

**COMMITTEE ON
GOVERNMENT REFORM AND OVERSIGHT**

TESTIMONY PROVIDED BY

ROGER KOBAYASHI, MD

**ON BEHALF OF
IMMUNE DEFICIENCY FOUNDATION**

MAY 7, 1998

10:00 A.M.

Good morning, Representative Shays, members of the Subcommittee and guests. Thank you for inviting me to describe in human terms how this shortage has affected our patients. In the next five minutes, I will tell you about how those of us in the “medical trenches” have been affected and what we have done during this period of grave IVIG shortage.

My name is Roger Kobayashi and I am a practicing allergist immunologist from Omaha, Nebraska and a Clinical Professor of Pediatrics at the UCLA School of Medicine in Los Angeles. In the clinics where patients with immunodeficiency are seen, there continues to be a worrisome shortage of IVIG. One of my colleagues, Dr. David Rosen, a pediatric hematologist from Wichita, KS could not obtain IVIG for one of our mutual patients, Troy Ayres, a college freshman with hyper-IgM syndrome, which is generally fatal unless IVIG is available. He used to receive his treatments in Dr. Rosen's office however, I recently received a letter from Troy's mother and she relates: “The blood specialist doctor (Dr. Rosen) was unable to receive supplies and therefore, Troy was infused at the hospital. However, the hospital did not have enough and called three (3) other hospitals in Wichita and they were all out. Troy's doctor in Wichita has put him on the priority list, but it still worries me one of these times, he will go in and there won't be any. This is a life and death situation for Troy because he does not make any antibodies.” This story is repeated over and over again in the Midwest and elsewhere.

In a survey done by the Immune Deficiency Foundation and reported at the HHS, Blood Safety meeting on April 27, 87% of doctors taking care of children and adults with immune deficiency reported difficulty obtaining IVIG in the past (6) months. More significantly, of those doctors taking care of the most patients, that is following 25 or more individuals, 93.4% reported difficulty in obtaining IVIG.

Let me tell you about our experience. I have been a practicing immunologist allergist in Omaha for the past seven- (7) years after leaving full-time academics and have begun to serve as a regional caregiver for patients requiring immune globulin. I am privileged to take care of approximately 75 to 80 children and adults receiving IVIG within a five- (5) state area and infuse approximately 30 patients in our Omaha offices. I have been able to receive IVIG product directly from some of the manufacturers. I am on their highest priority list for immune globulin. Yet, in the fall of last year and continuing to the present time, I have experienced significant shortages where, from day-to-day, our group has been worried whether we would have enough IVIG to infuse our patients. After considerable consternation, a letter, dated February 21, 1998 (copy provided to the Committee) was sent to our patients. Several points were made.

- 1. The situation had become critical**
- 2. We could not guarantee that we had enough IVIG for our patients.**

3. We had to ration, switch products, increase intervals or decrease the amount of IVIG given.

In addition, when new immune deficient patients were referred to me, and IVIG was required, I was quite concerned whether we would be able to secure product for these new patients.

Similarly, hospitals in Omaha and Lincoln have often been unable to obtain supplies for patients and frequently, those patients I follow who are receiving IVIG at hospitals or associated clinics at distant sites have also great difficulty in obtaining supplies. One of my patients suffering from hypogammaglobulinemia and severe lung disease, which requires him to be on continuous oxygen supplementation, was recently admitted to a major Omaha hospital with acute bacterial pneumonia. In addition to antibiotics, he required IVIG and the hospital could not get the brand he uses. Since he had severe reactions to other IVIG brands, the hospital called us to see if we had the brand that he used. We volunteered some from our supplies. One month later, the hospital still has not been able to replace what they borrowed from us. Like other hospitals throughout the country, hospitals in our area have searched desperately for IVIG from their contractual sources as well as from secondary wholesalers.

Mr. Ted Tianello, Head of Pharmacy Administration at Omaha Methodist Hospital, a major university affiliated institution tells me that they are constantly worried about IVIG shortages. They have assigned one (1) pharmacist whose sole responsibility at this time, is to call around the country to see if IVIG is available. He also told me that they called their friends on the East Coast and Florida to see if any was available. I found it admirable and compelling that the pharmacy department was doing all within their power to find enough IVIG for patients. Mrs. Linda Kuhlengle, whose children I take care of, is Chief Pharmacist and purchaser for Bergan-Mercy Hospital, the busiest private hospital in Omaha. She often cannot get IVIG for their cancer specialists who require it for their patients. She and others spend countless hours calling their contacts to try and obtain product. She is in the unenviable position of being on the receiving end of the anger and frustration from the doctors because the pharmacy is unable to secure IVIG.

What does it mean when 87% of doctors recently surveyed have difficulty in obtaining IVIG? What does it mean when 45% of responding physicians report negative health impact on their patients as a result of these shortages? What does it mean when 45% of patients responding report adverse health effects? What does it mean when I, as a physician, find it difficult to ration IVIG because I am personally involved in caring for these patients on a close and intimate basis, worrying where and whether adequate supplies will be available to meet the needs of these patients. Chairman Shay, Members, it means that this is not a good situation. Soon you will be hearing from Donna Hobson, the President of the Nebraska Chapter of the Immune Deficiency Foundation and a

patient of mine with common variable immunodeficiency. She will tell you about the ongoing fear and anxiety worrying about whether IVIG is available.

The Chairman is acutely aware of the current shortages of IVIG. The Chairman is acutely aware of the concerns of these patients because of these shortages. The Chairman is aware of the NIH Consensus Conference recommendations on the use of IVIG. The Chairman is aware of the excellent reviews published by Dr. E. Richard Stiehm, of UCLA, and Drs. Buckley and Schiff, of Duke University, regarding the recommended uses of IVIG. The Chairman is aware of the recommendation made by the Advisory Committee on Blood Safety and Availability. The Chairman is aware of the recommendations of the FDA and the IPPIA, ably represented by Mr. Jan Bult. Let me say that I endorse and am encouraged by the 14 recommendations thoughtfully outlined by the Advisory Committee on Blood Safety and Availability headed by Drs. Arthur Caplan and Stephen Nightingale. I especially support short-term recommendation #2, which reads as follows:

The Department of Health and Human Services should explore, in collaboration with industry, health care providers, and appropriate consumer groups, methods to optimize and standardize allocation of available products in an equitable manner, including management of emergency supplies and programs that distribute products directly from manufacturers to registered consumers.

This short-term recommendation has also been set forth by Mr. Jan Bult of IPPIA. I strongly urge that supplies be made available to patients most in need and who would be seriously harmed if product were unavailable. Similarly, I strongly support recommendation #5 from the long-term category, which states:

The National Institutes of Health and industry should support the continued evaluation of the use and appropriate dose of intravenous immunoglobulins for indications where its benefit requires further- delineation, and the results of these evaluations should be rapidly disseminated to the public.

We need to have valid information regarding use in diseases where IVIG may be of benefit.

In closing, Mr. Chairman, let me again state that it is the uncertainty of not knowing whether IVIG will be available when you come in for monthly infusions that causes fear and anxiety among patients and worry among doctors. As stated in my letter to the patients, our group has begun rationing product and the personal turmoil of having to make decisions, which might compromise the best care, I can give my patients has been a disturbing burden.

In ending, I would emphasize that even in a small state like Nebraska, we are feeling the effects of the shortage similar to our brethren in Texas, California, New Jersey, Florida and elsewhere. Thank you.