AMA
AMERICAN MEDICAL ASSOCIATION

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January 17, 2014

The Honorable Randi Becker
Chair, Senate Health Care Committee
Washington State Senate
110 Irv Newhouse Building
PO Box 40402
Olympia, WA 98504-0402

Re: AMA support for Senate Bill 6091, "An Act relating to the prescription of biological products and interchangeable biological products"

Dear Chairwoman Becker:

On behalf of the American Medical Association (AMA) and our physician and student members, I am writing in support of Senate Bill 6091, "An Act relating to the prescription of biological products and interchangeable biological products." The AMA supports this bill because it safeguards 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 bill, 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 that establishes an abbreviated approval pathway for biological products that are either "highly similar" (i.e., biosimilar) to, or further demonstrated to be "interchangeable" with, an 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. This bill accomplishes that important balance.

For the aforementioned reasons, the AMA supports Senate Bill 6091. 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: Washington State Medical Association
Senator Bruce Dammeier
Senator Jamie Pedersen