MEDICAL ASSOCIATION
OF THE STATE OF ALABAMA®

February 21, 2017

Members of the House Health Committee
Alabama House of Representatives
Alabama State House
11 South Union Street
Montgomery, AL 36130

The undersigned state medical societies, representing thousands of Alabama physicians and hundreds of thousands of their Alabama patients, ***humbly request your opposition to House Bill 82*** related to biologic pharmaceutical substitution, which has been assigned to the House Health Committee. As written, HB 82 would lower pharmaceutical safety standards in Alabama law below those in federal law and set by the FDA; would withhold critical health information from patients and their physicians; and, would dramatically increase administrative burdens on physicians.

For background purposes, biologics are highly complex pharmaceuticals made from living organisms, hundreds if not thousands times more complex than chemical drugs. As a class of pharmaceuticals, they have demonstrated the ability to not only improve, but save patients' lives and in some instances, may even do so at a reduced cost. However, health and safety concerns are particularly significant when terms like "biologic," "biosimilar" and/or "interchangeable" are used synonymously as they are in HB 82, because federal law and FDA guidelines recognize the stark contrasts between these terms. Further, any claims that biosimilars are simply generic versions of biologics are completely false.

While all biosimilars are biologics, only biologics having met specific federal criteria can be deemed biosimilar to another biologic. As well, federal law makes a clear distinction between "biosimilar" and "interchangeable." Federal law specifically requires a clearly stated and much higher threshold for a biological product – even one deemed biosimilar – to be determined "interchangeable" with another biologic.

Clearly, federal law establishes major differences between "biosimilar" and "interchangeable" biologics with "interchangeable" being a significantly higher regulatory threshold to meet for biologic manufacturers seeking interchangeability of their biologics. If these terms are allowed to be deemed synonymous in Alabama law as HB 82 would allow, the complications could be severe, even life-threatening in patients taking these pharmaceuticals. Unfortunately, HB 82 would do just that.

Proponents of HB 82 – a coalition of health industry groups led primarily by biologic pharmaceutical manufacturers and pharmacy benefit managers – claim HB 82 will provide a process by which biosimilar products may be substituted for their brand name biologic counterparts and by which physicians issuing prescriptions for such pharmaceuticals and patients taking them may be notified of any substitution that is made.

Instead, however, HB 82 would:

> Lower safety standards – the bill would significantly lower the standards for biologic/biosimilar "interchangeability" far below those set in federal law and FDA guidelines and place patients at risk by equating "interchangeability" with "therapeutic equivalence" in Alabama law.
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> Withhold critical health information from physicians and patients – while the bill does call for communication with a physician when a prescribed biologic is substituted, the bill would allow 5 whole business days to pass before such communication is required. Communication with a patient regarding substitution is satisfied in HB 82 by simply recording the pharmaceutical information on the prescription label. There is no requirement to verbally explain the substitution to the patient or obtain their consent prior to making the substitution.
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> Increase burdens on physicians – the bill would require physicians to constantly check multiple websites and/or pharmacy records systems to see if any of their patients' prescriptions have been substituted. HB 82 would allow the "notice requirement to the prescribing physician" to be satisfied simply by a pharmacy benefit manager's posting the substitution to an obscure pharmacy benefit management records system where the physician is unlikely to see it.

For the reasons listed above – lowering safety standards, hiding critical health information from physicians and patients and increasing hassle factors for physicians – ***the undersigned Alabama medical societies cannot support HB 82 in its current form***. We have requested the proponents of HB 82 to amend the bill in the following ways to ensure patient safety is prioritized and continuity of care is prioritized:

1. Uphold high standards – the bill should be amended to uphold the high standards for biologic/biosimilar "interchangeability" by mirroring federal law and FDA guidelines. Alabamians should not settle for lower standards on biologics than those set at the federal level.

2. Provide transparency in notification to physicians and patients – physicians and their patients should be notified immediately when substitution of a prescribed biologic with an interchangeable biosimilar is made.

3. Seamlessly notify physicians of substitution – physicians should be notified immediately when substitution of a prescribed biologic with an interchangeable biosimilar is made via facsimile, telephone or through the electronic prescribing system the physician used to issue the biologic prescription.

Thank you for your commitment to ensuring the highest quality of care for Alabamians. We strive, as medical societies and individual physicians serving your constituents, to provide the highest quality of care to our patients each day. With the ever-increasing cost of prescription medications showing no signs of slowing, the goal of easing patient access to equally safe, less expensive biologics is indeed worthy of pursuit. But lower price should not come at the expense of our patients, who are your constituents, your family members, perhaps even yourselves. Our medical societies are committed to fighting for the highest standards of care for the prescription of and treatment with biologic and biosimilar products and ensuring those standards are not lowered in Alabama law.

Therefore, we the undersigned Alabama medical societies urge your support for the aforementioned changes to HB 82 in order that Alabama patients aren't subjected to lower standards for biological therapy.

If you have questions, please contact the Government Relations Department of the Medical Association of the State of Alabama at (334) 261-2000 or by email, kcampbell@alamedical.org.

Sincerely,

Medical Association of the State of Alabama
Alabama Society of Allergy & Immunology
Alabama State Society of Anesthesiologists
Alabama Chapter, American College of Cardiology
Alabama Chapter, American College of Emergency Physicians
Alabama Academy of Family Physicians
Alabama Section, American Congress of Obstetricians and Gynecologists
Alabama Academy of Ophthalmology
Alabama Orthopaedic Society
Alabama Society of Otolaryngology - Head & Neck Surgery
Alabama Chapter, American Academy of Pediatrics
Alabama Society of Plastic & Reconstructive Surgery
Alabama Psychiatric Physicians Association
Alabama Academy of Radiology
Alabama Chapter, American College of Surgeons
Alabama Thoracic Society
Alabama Urological Society
Alabama Gastroenterological Society
Alabama Academy of Neurology
Alabama Society for the Rheumatic Diseases

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