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Patient Advocates and Health Care Provider Groups Applaud Filing of the 'Safe Step Act' in U.S. House and Senate

Legislation puts common sense guidelines around insurance industry practice of *"step therapy"*

WASHINGTON, D.C. – Today, patient and health care provider groups from across the country applauded the reintroduction of legislation aimed at putting reasonable parameters around the insurance industry protocol known as "step therapy" or "fail first". The bill (S.652) is sponsored in the Senate by Senators Lisa Murkowski (R-AK), Maggie Hassan (D-NH) Doc Marshall (R-KS), Jacky Rosen (D-NV). The House version of the bill is sponsored by Representatives Brad Wenstrup (R-OH-2), Raul Ruiz (D-CA-36), Lori Chavez-DeRemer (R-OR-05) Lucy McBath (D-GA-6) Mariannette Miller Meeks (R-IA-2) and Earl Blumenauer (D-OR-03).

"The Safe Step Act" mirrors legislation passed in more than three dozen states across the country. When passed into law the legislation will bring similar patient protections to employer health plans that are regulated on the federal level.

Currently, health plans can require patients to try and fail on one or more medications before the plan will cover the treatment initially selected by the patient and their health care provider. Delays in getting the proper treatment can lead to irreversible disease progression and worsening of a patient's medical condition.

"NPF applauds Congress for reintroducing the Safe Step Act in the 118th Congress," says Leah M. Howard, J.D., the President and CEO of the National Psoriasis Foundation (NPF). "Step therapy places an enormous barrier between the 8 million people in the U.S. who live with psoriatic disease and the treatments they need. One study found that over 99% of step therapy protocols were more stringent than the treatment guidelines for psoriasis. Unfortunately, the resulting delays in care can lead to more skin area affected by plaques that crack and bleed, causing missed workdays and social isolation. Prolonged systemic inflammation from psoriatic disease can result in irreversible outcomes like joint damage or the development of type 2 diabetes."

During the 117th Congress, similar legislation had more than 230 co-sponsors in both chambers.

"We hear every day from patients experiencing challenges getting the treatment their doctor has prescribed," said Steven Taylor, President and CEO of the Arthritis Foundation. "All too often patients are asked to fail on 2, or 3, or even 4 medications before they can get the one originally prescribed, all the while experiencing worsening disease. Further, patients are sometimes asked to step through a drug they've already failed on or have to wait weeks before their appeal is reviewed. State legislatures across the country have passed step therapy reform, putting in place common sense solutions to help patients get their medications in a timely manner. It's time for Congress to do the same."

The Safe Step Act does not ban the use of step therapy, but instead puts common sense parameters and reasonable timelines around the practice. The legislation will give patients and their doctors a transparent and standardized process to appeal step therapy requirements for patients needing a particular treatment.

"Underserved and minority patients face unique challenges to cardiovascular care and treatment that impact their health outcomes. The ability to access new treatments is often hampered by utilization management processes, such as step therapy, that are put in place by health insurance plans. Physician practices that serve a majority of patients from underserved and minority populations are oftentimes already stretching resources to meet the needs of their patients, making it difficult to devote the time necessary to respond to health plan treatment denials or 'fail-first' requirements that may be harmful to patient health and safety. These challenges create unique barriers to care for African American cardiovascular patients and exacerbate existing treatment and health outcome disparities. The Association of Black Cardiologists endorses the Safe Step Act as a reasonable approach that prioritizes patient care and safety," said Anekwe E. Onwuanyi, MD, President of the Association.

"Pediatric patients with diseases and disorders of the gastrointestinal system and their physicians routinely encounter insurance companies that take a 'fail first' approach to therapeutic treatment as a matter of policy. When pediatric gastroenterologists seek reauthorization for a previously approved treatment, it has become commonplace for insurance companies to deny authorization and require the child to switch to another therapy even though they are stable on their existing treatment, said Jenifer Lightdale, MD, President of the North American Society for Pediatric Gastroenterology, Hepatology and Nutrition. "This practice must stop and is why the North American Society for Pediatric Gastroenterology, Hepatology and Nutrition endorses the Safe Step Act and asks for its passage by Congress."

"No two patient stories are the same and a one-sized-fits-all treatment plan puts all people at risk. To prevent negative medical consequences, treatment should be recommended and prescribed by medical professionals in collaboration with the patient and not dictated by insurers. For these reasons United Ostomy Associations of America Inc. (UOAA) stands in support of the Safe Step Act" said UOAA President, Cheryl Ory.

"These policies cause real physical and mental pain for our patients, senselessly delaying our ability to provide relief for often debilitating conditions. Treatment decisions belong with patients and their physicians, who understand their conditions best," said Mark Kaufmann, MD, FAAD, President, American Academy of Dermatology Association.

"Rationing healthcare is never a good thing for patients, especially for patients living with chronic health conditions such as HIV/AIDS. It is especially true for prescription medications. Unfortunately, an increasingly common technique involves private and public healthcare payers requiring step therapy...or step protocol...or fail first requirements. Sadly, such requirements not only undermine the provider-patient relationship, they also have proven to be less cost-effective in the long run," said Brandon M. Macsata, CEO of the ADAP Advocacy Association.

The "Safe Step Act" is supported by more than 200 patient and provider organizations.

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