

Plasma Protein Therapies: A Unique Sector of the Biotherapeutics Industry

- Not all drug manufacturers are the same – the branded pharmaceuticals, the generics, the biologicals, the vaccines, and the plasma protein therapeutics industries not only offer different value to the patient, but also require considerably different business models and cost structures.
- With regard to manufacturing costs (including the acquisition costs of the raw materials), the leading outlay for pharmaceutical companies is the sales and marketing of their products, while manufacturers of plasma protein therapies spend the majority of their resources on manufacturing.¹ Threats of emerging pathogens may increase the overall manufacturing costs of plasma protein therapies because manufacturers may have to develop new tests and viral inactivation and viral reduction procedures. ***Specifically, plasma protein therapies cost nearly four times more to manufacture than traditional pharmaceutical products.***²
- Plasma protein therapies, including immune globulin, involve complex manufacturing processes that require substantial upfront cash outlay and planning.³ The manufacturing process takes between seven to twelve months from plasma collection at donor centers to FDA lot release and involves numerous steps such as plasma collection, laboratory testing, fractionation and quality control testing and lot release.⁴
- Unlike traditional pharmaceuticals, the economic viability of the plasma protein therapeutics industry depends on maintaining strong markets for all plasma therapies. For example, immune globulin manufacturing decisions depend not only on the market conditions for immune globulins but also for other plasma derived products and coagulation factors.⁵ Typically, as many as six different therapies can be produced from a single donation of human plasma; yet production costs for plasma derived therapies remain relatively constant regardless of whether one, two, or six different therapies are produced. ***This is because the single largest manufacturing cost is the collecting and testing of human plasma.***

¹ See Charles Waller, *Historical Perspective on Blood and Plasma Products*, in 7 PHARMACEUTICALS POLICY AND LAW, BLOOD, PLASMA AND PLASMA PROTEINS: A UNIQUE CONTRIBUTION TO MODERN HEALTHCARE 17, fig. 2 (J.L. Valverde ed., 2005) (providing a comparison of the plasma industry with the pharmaceutical industry through the analysis of Smith Barney estimates from December 2003 and the 2004 Annual Reports of major pharmaceutical companies).

² *Id.*

³ U.S. Department of Health and Human Services Office of the Assistant Secretary for Planning and Evaluation (ASPE), *Analysis of Supply, Distribution, Demand, and Access Issues Associated with Immune Globulin Intravenous (IGIV) Final Report*, 2.3.1., February 2007.

⁴ *Id.*

⁵ *Id.*

- In order to cover the production costs, manufacturers must be able to sell multiple products from each plasma donation. Moreover, because the patient populations who are treated with plasma protein therapies are designated by the government as rare disease populations (less than 200,000 people per disease) manufacturers must maximize the number of therapies they produce from each liter of plasma to meet all patient needs regardless of individual therapy utilization.
- As opposed to traditional pharmaceuticals – and even most biologics – by the time a plasma protein therapy is ready for infusion to a patient, the product has been the subject of two rigorous and wholly distinct set of regulatory requirements including inspection, licensure and adherence to good manufacturing practices. This is because the production of plasma protein therapies consists of two separate processes: the collection of human plasma and the production of safe, pure and potent therapies from that plasma. Each of these distinct processes are highly regulated and separately licensed by the US Food and Drug Administration. The imposition of two sets of regulatory requirements, while appropriate, adds significant cost to the production of plasma therapies.