



*Sound Policy. Quality Care.*

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June 24, 2009

Honorable Edward M. Kennedy  
Chairman  
Senate HELP Committee  
317 Russell Senate Building  
Washington, D.C. 20510

Honorable Michael B. Enzi  
Ranking Member  
Senate HELP Committee  
379 A Russell Senate Building  
Washington, D.C. 20510

Dear Chairman Kennedy and Ranking Member Enzi:

The undersigned members of the Alliance of Specialty Medicine (Alliance) applaud your efforts to establish a pathway for biosimilars/follow-on biologics, but are concerned by attempts to eliminate incentives for the development of next-generation therapeutics.

The Alliance is a coalition of 10 national medical specialty societies representing approximately 200,000 physicians is dedicated to the development of sound federal health care policy that fosters patient access to the highest quality specialty care. Biotechnology has produced novel therapeutic agents that have markedly increased the ability to treat patients suffering from serious illnesses, and medical specialists increasingly rely on biologic medications to provide optimal care for patients.

The evolution of medicine through biotechnology has been a remarkable advance for how we treat patients under our care. However, the continued development of new biologics is needed if we are to continue to advance patient care. That is why we are concerned that some are attempting to eliminate incentives for the development of new next-generation therapies. Given the urgent challenges facing patients today and the need for physicians to have new tools to fight disease it is inconceivable that policy makers would decide in advance which therapies are deserving of development incentives and which one's are not.

As physician specialists we hold patient safety as the highest priority when considering provisions in biosimilar legislation. In that regard, the Alliance strongly endorses legislative language providing the Food and Drug Administration with the ultimate authority on biosimilar safety and effectiveness determinations. The development of next-generation medicines that are safer and more effective for patients is in keeping with those priorities, and we urge you to oppose any proposals that would eliminate incentives to bring forth new medicines.

Thank you for your commitment and leadership on this issue.

Sincerely,

American Association of Neurological Surgeons  
American Association of Orthopaedic Surgeons

American Gastroenterological Association  
American Society of Cataract and Refractive Surgery  
American Urological Association  
Coalition of State Rheumatology Organizations  
Congress of Neurological Surgeons  
Heart Rhythm Society  
Society for Cardiovascular Angiography and Interventions