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OP Ed: The Rush to Healthcare Reform with 'Generic' Biologics: Safety First

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This summer, the House Energy and Commerce Committee voted overwhelmingly to 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.

The vote in the Committee to approve biosimilars was lopsided, with the fight over them and “data exclusivity” bare-knuckle politics at its worst. Innovator drug companies, on one side, wanted to control patents on biologic drugs and delay the marketing of “biosimilars” as long as possible. The generic drug companies, on the other, wanted to be able to sell follow-on biologics as soon as possible. Because billions of dollars are at stake, this fight over “data exclusivity” overshadowed a much more critical issue: the need to ensure that these follow-on biologic drugs are safe and effective for patients.

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.

For example, there is potential for unanticipated adverse events or immune responses to a biologic drug. In one well-known example, many patients who developed antibodies against a follow-on anti-hemophilia biologic had serious adverse effects.

Minor changes in the manufacturing process were responsible for an immune response not seen with the former product. Also, there's the possibility of impurities or contaminants that are not readily identified or quantified. Only a year ago, several hundred people died from the adulteration of heparin, an event that was undetected with the existing tests to ensure drug potency.

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 biosimilar drugs are to be one benefit of healthcare reform, patient safety must be the top priority. 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 and based, in part, on recently issued guidelines of the European Medicine Agency. 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 an advocacy group of scientists, clinicians, and patients working to combat thrombosis or blood clotting disorders, we are intent on having healthcare reform that makes top priority the safety of our patients who will take these follow-on biologics. 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 be a great benefit to our patients, but only if the patients 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.

Biologics are not like conventional drugs and, therefore, Congress must pay very close attention to the approval process for follow-on biologics to ensure these medicines are not just less expensive, but equally safe and effective. The medical community understands that healthcare reform is critical for America and that many politicians are staking their futures on this legislation. But it needs to be done right or it won't benefit anyone, including patients, doctors and politicians.