



Biosimilar and Follow-on Anticoagulants

Jonathan Sonis, Education and Outreach Coordinator, NATF

Ilene Sussman, Executive Director, NATF

At the core of NATF's mission is "to improve patient care, outcomes, and public health." We believe it is imperative that patients have access to the medications they need, and generics often make this possible: everyone can agree that the widespread availability of generic acetaminophen has improved patients' wellness and lowered healthcare costs.

However, some drugs are more complex than small molecules like acetaminophen, which can be synthetically reproduced easily. Heparin and heparin derivatives, long used for blood anticoagulation, are one of the more complex classes of drugs. Derived from a porcine source and with a variable and complex structure, heparin's uniqueness as a molecule prohibits easy generic substitution.

United States Representative Henry Waxman (D-CA) has recently introduced the "Promoting Innovation and Access to Life-Saving Medicine Act" (H.R. 1427), which would allow the FDA to "approve abbreviated applications" for "biosimilar" and "biogeneric" biological products; the same bill has been introduced in the United States Senate by Senator Schumer of New York. Representative Eshoo (D-CA) has introduced a competing bill in the House, which would provide new biological drugs a longer period of market exclusivity and would require more comprehensive clinical testing of generics than would Waxman's legislation. However, neither bill requires testing as extensive as that required for innovator products, which is especially necessary for complex agents derived from animal sources.

Therefore, it must be recognized that while the rushed approval of generic biological products sounds promising for increasing the availability and decreasing the cost of such biologics as heparin, it is a dangerous and medically irresponsible idea.

"Biosimilar," as defined in H.R. 1427, refers to an agent which is "comparable to the innovator product." This is a very loose term with regards to a drug such as heparin, which is derived from an animal source. Certainly, differing environments affect animal growth; many biotechnology firms are avoiding animal sources altogether for their cell culturing processes particularly to avoid this variability. Allowing for the sourcing of heparin from varied sources would likely decrease the predictability of the drug's anticoagulant effect, ultimately leading to increased incidence of bleeds and clots.

Further, it is imperative to consider the biosafety risk associated with the allowance of less-studied biological products into the market. From the heparin contamination recalls within the last several years, we have all learned the importance of scrupulously monitoring the sources of biological products before they reach market. Specifically of concern to the NATF is the potential presence of dangerous viruses, prions (self-replicating misfolded proteins), and other irregularities in minimally tested biological material. By allowing heparin generic equivalents to be administered to patients after



only an abbreviated approval process, the likelihood of such potentially devastating contamination is increased.

Finally, while “Promoting Innovation” is prominently present in the bill’s title, the reality is that such legislation may have the opposite effect: if the second or third developer of a biologic is granted shorter and less expensive regulatory and licensing measures, does this actually discourage innovation and instead encourage the notion of being second to market?

For these reasons, it is the North American Thrombosis Forum’s stance that, while well-intentioned, Representative Waxman’s bill, and, to a lesser extent, Representative Eshoo’s, will have a net negative effect on public health outcomes in the United States. It is of great importance not to enact legislation which is pennywise and pound foolish, initially decreasing medication costs while ultimately increasing medical bills.

We hope that the public and congress alike will come to understand the dangers of such legislation, and that a more comprehensive, stronger solution to reducing medication costs in the U.S. can be reached.