Patients Alliance for
Drug Safety Protections

September 21, 2016

The Honorable Chuck Grassley
Chairman
Committee on the Judiciary
U.S. Senate
Washington, DC 20510

The Honorable Patrick Leahy
Ranking Member
Committee on the Judiciary
U.S. Senate
Washington, DC 20510

The Honorable Mike Lee
Member
Committee on the Judiciary
U.S. Senate
Washington, DC 20510

The Honorable Amy Klobuchar
Member
Committee on the Judiciary
U.S. Senate
Washington, DC 20510

Dear Chairman Grassley, Ranking Member Leahy and Senators Lee and Klobuchar,

As members of a broad-based coalition of public health, patient advocacy, health professional and disease organizations called The Patients' Alliance for Drug Safety Protections (Patients' Alliance), we advocate for the 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 would never have been approved without Risk Evaluation and Mitigation Strategies (REMS) to ensure safe use.

On behalf of these Americans, we are greatly concerned about legislative proposals now being considered that would force the sale of medicines carrying serious risks to generic marketers for comparison (bioequivalence) testing and permit separate generic REMS without what we feel are sufficient safeguards to prevent harmful exposure to patients, medical professionals, and others. Although our organizations recognize the value of generic drugs and biosimilars to patients and the medical community, we are also aware that medicines subject to REMS – and especially those approved with restrictive "Elements to Assure Safe Use" (ETASU) – can cause terrible birth defects, organ damage, and even death when not handled and administered with the utmost care.

For this reason, we believe all developers of generic versions of REMS drugs should be required to demonstrate their capabilities to adhere to the same rigorous standards as those employed by the brand name to ensure safe use. Accordingly, we have significant misgivings about current legislative proposals, such as the recently introduced ''Creating and Restoring Equal Access to Equivalent Samples Act of 2016'' or the ''CREATES Act of 2016,'' that discount the need for REMS with ETASU.

Our specific concerns involve proposals that would limit the FDA's authorization process for obtaining samples for bioequivalence testing and curtail the methods the agency now employs to verify a generic manufacturer's risk management plan to prevent harmful exposure to a drug known to carry significant risks, as well as permit separate generic REMS of unproven safety. We believe these

provisions are the result of a lack of understanding about the purpose of REMS protocols, largely because almost a decade has passed since Congress passed legislation authorizing REMS and the sense of urgency that led to these requirements has been replaced by a number of misperceptions, especially about medicines marketed with ETASU.

To address this awareness gap, in October 2015, the Patients' Alliance was formed to raise awareness of the importance of REMS and the integrity of safety programs like REMS with ETASU as tools that advance patient safety and protect public health. This includes educating policymakers that under Section 501-1(f) of the Food, Drug and Cosmetic Act, REMS with ETASU are necessary to assure the safe use of certain drugs due to their inherent toxicity or potential harmfulness.

Specifically, the law allows FDA to mandate REMS with ETASU when "the drug, which has been shown to be effective, but is associated with a serious adverse drug experience, can be approved ONLY IF, OR WOULD BE WITHDRAWN UNLESS, {emphasis added} such elements are required as part of such strategy to mitigate a specific serious risk." Simply put, the law makes clear that without these controls, the drug could not be approved and patients would be denied access to a value medicine for their disease.

Yet, it is our understanding that at a Senate Judiciary Subcommittee on Antitrust hearing on June 21, witnesses told the Subcommittee that the proposed CREATES Act would codify and not change the FDA's current practice of authorizing samples of a REMS drug for bioequivalence testing and that separate generic REMS would not introduce new safety concerns. We respectfully disagree. The bill does not require evidence demonstrating that separate REMS will ensure the same level of safety, and would apparently permit unproven generic REMS to be approved behind closed doors without stakeholder review. Moreover, unlike the established procedures whereby FDA permits an innovator company to sell samples after reviewing documentation from the generic manufacturer that the drug will be handled, dispensed and administered under comparable safety protocols, the bill would only require generic marketers to attest that this is the case. As such, FDA would be precluded from investigating whether the generic developer has the safety track record and capability to follow a rigorous risk management system. This lax system is not in the public interest, could put patients at risk of significant harm and creates disincentives for the future development and marketing of higher-risk drugs, especially to treat rare disorders, due to liability concerns.

Although the goal of speeding the development of less expensive generic medicines and biosimilars is laudable, we urge legislators to act with an abundance of caution when considering proposals such as the CREATES Act. If the current system is changed, then it must include a robust FDA process that goes beyond reviewing self-attestation forms and includes a review of a product developer's actual capabilities and its safety history, require evidence demonstrating that safety will remain the same and a public process for review of separate generic REMS before they are approved. We understand the need to increase competition in the drug marketplace but ask that policymakers thoughtfully consider the health and safety of patients with serious and life threatening health conditions before moving forward with any proposal.

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Thank you for your consideration of our views.

Sincerely,

Alliance for the Adoption of Innovations in Medicine
American Autoimmune Related Diseases Association
Association of Women's Health, Obstetric and Neonatal Nurses
C-Change
Consortium of MS Centers
Center for Lawful Access and Abuse Deterrence (CLAAD)
Cutaneous Lymphoma Foundation
HealthyWomen
International Myeloma Foundation
March of Dimes
Myelodysplastic Syndrome Foundation
National Association of Nurse Practitioners in Women's Health
OTIS/MotherToBaby
Patients Rising
Society for Women's Health Research
The Teratology Society