

November 15, 2018

Senator Mitch McConnell
Senate Majority Leader
317 Russell Senate Office Building
Washington, DC 20510

Senator Charles Schumer
Senate Minority Leader
322 Hart Senate Office Building
Washington, DC 20510

Senator Lamar Alexander
Chairman
Senate Health, Education, Labor, and Pensions
Committee
428 Dirksen Senate Office Building
Washington, DC 20510

Senator Patty Murray
Ranking Member
Senate Health, Education, Labor, and Pensions
Committee
428 Dirksen Senate Office Building
Washington, DC 20510

Dear Majority Leader McConnell, Minority Leader Schumer, Chairman Alexander, and Ranking Member Murray:

The undersigned organizations, representing millions of patients, advocates, caregivers, and health care professionals urge the Senate to take swift action to address a major public health concern for patients and their physicians by passing S. 3519, the Making Objective Drug Evidence Revisions for New Labeling Act (MODERN Labeling Act).

Patients and their caregivers, physicians, and nurses, need high quality sources of information about the prescription drugs they use, and that means up-to-date drug labels. While many sources of information exist, none can deliver as strong assurances of reliability and scientific accuracy as FDA-approved product labels. Labels are the most carefully-vetted sources of prescribing information available today and play a critical role in safeguarding the public health. A recent study by Friends of Cancer Research (*Friends*) shows that many drug labels are considerably out of date, despite the critical role they can play in informing treatment decisions, and offer guidance to prescribers on the appropriate and safest use of drugs to treat patients.

Senators Orrin Hatch (R-UT) and Michael Bennet (D-CO) have introduced S. 3519, the MODERN Labeling Act. The bill addresses a discrepancy that can occur when new scientific information relevant to a drug's indication is not incorporated into its label. This often occurs to generic drugs, particularly those whose reference listed drug (RLD) has been removed, which leaves an inaccurate or incomplete generic drug label "frozen in time". The legislation addresses this issue by giving the FDA the authority to require updating of generic drug labels where the RLD has been removed to reflect new information relevant to the drug and its use. This Act also determines a process through which the FDA can identify labels to be updated, notice label holders, and allows for a process for label holders to submit modifications to the notice.

We urge immediate passage of the MODERN Labeling Act by the Senate HELP Committee, and the full Senate, to address this public health concern to ensure the FDA can update outdated labels and protect patients across the country.

Sincerely,

Alliance for Aging Research
American Association for Cancer Research (AACR)
American Cancer Society Cancer Action Network (ACS CAN)
Cancer Support Community
Children's Cause for Cancer Advocacy
Fight Colorectal Cancer
Friends of Cancer Research
Lung Cancer Alliance
LUNgevity
National Alliance on Mental Illness
National Comprehensive Cancer Network (NCCN)
National Multiple Sclerosis Society
National Organization for Rare Disorders
St. Baldrick's Foundation
Susan G. Komen