

**IMMUNE DEFICIENCY FOUNDATION**

**IGIV SHORTAGE: UPDATE**

*PHYSICIAN SURVEY RESULTS AUGUST 1998*

**FOOD AND DRUG ADMINISTRATION  
BLOOD PRODUCTS ADVISORY COMMITTEE  
MEETING**

**SEPTEMBER 17-18, 1998**

IDF conducted a Physician Survey in April 1998 documenting the depth of the IGIV shortage and its human consequences. The results of the physician survey were presented to the Department of Health and Human Services, Advisory Committee on Blood Safety and Availability and the U.S. Congress in April and May 1998 respectively. The Survey data has also become the basis for an upcoming issue of the CDC's, Morbidity and Mortality Weekly Report.

IDF conducted an update of the April survey in August 1998. The data collected in August 1998 shows slight improvement in supply access, however, there is still a significant shortage reported by physicians who treat over 25 primary immunodeficient patients. Recent Congressional hearings brought to light the fact that production is hindered due to problems with manufacturers' compliance with cGMP's. **The plasma fractionation industry is well below 100% of production.** Manufacturers and the government continue to speculate about the amount of IGIV that will be available to the US marketplace in the upcoming months. It is anticipated that production could be as low as 60 to 65% during the last quarter of 1998 and into the first quarter of 1999. This forecast compels the IDF to continue to encourage this Committee to remain keenly aware of the product shortage crisis during decision making.

UPDATE: Physician Survey on IGIV shortages August 1998 versus April 1998

1. We conducted an update survey of Physicians treating over 25 patients covering the period from May through August 1998. 102 Physicians returned the survey.
2. The May through August period shows modest improvement among physicians using large quantities of IGIV although these physicians still report a serious shortage. 89.9% report difficulties obtaining IGIV during this period compared to 93.4% in April.
3. Physician strategies for coping with the IGIV shortage include employing multiple strategies. In August physicians report: 63.3% postponed scheduled infusions; 73.5% switched patients to different brands; 53.9% increased the interval between infusions and 37.3% reduced the dosage.
4. When asked how much difficulty they experienced in obtaining normal supplies of IGIV the majority of physicians reported **some difficulty** in August versus the majority reporting **a lot of difficulty** in April. This trend from "a lot of difficulty" to "some difficulty" may indicate a slightly improved supply or it may also indicate that physicians became desensitized to the shortage. There is also the possibility that these physicians have become more skilled in obtaining IGIV from alternative sources.
5. 44.9% of physicians currently report **negative health consequences** for their patients.
6. Most notably, of physicians commenting on the type of negative health consequences for their patients, 61.5% report **INCREASED INFECTIONS**, which can be life threatening for primary immunodeficient patients.

We would note that although there was a slight increase in IGIV lot release during the period from April to August 1998, significant problems remained within the medical community with respect to access of IGIV for treatment of primary immunodeficient patients. Direct distribution solutions must be put into place immediately as further reductions in production and release materialize.