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FINAL

SUMMARY REPORT OF THE PUBLIC MEETING ON PATIENT AND PHYSICIAN CONCERNS WITH ACCESS TO INTRAVENOUS IMMUNOGLOBULIN (IVIG)

Submitted to:
U.S. Department of Health and Human Services
Office of the Assistant Secretary of Planning and Evaluation (ASPE)
Attn: Amber Jessup
200 Independence Avenue, S.W.
Room 446F.1
Washington, D.C. 20201

Submitted by:
Eastern Research Group, Inc.
110 Hartwell Avenue
Lexington, MA 02421
www.erg.com

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ERG

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INTRODUCTION

A public meeting was held on September 28, 2006, at the Sheraton Crystal City Hotel in Arlington, Virginia to obtain public comments on supply, distribution, demand, and access issues associated with Intravenous Immunoglobulin (IVIG). This summary report highlights the experiences and concerns that meeting participants shared regarding patient and physician concerns with access to IVIG. Approximately 125 people attended the meeting in person and approximately 50 people joined the meeting via conference call.

Jan Connery of Eastern Research Group, Inc. (ERG) served as meeting facilitator and opened the meeting by explaining its purpose. The meeting was an initial step in an analysis of IVIG supply, distribution, demand, and access issues being conducted by ERG for the U.S. Department of Health and Human Services (DHHS) Office of the Assistant Secretary of Planning and Evaluation.

Dr. Aylin Sertkaya of ERG provided background information on the motivation for the study. HHS has received reports of problems in accessing IVIG by patients and physicians, changes in sites offering IVIG services, and difficulties in obtaining IVIG products. These issues may have potential public health consequences, and the dynamics of the market may be important factors to examine in addressing these issues, she said. ERG's analysis will examine IVIG supply, distribution, demand, utilization, and patient access using information from a variety of sources, including written and oral public comments.

John Eyraud of ERG thanked the meeting attendees for their participation, said that ERG may contact some meeting participants to clarify information presented if needed, and welcomed and encouraged other people to submit comments by the October 15, 2006 deadline.

Some of the issues identified by meeting participants included:

- Inadequate coverage and reimbursement by Medicare and other insurance companies for IVIG treatments.
- Health care impacts resulting from fewer IVIG treatments.
- Switching of patients to other IVIG products or treatment locations.
- Product access, allocation, and shortage problems.

This report summarizes the issues listed above as expressed in the comments provided by meeting participants. Possible solutions to the IVIG supply and access problems that meeting participants discussed are also presented.

MEDICARE AND OTHER INSURANCE REIMBURSEMENT

Many speakers at the meeting indicated that Medicare changes and reimbursement were key problems. Some people also discussed problems with private insurance companies. Dr. Mark Stein,*[1] a physician with Allergy Associates of the Palm Beaches, said that he has experienced

[1] * Speakers' names with an asterisk (*) indicate that comments made by them are included in more than one section of this report.

delays in Medicare reimbursements of up to 8 months. Also, the roughly $60 Medicare reimbursement per infusion is grossly inadequate, he said. Readjustments are needed. Physician reimbursements received with a six-month lag time make no sense, said Dr. Stein.

Ms. Julie Birkofer of the Plasma Protein Therapeutics Association (PPTA) said that the PPTA represents the leading producers of IVIG. She said PPTA members are concerned about patient access to IVIG, especially Medicare patients. The difficulties are associated with the seismic shifts in Medicare reimbursements in 2005 and again in 2006, she said. Consumers have experienced difficulties in obtaining care when the reimbursement method changed in 2005 for physician offices and then in 2006 for hospital outpatient departments. IVIG is a unique therapy, a sole source biologic with no generic equivalent, and no one size fits all, said Ms. Birkofer. Patient access must be restored to all brands of IVIG appropriate to individual patients, she said.

Present payment rates fail to adequately reimburse for IVIG under Medicare Part B, said Ms. Birkofer. The methods must recognize that IVIG therapies are vastly different from other pharmaceuticals. Obtaining an adequate supply of human plasma involves a significant investment of resources. It takes 7 to 12 months to manufacture IVIG. The current average sales price (ASP) plus 6 percent payment system is inadequate, she said, is driving complaints regarding IVIG availability, and explains patient problems with access to care.

Merle-Jean Peterson, an IVIG patient, said that in 2006 a hospital told her doctor not to send IVIG patients to the hospital. Ms. Peterson then had several infections. Her primary insurance company told her that they would not cover home health care for IVIG. Her secondary insurance company told her that they would cover some of her IVIG treatment if Medicare paid the rest; Medicare would not. When she contacted Medicare, they told her that they had received no complaints about IVIG. So she tried to send in a complaint. They sent her 12 pages of paperwork to fill out to file a complaint – she felt that she needed a lawyer to do so, so she ended up not sending in the complaint forms; she will try to do so. She spoke to many people and different agencies, and received a different answer each time.

Dr. Joseph Bailes spoke on behalf of the American Society of Clinical Oncology (ASCO), which conducted an informal survey of its members regarding access and health problems related to IVIG; 68 physician offices responded. The ASCO survey indicated that Medicare reimbursement for IVIG is a serious problem. Respondents reported a wide range of prices paid, which were often much higher than Medicare payments. The average price paid by respondents was about $40 per 500 milligrams for lyophilized IVIG and $50 for non-lyophilized IVIG. Medicare payments were about $25 to $30. The Medicare add-on payment has not been a solution.

Edith Marshall with the Public Hospital Pharmacy Coalition (PHPC) said that the PHPC comprises 400 Disproportionate Share Hospitals (DHS) hospitals. Under Medicare 340 B, prices have a statutory ceiling, she said; changing prices is a violation of the law unless the change is registered with DHHS. PHPC conducted a survey in which 50 percent of hospitals reported that they could obtain enough IVIG; 80 percent reported they have been unable to get any IVIG at 340 B prices. This is a crisis, she said. Public hospitals have special problems. They have many patients who are indigent and also others who are unable to pay. Some hospitals have been told by distributors that they cannot give them IVIG at 340-B prices – that it is the manufacturers' obligation to do so. This is more than just a mismatch of supply and demand, said Ms. Marshall,

and does not make sense. Allocations are based on 2004 levels, and there is a shortage now. An adequate supply is desperately needed, and she appealed to the government to look into the situation of allocation, distribution, and supply.

Congressman Mark Foley said that the 16th District in Florida has the fifth or sixth largest Medicare population in the United States. Two years ago, local immunologists and patients said that doctors could no longer treat IVIG patients because Medicare reimbursements were too low, so patients were then treated in hospitals, where they are susceptible to illness. He has met with manufacturers, distributors, group purchasing organizations (GPOs), and patients; there is no consensus on what the problem is. Some hospitals said they are cutting off IVIG services entirely. Congress and government agencies are looking into solutions; but people are dying now, he said. There is general consensus that reimbursement is not covering costs. Using an average sales prices rather than an average wholesale price may help.

Congressman Foley said that we must do a major restructuring of Medicare. Cutting reimbursement often leads to illnesses in IVIG patients. We need to work to enhance Medicare as a wellness model, not just a sickness model, he said. This issue won't go away. There will be some vehicle (e.g., a Congressional bill) to tack a solution onto, he said, but first a solution must be found.

Christine Butler, an IVIG patient, said that at various times her IVIG medication became unavailable. Her doctor agreed to accept Medicare, but countless other patients do not have coverage, she said. She could not afford IVIG treatments without Medicare and Blue Cross of Alabama coverage; without it, her life would be endangered. Her quality of life is much better while on IVIG.

Melissa Haffron said she has experienced both sides, as a parent of an IVIG patient and working for an immunologist. She said the results of IVIG treatment are amazing. The biggest battle is reimbursement and managed care, she said. When her child was first diagnosed, it took months to go through the process and up to 6 months to get approved. With Medicare changes, they had to switch from one place to another, and then were told her child had a pre-existing condition. At clinics, the dose was changed, and products were different. There has been extensive paperwork for every infusion. New patients may find it nearly impossible to get treatment.

David Elkayam,* a physician with the Bellingham Asthma, Allergy & Immunology Clinic, said IVIG patients are productive members of society. IVIG treatment needs to be delivered by people with adequate training, he said. Because of low reimbursements, clinics face financial burdens and cannot sustain providing treatments, given the need for nursing staff and time constraints on doctors. His clinic had to eliminate two full-time nursing positions. Doctors no longer have the time available to pick up on more subtle or early signs of illness. He also said that there needs to be a permanent additional payment.

Gerald Reice, an IVIG patient, said medical care is a right, not a privilege. He lost this IVIG treatment because of Medicare problems. It is very cruel that the government is not funding IVIG properly, he said. He will continue to call on senators and congressmen as long as his son can carry him into their offices, he said.

Michael Rigas of Crescent Healthcare said his company is an alternative site infusion provider. Some patients now either need a secondary provider, or must have large amounts of money to pay for treatments. Some patients have stopped treatment altogether, he said. Mr. Rigas said that Crescent Healthcare conducted a survey in which results indicated, among other things, that changes in Medicare reimbursement for IVIG had a number of impacts on patient access. Some of the survey results show that from 2005 to 2006, of 101 Medicare Part B patients who responded to the survey:

- 25 percent of the patients switched IVIG due to allocation issues,
- 50 percent of patients switched product due to access issues,
- 100 percent of patients experienced changes in administration location,
- 5 percent of patients received fewer treatments,
- 100 percent of patients had reimbursement problems, and
- 10 percent of patients had worsened health status.

Similar results were found for Medicare Part D patients, some of whom also received lower dosages. Mr. Rigas also said that IVIG patients started off in 2003 in doctors' offices, and reimbursement was sufficient. In 2005, reimbursement was lowered. Patients then went to hospital outpatient clinics; in 2006, reimbursement was lowered for those treatments. Patients then received home care under Part D; many of these patients cannot afford the Part D co-pay and are again receiving treatment in hospitals.

Susan Pappas of Critical Care Systems (CCS) said her firm is a provider of infusion care at home and at alternate-site settings. They serve 560 home IVIG patients. CCS supports expanded Medicare coverage of home administration of IVIG, she said. The new Medicare Part B home IVIG care coincided with significant reductions in Medicare reimbursement for IVIG administered in physicians' offices and outpatient clinics. Essentially, there now are no outpatient treatment settings for these patients, she said.

Current Medicare reimbursement for IVIG treatment is below the acquisition cost, said Ms. Pappas. Also, for home administration of IVIG, Medicare does not reimburse for administration costs, supplies, and equipment, as it does for doctors' offices or outpatient clinics. In addition, Medicare Part B benefits apply only to primary immune deficiency diagnoses (PIDD), which are a small portion of the population with a medical need for IVIG. Medicare must expand beyond PIDD, she said. Medicare Part B reimburses for administration costs, supplies, and equipment, in addition to the IVIG product itself in physicians' offices and outpatient clinics. This reimbursement does not exist for IVIG administered in the home. For home care, Medicare Part D does not cover pharmacy costs, professional services, administration, supplies, equipment or home nursing visits.

Rosa Luna, a registered nurse, said that some patients drive up to 2 hours to receive IVIG treatments, and some clinics have had to shut down. She said there is no reimbursement for supplies needed to administer IVIG, and items that are covered by reimbursement are not getting fully covered by reimbursement costs. Human health needs to be the focus; insurance companies

should not be making the decisions, she said. Allocation of product is also a key issue for some patients. She also indicated that private insurance companies are following the lead of Medicare.

Natacha Pires of the Neuropathy Association said that IVIG is an effective treatment for a number of different neuropathy conditions. For some patients, IVIG is the only treatment. Without it some patients are unable to walk and are paralyzed. There are hidden costs that are not covered by reimbursement, she said, such as administering, billing, and inventory. Sending a patient to a hospital outpatient clinic for IVIG treatment can cost $17,000; comparable visits to a doctor's office would cost $4,000. Access to IVIG treatment needs to be restored. Delays or lack of treatments affect morbidity and mortality, she said.

HEALTH CARE IMPACTS

A number of patients and physicians discussed specific health impacts they or their patients have experienced when switched to other IVIG products or if they received less frequent IVIG treatments, often due to Medicare or other insurance changes. Dr. Robert Dracker, a private practice physician, said that this was his fifth trip to Washington, DC on this issue. He has patients who use IGIV and have been removed from treatment. IGIV is different from other pharmaceuticals, he said; removal from treatment can have effects on morbidity and mortality, which is why his patients were not there with him that day. He said the situation was extremely frustrating, and that this plight must end. He has heard an incredible number of excuses; meanwhile, patients can no longer walk or have died.

Rose Mary Istre of the Mytositis Association said she appreciates the need for data, but that while Congress and DHHS are studying the problem, people are dying. Ms. Istre discussed the situation of people on IVIG getting better, walking after being unable to do so once on IVIG; going to infusion centers, then having to go to hospitals instead of infusion clinics. She said hospitals are not a good place for immuno-compromised patients because of the risk of infections there. She asked why patients are having trouble getting into hospitals and getting the brand of IVIG product they need. She said Congress needs to be educated, and has thus far been myopic about this issue; people are dying. She gave the names of two people who had testified before the House Ways and Means Committee in 2005 about problems of IVIG access who have since passed away.

Dr. Stein* said that some patients have to drive an hour or more to get treatment or the product they need, and thus some patients have removed themselves from treatment. Some have been hospitalized, readmitted, and are at constant risk of death. In addition, some hospital nurses do not have expertise in administering IVIG medications. His region is down to one hospital providing IVIG treatment, and only one product is available. That product contains sucrose, which is a problem for some patients who can't tolerate sucrose; they discontinue treatment and run the risk of infection.

There is no access to office care for IVIG patients, Dr. Stein said, and problems of severe reactions have occurred when treatment has been administered in hospitals. In Florida, it has been reported that because of shortages of IVIG, some patients can only get it every three months instead of every month as they need. Some patients can't get the medication unless their IG levels drop below a certain level.

Fred Modell of the Jeffrey Modell Foundation said that his son died at age 15 from immune deficiency disease, which affects one million Americans. IVIG gave his son 15 years of life, Mr. Modell said. After his son Jeffrey died, he and his wife set up a foundation in their son's name. They have heard from thousands of patients. Without treatment, immune disease can be fatal, and alternative treatments to IVIG often do not exist, Mr. Modell said. Doctors need adequate reimbursement. The government wants to do the right thing but data are needed.

The Jeffrey Modell Foundation collected data based on 86 referral centers. The study found that treatment is not accessible for some patients, or that doctors cannot provide treatment because they will not be reimbursed. One question researched was whether a difference in quality of life existed between diagnosed and undiagnosed patients. He stated that undiagnosed patients spent 19 days per year in the hospital compared to 6 days for diagnosed patients. Further, undiagnosed patients suffered 3 bouts of pneumonia per year compared to 1 bout for diagnosed patients. Undiagnosed patients made 17 trips to hospital emergency rooms per year compared to 12 for diagnosed patients. How can we wait to solve the IVIG problems, Mr. Modell asked? He said our statutes enable us to act.

Dr. Joseph Bailes* discussed the results of another survey conducted by the American Society of Clinical Oncology (ASCO) of physician offices (68 offices responded). According to the survey, many physicians refer their patients to hospitals for IVIG treatment to avoid financial losses, with some patients traveling long distances to get there, said Dr. Bailes. The survey found a number of adverse health effects experienced by patients resulting from the IVIG situation, including:

- Increased bleeding episodes,
- Bruising,
- Infections,
- Hospitalizations due to delayed treatment,
- An increase in transfusions and splenectomies,
- Side effects including allergic reactions due to patients having to switch from one brand to another, and
- Dose and treatment reductions due to shortages of IVIG – 42% of survey respondents said that they give patients less than a full dose; 31% said they give patients fewer treatments.

Sarah Lazarus, an IVIG patient, said that in 2005, Medicare would not cover her doctor's costs for IVIG treatments. Since 2005 when Medicare would not cover IVIG treatments, she has had several illnesses. She became disabled, and could not work. Her quality of life went on a downward slope.

Dr. Mark Ballow,* a physician, professor at the State University of New York at Buffalo, and a representative of the American Academy of Allergy, Asthma & Immunology, said that IVIG illnesses are life threatening for some patients. IVIG is a life-saving therapy for these

patients, with no alternative therapy available. IVIG medications are complex biological products and should be classified as biological response modifiers, he said. There is a risk of adverse effects manifesting because of the unavailability of IVIG products.

Changes in utilization are important to enhance IVIG availability and control costs, said Dr. Ballow. Utilization guidelines based on evidence-based medicine is a reachable long-term goal, he said. IVIG is the only therapy that is allowed to be cut. Can you imagine treating a diabetic with insulin three times a week when he needs it every day, or reducing his dose? Patients need access to different products and ensured product safety, he said.

Dr. Ballow said the costs of IVIG treatments are high because it is a complex biologic product with adverse effects. Nurse-to-patient ratios need to be 1:1 or at most 1:2; long infusion times are needed (e.g., 6 hours). There are upfront costs in acquisition and administration. Reimbursement is totally inadequate. He also said that allocation is an issue; 70 percent of IVIG is off-label, and this use should not be belittled.

Marcia Boyle of the Immune Deficiency Foundation said the foundation has conducted three surveys of patients, doctors, and hospitals. One area explored was the comparison of Medicare vs. non-Medicare patient care. Ms. Boyle presented preliminary findings. Of 3,000 surveys mailed, 763 were completed. She said some patients are being forced to other sites of service. Problems such as obtaining IVIG, time intervals, and negative health effects fall disproportionately on Medicare patients, the survey results indicate.

Several meeting participants said that the same continuity and quality of care cannot be provided in a hospital facility as the care provided in a doctor's office.

SWITCHING OF PATIENTS TO OTHER IVIG PRODUCTS OR TREATMENT LOCATIONS

Patients, physicians, and patient advocates participating in the meeting said that many patients were forced to switch products because the ones they used and needed became unavailable, and also that many patients were required to switch to different locations to receive IVIG treatments. Negative consequences were reported when either of these situations occurred.

Melissa Schweitzer of the IVIG Access Coalition, the Washington Strategies Consulting Group, and a patient, said that she has talked with patients and doctors. In 2005, many patients were told they could not continue their IVIG infusion, that it was a reimbursement problem, and that they would have to drive many miles to hospitals to receive treatment. Patients encountered inexperienced providers and were switched to other products and locations. She said that because of IVIG, she has been able to have a career and be a wife and mother. Ms. Schweitzer said that she understands the importance of collecting data, but action needs to be taken immediately.

Joanne La Douceur, an IVIG patient and a registered nurse, said after IVIG infusions, she felt better and her infection rate went down. When she switched clinics to get IVIG treatments, the second clinic had a different brand of product and she had severe side effects from it. When she was having subcutaneous treatments at home, the product she used became unavailable and she had to switch products again. The specific product she needs is difficult to find.

Ann Walton, an IVIG patient, said that she lost most of her adult life to immune disease. She is now building a life for the first time, at age 59. If IVIG infusions are delayed by even a

few days, she gets sick. She is working part-time but it is difficult to support herself with only part-time work. She has had difficulty scheduling hospital or clinic visits, as she can only get infusions on nights or weekends, given her job. Only home health care can accommodate these types of hours. However, home health care is not covered by Medicare, even though it is less costly than institutional care, she said.

Imogene Moore, an IVIG patient, said that initially Medicare said they would not cover IVIG treatments because "IVs don't cure." She sought secondary insurance. Her costs are $1,500 every 3 to 4 weeks. Medicare has relented and covered the cost. Nevertheless, she experiences numerous billing problems. Costs got so high and Medicare reimbursements were so low that her doctor stopped giving treatments in his office. She then began going to the hospital for treatment. She said that she has sat several hours in a clinic waiting for medication to arrive. Sometimes it is not available at all and she has had to wait for two weeks, in constant pain. At times she has been switched to other (cheaper) IVIG products, but she had negative reactions to these other products. It is unfair that IVIG is not always available when needed. Patients are able to live independently because of IVIG, she said.

Adele Kirkpatrick, an IVIG patient, said she was barely functioning before she received IVIG treatments. She has tried several IVIG products but experienced side effects with all except one product. At one time her local hospital did not have the product she needed, so she had to travel a longer distance to another hospital. The nurse there treated her badly. A company said that they could provide her with specific treatment at home, but she was told that her insurance does not cover home care. Medicare rejected treatments at a doctor's office. Medicare pays millions for terminally ill patients, she said; so why won't they pay to keep IVIG patients alive?

PRODUCT ACCESS, ALLOCATION, AND SHORTAGES

Inadequate access to IVIG products in general and to specific IVIG products that patients need was a common theme discussed by meeting participants. Some speakers also discussed the uneven allocation of specific product brands. Many participants raised the issue of shortages of IVIG; the question of whether a real shortage exists was not clearly answered at the meeting, but a number of speakers said that improved allocation and distribution of IVIG would help solve the access and apparent shortage problems.

Mary Simon, an IVIG patient, said it took the medical community 20 years to diagnose her. She was denied IVIG by one HMO and was forced to switch to another company. She is allergic to all brands of IVIG but one – and that one is not covered by reimbursement. She went to a hospital because her doctor could not afford the medication. The hospital could not get the brand she needed. Then the hospital told her that it no longer administered IVIG, and gave no reason. Ms. Simon believes that lack of reimbursement and inadequate reimbursement rates are the cause of the problems. She said she never knows from month to month whether she will receive treatment. In April of 2005, Ms. Simon received a $9,000 bill because her doctor was not reimbursed. She and other patients cannot afford this. She is paying $25 a month, which means the debt will be paid off in 30 years.

Patty Mitzenmacher, a patient advocate for her child, said she has experienced the IVIG situation from all sides, including working with providers. Her son uses IVIG for off-label use, and it is the only treatment that works for him. At some point after July 2005, certain types of

IVIG medications became unavailable, and there were delays in reimbursements. She called a drug company, and they told her there was no shortage. She called around and was able to find the needed medication. Unless you were a wholesaler, she said it was difficult to get the medication. Her insurance company wanted her to administer the treatment at home; because of her son's condition, this was not a viable option. The local hospital said it would not administer the medication. Why do people have to become experts to deal with the situation, she asked? It is a lot to deal with, in addition to the illnesses.

Dominick Spatafora of the Neuropathy Action Foundation said that IVIG has been a miracle drug for him. Doctors say there is a national shortage of IVIG medication; others say there is no shortage, he said. An insurance company told Mr. Spatafora that there is an acute national shortage due to manufacturing levels. One clinic had a large supply and offered the medication to him, but his insurance company would not cover it. A company near his home had a supply, but because his name was not on their list, he could not get it from them. At one point, Mr. Spatafora was unable to obtain the brand of IVIG he needed. He received an alternative brand, but had severe side effects. After three months without treatment, he became paralyzed in one hand. He contacted the government and the media. He won an appeal, got the treatment, and the use of his hand has been restored. He is a well connected individual – what about others, such as Medicare recipients, the elderly? What are they to do, he asked? Health care decisions must be made by doctors, not insurance companies, said Mr. Spatafora. No one "cookie cutter" approach works for all patients. IVIG patients can live better lives.

Dr. Bailes* said IVIG is used by oncologists to reduce infection risk in some patients who have low immunoglobulin levels, as well as for other patient conditions. Results from an American Society of Clinical Oncology survey of 68 physician offices indicated that there continues to be a shortage of IVIG, and approximately 50 percent of practices have been unable to purchase the full quantity of IVIG they needed. Most also experienced significant delays in obtaining IVIG, said Dr. Bailes.

Ronald Hartmann with MedAssets, a health care purchasing organization and the third largest group purchasing organizations (GPO) in the United States, said his organization works with 1,400 hospitals and 23,000 providers. He said that he was not representing the industry at the meeting, only MedAssets. His company contracts with manufacturers and has a significant role in allocation of products. Manufacturers have allocated based on historical needs. But patients have shifted locations. And health care providers can and do choose to go from one GPO to another. He emphasized that the product should move with the customer. Patients must be the number one priority, he said.

Mary Kruczynski of the Community Oncology Alliance said that two issues affect her as a practice administrator: obtaining approval from patient insurance carriers, and the reimbursement process. What products are available? What quantity will be available that month? If an insurance company does approve coverage for IVIG treatment, the patient needs to be scheduled in a busy infusion suite. There is often a long wait until their scheduled date. It is difficult to explain to patients why they have to go to a hospital for treatment. It is an exasperating process, sometimes with no reimbursement. Ms. Kruczynski said that she is sometimes contacted by home care companies that have no experience in administering IVIG. She wondered why sometimes home care companies can get IVIG, and public hospitals cannot. Are the shortages contrived, she asked?

Is there an IVIG product shortage, Congressman Foley* asked? Many hospitals cannot obtain the product at all; others must triage patients, giving IVIG to those who need it the most. There is a "channel conflict" – a shift in the setting in which patients receive treatment, but the product is not following them there. The process of how contracts are done should be looked at, he said. Many hospitals in Florida do not offer IVIG in an outpatient setting. Other options continue to be explored.

Peggy Hassel, an IVIG patient, said that when the laws changed, she could not get the IVIG medication that she was taking and needed. When doctors could no longer administer treatment, she went to hospitals for treatment. Subsequently she had no place to go to get treatments. She purchased the medication with her own money. As of this week, she said, she can no longer get the IVIG medication she needs in the hospital, and has no where to turn. She needs the IVIG treatments to survive. Doctors have been cut out of the loop. Medicare does not meet the needs of IVIG patients at an affordable cost, she said. Companies will sell the medication outside the country, and patients in the U.S. will die.

Betty Gordon, a patient and member of the Immune Disease Foundation, said product choice and reimbursement are the key issues. She said that in 2004, without warning, she could no longer get her particular IVIG product. She ended up in the emergency room. After numerous phone calls, she was able to obtain the product she needed. One hospital tested all IVIG patients' IG levels because reimbursement is not sufficient to cover costs for all; those patients who refused testing and those with the highest IG levels would not receive treatment. IVIG access should be the same all over the United States. Some patients need IVIG to stay alive, she said.

Jenny Peckenpaugh, an IVIG patient involved with the Immune Deficiency Foundation, tried to stay in college once she was diagnosed with immune deficiency; she kept registering for classes, then dropping out due to illness. Her prospects for law school were destroyed. She is now in better health with IVIG treatments, but not back to full health. In 2006, she had trouble getting the product she used and switched to another company to get it. Other patients also have trouble getting their IVIG products, and some are panicking. Doctors are encountering shortages of IVIG products, manufacturers are saying there are no shortages, and supplies of products are being reallocated. The distribution strategy of IVIG products is not very successful, she said. Locations of treatment are being switched, and sometimes there is too long a time between treatments. Patients are suffering. The system is broken, she said.

Dr. Jonathan Katz, a physician, member of the Guillain Barre Foundation, and professor at Stanford University, said he agrees that there is a gigantic access problem. The reasons for the problem, as discussed may other speakers, include inadequate payments to doctors and infusion clinics, difficulty admitting patients to hospitals, lack of FDA approval for certain treatments, and payment delays. Explaining to patients why you cannot treat them is extremely difficult. How did we get here in the first place, he asked? IVIG treatment for neuropathy began in 1995. Patient response was good, and use of the treatment grew. From 1999 to 2001, the pendulum swung too far in the other direction. A short-term solution is to fix the reimbursement problem. A long-term solution is to think about how doctors can understand the disorders and develop data that indicate which patients respond most to IVIG.

Elaine Hill, an IVIG patient, said that because of IVIG treatment, she has been able to be a daughter, mother, and grandmother. She said she has been hospitalized a number of times

because she went undiagnosed for so long. She needs a specific IVIG product. My life is literally in your hands; I want to continue to live, she said. Even if IVIG patients have disabilities, our lives are productive, said Ms. Hill. She loved her work and wished she could still do it. She said previously there was a shortage of IVIG in southern Florida because much IVIG product was shipped out of the United States to other countries; enough needs to be kept in the U.S. if it is needed here.

Patricia McHugh, an IVIG patient, said her hospital couldn't always get the IVIG product she needed, and she sometimes received half of her usual dose. She said she cannot express the gratitude she feels for being able to get IVIG treatments; without them, the future is bleak. She is also angry, she said, that the system doesn't care about patients. She called the 800 number at the Medicare office, but no one was there to talk to. There is a wall between the patient and the system, she said. The issue is complex, but a short-term solution is needed quickly so that patients can receive treatments. Save my future, she said.

Bruce Bunyan* with Talecris Biotherapeutics said he supports giving each patient and doctor the IVIG treatment that is effective for them. There is an access issue that is clearly linked to Medicare, he said. There are also issues with the gray markets and distribution. He reported that Talecris has increased production by 75 percent over the last 5 years. He also noted that Talecris makes available an emergency supply of their IVIG product and that this emergency supply has never been exhausted. Talecris has also passed on only moderate price increases despite having made large capital investments and incurring increases in production costs.

Marsha Bond, an IVIG patient, said that after 2 years with IVIG therapy, she hopes to be able to return to work soon. She is no longer able to get the treatments in a doctor's office, so goes to a hospital. But there are delays in getting treatment, and every month there are different products available. She has had some severe side effects with some products. There are allocation issues; the infusion clinic can find products, but not at affordable prices. Sometimes she has to skip treatments. Without treatment or with delays, some people she knows get sick. It is Russian roulette with life every month – will I get IVIG treatment this month? People should be able to get the treatments they need, she said.

Mr. Bennis, an IVIG patient, said that there is a common theme at the meeting: Medicare has cut back so much. He has not been getting his proper dose, and Medicare has taken away physician care. Something has to change, Mr. Bennis said. Hospitals and doctors say there is a shortage. He has called companies, and they say there is no shortage. There are too many middle people making a profit, he said. People are dying.

Jayson Slotnick, director of Medicare reimbursement at a biotechnology trade organization involving 1,100 companies and institutions, said there is a need to ensure adequate access to IVIG products and to find solutions to reimbursement and access issues. Some IVIG products with no sugars must be available for diabetics, for example. A unique code is needed for each brand of product.

Eugene Richardson, an IVIG patient, said he had to give up a long military career due to immune-related illness. He had a new career for another 14 years, but his condition relapsed. He was receiving IVIG infusions at his doctor's office, when suddenly Medicare was no longer reimbursing treatments. He was sent to a hospital for treatments, where he had to change

products, and then was told that product was no longer available. He ended up in the emergency room and in a wheelchair with pain. He changed products again, was no longer wheelchair-bound, and all his symptoms decreased. He is now very anxious about the ability to continue receiving treatments. He said some IVIG patients should not be compared against other IVIG patients - who is worse off should not be asked.

Michelle Vogel with Washington Strategic Consulting agreed that some patients should never be pitted against other patients, such as patients who use IVIG for on-label and off-label uses. Access needs to be restored for all patients, she said.

Donald Davies, a pharmacy analyst for many years, said there are product shortages, usage of IVIG products is up, and there is an issue of output from manufacturers verses demand. Also, one manufacturing plant has shut down, and raw materials collection sites have been reduced, he said.

Susan Pentlin, an emeritus professor and an IVIG patient, said that she used to go to a medical center for IVIG infusions, but in 2006 everything changed. She started going to a hospital for treatments, and available product brands were different. She had difficulty scheduling appointments, and sometimes IVIG was not available at the hospital. When treatments were delayed, she would get sick. She has talked to administrators and insurers. Sometimes her charts were not available when she had to switch treatment locations, and she has sometimes received only half her usual dose.

POSSIBLE SOLUTIONS

Several people at the meeting included some possible solutions to the IVIG supply and access problems in their comments. Ms. Birkofer* said it is important that a market-based reimbursement methodology be used that reflects the average sales price and also addresses consumer concerns and access needs. She said that approximately 19 million grams of IVIG have been distributed in the marketplace (through the first 7 months of 2006), yet there is a patient access problem. A comprehensive, permanent solution is needed. She said the Plasma Protein Therapeutics Association proposes the following solutions:

- A permanent payment adjustment to make Medicare payments more reflective of the true costs to providers,
- Separate payments for each brand of IVIG therapy, rather than grouping them together,
- Making the “temporary” pre-administration codes permanent, and
- Reimbursing IVIG administration as a biologic response modifier (BRM).

Dr. Elkayam* said the system needs to:

- Support permanent add-on payments.
- Use separate J codes for each IVIG product, and
- Pay doctors at higher levels needed to obtain these biological agents.

Mr. Bunyan* agreed that some of the IVIG problems can be addressed in part by providing separate J codes for IVIG products rather than lumping them under a single code, and having administering fee reimbursements. He also said that working with contractors and local companies is important.

CLOSING REMARKS

Jan Connery of ERG closed the meeting by saying that we are all grateful to those people who shared their personal stories and to the organizations that shared information. She said an analysis report on the IVIG situation will be available in early 2007 and will be posted on the U.S. Department of Health and Human Services website, and that all meeting attendees will receive notification of its availability.