

September 16, 2011

Reference No. FASC11063

The Honorable Patty Murray
Co-Chairman
Joint Select Comm. on Deficit Reduction
United States Senate
Washington, DC 20510

The Honorable Jeb Hensarling
Co-Chairman
Joint Select Comm. on Deficit Reduction
United States House of Representatives
Washington, DC 20515

Dear Co-Chairmen Murray and Hensarling:

The Plasma Protein Therapeutics Association (“PPTA”), is keenly aware of the difficult task and decisions confronting the Joint Select Committee on Deficit Reduction (“Committee”). Recognizing the challenges that lay ahead, we respectfully urge the Committee to recognize the importance of preserving patient access to plasma protein therapies. Specifically, should the Committee adopt proposals affecting health care coverage and reimbursement, we encourage consideration of the impact such proposals will have on plasma protein therapies and the people with rare diseases who depend on these important medicines.

Pending proposals which threaten patient access and the sustainability of the plasma protein therapy industry, as explained in greater detail below, include:

- *Reduction of Medicare Part B reimbursement from Average Sales Price (“ASP”) +6%.* We understand that some members of Congress have recommended a decrease in ASP to a level below the current ASP +6%. Plasma patients rely on regular, often weekly, infusions for life-sustaining treatments. Thus, any reduction to ASP would likely cause interruptions in site of care and expose immune-compromised patients to the dangers of the hospital setting (such as increased risk of infections). **To protect plasma patient access, PPTA urges the Committee to maintain the ASP reimbursement rate at +6%.**
- *Movement of products currently covered in Medicare Part B into Part D.* The unique biologic nature of plasma protein therapies means plasma patients require a diverse selection of therapies, often using several brands, for effective treatment. Moving plasma products from Part B to Part D could limit access to just two brands, exposing patients to an array of adverse events, as well as greater cost sharing. **PPTA urges the Committee not to shift plasma protein therapies from a Part B to D shift to protect the health of patients who rely on these products.**
- *Legislative expansion of agency authority to implement least costly alternative (“LCA”) reimbursement policies.* Where different products in a therapeutic class are not interchangeable, as is the case for most plasma protein therapies, imposing LCAs would very likely limit patient access to effective treatment. **PPTA urges the Committee to exclude plasma protein therapies from LCA policy.**
- *Expansion of the 340B Drug Pricing Program to the inpatient hospital setting.* Expanding 340B discounts to the inpatient setting exceeds the policy goals of the 340B program, and could impede manufacturers from producing certain plasma products that have extraordinarily low margins, including albumin and antithrombin III. **PPTA strongly opposes 340B inpatient expansion.**

PPTA represents human plasma collection centers and the manufacturers of lifesaving plasma-derived medicinal therapies and their recombinant analogs.¹ Collectively, these therapies – both plasma-derived and recombinant – are known as “plasma protein therapies.” The manufacturer membership of PPTA in the United States (“U.S.”) currently includes Baxter Bioscience, Biotest, Cangene, CSL Behring, Grifols, and Kedrion.

The vast majority of plasma protein therapies are approved for marketing in the U.S. by the Food and Drug Administration (FDA) solely for the treatment of rare diseases, disorders, and conditions.² These rare conditions are genetic, chronic, and life threatening (e.g., alpha-1 antitrypsin deficiency, bleeding disorders, and primary immune deficiency diseases (“PIDDs”), but also can be acute rare conditions (e.g., hepatitis B reinfection in liver transplant patients, and idiopathic thrombocytopenic purpura (“ITP”)).³

As you explore potential policy changes, PPTA would like to underscore that previous reimbursement cuts for plasma protein therapies reimbursed under Medicare Part B have resulted in well documented difficulties for some rare disease patient populations in accessing the most appropriate plasma protein therapy for their individual needs. Appropriate reimbursement levels allow for treatment protocols that will reduce health care expenditures by preventing physician visits, hospitalizations, and surgical interventions.

- **Maintain ASP Reimbursement at ASP +6%.** Two 2007 reports from the Department of Health and Human Services (“HHS”),⁴ documented that reimbursement cuts associated with the implementation of ASP for intravenous immune globulin (“IVIG”) were a significant contributing factor in serious patient access problems that persisted for years. Further, a more recent HHS Office of Inspector General (“OIG”) report issued in 2010 showed that hospital-based ASP reimbursements for IVIG products were the most at risk, as compared to all other products subject to the review of failing to cover hospital acquisition costs.⁵ In this analysis, OIG compared hospital acquisition costs to Medicare payment amounts for 32 different drugs under the Hospital Outpatient Prospective Payment System. As demonstrated by the documented history of patient access problems resulting from Part B reimbursement reductions for IVIG, as well as OIG’s recent findings on Medicare payments as compared to hospital acquisition costs for these treatments, it is very likely that further reductions in the ASP for plasma protein therapies would create a serious threat with respect to patient access. For this reason, PPTA urges the Committee to maintain the ASP reimbursement rate at ASP +6%.

¹ Plasma protein therapies include albumin, alpha₁-proteinase inhibitor, antithrombin III, blood clotting factors, C1 esterase inhibitor, fibrin sealant, immune globulin, hyperimmune immune globulin, and protein C concentrate, from this human plasma. Some of our members also use recombinant DNA technology to produce blood clotting factors.

² In the U.S., a “rare disease or condition” is generally defined as a disease or condition that affects less than 200,000 people. See 21 U.S.C. § 360bb(a)(2) (2006).

³ ITP can also be a chronic condition.

⁴ HHS OIG, INTRAVENOUS IMMUNE GLOBULIN: MEDICARE PAYMENT AND AVAILABILITY (OEI-03-05-00404) (APR. 2007); See OFFICE OF ASS’T SECRETARY FOR PLANNING AND EVALUATION, U.S. DEP’T OF HEALTH AND HUMAN SERVS., ANALYSIS OF SUPPLY, DISTRIBUTION, DEMAND, AND ACCESS ISSUES ASSOCIATED WITH IMMUNE GLOBULIN INTRAVENOUS (IGIV) 2-18 (2007).

⁵ HHS OIG, MEMORANDUM REPORT: PAYMENT FOR DRUGS UNDER THE HOSPITAL OUTPATIENT PROSPECTIVE PAYMENT SYSTEM (OEI-03-09-00420) (OCT. 22, 2010).

- **Continue to determine average sales price (“ASP”) payment rates for intravenous immune globulin products as they now are determined.** PPTA is sympathetic to the concerns of some Members of Congress that the current application of the ASP methodology has failed to discourage providers from prescribing drugs and biologicals based on their relative reimbursement rate, rather than their relative efficacy. We are, however, concerned that the Joint Committee may consider amending the ASP statute to reimburse all Part B drugs according to the volume weighted average ASP of each therapeutic class. In the past, reimbursing IVIG in this manner created a scenario in which providers prescribed the therapy based on reimbursement, according to the above mentioned study that the Office of the Assistant Secretary for Planning and Evaluation (“ASPE”) of the HHS commissioned in 2007.⁶ Like many therapeutic classes of plasma protein therapies, IVIG is well-established with eight brands currently available for U.S. patients. Due to varying manufacturing processes, each brand of IVIG is a non-interchangeable, unique biological despite having the same active ingredient (the immunoglobulin G protein). Following a 2007 Centers for Medicare & Medicaid Services (“CMS”) policy change that called for the reimbursement of most brands of IVIG according to their individual ASPs as required by statute, the PIDD community faced fewer treatment delays, brand switches, and shifts in site of service. The ASP statute must continue to direct CMS to reimburse IVIG in this manner, so that patients have access to the full range of therapies.
- **Preserve Part B coverage of plasma protein therapies.** If the Committee is considering consolidating drugs and biologicals under Medicare Part D, PPTA respectfully urges you to exempt plasma protein therapies from that consolidation. Users of plasma protein therapies are particularly concerned that limiting coverage to Medicare Part D instead of providing Part B coverage, will: (1) increase their cost sharing obligations, and (2) impede access to the therapy best suited for the individual needs of the patient because Part D formularies are only required to offer two brands in a therapeutic class, and Part D allows its plans to require step therapy and prior authorization.
- **Plasma protein therapies should be excluded from LCA policies.** If the Joint Committee adopts the Medicare Payment Advisory Commission’s recommendation to establish in statute LCA policy, PPTA strongly recommends the Committee exclude from such policy therapies that FDA has approved solely for the treatment of one or more rare diseases or conditions. In addition, there should be procedural protections put in place, namely prohibiting CMS and local contractors from imposing an LCA policy unless there is a notice and comment period.
- **Resist further expansion of the 340B Drug Pricing Program.** PPTA strongly opposes expanding the 340B program into the inpatient setting. Such an expansion would go well beyond the policy goal of the program, focusing on access to outpatient drugs. Congress established the 340B program to restore discounts on outpatient drugs and biologicals purchased by federally funded clinics and public hospitals serving large numbers of low-income and uninsured patients.⁷ Prior to enactment of the Medicaid

⁶ See OFFICE OF ASS’T SECRETARY FOR PLANNING AND EVALUATION, U.S. DEP’T OF HEALTH AND HUMAN SERVS., ANALYSIS OF SUPPLY, DISTRIBUTION, DEMAND, AND ACCESS ISSUES ASSOCIATED WITH IMMUNE GLOBULIN INTRAVENOUS (IGIV) 2-18 (2007).

⁷ See H.R. REP. NO. 102-384 (II) (1992); SEE ALSO 138 CONG. REC. S17903 (Oct. 8, 1992) (statement of Sen. Kennedy).

outpatient drug rebate program, these entities had been receiving discounts on outpatient drugs offered voluntarily by manufacturers. In addition to exceeding the legislative intent of the program, expanding to the inpatient setting could impede the ability of manufacturers to produce certain plasma-derivatives that are not only primarily used in the inpatient setting but also have extraordinarily low margins, such as albumin and antithrombin III.

- **Ensure Medicare beneficiaries have access to affordable care.** PPTA opposes any proposal that would affect Medicare beneficiaries' ability to access medically necessary due to increased out of pocket costs. We are particularly concerned about any potential changes to Medigap or other secondary insurance plans. Increased cost-sharing obligations for Medicare beneficiaries that require regular infusions or injections of plasma protein therapies could affect the ability of these patients to obtain these lifesaving therapeutic interventions.

Thank you for the opportunity to share our recommendations with you regarding issues that may come under consideration by the Joint Select Committee on Deficit Reduction. Should you have any questions, please contact Kym Kilbourne, Director, Public Affairs at kkilbourne@pptaglobal.org, and Everett Crosland, Manager, Federal Affairs, at ecrosland@pptaglobal.org.

Sincerely,



Julie Birkofer
Senior Vice President, North America