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September 13, 2017

The Honorable Michael Burgess, M.D.  
Chairman, Subcommittee on Health  
Energy and Commerce Committee  
2125 Rayburn House Office Building  
Washington, DC 20515

The Honorable Gene Green  
Ranking Member, Subcommittee on Health  
Energy and Commerce Committee  
2322A Rayburn House Office Building  
Washington, DC 20515

Dear Chairman Burgess and Ranking Member Green:

On behalf of GSK and our over 15,000 employees in the United States, thank you for holding today's hearing entitled "Modernizing FDA's Regulation of Over-the-Counter Drugs" to consider draft legislation updating the Over-the-Counter (OTC) Monograph system.

As you may know, OTC medicines play a vital role in our nation's healthcare system, providing access, affordability, empowerment and trust. OTC medicines allow individuals and families to meet their everyday healthcare needs, including 96% of U.S. adults reporting that OTC medicines make it easy for individuals to care for minor medical ailments and 93% of U.S. adults preferring to treat their minor ailments with OTC medicines before seeking professional care.

At GSK, our mission is simple. We want to help people do more, feel better, and live longer. GSK Consumer Healthcare embodies the company's overall mission by being the largest manufacturer globally for OTC products reaching over one billion people and assists in the ability for Americans to address these routine healthcare challenges. Our brands are organized into five categories: Pain Relief, Respiratory, Oral Health, Nutrition/Gastro Intestinal, and Skin Health.

OTC Monograph Reform will help foster the growth and availability of these vital medicines. GSK believes that policy reforms could make the system even more flexible, responsive, and accommodating to innovation. Ultimately, this will broaden choice for consumers so they can better meet their individual needs for OTC medicines.

We thank you for your collective leadership in holding today's hearing, and we hope that the Subcommittee moves forward with consideration of this legislation. Ultimately, modernizing the OTC Monograph system will ensure that FDA and industry can update products with safe, effective ingredients in the market today, and so that FDA has the resources to approve safety labeling changes and innovation in the OTC market.

If GSK can ever be of assistance to you or your staff, please do not hesitate to contact Michael Calvo, Manager, Federal Government Relations, at (202) 715-1041 or via email at [michael.j.calvo@gsk.com](mailto:michael.j.calvo@gsk.com).

Sincerely,

Colin Mackenzie