Biosimilars Colloquy

Senator Harkin:

One of the provisions in the bill will address a problem in existing drug law that will speed the approval of lower cost generic drugs and help reduce costs for consumers.

The provision modifies existing FDA specified procedures governing products that have serious side effects or are prone to abuse. These procedures, known as Risk Evaluation and Management Strategies (REMS), deter the abuse of medications, and protect patients from the unique risks associated with these products. REMS often restrict the sale and distribution of these products, to prevent them from being diverted or misused.

Recent reports have highlighted how these REMS are making it more difficult for generic manufacturers to get samples of these products, in order test and develop more affordable versions of these medicines. Our bill addresses this problem by prohibiting manufacturers of products covered by REMS from restricting the resale of these products to generic manufacturers who agree to follow the same types of safety procedures.

It's my understanding that the text of the current bill needs some clarification to make clear that it would apply to biosimilar drugs. Is that your understanding, Senator Enzi, and will you agree to continue to work to modify the language to cover biosimilars.

Senator Enzi:

That is correct. Our shared intent was that this provision should apply to biosimilars. This provision is an important offset to other costs in the bill. It is vitally important that this provision be drafted correctly and consistent with our intent, so that the overall bill will not increase the deficit.

I will commit to work with you to resolve this issue and also make whatever additional changes are necessary to guarantee that the costs associated with the overall bill are fully offset.