

June 30, 2021

The Honorable Nancy Pelosi
Speaker
U.S. House of Representatives
Washington, D.C. 20515

The Honorable Kevin McCarthy
Minority Leader
U.S. House of Representatives
Washington, D.C. 20515

The Honorable Charles E. Schumer
Majority Leader
United States Senate
Washington, D.C. 20510

The Honorable Mitch McConnell
Minority Leader
United States Senate
Washington, D.C. 20510

Re: Patient-Centered Drug Pricing Policies for Autoimmune Patients

Dear Speaker Pelosi and Leaders Schumer, McCarthy, and McConnell:

On behalf of the estimated 50 million Americans with autoimmune and immune-mediated diseases, the American Autoimmune Related Diseases Association (AARDA) and the additional undersigned organizations write to you regarding the vital work being done in Congress to address issues relevant to patient access to care and drug affordability. The COVID-19 pandemic has brought to light health inequities across the country and world, and individuals living with autoimmune disease have experienced significant challenges. Serious illness, job loss, financial difficulties, obstacles to accessing health care, and, too often- death, has affected individuals and families living with autoimmune disease. As we work to build back from the pandemic, we welcome an opportunity to collaborate on public policy solutions that bring savings to individuals at the pharmacy counter and protect critical access to treatment.

AARDA is dedicated to the eradication of autoimmune diseases and the alleviation of suffering and the socioeconomic impact of autoimmunity. AARDA is the only national nonprofit organization dedicated to bringing a national focus to autoimmune diseases, which are a major cause of serious and chronic health conditions for millions of individuals. AARDA is also the founder and facilitator of the National Coalition of Autoimmune Patient Groups (NCAPG), a coalition of over 50 organizations representing numerous autoimmune diseases.

Autoimmune and immune-mediated diseases are lifetime afflictions- there are no cures and they are among the leading causes of disability in this country. Individuals and families living with these diseases depend on many of the medicines that will be impacted by the drug pricing policies set forward recently in Congress. Below we outline the some of the proposed policy issues and how they impact patients with chronic diseases, especially those with autoimmune diseases, and we point to policy solutions that could immediately address affordability for patients at the pharmacy counter.

Concerns with Foreign Reference Pricing

Quality Adjusted Life Years (QALY) Are Inherently Discriminatory and Restrict and Deny Patients with Disabilities and Chronic Illness Access to Medicines

In the last year, multiple policy proposals that have included using other countries' drug prices to set a benchmark price for therapies have been introduced to address drug costs. In each of these proposals,

countries included in the reference pricing utilize the QALY, a measure used by countries, health systems, insurance companies, and health economists to measure disease burden by quantity and quality. Most recently, H.R. 3 as introduced in the House, would use a foreign reference price methodology to set drug prices to a maximum fair price (MFP) and would be tied to countries that use the QALY metric. As the National Council on Disability recently stated regarding the QALY “...it’s use in the US would result in rationing care to seniors and people with disabilities”¹. Using a formula that discriminates against any one group, not to mention many groups that include the most vulnerable among us, is more than concerning- it is a non-starter. Patients and their clinicians should be making decisions about the right course of treatment at all times.

Restricting Access to Vital Medicines Now and Lack of Future Cures

In addition to QALYs, we have strong concerns that foreign reference pricing will cause significant access delays or even permanent disruption to life-saving treatment currently and in development within the U.S. drug and innovation pipeline. It is estimated that millions of Americans with autoimmune disease have no current FDA-approved therapy. As the Congressional Budget Office stated in their review of H.R. 3, approximately 8 fewer drugs would be introduced to the market over the next decade and about 30 fewer drugs over subsequent years² if H.R. 3 foreign reference prices were enacted. Other reports estimate the number could be significantly higher³ for the significant number of medicines in development for individuals living with an autoimmune disease that could be destabilized if a policy like foreign reference pricing was enacted. Many living with an autoimmune disease seek hope that a medicine in the current pipeline could bring relief, and the idea that it could disappear is beyond frightening- it is cruel. Below we have highlighted patient-focused policy solutions that would immediately impact drug affordability for patients.

Patient Focused Policy Solutions

Counting Copay Assistance Toward Deductible, and Instituting Out-of-Pocket Caps

As cost-sharing payment distribution continues to rely more heavily on prescription deductibles and coinsurance⁴, out-of-pocket costs for patients rise, increasing the need for relief. In a recent survey conducted by AARDA with autoimmune disease, 92% of patients say that prescription drug out-of-pocket costs are too high and that copay assistance allows them to access medication they couldn’t previously afford⁵. Protecting copay assistance inasmuch as it can continue to count toward the deductible brings savings to patients immediately. Additionally, instituting cost-sharing caps at a federal level to cap the amount a patient must pay out of pocket for a medication would also ensure direct savings to patients. These policies ensure immediate savings for patients at the pharmacy counter, and address affordability during a time when patients living with autoimmune disease need it the most.

Ensuring Discounts Go Directly to the Patient; Addressing Rebates and Pharmacy Benefit Managers

Patients have, by and large, not seen tangible benefits from the negotiations of commercial health plans and pharmacy benefit managers (PBMs). In fact, research has shown that PBMs are retaining up to 40

¹ NCD Letter to House Committees with Concerns Regarding H.R. 3, <https://ncd.gov/publications/2021/ncd-letter-house-committees-concerns-regarding-hr-3>

² Research and Development in the Pharmaceutical Industry, Congressional Budget Office. April 2021 https://www.cbo.gov/publication/57126#_idTextAnchor000

³ Government Scorekeepers Likely Underestimate the Impact of Lower Drug Costs Now Act (H.R. 3) on Investment in Innovative Medicines <https://www.crai.com/insights-events/publications/government-scorekeepers-likely-underestimate-the-impact-of-lower-drug-costs-now-act-h-r-3-on-investment-in-innovative-medicines/>

⁴ KFF analysis of IBM MarketScan Commercial Claims and Encounters Database, 2004-2018

⁵ AARDA Patient Copay Assistance Survey, Sept 2020, https://www.aarda.org/wp-content/uploads/2020/09/AARDA-Survey-One-Pager_final.pdf

percent⁶ of rebate dollars to enhance their own revenues and, because negotiated rebates are often based on a percentage of a drug's list price, PBMs are incentivized to give formulary preference to higher-priced pharmaceuticals. This hurts patients because, in many cases, copays and out-of-pocket costs are based on a drug's list price.

Patient-centered public policy will require mandated transparency for PBM operations, so public and private payers and consumers can fully understand how negotiated discounts are being disbursed. As well, we fully support efforts to ensure that those rebates and discounts, minus appropriate fees for PBM services, are alleviating cost burdens for patients at the pharmacy counter.

Let's work together to find solutions to patient access and affordability, innovation, and continuing to secure tomorrow's cures today by investing in the promising pipeline that have already delivered many vital drugs to patients living with autoimmune disease. AARDA and the undersigned organizations deeply appreciate the hard work you have undertaken to address issues of drug affordability.

Please contact Brett McReynolds, AARDA VP of Policy, at bmcreynolds@aarda.org. We look forward to continue working together to advance patient-centered policies that address affordability and access.

Sincerely,

ACCSES

Advocacy & Awareness for Immune Disorders Association (AAIDA)
Advocates for Responsible Care(ARxC)
Aimed Alliance
Allies for Independence
American Academy of Allergy, Asthma & Immunology
American Association of Clinical Urologists
American Autoimmune Related Diseases Association
American Behcet's Disease Association (ABDA)
Applied Pharmacy Solutions
APS Foundation of America, Inc
Arthritis Foundation
Asthma and Allergy Foundation of America
Axis Advocacy
Born a Hero, Research Foundation
Breast Cancer Resource Center
California Access Coalition
Caregiver Action Network
Children with Diabetes
Chronic Care Policy Alliance
Color of Crohn's and Chronic Illness
CURED Nfp
Dysautonomia International

Fabry Support & Information Group
Foundation for Sarcoidosis Research
Global Healthy Living Foundation
Global Liver Institute
Good Days
ICAN, International Cancer Advocacy Network
International Pain Foundation
International Pemphigus Pemphigoid Foundation
Lupus Foundation of America
Male Breast Cancer Coalition
Multiple Sclerosis Foundation
National Alopecia Areata Foundation
National Infusion Center Association (NICA)
National Organization of Rheumatology Management
National Psoriasis Foundation
Neuropathy Action Foundation
Nevada Chronic Care Collaborative
PANDAS Network
Partnership to Fight Chronic Disease
Patients Rising Now
Rheumatology Nurses Society
Scleroderma Foundation
Siegel Rare Neuroimmune Association
Sjögren's Foundation

⁶ *Pharmacy Benefit Managers: Can They Return to Their Client-Centered Origins?* Altarum Healthcare Value Hub, Research Brief No. 23, Jan. 2018 https://www.healthcarevaluehub.org/application/files/1315/6375/5073/RB_23_-_Pharmacy_Benefit_Managers.pdf

Spondylitis Association of America
The National Adrenal Diseases Foundation
(NADF)
Triage Cancer
Vasculitis Foundation

wAIHA Warriors
Whistleblowers of America