



Patients Alliance for
Drug Safety Protections

May 5, 2017

The Honorable Gus Bilirakis
Health Subcommittee
House Energy & Commerce Committee
2125 Rayburn House Office Building
Washington, DC 20515

The Honorable Kurt Schrader
Health Subcommittee
House Energy & Commerce Committee
2125 Rayburn House Office Building
Washington, DC 20515

Dear Representative Bilirakis and Representative Schrader:

On behalf of the Patients' Alliance for Drug Safety Protections, a coalition of public health, patient advocacy, health professional, and disease organizations, we thank you for including a Government Accountability Office (GAO) study on Risk Evaluation and Mitigation Strategies (REMS) in HR 749, the Lower Drug Cost Through Competition Act. Our organizations represent millions of Americans with serious diseases, such as cancer, multiple sclerosis, kidney disease and other life-threatening conditions, many of whom rely on drugs and treatments that would not be available to them without REMS.

A GAO study will provide up-to-date, accurate and objective information on the need for REMS to alleviate the risks of potentially fatal complications, severe allergic reactions, birth defects, organ damage, and serious infections that may result from the inappropriate use or mishandling of high-risk drugs. Also of importance, the study can demonstrate the importance of FDA-mandated restrictive REMS protocols, known as Elements to Assure Safe Use (ETASUs), to advance patient safety and protect public health. Moreover, this study can provide data to help decide whether some existing REMS are still needed and to develop an evidence-based pathway for those that are no longer necessary.

We realize the need for rapid development of generic drugs, and appreciate the positive impact lower-cost treatments have had on the well-being of patients and their families. However, these improvements cannot jeopardize these same patients' safety. The REMS protocols help to ensure that patients get the drugs they need without unnecessary risk.

Once again, thank you for including the GAO report in HR 749. We look forward to working with you to ensure that patients can access the affordable, life-saving, and safe drugs and treatments they need. For more information, please contact Stacey Worthy, Executive Director of the Alliance for the Adoption of Innovations (Aimed Alliance) at sworthy@aimedalliance.org or (202) 644-8525.

Thank you for your consideration of our views.



Patients Alliance for Drug Safety Protections

Alliance for the Adoption of Innovations in Medicine
American Autoimmune Related Diseases Association
Association of Reproductive Health Professionals
Association of Women's Health, Obstetric & Neonatal Nurses
Center for Lawful Access and Abuse Deterrence
Cutaneous Lymphoma Foundation
HealthyWomen
Leukemia & Lymphoma Society
March of Dimes
Myelodysplastic Syndromes Foundation
National Association of Nurse Practitioners in Women's Health
Patient Power
Patients Rising
Teratology Society