Making Objective Drug Evidence Revisions for New Labeling Act Introduced to Senate

Senators Hatch and Bennet Introduce Bipartisan Solution to Important Public Health Issue

September 28, 2018 – Washington, DC – Friends of Cancer Research (*Friends*) applauds Senators Orrin Hatch (R-UT) and Michael Bennet (D-CO) for responding to a recently identified public health issue and swiftly proposing a solution to an issue impacting patients and their physicians around the country. Sen. Hatch and Sen. Bennet took an important bipartisan step forward by introducing the Making Objective Drug Evidence Revisions for New Labeling Act or MODERN Labeling Act today.

The legislation addresses the prevalence of outdated labels for drugs by giving the U.S. Food & Drug Administration (FDA) the authority to require updating labels to reflect new information relevant to the drug and its use when the approved label has been withdrawn. 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 are truly grateful for the work Sen. Hatch and Sen. Bennet, along with their staff, did to translate a study that was conducted by *Friends* into a legislative solution in such a short amount of time," said Jeff Allen, President & CEO of *Friends*. "We commend their bipartisan action to improve public health and urge Congress to pass the MODERN Labeling Act into law."

Earlier this year, *Friends* hosted a congressional briefing on the topic of outdated labels. At the briefing, new data was presented showing that a striking number of FDA-approved prescription drug labels are out of date. The study, "Outdated Prescription Drug Labeling: How FDA-Approved Prescribing Information Lags Behind Real-World Clinical Practice," was published in the peer-reviewed journal *Therapeutic Innovation and Regulatory Science*. The article showed that most FDA-approved cancer drug labels are missing critical information on drug effectiveness.

“My main fear is that outdated recommendations on labels wind up harming patients,” said Dr. Janet Woodcock, Director of the Center for Drug Evaluation and Research at FDA, in March during the *Friends* congressional briefing.

The authors of the report analyzed information on 43 drugs approved during a 12-year period from 1999 to 2011, comparing the number of FDA-approved indications visible on labeling to the number of uses recommended in the National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium. The report found there were more than four times as many uses on the Compendium than on drug labels, a huge discrepancy considering both purport to offer prescribers guidance on the appropriate uses of cancer drugs. The report also found that 56% of the uses included in the Compendium were “off label,” meaning that these uses were not approved by the FDA.

Dr. Woodcock, among others, stated that the primary concern over outdated prescription drug labels is that physicians prescribing drugs outside of their area of expertise who look to labels to inform their decisions may come away with incomplete or incorrect information. It was also noted that patient harm can result from prescribers using outdated labels to learn about drugs they don’t typically use.

About Friends of Cancer Research

Friends of Cancer Research (*Friends*) drives collaboration among partners from every healthcare sector to power advances in science, policy and regulation that speed lifesaving treatments to patients. For more information, please visit www.focr.org.