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March 13, 2014

The Honorable Phil Gingrey, MD
U.S. House of Representatives
442 Cannon House Office Building
Washington, DC 20515

Dear Dr. Gingrey:

On behalf of the physician and medical student members of the American Medical Association (AMA), I am writing in support of H.R. 3742, the “Antibiotic Development to Advance Patient Treatment Act of 2013” (ADAPT). We laud your effort to establish an approval pathway that would accelerate patient access to urgently needed new antibacterial medications that are intended to treat serious, life-threatening infections where there exists an unmet medical need. The alarming rise in antibiotic resistance requires a multi-prong approach, including streamlining regulatory requirements that may impede approval of treatments in targeted patient populations.

H.R. 3742 would authorize the Food and Drug Administration (FDA) to evaluate a medication’s safety and efficacy in substantially smaller, accelerated clinical trials than currently required. Upon approval, the treatment would be narrowly indicated for use in a small, specific population of patients for whom the benefits of the drug have been shown to outweigh the risks. The AMA supports establishment of such a limited population antibacterial drug (LPAD) mechanism to provide a predictable and feasible FDA approval pathway for pharmaceutical companies seeking to develop antibacterial drugs to treat serious and life-threatening infections where there is a lack of sufficient or satisfactory therapeutic options through legislative or regulatory means.

Upon passage of H.R. 3742, the AMA is committed to working with the Infectious Diseases Society of America, other medical societies, and the health care community to educate physicians about LPAD products, including their benefits and risks. We strongly support the ADAPT provision that requires labeling to include information regarding the drugs’ limited indication, granting FDA authority to pre-review the drugs’ promotional materials, and directing the Centers for Disease Control and Prevention (CDC) to monitor the drugs’ use. We further applaud the H.R. 3742 provision that explicitly provides that the LPAD pathway amendments do not restrict the practice of medicine nor seek to restrain physician clinical decision-making.

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We appreciate your leadership on behalf of physicians and look forward to working with you to advance this important legislation.

Sincerely,

James L. Madara, MD