U.S. Physician Perspectives on Biosimilar Substitution and Reimbursement Practices

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BACKGROUND

- Biologic medicines are highly-effective products used to treat serious and chronic conditions including rheumatoid arthritis, psoriasis, ulcerative colitis, Crohn's Disease, and cancer.
- Biosimilars are highly similar, but not identical, to the originator biologics on which they are based. They offer new treatment options for patients at reduced cost and promote price competition between products.
- The high cost of biologic therapies incentivizes payers to change coverage policies in order to switch patients to lower-cost (or more profitable) products.
- While biosimilars are safe and effective medicines, treatment plans are not universal and are developed over time by physicians and patients. Patients often try multiple products before finding one which stabilizes their condition.
- Accordingly, physicians and patients have expressed concerns about unnecessarily switching between biologic medicines, particularly when the patient is stable and well-treated on their current medicine.
- The U.S. FDA has attempted to address these concerns by creating a designation of "interchangeable" to a biosimilar which has demonstrated that a patient can be repeatedly switched between it and its reference product and expect the same result, without additional risks, as a patient who was not switched.
- The FDA has also adopted a suffix-based biologic naming policy which distinguishes a biosimilar from its reference product and all other biosimilars to that product. This helps avoid inadvertent or inappropriate substitution; as well as improving pharmacovigilance for biosimilars (e.g. accurate attribution of adverse events to the correct product) and promotes increased manufacturer accountability.

OBJECTIVE

- The survey empirically documents attitudes of 401 U.S. prescribers of biologics from 12 specialties on: biosimilar safety and efficacy; prescribing biosimilars to patients; switching patients to biosimilars; third-party switching of patients for cost/coverage reasons; payer reimbursement practices; preferred biosimilar access scenarios; and implications of FDA interchangeability and naming policies.
- This survey is part of a series of physician surveys covering 13 countries and dating back to 2011. These including surveys of U.S. physicians in 2012, 2015 and 2019.
- These surveys may be viewed at www.safebiologics.org/surveys.

METHODOLOGY

- In September 2021, a web-based quantitative survey was conducted of 401 practicing U.S. physicians. All prescribe biologics.
- Participants were drawn in roughly-equal proportion from 12 specialties in which biologics are routinely prescribed and were provided an honorarium for their time.

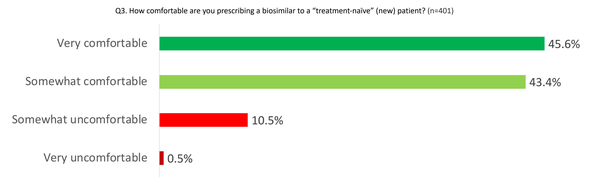
VIEW ASBM SURVEYS

RESULTS

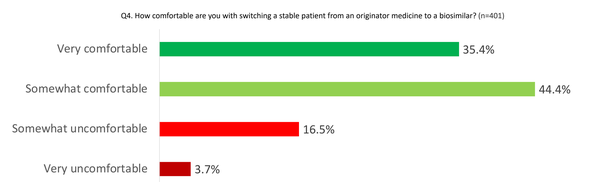
CONFIDENCE IN BIOSIMILARS

- 92% of respondents expressed confidence in the safety and efficacy of biosimilars:

- 89% would prescribe a biosimilar to a new (bio-naive) patient:

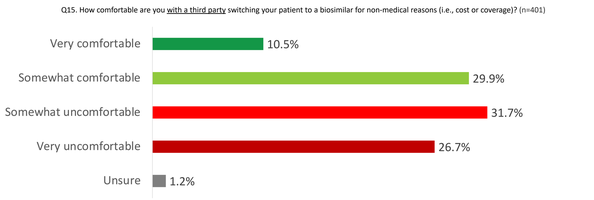


- 80% are comfortable switching a stable patient to a biosimilar themselves:

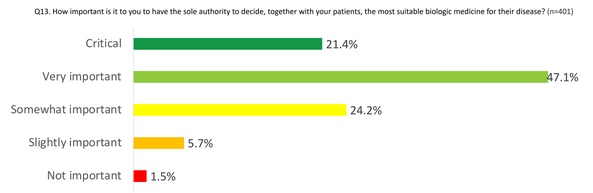


CONTROL OF TREATMENT DECISIONS

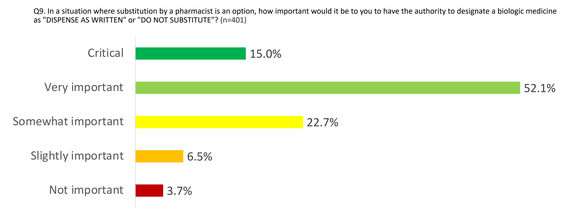
- However, a majority (58%) are uncomfortable with third-party substitution for non-medical reasons (e.g. cost, coverage):



- 69% of US physicians surveyed consider it "very important or critical" that patients and physicians decide the most suitable biologic to use- be it the originator or one of the biosimilars to that product.

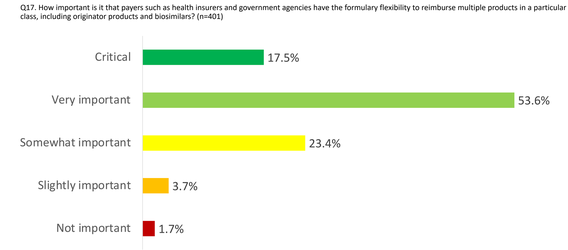


- 67% of respondents consider it "very important" or "critical" that they're able to prevent a substitution they feel is inappropriate:



REIMBURSEMENT PRACTICES

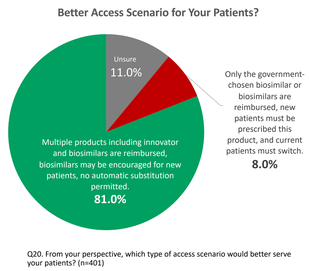
- 71% considered it highly important that payers (public and private) should reimburse multiple products in a given class-including originator and biosimilars:



- 74% considered it highly important that payers consider factors other than cost when determining coverage.

PREFERRED BIOSIMILAR ACCESS SCENARIO

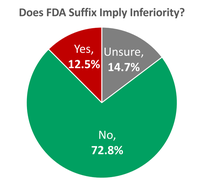
- 81% believe their patients would be best served under a biosimilar access scenario popular throughout most of Western Europe- in which biosimilars and originator products are both reimbursed, biosimilars may be encouraged for new patients, but automatic or pharmacy-level substitution is not permitted.



- Only 8% supported an access scenario implemented by several Canadian provinces, in which only a preferred, government-chosen product is reimbursed and to which both new and stable patients must be switched. 11% were unsure.

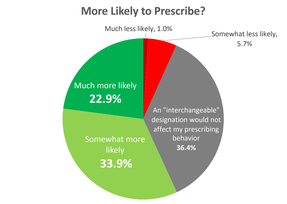
FDA BIOSIMILAR NAMING SYSTEM

- 73% of respondents feel that the distinguishing suffix the FDA requires to differentiate biosimilars from their reference products and each other does NOT suggest or imply inferiority, while 13% feel it does, and 15% are unsure.

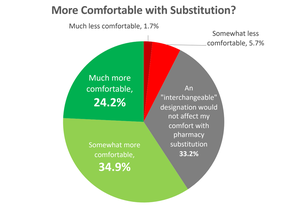


INTERCHANGEABLE BIOSIMILARS

- An FDA designation of "interchangeable" (meaning additional data has shown that repeated switching between originator and biosimilar will provide the same result without additional risks relative to unswitched patients) makes 57% of physicians more likely to prescribe the interchangeable biosimilar.



- An "interchangeable" designation also makes a majority (59%) more comfortable with a pharmacy-level substitution of the interchangeable biosimilar in place of the prescribed originator product.



CONCLUSIONS

- U.S. physicians are highly comfortable prescribing biosimilars, and with switching patients to a biosimilar themselves.
- Despite this, a majority maintain that they, with their patients, should have sole control over treatment choices including-especially the decision to switch a patient who is stable on their current biologic.
- Accordingly, a majority continue to have concerns with third-party-initiated switching for non-medical reasons (e.g. cost, coverage, greater profit, manufacturer rebates).
- In addition, strong majorities believed that payers should reimburse multiple biological products in a given class, including the originator along with its biosimilars; and that both private and public payers should consider factors other than cost when determining coverage.
- A large majority of physicians do not believe that the FDA's use of a suffix (to distinguish biosimilars from their reference product and other biosimilars to that product) imply inferiority. This is perhaps unsurprising because all new originator biologics receive these suffixes as well.
- FDA designation of a biosimilar as "Interchangeable" shows promise as an effective means of addressing these lingering concerns for most physicians.
- For example, an interchangeability designation makes the majority of respondents more comfortable prescribing the interchangeable biosimilar, and the majority more comfortable with a third-party substitution of the biosimilar in place of a prescribed originator product.

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 poster, please contact media@safebiologics.org

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