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February 16, 2017

Representative April Weaver Chair, House Health Committee

Senator Jim McClendon Chair, Senate Health and Human Service Committee

Alabama Legislature 11 South Union Street Montgomery, AL 36130

Dear Representative Weaver and Senator McClendon:

On behalf of the Board of Directors of the National Hispanic Medical Association, we urge you to vote yes for HB 82, FDA-designated interchangeable biological drug products.

This bill authorizes a pharmacist to substitute an alternative biological product when filling a prescription for a prescribed biological product if the alternative biological products is designated as interchangeable with the reference product and communication is provided to the patient and physician that a substitution was made. The bill would also require that the substitution of a biological product be communicated to the patient.

We recognize the rising use of biologics and biosimilars in our population now aging with increased chronic disease. Biosimilars go through an extensive review process and manufacturers are required to submit immense studies and data demonstrating a products' efficacy and ensuring it is safe for use by consumers. A pathway for biosimilar regulation in the U.S. was established as a provision of the 2008 Patient Protection and Affordable Care Act (ACA) and in 2012 the FDA issued draft guidelines for biosimilars and a list of biosimilars and interchangeable biological products.

In summary, the National Hispanic Medical Association recommends your support for HB 82 before the end of session to clarify the procedures for biosimilar substitution for biologic treatments in a way that increases safety for the patient. We are especially supportive since this bill will provide increased access to quality treatment for Hispanics and all persons from Alabama with chronic diseases.

Sincerely,

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Elena Rios, MD, MSPH, FACP President & CEO