Biosimilars:
Breaking Down Barriers to Patient Access

Since it was created in 2007, the Food & Drug Administration's (FDA's) Risk Evaluation and Mitigation Strategies (REMS) has been an important tool for patient safety by ensuring that the benefits of a drug or biological product outweigh its safety risks. FDA-mandated REMS serve a clear public health purpose, yet some brand drug companies have been misusing this patient safety program and other restricted access drug programs to extend market monopolies, intentionally limiting patient access to biosimilars. These abuses are growing, resulting in delayed approval of biosimilars, costing patients, the federal government and the health care system billions of dollars.

For more information, visit stopREMSabuse.com.

Biosimilars are
safe, effective alternative
versions of expensive brand biologic medicines.

Current estimates suggest that biosimilars could save consumers as much as
$250 billion
in the next 10 years.[1]

BARRIERS TO ACCESS

Current law clearly states that a brand manufacturer cannot use a REMS program to block or delay approval of a competitive product. Certain brand companies have been exploiting a loophole in the law to block access to product samples needed to reverse-engineer biosimilars for FDA approval,

denying patients access to safe, affordable drugs.

OPPORTUNITY FOR MISUSE IS GROWING

FDA requires REMS for
~40%
of new drug approvals[2]

Brand drug companies misuse REMS and REMS-like programs to protect even more products from competition.

LOST SAVINGS AT THE EXPENSE OF PATIENTS[3]

As the biosimilar market develops, the inability of companies to obtain samples of brand biologics for early development testing purposes will also cause access delays and keep drug prices artificially high.

~$140M for every $1B in biologics sales =
$14B in lost savings[3]

WE CAN BE SAFE & FAIR

The Biosimilars Council is committed to safeguarding patient safety. Our members strongly support current FDA-mandated REMS programs to ensure that the benefits of a drug outweigh its safety risks.

Ending the exploitation of loopholes that delay access to biosimilars will help to provide patients with safe and competitive drug choices.

References
1. The $250 Billion Potential of Biosimilars, Express Scripts Int'l (April 23, 2013). Available at: http://bit.ly/2qYlu4Z. Accessed May 30, 2017.
2. Brief Amicus Curiae of Generic Pharmaceutical Association, Actelion Pharmaceuticals Ltd. v. Apotex Inc., (No. 1:12-cv-05743- NLH-AMD), (D.N.J. Mar. 2013). Available at: http://bit.ly/2r6CofI. Accessed May 30, 2017.
3. Lost Prescription Drug Savings from Use of REMS Programs to Delay Generic Market Entry. Matrix Global Advisors (July 2014) Available at: http://bit.ly/28ToVmx. Accessed May 30, 2017.

For more information about barriers to patient access, visit stopREMSabuse.com or learn more about biosimilars at:

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The Biosimilars Council
A Division of the Association for Accessible Medicines