Patient Safety and Generic Biologics
A message from the North American Thrombosis Forum

Congress is currently debating health care reform. Both the House and Senate have versions of legislation that establish a pathway for the Food and Drug Administration to approve generic versions of biologic medicines (known as “follow-on biologics” or “biosimilars”). The potential of these new agents to reduce costs is why we believe follow-on biologics are a critical component for meaningful healthcare reform.

Biologics are not like conventional pharmaceuticals. They are complex substances closely related to those found in the human body. Each biologic drug has different starting materials and manufacturing processes so that the final product always varies physically and chemically, in subtle but important ways. Although a biologic might appear similar to the innovator product in laboratory tests, inherent variability could lead to important differences in potency, safety, or effectiveness when administered to a patient.

We understand that healthcare reform legislation is a massive undertaking with many competing interests and that, when compared to a fight over billions of dollars, threats to patient safety from follow-on biologics may be easily overlooked. If approval of biosimilar drugs results from healthcare reform, patient safety must be the top priority and must be ensured prior to making these drugs available to the U.S. public. Ultimately, the success or failure of healthcare reform will be gauged by whether it improves the lives of the American people.

Our recommended changes to the drafted legislation are straightforward. First, it is critical that this piece of healthcare reform requires well-designed and properly conducted clinical trials demonstrating safety and efficacy of biosimilars. Abbreviated trials are encouraged, when appropriate, but never at the cost of safety. Also, potency and biological effects of the biosimilar and approved product must be equivalent. The FDA must also set out clear criteria to demonstrate whether biosimilars can be substituted for approved products (interchangeability), and biosimilars themselves must be excluded as reference products. Lastly, long-term safety must be established and rigorously monitored in patients treated with biosimilars.

As a nonprofit advocacy group of scientists, clinicians, and patients working to combat thrombosis or blood clotting disorders, we at the North American Thrombosis Forum (NATF) (www.NATFonline.org) are intent on having healthcare reform that makes patient safety the top priority. Of particular concern is the risk of new highly complex biologics derived from the “clot-stopping” drug, heparin. Clearly, the availability of cheaper biosimilars will benefit our patients only if they are not risking their lives by taking these drugs. The lack of sufficient protection for patient safety in the current biosimilar legislation affects all biologics, including cancer therapies and hormonal treatments. This unresolved problem is of great concern to NATF. The medical community understands that healthcare reform is critical for America but it needs to be done correctly.

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The North American Thrombosis Forum (NATF) is a 501(c)(3) nonprofit organization that focuses on unmet needs and issues related to thrombosis and cardiovascular diseases
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