Conclusions: Based on the above discussion and documentation research, the consensus of the participants was that FDA should go further than EMEA and request one trial for each indication of each biosimilar LMWH. The final consensus statement of the conference was that there is a need for a **Call to Action,** which should concentrate on implementing the following 4 points.

1. Patient safety and product efficacy are the critical concerns and must not be compromised.
2. Patient safety and product efficacy must be demonstrated in valid phase III clinical trials designed for specific indications.
3. Approval guidelines must ensure that any biosimilar and its reference innovator product be interchangeable for each intended use based upon scientific and clinical data.
4. Appropriate guidelines for biosimilars should be developed for each specific class of therapeutic agents (e.g. proteins, complex sugars, nucleic acids).

More details can be found at: http://www.natfonline.org/NATFbiologicsstatement.php