April 8, 2015

The Honorable Fred Upton
Chairman
Committee on Energy & Commerce
2125 Rayburn House Office Building
Washington, DC 20515

The Honorable Frank Pallone
Ranking Member
Committee on Energy & Commerce
2415 7Rayburn House Office Building
Washington, DC 20515

Dear Chairman Upton and Ranking Member Pallone:

The undersigned organizations collectively advocate on behalf of millions of men and women whose chronic health conditions (cancers, Crohn's disease, bowel disorders, chronic obstructive pulmonary disease, HIV, lung conditions, multiple sclerosis, seizures, schizophrenia) and rare disorders are treated effectively with medicines that may never have been approved without Risk Evaluation and Mitigation Strategies (REMS) to ensure safe use.

We are greatly concerned about legislative proposals that are being considered that may force the sale of medicines carrying serious risks to generic marketers for clinical (bioequivalence) testing without what we feel are sufficient safeguards to prevent harmful exposure. Although our organizations recognize the value of generic drugs to patients and the medical community, we are also aware that medicines subject to REMS can cause terrible birth defects, organ damage and even death when not handled and administered with utmost care, and we believe that any generic version of these drugs should have the same rigorous safeguards as those employed by the brand name to ensure safe use.

REMS, first authorized under the Food and Drug Administration Amendments Act of 2007 (FDAAA), gave FDA authority to require REMS from manufacturers as a condition of drug approval or post-approval to mitigate risk through certain actions. Through the FDA Safety Improvement Act of 2012 (FDASIA), Congress reaffirmed the need for a rigorous REMS program to prevent life-threatening complications, severe allergic reactions and serious infections resulting from the inappropriate use or handling of higher risk drugs.

Recognizing that REMS drugs are a unique set of important medicines, FDA streamlined the REMS program to concentrate on mitigating the risks of only the most potentially dangerous drugs. The result is that today, REMS programs are rare and only authorized when necessary to protect patients from potentially severe adverse events. Currently, only 71 medications have authorized unique REMS programs in place, while six more products exist in shared REMS systems. Less than half of these medicines (34) are subject to the more restrictive "Elements to Assure Safe Use" (ETASU) and an even smaller number require restricted distribution systems to meet the terms of these REMS programs.

Based on the current REMS safety protocols, nearly a dozen medicines subject to REMS have gone generic, including nine subject to more strict ETASU provisions. Moreover, a growing number of "abbreviated new drug applications" for new generic medicines have been filed with FDA resulting from bioequivalence testing of drugs subject to REMS. This is due to established procedures

whereby FDA permits an innovator company to sell samples of a REMS drug for bioequivalence testing after receiving documentation from the generic manufacturer that the drug will be handled, dispensed and administered safely. With a view towards accelerating this process, FDA issued draft guidance in December 2014 clarifying the process by which a generic manufacturer may obtain a letter from FDA stating the safety protections proposed for the clinical study are comparable to those in the innovator company's REMS program.

Today, the REMS program envisioned by Congress and implemented by FDA has become an essential tool to advance patient safety, protect public health, and provide access to innovative medicines that would otherwise not be available. Therefore, it is critically important for policymakers to ensure the drug safety protections REMS makes possible are guarded closely and modified only after the most careful consideration with patient safety in mind. Accordingly, policies that would allow the forced sale of drugs known to carry high risks without required safeguards to ensure these medicines are handled and administered safely are not in the public interest and should not be implemented.

As Congress considers legislation relating to FDA matters, it is critical that REMS programs and its Elements to Assure Safe Use (ETASU), including restricted distribution systems, are considered essential drug safety mechanisms, which should not be weakened.

We appreciate your consideration of the issues raised in this letter, and look forward to working closely with the Committee on this important matter.

Sincerely,
Society for Women's Health Research (SWHR®)

Alliance for the Adoption of Innovations in Medicine
American Autoimmune Related Diseases Association
American Chronic Pain Foundation
American College of Nurse-Midwives
American College of Obstetricians and Gynecologists
American Gastroenterological Association
Aplastic Anemia & MDS International Foundation
Association of Community Cancer Centers
Association of Women's Health, Obstetric and Neonatal Nurses
Center for Lawful Access and Abuse Deterrence
Crohn's and Colitis Foundation of America
Cutaneous Lymphoma Foundation
Dupuytren Foundation
Genetic Alliance
Global Genes
HealthyWomen
International Myeloma Foundation
Lymphoma Research Foundation
Men's Health Network

Myelodysplastic Syndromes Foundation
NAMI
National Association of Nurse Practitioners in Women's Health
National Consumers League
National Multiple Sclerosis Society
Rare Disease United Foundation
RetireSafe
Society of Gastroenterological Nurses and Associates
Schizophrenia and Related Disorders Alliance of America