Immune Deficiency Foundation

Fostering a community empowered by advocacy, education, and research

December 3, 2021

The Honorable Charles Schumer
Majority Leader
United States Senate
322 Hart Senate Office Building
Washington, DC 20510

The Honorable Ron Wyden
Chairman, Committee on Finance
United States Senate
221 Dirksen Senate Office Building
Washington, DC 20510

Re: Exclude plasma protein therapies from Medicare price negation provision

Dear Leader Schumer and Chairman Wyden:

On behalf of all people impacted by primary immunodeficiency (PI), the Immune Deficiency Foundation (IDF) urges you to ensure the Build Back Better Act does not make it more difficult for people with PI – including Medicare beneficiaries – to access life-sustaining medications derived from donated blood plasma. Specifically, **I urge you to ensure that any provision permitting direct negotiation on the price of Medicare Part D drugs excludes therapies derived from human blood plasma, which include immunoglobulin (Ig) products used to treat people with PI.**

IDF is the national patient organization dedicated to improving the diagnosis, treatment, and quality of life of people affected by PI through fostering a community empowered by advocacy, education, and research. Individuals with PI have one of the more than 450 rare disorders in which a person's immune system fails to function properly because of genetic or intrinsic defects. These individuals are highly susceptible to recurrent, persistent, and severe infections of the sinuses, skin, throat, ears, lungs, brain, and spinal cord, as well as urinary and intestinal tracts, often requiring significant interventions and hospitalization.

Fortunately, people with PI have an effective treatment in immunoglobulin (Ig) therapy, which is derived from human plasma that undergoes a rigorous purification and manufacturing process before being developed into treatments. Regular, lifelong Ig treatments restore the antibodies that the body is unable to produce and allow a person with PI to live a full life. Unfortunately, since they are derived from donated blood plasma, Ig products have long been in shortage and faced supply chain issues. In the summer of 2019, the Food and Drug Administration (FDA) confirmed this ongoing shortage and noted that it could impact patient care.[1]

Given the unique challenges associated with the development of Ig and other plasma protein therapies, we urge you to broaden the therapeutic exceptions currently written into the House-passed Build Back Better Act to also include plasma protein therapies. As you know, the House-

[1] See: https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/information-about-immune-globulin-human-product-shortage

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passed bill already includes several exemptions, including ones based on a product's post-approval period, as well as for products developed by small biotech companies, those that fall under a certain level of Medicare spending, and those whose only FDA indication is to treat an orphan condition.

Adding Ig and other plasma protein therapies to those excluded from the policy makes sense for several reasons:

- Ig is already subject to shortages, as confirmed by the FDA. As the voice of patients whose health depends on access to Ig, we are very concerned that including such a product already subject to shortages would cause further harm.

- Ig and other plasma protein products are different from other types of drugs because much of the costs of innovation and development occur in the collection of plasma, refinement and development of medications and routes of administration. This differs from other drugs where the costs of raw materials and manufacturing are relatively modest compared to the larger upfront research and development costs.

- The maximum fair price schedule included in the House-passed bill would negatively impact Ig and other products that have more distant FDA approval dates and whose costs are more heavily dependent upon the cost of raw materials and manufacturing.

- There is precedent for excluding Ig and other plasma protein therapies from CMS policies. For example, intravenous immunoglobulin (IVIG) was excluded from the proposed most favored nation innovation model. CMS also exempted plasma protein products from a third-party vendor model for Medicare Part B over 15 years ago in response to concerns about patient access.

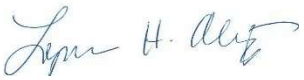
- The House-passed bill excludes any drug "designated as a drug for only one rare disease or condition…and for which the only approved indication (or indications) is for such disease or condition." We note that many users of plasma protein therapies are rare disease patients like those with PI.

I understand the challenges you are navigating, including addressing the costs of prescription medications and achieving adequate savings to pay for other provisions of the bill. Excluding plasma protein therapies will not negatively impact these overarching goals and would not lead to a significant reduction in potential savings. However, if the provision is not changed, access challenges for the PI community will be exacerbated. If individuals are unable to access Ig therapies, their conditions could worsen and require more intensive and costly treatments, such as inpatient hospitalizations, increasing government expenses.

As you work to complete the Build Back Better Act, I urge you on behalf of PI patients and other users of plasma protein therapies to broaden the existing exemption contained within the House-passed iteration of the legislation to include plasma-derived products.

Thank you for your prompt attention to this matter. If you have any questions, please contact me at lalbizo@primaryimmune.org.

Sincerely,



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