AMA
AMERICAN MEDICAL ASSOCIATION

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January 31, 2014

Blake Bell
Counsel and Government Liaison
Mississippi State Medical Association
P.O. Box 2548
Ridgeland, MS 39158-2548

Re: AMA support for Senate Bill No. 2731 and House Bill 1268, Acts "To Provide for the Substitution of Interchangeable Biological Products"

Dear Mr. Bell:

On behalf of the American Medical Association (AMA) and our physician and student members, I am writing in support of Senate Bill (S.B.) 2731 and House Bill (H.B.) 1268, Acts "To Provide for the Substitution of Interchangeable Biological Products." The AMA supports these bills because they safeguard patient safety while simultaneously ensuring that physicians retain their prescribing autonomy.

AMA supports physician discretion and substitution limited to interchangeable biosimilars

As noted in the legislation (by reference to the United States Code), biologics comprise a wide range of products, including vaccines, blood and blood components, allergenic extracts, human cells or tissue intended for implantation, transplantation, infusion or transfer into human recipients and more. These represent a complex array of pharmaceutical products, and current legislation governing generic substitution may not be adequate to address the unique nature of biologics.

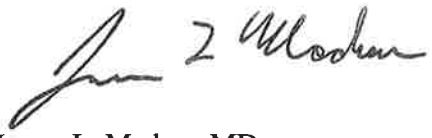
Under current federal regulations, a sponsor may seek approval of a "biosimilar" product under section 351(k) of the Public Health Service Act which establishes an abbreviated approval pathway for biological products that are either "highly similar" (i.e., biosimilar) to, or further demonstrated to be "interchangeable" with, U.S. Food and Drug Administration (FDA) licensed biological product. The AMA agrees that substitution should be limited to only those biosimilar biologic products deemed "interchangeable" by the FDA. Please note that there is no such thing as a generic biologic.

Further, physicians should retain authority to designate whether a brand name reference product is dispensed. If the physician – based on medical research and his or her experience – prefers the brand product, then the physician can help protect his or her patients by ensuring that the specific brand is prescribed. Pharmacists should only be allowed to substitute an interchangeable – and only an interchangeable – biologic product as defined by 42 U.S.C. §262(k)(4), when prescribers authorize substitution or fail to indicate a preference. These bills accomplish that important balance.

For the aforementioned reasons, the AMA supports S.B. 2731 and H.B. 1268. If you have any questions, please feel free to contact Daniel Blaney-Koen, JD, Senior Legislative Attorney, Advocacy Resource Center, at daniel.blaney-koen@ama-assn.org or (312) 464-4954.

Thank you for your efforts on this important public health issue.

Sincerely,



James L. Madara, MD

cc: Charmain Kanosky
Neely Carlton