

On behalf of Raymond C. Scheppach, Ph.D., Executive Director of the National Governors Association, I am formally responding to the letter from Chairman Frank Pallone and Ranking Member Nathan Deal requesting information on biosimilar pharmaceutical products. The National Governors Association has just begun to focus attention on this emerging issue, and while our official policy does call upon Congress and the FDA to establish a workable regulatory framework that will ensure timely access to safe, effective, and more affordable products, I regret to inform you that we do not at this time have sufficient expertise or consensus to be able to fully respond to the list of questions you provided. I am enclosing the full extent of the NGA position below. I realize that it does not come close to fully answering the many thoughtful questions you have posed, but it represents the totality of our current position.

From NGA Executive Committee Policy EC-16 Medicaid Reform

**16.2.1 Prescription Drug Improvements.** The DRA made a number of important reforms in the area of pharmaceutical benefits and pricing. CMS must continue to work with states as it implements the new definition of the Average Manufacturer Price to ensure it remains an accurate and useful benchmark. Governors are interested in ensuring the appropriate reimbursements for prescription drugs and continue to oppose arbitrary increases, such as mandated dispensing fees. States' experiences with the Medicare Part D benefit raise concerns that Medicaid is not actually receiving the competitive prices in the market, and more reforms are necessary to ensure that this is realized. *Furthermore, Governors encourage Congress and the Food and Drug Administration to establish a workable regulatory framework that will enable timely access to safe, effective, and more affordable biosimilar pharmaceutical products. By taking such action, lower cost biopharmaceutical products could be available to Medicaid recipients as well as other health care consumers.*

If you have any further questions or comments, please feel free to contact me at any time.

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