

Congress of the United States
House of Representatives
Washington, DC 20515

March 14, 2022

The Honorable Robert C. “Bobby” Scott
Chairman
Education & Labor Committee
U.S. House of Representatives
Washington, D.C. 20515

Dear Chairman Scott:

Thank you for your ongoing leadership of the Education & Labor Committee. We are writing to request a markup of H.R. 2163, the Safe Step Act of 2021 in the coming months. This bipartisan bill will put the health care decisions back in the hands of patients and their doctors and is cosponsored by 108 of our House colleagues, including 16 members of the Education & Labor Committee, and is supported by over 200 national patient- and provider-based organizations.

Step therapy protocols often requires patients to try different medications or treatments before their insurance will cover the treatment initially selected by their provider. Unfortunately, step therapy protocols can cause delays in care and often ignore a patient’s unique circumstances and medical history. That means patients may have to use medications that previously failed to address their medical issue, or – due to their unique medical conditions – could have unnecessary or even dangerous side effects. The bipartisan Safe Step Act responds to challenges faced by patients, many with debilitating chronic health care conditions, in accessing the appropriate treatment in a timely manner. The bill establishes common sense guardrails and a swift exceptions process for patients in need. It is important to note that this legislation does not ban insurance companies from including step therapy protocols in their plan design, it just seeks to ensure that they are used judiciously and do not cause harm or delay appropriate care to patients.

Researchers at Tufts Medical Center recently found that step therapy was applied to 38.9 percent of drug coverage decisions, and more than half (55.6 percent) of those decisions required more steps than the clinical guidelines for diseases like multiple sclerosis, psoriasis, psoriatic arthritis, or chronic migraines.¹ In addition, emerging evidence demonstrates that barriers to access caused by utilization management, including step therapy, increases costs for the U.S. health system and results in poorer health outcomes. A recent study found that utilization management was associated with \$93.3 billion in annual costs to various stakeholders.² For example, the inclusion of prior authorization, including step therapy, in formularies for inflammatory bowel disease

¹ Variation In Use And Content Of Prescription Drug Step Therapy Protocols, Within And Across Health Plans. Kelly L. Lenahan, Donald E. Nichols, Rebecca M. Gertler, and James D. Chambers. Health Affairs 2021 40:11, 1749-1757

² Quantifying the Economic Burden of Drug Utilization Management on Payers, Manufacturers, Physicians, and Patients. Scott Howell, Perry T. Yin, and James C. Robinson. Health Affairs 2021 40:8

treatments increased the likelihood that a patient requires hospitalization, surgery, and/or emergency room visits by 12.9 percent within 180 days.³

With this in mind, we respectfully urge the Committee to mark up the Safe Step Act, a common sense solution that streamlines the step therapy process in order to ensure patients are able to access appropriate treatments safely, efficiently, and without unnecessary delay.

Thank you for your consideration, and we look forward to working with you on this critical legislation.

Sincerely,



Representative Raul Ruiz, M.D.



Representative Brad R. Wenstrup, D.P.M.



Representative Lucy McBath



Representative Mariannette J. Miller-Meeks, M.D.

CC: The Honorable Virginia Foxx, Ranking Member, Education & Labor Committee

³ Delays Related to Prior Authorization in Inflammatory Bowel Disease. Constant BD, de Zoeten EF, Stahl MG, Vajravelu RK, Lewis JD, Fennimore B, Gerich ME, Scott FI. Pediatrics. Accepted 2021. Article in Press.