

January 15, 2026

Dear Leader Thune, Leader Schumer, Speaker Johnson, and Leader Jeffries:

On behalf of the patients, consumers, and taxpayers we represent, the undersigned organizations urge you to include a bipartisan, commonsense policy that will increase patient access to affordable generic medicines in the January 30th appropriations and health extenders legislation. This legislation, the *Increasing Transparency in Generic Drug Applications Act* (S. 1302/H.R. 1843) seeks to accelerate complex generic drug approvals by enabling the FDA to provide robust technical feedback to manufacturers regarding pending generic drug applications. This legislation has cleared both the Senate Health, Education, Labor, and Pensions (HELP) and House Energy and Commerce Committees in recent years and passed the House of Representatives last Congress with overwhelming bipartisan support as part of the Lower Costs, More Transparency Act.

This legislation will cut through unnecessary bureaucratic red tape and allow the FDA to provide feedback to generic drug manufacturers on the quantitative and qualitative assessment required for FDA approval. Generic drugs are required to have the same formulation, and the same active and inactive ingredients, as the brand reference drug. Prior to 2015, FDA would provide feedback to generic drug applicants about whether their drug met these requirements, and if not, which ingredient(s) deviated from the reference listed drug and their direction (e.g., too high or too low). However, FDA abruptly changed this practice in 2015 and the Agency no longer provides either the ingredient(s) at issue or the general direction of the deviation. This lack of feedback has unnecessarily prolonged the application and approval process and significantly delayed patient access to these lower-cost treatments, often far beyond the time period envisioned by Hatch-Waxman.

As you know, generics and biosimilars provide vast savings for patients and the healthcare system, totaling \$467 billion in 2024 alone and more than \$3.4 trillion over the past decade. Further, in addition to lowering patient out-of-pocket costs and improving access to generic medicines, the Congressional Budget Office (CBO) projected this legislation will save approximately \$1.2 billion over 10 years, making this an attractive pay-for as Congress considers extension of expiring government healthcare programs.

We strongly believe this commonsense, bipartisan, bicameral policy will help maintain the important balance between innovation and access, enable FDA to ensure timely review of lower-cost generic medicines, and reduce beneficiaries' out-of-pocket spending on prescription drugs. We urge you to include the *Increasing Transparency in Generic Drug Applications Act* in the upcoming January 30th appropriations and health extenders legislation to expand access to affordable medicines, streamline the approval of complex generic medicines, and drive more than \$1 billion in savings for the federal government.

AiArthritis

Allergy and Asthma Network

American Cancer Society Cancer Action Network

American Diabetes Association

Arthritis Foundation

Asthma and Allergy Foundation of America

Autoimmune Association
Boomer Esiason Foundation
The Bonnell Foundation
Children With Diabetes
Color of Gastrointestinal Illnesses
Cystic Fibrosis Research Institute (CFRI)
Diabetes Leadership Council
Diabetes Patient Advocacy Coalition
The Diabetes Link
Emily's Entourage
HealthyWomen
International Foundation for Autoimmune & Autoinflammatory Arthritis
The Lupus Foundation of America
National Multiple Sclerosis Society
Patients Rising
RockCF