

**COMMITTEE ON  
GOVERNMENT REFORM AND OVERSIGHT**

**WRITTEN TESTIMONY SUBMITTED BY**

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10:00 A.M.**

I would like to thank this Subcommittee for inviting me to submit information to this session on the topic of hepatitis C follow-up for patients who received intravenous immunoglobulin in the years 1991 to 1994.

My name is Charlotte Cunningham-Rundles, and I am a professor of Medicine, Pediatrics and Biochemistry at the Mount Sinai School of Medicine in New York City. I am also a member of the Immune Deficiency Foundations Medical Advisory Committee. My interests have been in the laboratory study and clinical treatment of primary immunodeficiency diseases. There are about 50 or more of these diseases; many of these result in frequent and life-threatening infections. Due to these genetic defects, there are an estimated group of more than 20,000 people in the United States, including infants, children and an enlarging population of adults, who are not able to make antibodies, and who receive regular infusions of a plasma derivative rich in these antibodies.

Antibodies are complex proteins found in the serum portion of the blood called gammaglobulin or immunoglobulin; these proteins are vital for protection against bacterial, viral, and other infections. Gammaglobulin pools from human blood contain antibodies of tremendous variety representing the immune experience of thousands of donors. Patients who do not make their own antibodies are completely dependent upon these infusions, which they receive every three or four weeks, in most cases, for the rest of their lives.

Since the introduction of these products, our patients can look forward to a normal, or near normal life span; however, adverse events associated with the administration of immunoglobulin have occurred, and have forever changed or ended the lives of some patients. Most recently some of our patients have experienced an outbreak of Hepatitis C due to the use of intravenous immunoglobulin products. In July 1994, 112 cases were reported, but this was just the first wave. How many people were ultimately found infected? This has been a tragedy for the individuals who have been affected, but an additional tragedy is that we have not learned anything about Hepatitis C from this event. We have not established a national registry of these cases, and thus have no way to learn anything about the natural history of this disease in this patient group. We are unable to counsel our patients concerning the best treatment, relate the disease severity to immune functions, give an estimate of the number of cases who have needed a liver transplantation, or give any results about the outcome of this procedure and for which patient it proved the most useful. A national registry would be a most valuable scientific resource for physicians who are still dealing with the aftermath of this outbreak, and for scientists who want to learn more about this common disease. While Hepatitis C is no longer a threat to our patient population due to additional viral screening and viral inactivation steps, we should not throw away this opportunity to learn what this lesson has to teach.

To summarize I would like to make the following recommendations:

1. The FDA, NIH, or CDC should establish a sufficient look-back and registry program to determine how many cases of Hepatitis C occurred in the United States, in recipients of intravenous immunoglobulin during the relevant years.
2. Determine if the immune defect involved related to the disease outcome.
3. Determine what anti viral drugs worked.
4. Determine the degree of liver disease which developed, if liver transplantation was done, and its outcome.