

V. Current Trends in Plasma Product Manufacturing (Informational)

Blood Products Advisory Committee Meeting, July 23, 2004

Current Trends in Plasma Product Manufacturing

Issue

The plasma fractionation industry has undergone a number of changes within the past year, including reductions in plasma collection and manufacturing consolidations, which may impact product supply. FDA seeks industry's perspective on the state of the industry, the extent of these changes, and the potential impact on product availability.

Background

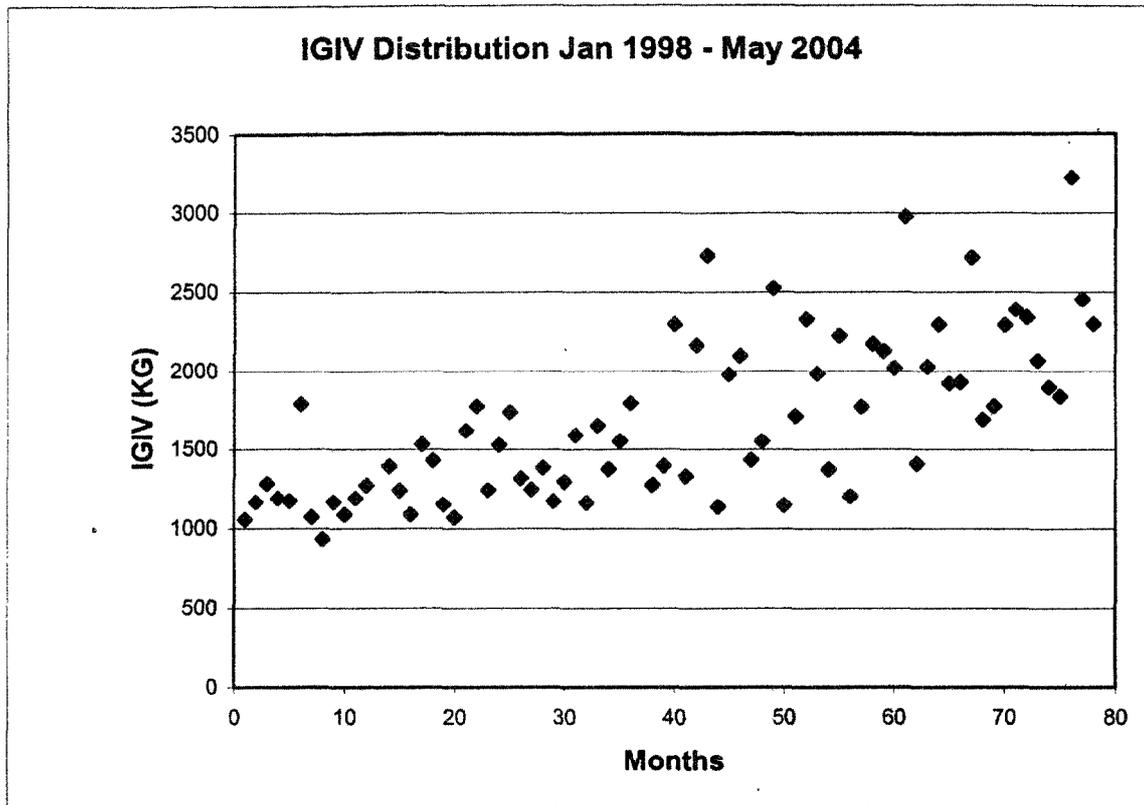
Recent trends in the plasma derivative industry may affect product availability. These include announcements from major plasma derivative manufacturers, Baxter Healthcare and ZLB Behring, about closures of plasma collection centers and some manufacturing plants, cut-backs in the workforce, and reduced plasma collections.

In addition to these changes, a number of industry consolidations and the appearance of a new sponsor have changed the landscape of plasma fractionators licensed in the US. Probitas, the Spanish blood product manufacturer, recently purchased the Alpha Therapeutic fractionation facility through its Grifols subsidiary. CSL, an Australian corporation, acquired Aventis Behring Plasma Therapeutics and formed ZLB Behring. Bayer AG has announced a divestiture of its plasma fractionation operations and is seeking a new owner for this facility. Octapharma, a Swiss based company, has recently entered the US market with a new immune globulin product.

It is FDA's policy to help prevent or alleviate shortages of medically necessary biological products, since such shortages can have significant public health consequences. While consolidations, new manufacturing procedures, and new manufacturers may bring about more efficient production of products, and a better balance of supply with demand, we must remain alert to the potential that these changes could affect the availability of products.

Severe blood product shortages took place twice in the past seven years: IGIV in 1997-98; and recombinant factor VIII in 2000. These shortages occurred for a number of reasons including industry-wide compliance issues, increased demand, insufficient manufacturing capacity, and issues related to Creutzfeldt Jakob disease.

The present supply situation is much different from that of 1997-98 and 2000. The availability of plasma derivatives and analogous recombinant products has increased substantially. In 1998, approximately 14,500 kilograms of IGIV were distributed in the US; in 2003 about 25,000 kilograms were marketed. In 2000, about 700 million units of recombinant factor VIII were distributed; in 2003 almost 1 billion units were distributed.



Although plasma products are not now in short supply, the effects on product availability of reductions in manufacturing capacity and plasma collection, and changes in manufacturers, bears close watching. FDA will continue to monitor product distribution through monthly reports it obtains from industry; encourage submission of reports about product availability from consumers, healthcare workers, and distributors; provide information to interested parties about shortages when they occur; facilitate rapid regulatory review of new products; and expedite lot release.

The Plasma Protein Therapeutics Association will present their perspective on the state of the plasma fractionation industry, particularly with respect to issues affecting product availability.