

**FDA
BLOOD PRODUCTS ADVISORY COMMITTEE
MEETING**

**STATEMENT OF THOMAS L.MORAN
PRESIDENT, IDF**

**ON BEHALF OF:
IMMUNE DEFICIENCY FOUNDATION**

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As Patrick Collins has just pointed out, there are serious personal consequences when patients are unable to obtain or afford their therapies. In testimony at previous BPAC meetings the Alpha One Foundation and the Immune Deficiency Foundation have reported the serious adverse health consequences within our communities resulting from shortages of plasma derivatives.

It might be useful to re-visit one piece of data from the IDF physician surveys conducted in April and August of 1998. This data captures how physicians and the pharmacists, who order for them, adjust to market shortages and how this might affect patient health. Many of the strategies described on this slide reduce consumption of IGIV, which can lead to adverse health consequences for primary immunodeficient patients.

In response to this phenomenon the IDF in cooperation with the six IGIV brand owners and FFF Enterprises established the Safety Net Program to provide IGIV on an emergency basis to physicians stipulating need based on medical necessity.

To date, 368 physicians have enrolled in the Safety Net Program. 76,841 grams of IGIV have been shipped, benefiting 1,224 patients in 43 States. 68% (826) of whom have a diagnosis of primary immunodeficiency disease.

Addressing the US inventory of IGIV, IPPIA reports that the current level available for consumption is 10 days in contrast to 11 days during this same time period in 1998.

The apparent discrepancy between Patrick Schmidt's trend data and the Safety Net trend probably lies in the fact that if there is a softening in the general market for IGIV, spot shortages still exist.

I would however caution FDA to avoid over-interpretation of short-term trends in a market where we know we are still 10% below historical supply levels.

This leads me to the main point that plasma consumers would like to make. As product shortages persist, the market adjusts to fit the current supply reality. Equilibrium occurs. As a result of these behaviors, demand adjusts to supply. However, the public health consequences of those adjustments must be understood in order to develop appropriate public policy responses.

The question of the current, theoretical upper limits of demand is interesting for corporate planning and investment. In markets like IGIV, A1PI and certain clotting factors, where there is 100% consumption of existing product, are we failing to meet the therapeutic needs of patients with accompanying adverse health consequences?

I would assert that this is precisely the case today. I am recommending that a collaborative effort be undertaken. In the current market to assess the health effects of current supply levels. If we can engage the cooperation of these key groups, we might be able to accomplish this task in an efficient, timely manner.

For example,
Analysis of the current distribution and uses of products according to the following parameter might provide us the answers we are seeking.