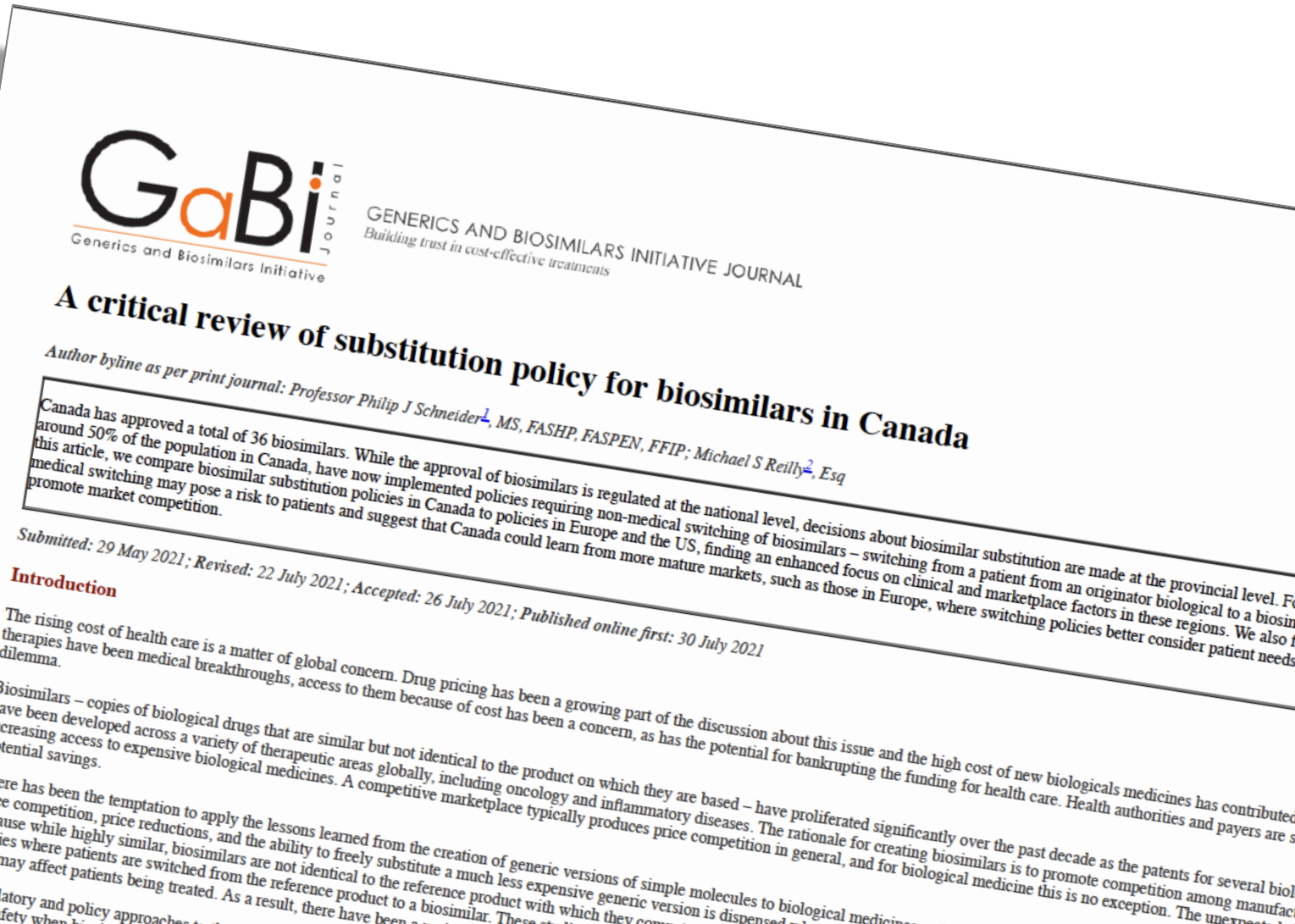
As we head into our closing panel, let's examine some of the issues raised …

Things to Consider When Assessing Canadian Non-Medical & Forced Switching Policies

1. Does it effectively achieve Savings?
2. Does it prioritize the Patient?
3. Does it adequately consider Physician Concerns/Objections?
4. Does it reflect the principles upon which it was enacted (i.e. as a means of “catching up to Europe”.)
5. Does it promote sustainable biosimilar market?
6. Does it build confidence in biosimilars?

We discuss several of these factors in our GaBI Whitepaper: "A Critical Review of Substitution Policy for Biosimilars in Canada"

- *By Michael S Reilly, Esq and Professor Philip J Schneider, MS, FASHP, FFIP, FASPEN*
- *GaBI Journal, Volume 10 / Year 2021 / Issue 3*



GaBI Journal
Generics and Biosimilars Initiative

GENERICS AND BIOSIMILARS INITIATIVE JOURNAL
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A critical review of substitution policy for biosimilars in Canada

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Canada has approved a total of 36 biosimilars. While the approval of biosimilars is regulated at the national level, decisions about biosimilar substitution are made at the provincial level. Fo
around 50% of the population in Canada, have now implemented policies requiring non-medical switching of biosimilars – switching from a patient from an originator biological to a biosim
this article, we compare biosimilar substitution policies in Canada to policies in Europe and the US, finding an enhanced focus on clinical and marketplace factors in these regions. We also f
medical switching may pose a risk to patients and suggest that Canada could learn from more mature markets, such as those in Europe, where switching policies better consider patient needs
promote market competition.

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Introduction

The rising cost of health care is a matter of global concern. Drug pricing has been a growing part of the discussion about this issue and the high cost of new biologicals medicines has contributed
therapies have been medical breakthroughs, access to them because of cost has been a concern, as has the potential for bankrupting the funding for health care. Health authorities and payers are s
dilemma.

Biosimilars – copies of biological drugs that are similar but not identical to the product on which they are based – have proliferated significantly over the past decade as the patents for several biol
have been developed across a variety of therapeutic areas globally, including oncology and inflammatory diseases. The rationale for creating biosimilars is to promote competition among manufac
increasing access to expensive biological medicines. A competitive marketplace typically produces price competition in general, and for biological medicine this is no exception. The
potential savings.

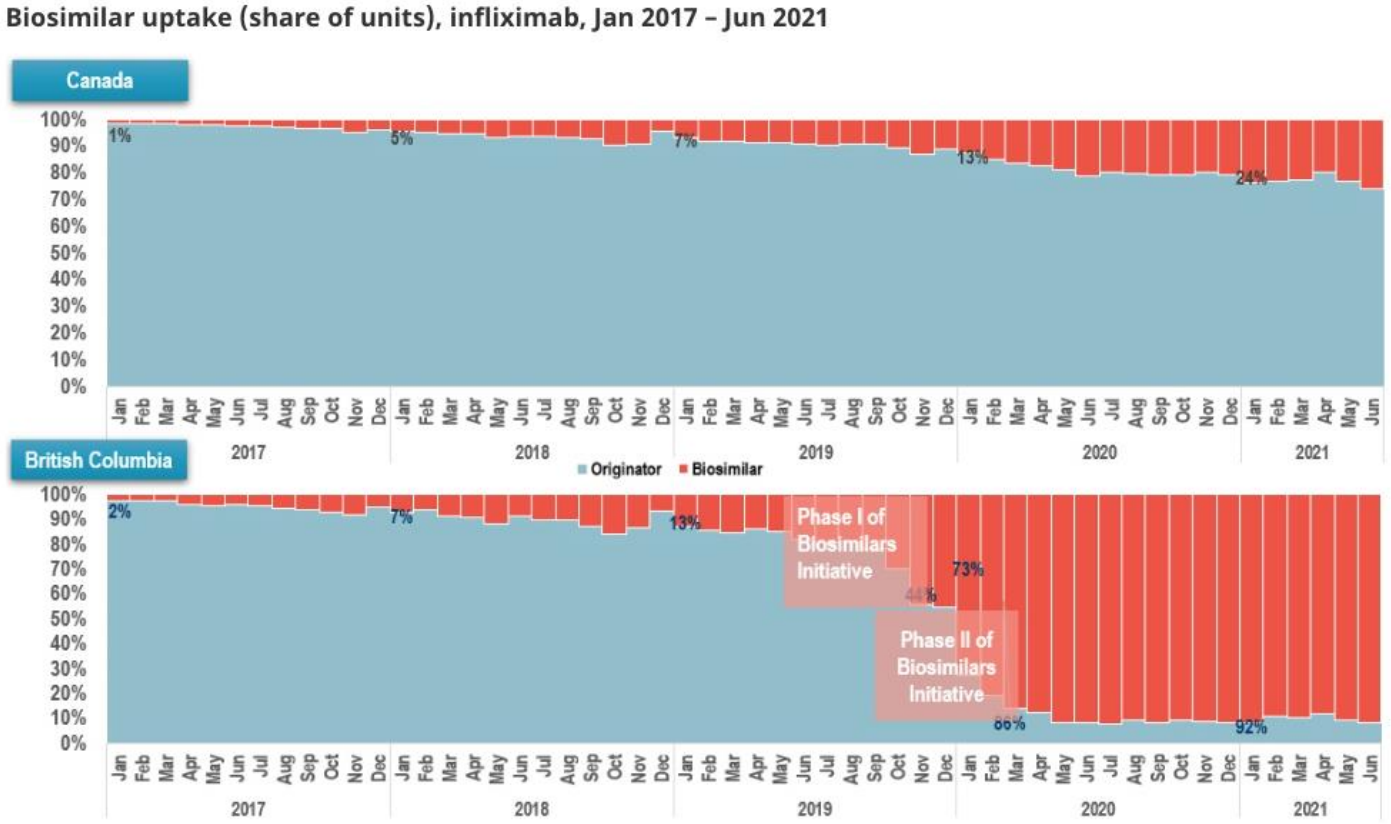
There has been the temptation to apply the lessons learned from the creation of generic versions of simple molecules to biological medicine
price competition, price reductions, and the ability to freely substitute a much less expensive generic version is dispensed
because while highly similar, biosimilars are not identical to the reference product with which they
studies where patients are switched from the reference product to a biosimilar. These
that may affect patients being treated. As a result, there have been

Regulatory and policy approaches
and safety when

Savings – Short Term vs. Long Term?

- 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)



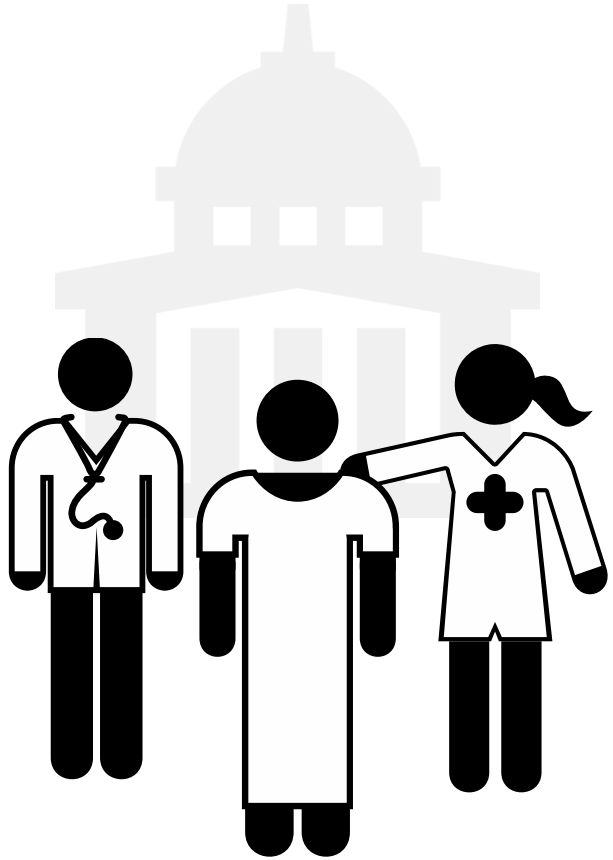
https://www.canada.ca/en/patented-medicine-prices-review/services/npduis/analytical-studies/slide-presentations/biosimilars-cadth-2021.html

Prioritizing the Patient?

- Patient objections to forced switching policies have been well-documented for years.
- While creating numerous exceptions to these policies can mitigate some of their worst effects, it highlights the problem:
- The policy itself is wrong at its core because it makes the patient-physician relationship secondary or tertiary, rather than central to patient care.

Physician Concerns?

- **One of the roles of clinicians is to function as learned intermediaries that can balance patient-specific factors against policies made by governments (and other payers) based on population-derived factors.**
- **As we have seen, Canadian NMS policies are typically enacted despite a lack of acceptance – and often strong objections – among physicians.**



"Non-medical switching in patients being treated with a reference biologic **is generally not accepted by learned societies and the consulted clinicians."**

– "Safety of switching biologics and their interchangeability", INESS Report (Quebec), May 2020

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

Sustainability? Whitepaper 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.

Building Confidence in Biosimilars?

- **Physician confidence in biosimilars is high, in Canada and elsewhere.**
- **But they want more data showing safety of switching---and they still want to be involved in substitution decisions.**
- **Data show these attitudes are consistent among physicians worldwide.**
- **Ignoring and dismissing these concerns does NOT build confidence.**
- **In contrast, the U.S. is achieving uptake rates comparable to those of Europe (40%-80+% range) by addressing these concerns (interchangeability, state substitution laws, etc.)**

Why is Non-Medical/Forced Switching Failing?

- Health policies should always begin and end with THE PATIENT.
- The PATIENT/PHYSICIAN relationship is central to making treatment decisions – a policy which removes this from the equation must meet a VERY high burden of proof.
- It is clear that Canadian Non-Medical Switching/Forced Substitution policies are failing to meet this standard:
- They ignore physician concerns and objections, fail to let confidence grow through data, prioritize short-term savings over long-term savings that result from competition, and undermine growth and sustainability of biosimilar markets.
- In effect, they fail by seeking a shortcut to uptake/savings rather than creating conditions for the desired behaviors to occur naturally, e.g. European and U.S. markets.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