Public Meeting on Patient and Physician Concerns in Access to Intravenous Immunoglobulin (IVIG)

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P R O C E E D I N G S

10:00 a.m.

MS. CONNERY: Good morning, everyone. It's 10:00 a.m., by some clocks, anyway. We'd like to have an on time start. My name is Jan Connery. I'm with Eastern Research Group, also known as ERG, and we are a company that the Department of Health and Human Services has contracted with to conduct analyses and analysis of issues associated with access to intravenous immunoglobulin, or IVIG.

I will be your facilitator for this meeting, and I'd like to welcome you all here today and thank you for taking the time to be here. I'd like to note that we're joined by well over probably 50 folks in the room, and we also are joined by 50 -- over 50 folks who signed up to participate by phone, so I'd like to welcome both those in the room and those on the phone.

I also want to check with Marcella -- we

have an operator on the line because we have so many people connected -- to make sure that the technology is all working well. Can you hear me, on behalf of the folks on the phone; can you hear me well?

OPERATOR: Yes, Ms. Connery, we are able to hear you.

MS. CONNERY: Great. Thank you. The purpose of this meeting is to obtain public comment on issues associated with access to IVIG. This is the initial step in the analysis project that ERG will be conducting, and I am joined by two colleagues who I will introduce in a moment, and they will give you some background on this study and help you to understand how the meeting fits in the context of the study.

Before I do that, what I'd like to do briefly is review the agenda. For folks in the room, you should have that in the packets that you picked up when you walked in, and it's also similar to the agenda that's been posted on the meeting website in

the past couple of days. For folks that are on the phone, you should have received an e-mail later in the day yesterday that contained the four items that are in the registration packets that we have here in the room.

The agenda is really very simple. After the background remarks from my colleagues, I'm going to go over the process that we'll be using for the public comments, and then we will start that process, and we will be taking public comments up through our first break, which is at 11:30. For those of us on the East Coast, that will be our lunch break, and that's going to go for an hour and 15 minutes, and we'll start back in at 12:45.

At that point, we'll be joined by Congressman Tom Foley, a representative from Florida. Many of you probably know that he's also a member of the Ways and Means Committee and very interested in IVIG access issues, and so he will be here to say a few words, and that will be about 15 minutes.

Then, at 1:00 p.m., we'll start back in with the comment process and we'll go to 2:30 Eastern Time, then we will take our break. That will be 15 minutes. Then we'll resume the comment process and keep going until we have worked through all the commentors that are on our list.

I'll note that we do have a very full day today. We have a lot of folks who've signed up to comment, so we do anticipate going until probably 4:00 or even close to 5:00, or maybe until 5:00, but we will definitely get to everyone who's on the list.

I also want to note, especially for folks who are on the phone and maybe coming and going, that we will be taking our breaks on time, so starting at the time on the agenda and then coming back in to begin the comment process at the Eastern Time indicated on the agenda, just so you know that, so if you happen to be the commenter who is going to be -- is queued up to speak when the break ends, please be sure to be back here on time.

With that, I would like to introduce my colleagues to give you a little background. On my left is Dr. Aylin Sertkaya, and on her left is John Eyraud. Both are senior economists at ERG and both are co-directing the IVIG Issues Analysis Project.

DR. SERTKAYA: Well, thank you, Jan, and good morning. My name is Aylin Sertkaya and I'm a senior economist at Eastern Research Group. I'd like to start with giving you a quick background on our study. As you all know, IVIG is a valuable treatment for many seriously ill patients. However, the Department of Health and Human Services has been receiving reports of problems with access to IVIG from various patient groups and physicians.

In particular, these groups have been reporting increased difficulty in acquiring IVIG, changes in sites of service, fewer treatments, and problems related to switching among IVIG products.

So as a result of these reports, the Department of Health and Human Services Office of the

Assistant Secretary of Planning and Evaluation has contracted with us to obtain an independent evaluation of the potential public health consequences of access, and also to gain a better understanding of the IVIG market dynamics.

So to meet these objectives, our study consists of three main components; first, an analysis of IVIG supply and distribution; second, an analysis of IVIG demand and utilization; and finally, an analysis of any IVIG access problems, including their nature, size, and scope.

Let me also quickly tell you as to how we are carrying out these analyses. Currently, we're pooling and evaluating information from a variety of sources. These include published studies, research conducted and made available to us by patient groups, physicians, IVIG manufacturers, CMS and others, publicly and privately available databases, and also, interviews we're conducting with IVIG manufacturers, distributors, group purchasing organizations, hospital

and specialty pharmacies, infusion centers, physicians, and patient groups.

Now, as Jan indicated in her opening remarks, this meeting is designed to obtain public comment on access issues to be used in our analyses in conjunction with the other data and information being gathered.

I would like to conclude by emphasizing that we will carefully consider all the information you provide us here today and may follow up with some of you as needed to clarify any questions we may have during this process. Before I turn the microphone over to my colleague, John Eyraud, I would like to thank you all for being here today and sharing your experiences with us.

MR. EYRAUD: Thank you. I'm John Eyraud. In case some of you are curious about ERG, we are a contractor to federal agencies and we have performed numerous economic and regulatory studies over the past 22 years. One of our main practice areas is research

on the pharmaceutical industry and unrelated medical and regulatory issues.

We have been working on the IVIG study in recent weeks and we're still in the initial phases of our work. In this time, however, we have spoken with some of you in the audience. In today's session, we hope you will describe your personal or your organization's experience with the topics at hand.

It is helpful if you can provide any supporting studies or information, but that is not at all required today. We look forward to hearing your input. Thank you.

MS. CONNERY: Thank you, Aylin and John. What I'd like to do now is go over how we'll be handling the comment process. In your registration packets or e-mail, to the folks on the phone, you should have the list of commenters, and this will be similar to the preliminary list that we sent out earlier. That is the order in which we will be taking the comments.

It's based on the order in which people signed up, and we will also be alternating between a commenter in the room and a commenter on the phone, just to have some variety.

What will happen with each comment is I will announce your name, and I'm going to apologize in advance. I'm surely going to mispronounce some names. But what we'd like you to do when you begin your comment is to give us the correct pronunciation of your name and also, your affiliation for the record. For folks on the phone, please come to this floor mike. That's important so that we can make sure that everyone is being heard.

There will be, as we said in some of the pre-meeting communications, a maximum of five minutes for each comment. I will be tracking the time and I also -- for folks in the room, I do have some visual time cues, just to sort of let you know where you're at. One minute, 15 seconds, and then time is up. For folks on the phone, I'll be giving you a very brief

audio cue letting you know that it's 15 seconds. Hopefully, you'll have a clock in front of you so that you can monitor your own time.

We are going to need -- wherever you are when you're time is up, we are going to need to have you finish your sentence at that point and just end your comment. But there will be ways in which you can provide further comments that I'll mention in a moment.

It's important for us to be pretty strict about that for a couple of reasons. One is that we have a very full day. We have a lot of people who need to comment, and we want to be sure to get to all of you. Also, it's a matter of fairness for everyone, in terms of everyone having the same time. So I'd appreciate your cooperation in helping us follow those procedures.

At the end of the comment, it is possible now and then that Aylin and John may have a couple of -- one or two quick questions of clarification. These

will be very simple.

For example, if there was something that someone said that they didn't understand and they want to make sure they had a clear understanding, they would ask to clarify their understanding, or if there's a point that they might like to get more information on, they might ask you if more information is available, and then follow up with you later.

We don't have the time for a lot of back and forth today, but based on what they hear, they can decide whether to follow up with more detailed questions later. So if there are any follow-up questions, they'll be really quite brief and very simple.

I do wish for all the commenters that I could have given you exact times when we would call on you to comment, but unfortunately, that's not possible for a number of reasons. There are many variables that are not in our control.

Some people may take less than their five

minutes, and we've actually -- some people, when called upon, may not be there, and we've just heard this morning -- and I'm grateful to three people who actually took the time to contact us and say "I signed up but I'm actually not going to be there. I'm not going to be able to comment." Those are Commenters No. 9, 39, and 42. So we will be moving ahead at those points.

So for those reasons, we can't give you exact times. My personal best guess is that we'll be moving at a rate of about 12 to 15 commenters per hour that is scheduled for the public comments, so you can sort of do your own math. Especially for folks on the phone, if you want to come and go, that's fine. We recommend that you check back in periodically.

When I announce commenters, I will always say the number on the list so that you can quickly kind of learn where we're at and gauge your time accordingly.

Now, if you have a written copy of your

comments or documentation to support those comments, and you're here in the room, I'd like to introduce a colleague, Linda Stein from ERG. One of her roles here will be to collect any of that documentation that you might have here in the room and make sure that it gets to the ERG project team. So just hand it in to her at any time.

If you're on the phone, one of the handouts in here is called "Additional Information", and there is information in there about sending in additional comments and documentation, and so -- and written copies of your comments -- and so you can get those to us that way, either by e-mail or by regular mail.

For folks in the room, if you have a visual, maybe there's a graph or something that you'd like Aylin and John to be looking at that supports your presentation and you'd like them to be seeing it while you're making your comment, you can just hand that to me and I'll give that to them when you're called on.

If you're in the room and you have any logistical questions or needs, I'd like to introduce another ERG colleague, Erin Corina. She is our conference manager, and she'd be very happy to help you. See Erin with any of those questions. I'll also mention, for folks in the room, that the restrooms are located out the left and you keep going past the elevators and they're tucked in over there.

For folks on the phone, you -- because we have potentially so many people on the phone at once, you will be on mute, except when you're called on to comment, and when you are, by the way, the operator, Marcella, will be -- it'll take her just a couple of seconds to unmute your particular line, and then we'll hear your comment.

But we hope that we've anticipated and answered most of the questions that you may have through some of the pre-meeting communications and these comments right now, but in case there's anything more or any other questions you had about the process

or logistics, your contact for that is Laurie Stamatatos. Many of you have already been in touch with her in registering for the meeting, but again, her contact information, if you don't have it in other forms, is listed on the Additional Information handout.

So if you're on the phone and you do have a question you'd like to get the answer to, contact Laurie. She'll either be able to answer it directly or if need be, she can get in touch with us in the room and we'll get you that answer as quickly as possible.

Marcella, I'd just like -- Marcella, our operator, is going to be letting us know if there's any audio problem. Is that right, Marcella?

OPERATOR: That is correct, ma'am.

MS. CONNERY: Okay.

OPERATOR: And if someone is having a problem hearing, they can send star-zero --

MS. CONNERY: Okay.

OPERATOR: -- and let an operator know, and then we can contact your location.

MS. CONNERY: Okay, good, good. So on behalf of the people on the phone, we hope to maintain, and we have procedures to maintain, good audio feed the entire time, because that's obviously very important for the quality of this meeting. We want to make sure that everybody in the room can clearly hear those on the phone. As you can see, it's plugged into the speaker system, so that's going well so far. And vice versa, everybody on the phone can hear folks who are speaking in the room, one of several reasons why we'd ask you to use the microphone.

OPERATOR: Ma'am?

MS. CONNERY: Yes?

OPERATOR: Your line is starting to break up just a little bit. Have you walked away from the speakerphone a bit?

MS. CONNERY: No, I actually have a Lavalier

mike, which is following me around. Is that better?

OPERATOR: Yes, thank you.

MS. CONNERY: Okay. Yes, I'm not -- there isn't a speakerphone. My mike is with me, so I just have to make sure that it's very close to me, obviously. Okay. Okay. Now, a couple of notes about reports and so forth. First, I do want to mention that this entire meeting is being audiotaped for the record and from that, we will be producing transcripts, and those will be available to anyone who is interested. Also, Linda Stein, one of her roles here is to take notes and prepare a summary report of some of the main themes of the comments that were heard, and that will also be available.

If you are interested in obtaining a copy, you just need to contact Laurie Stamatatos, as detailed on here. Just let her know which, or maybe you want both of the documents. We expect that they will be available within the month and as soon as they are, we will send them out to anyone who's indicated

they are interested.

Then the question I'm sure many of you are wondering is when is that analysis report that ERG's working on going to be available. I did check with the Department of Health and Human Services about that, and it is anticipated to be available in early 2007. That's as precise as they can be about the time frame right now. Almost certainly, one of the channels of distribution will be their website, and I will get that web address for you and have it a little bit later.

So we're almost to the point where we're going to begin the process, and I'd just like to remind everyone really, as is pretty obvious from the agenda, this is about comment, it's about input, it's about open listening.

We don't have time on the agenda, and it's not a purpose of this meeting, to have any discussion or debate or any sort of decision-making. Rather, this is one of the many channels of input to this

project. The ERG project team leaders will be listening carefully and following up as needed.

I'd also like to note that if you don't feel you've been able to fit everything you'd like to say in your five minutes of comments, or if you were listening to other people comment and think, "Gee, there's more I'd like to say now. I wish I could comment again," or if you didn't sign up at all and you're sitting there saying, "Gee, I wish I had signed up," that you are welcome and encouraged to submit those thoughts in written form as written comments, which will be considered equally with the input from this meeting.

Again, the instructions for how to do that are on this handout, the Additional Information handout. They're also the same as the instructions for written comments that were available through the meeting website and other notices about the meeting, so we're very much appreciative of that.

Let me just check and make sure everything

is clear about the comment process. Folks in the room? Okay. I don't see any too-puzzled faces, so why don't we then begin with our first commenter? Our first commenter is Dr. Robert Dracker, and he's a commenter in the room. He is with us, coming to the phone right now. If you would give us your name and affiliation for the record.

DR. DRACKER: It's Dr. Dracker.

MS. CONNERY: Oh, Dracker?

DR. DRACKER: That's right.

MS. CONNERY: Oh, started off mispronouncing.

DR. DRACKER: I'm in private practice in the Syracuse, New York area, and my office is Infusacare Medical Services, which is a private office. It is not an infusion center, per se; it's run as a practice. This is my fifth trip to the Washington area over the last few years to deal with this issue. It's probably my last trip, so I have every intention to be very open and direct about my comments.

I have the pleasure of taking care of patients that require IVIG, both pediatric and adult, and for primary immune deficiency, secondary immune deficiency, and also, for patients with autoimmune disorders, including neurologic disorders.

I've often mentioned at these meetings that I've had that the product gamma globulin is very different from other products. It is not a pharmaceutical, it is a blood derivative, and one that is not interchangeable with other products, as I'm sure others will explain, but one that has to be given very careful consideration.

The problem I've had and the reason I am here today is that first of all, I'm here alone. The patients I cared for as a result of changes that were initiated through CMS are no longer cared for in my practice, so my patients have been (inaudible) my patients, and that has had very negative effects on my patients, both with regard to morbidity and mortality,

which, to be very honest with you, though, is that we're involved with this rationing process in health care which has occurred.

Both CMS and the manufacturers and now insurance companies are directly responsible for the negative effects on my patients. And so to any of them here, to consider the changes that have occurred that have had a negative effect is something that they are not responsible for, they are directly wrong about that, because it has significantly effected my patients.

So my patients are not here with me today. The last time they accompanied me was at the advisory committee, when there was a unanimous agreement to state that this should be considered a medical emergency, which was basically ignored. So I'm very hopeful that with your involvement, you can help us in this fight as things continue to get worse and worse.

I really don't have much more to say. This

is extremely frustrating for me. I've taken, on numerous days, on behalf of my patients -- even those that I no longer take care of -- and it's very difficult to be in a position when I always have full accountability and no excuses, and it seems that bureaucracy -- again, both private, from the industry's side, and also from government, has an incredible number of excuses, but they're not the person that has to see the patient who can no longer walk and is hospitalized because of infection, or has to go to the wake or the funeral of that individual.

So thank you for giving me a chance to speak first.

MS. CONNERY: Thank you very much, Dr. Dracker. Marcella, how was the audio on that?

OPERATOR: There is a little bit of breaking up. I think it had to do with the style of microphone, perhaps?

MS. CONNERY: Okay. I think we can make a

slight adjustment, and I think what that's going to be is you're going to have to point this mike in a -- for people commenting, just come very close and point it up or down, depending on your height. Okay.

The next commenter, and this is probably going to be someone on the phone, is Rosemary I-S-T-R-E.

MS. ISTRE: I'm here.

MS. CONNERY: Oh, Rosemary's here. Okay.

OPERATOR: I'm sorry. Now, she definitely is on the phone?

MS. CONNERY: No, sorry, she's in the room with us.

OPERATOR: Thank you.

MS. ISTRE: Okay. How's this for audio?

MS. CONNERY: Is that working, Marcella? Is that better?

MS. ISTRE: Can you hear me?

OPERATOR: Yes. Go ahead, ma'am.

MS. ISTRE: Okay. My name is Rosemary Istre. I'm a member of The Myositis Association. I lead a support group for those with this autoimmune neuromuscular disease in Southeast Texas, which includes the Houston area.

Pam Way is dead. Robert Miller is dead. I am very grateful to be here today and I thank you for what you are doing, and I appreciate the data and the charts and the graphs and analysis of any significance that you can come up with, and your report will come out in 2007. But while Congress and the Health and Human Services Department continues to study this, people are dying, and my days are numbered.

I have this empty wheelchair here for you to look at today because in May of 2005, I wheeled Pam Way before the Health and Human Services Blood Safety Committee Meeting. She literally begged for her life, and I am going to try to put a face and humanness into your data and your charts and your graphs.

Pam Way was very, very ill. She had myositis and she also had overlapping autoimmune illness. When my doctor, a specialist and expert, found her, she was almost dead. She was in bed. She could not walk, she could not talk, and she had labored breathing.

She decided to try IVIG therapy, and it was like a miracle, but it took a while. Gradually, over the months and over a couple of years, Pam Way began to sit up, to talk, to feed herself, to get dressed, and finally, she could stand up.

In December of 2000 (phonetic), (inaudible) her chair, let go of her walker, and decorated the infusion center for Christmas. We cried and we cheered, because we had saved someone.

But by January of 2005, when the Medicare bill took effect, Pam Way was taken away from her doctor, the expert, and from the Infusion Clinic of Safety, and rerouted to a hospital, as were other

autoimmune or immune deficiency or immune-compromised patients.

The hospital is not a good scenario, number one, for immune-compromised patients. They are at high risk for infections and infections are devastating to immunocompromised people. Pam is not unique. I am telling her story because this is echoing through all of America.

So Pam, in January, had trouble getting into the hospital because there wasn't a bed available. Then she had to wait for her regularly scheduled treatment. You see, Pam needed a certain brand of IVIG. There are several brands. But IVIG is a very individualized treatment. It is tailored to the patient, and Pam could not wait on her treatment until there was a bed available, until her brand was available.

The staff at the hospital was not set up to administer the treatment, so they kept calling the

doctor at the Infusion Center saying, "What do we do? How fast do we run this? She's having this reaction." She ended up in ICU and almost lost her life immediately.

Then the next weeks and months came and she was still begging for treatment. So we did what we thought was right, as Americans, and we contacted our representatives in Congress, and we virtually talked to every senator and every representative more than once.

I had to call the media and stage a demonstration in front of my Congressman's office to obtain a meeting with him, and again, we begged for our lives, knowing that Medicare sets the standard and sets the directive and other insurance companies would follow suit.

Pam Way is dead, Robert Miller is dead, while everyone continues to study this problem. But

Pam, with the last strength she had, had me wheel her in a wheelchair like this before the Health and Human Services Department in May of 2005. She was in a wheelchair, she couldn't walk, she could hardly talk, and we had oxygen for her to breathe, because of lack of continuity of treatment with a specific brand of IVIG in a doctor's setting, the expert.

We left that meeting with the promise that something would be done that day to help us, and Pam had hope, and she looked at me and she said, "I hope I matter." Well, she did not last while Congress and HHS continues to study this problem. She died and another person in my support group, Robert Miller, died.

There may be 50 people here speaking today. There may be 50 people in attendance. That doesn't begin to touch the number of patients out there who are affected and are too sick and who are too stressed

to be here to fight for their lives.

If you need more data, I am one of those (phonetic). I have dermatomyositis. Blue Cross/Blue Shield has aligned with Medicare. My days are numbered. When I have a flare-up with my illness, I have nothing now to fall back on. Please explain that to my family.

Are we at the mercy -- one thing we learned, that Congress needs to be educated. Another thing we learned was that mistakes can be made in Washington. Someone myopic, with a stroke of a hand, can sign something into law that sentences us to death, and now that Congress knows that, I am surprised, amazed, angered, and frustrated that people do not step up to the plate to fix this.

Is the pro-life agenda for those that are in the womb, or people who are brain-dead? Well, we are not brain-dead. We are healthy, functioning

individuals with our IVIG. Take it away from us, we are screaming out. We are not brain-dead. We want to live. Thank you for hearing me.

MS. CONNERY: Thank you very much for sharing that with us. Our next commenter is on the phone, and that is Mark Stein.

OPERATOR: Thank you, ma'am. One moment. Mr. Stein, your line is now open. You may make your comments.

MR. STEIN: Thank you. This is Mark Stein from Allergy Associates of the Palm Beaches in private practice. I'm also the Chairman of the IVIG Committee for the Florida Allergy, Asthma, and Immunology Society. I'm reporting on both my personal problems and the problems regarding the State of Florida.

First, I'll start by pointing out that (inaudible) apparently did a local review that if you do provide gamma globulin, it delays your

reimbursement for four to eight (inaudible), making it impossible for physicians to do this in their office.

MS. CONNERY: Excuse me, Mr. Stein, is there any way you can get closer to the phone or speak a little more loud?

MR. STEIN: Is that better?

MS. CONNERY: That's much better. Thank you.

MR. STEIN: Okay. Since the Medicare changes in reimbursement effective January of this year, we've had several hospitals in Florida discontinue outpatient gamma globulin infusion, one in our immediate area and one about an hour's drive from us.

This has resulted in patients removing themselves from gamma globulin treatment because they're unaware of any other access. We've had five patients in the last month arrive at our office from a distance of about an hour and a half in Okeechobee, Florida, where the hospital -- this is Raulerson

Hospital -- discontinued IV gamma globulin.

Some of these patients have been readmitted numerous times because of bronchiectasis associated with their primary immunodeficiency. These people are at constant risk of death when their product's been withdrawn.

We're down to one hospital who reliably supplies gamma globulin to our Medicare patients in the area. Unfortunately, they only have one product available and that's a sucrose-containing product. Sucrose-containing products have a higher incidence of renal problems, and some of our patients with renal disease have had to either temporarily discontinue their product, run the risk of infection, until we've been able to arrange an alternative process, such as home subcutaneous gamma globulin.

We see numerous problems with our patients, first of all, not being accessible to office care,

where they're better managed. We see patients in the hospital who have severe reactions to the gamma globulin which then require hospitalization or discontinuation of product with wastage, because there's no physician immediately accessible to manage it. They're supposed to (phonetic) manage severe reactions over the phone.

We've had reports in Florida, and I've had one patient who came down to me from Vero Beach, Florida, where the hospital said "Because of the shortage, you can only get your gamma globulin every three months, not monthly, as required."

We've had other hospitals in the area who have said "You will not get gamma globulin unless your immunoglobulin G-level drops below 400. Regardless of what level it takes for you to be sick, because of our limited supplies, that's going to be as much as we can give you."

We have issues relating to product selection. As you've heard, there are certain patients that only tolerate one product. We have one patient we'll hear from later today that had to drive about 50 miles and transfer to another physician to be able to get that product.

We've had patients whose venous access have been ruined by hospital nurses who didn't have the expertise of our IV nurses we have in our practice, where the patient can be usually easily accessed.

The biggest problem with this location is even if there is a change in budgeting where the product price would go up to where we could afford to purchase it and give it to patients (inaudible) local review, we can't afford to wait out four to eight months' worth of funding, waiting for reimbursement. Now, that's a local issue, but it is a major issue for people who provide services in their office.

We find that the efforts to provide a $60.00 per infusion -- roughly $60.00 per infusion reimbursement, when adjusted for cost, is grossly inadequate, and the fact that the readjustments in pricing and what physicians are reimbursed for gamma globulin in six months' time on a constant basis makes no sense, because we have almost an every six month increase in the cost.

MS. CONNERY: Mr. Stein, you have 15 seconds.

MR. STEIN: Okay. I think I covered the issues that I deem important for you, and hopefully, can provide additional information if needed. Thank you.

MS. CONNERY: Thank you very much. John and Aylin, if you do have -- just break in and let me know right away, okay? Otherwise, I'm just going to keep going on. Our next commenter is in the room with us. Julie Birkofer.

MS. BIRKOFER: Good morning. My name is Julie Birkofer. I'm the Executive Director in North America for the Plasma Protein Therapeutics Association, PPTA. This association represents the leading IVIG manufacturers in North America: Baxter BioScience, ZLB Behring, Grifols, Octapharma, and Talecris.

PPTA is pleased to be here this morning, and we appreciate the fact that the Department of Health and Human Services and ASPI is holding this important town hall meeting. We are all here today in this room out of concern that patient access to IVIG, especially for Medicare beneficiaries, has become increasingly difficult since the implementation of the MMA in 2005, in the physician office setting, the switch from AWP to ASP +6, and in '06, it was the impact in the hospital outpatient setting.

Again, this is not a coincidence that the

first reports of patient access difficulties began after this seismic change in how Medicare reimburses IVIG. It is vital that Medicare reimbursement for physician-administrated IVIG in the appropriate setting is adequate to sustain beneficiary access to care.

As we've heard, IVIG is a unique therapy. It is recognized by the FDA as a sole source biologic. There are no generic equivalents, and these are not a one-size-fits-all treatment. PPTA has been working with the community for over 18 months on this issue. We recognize the importance of applying a market-based reimbursement methodology that reflects the true cost of the therapy to the provider, such as is in intended by the average sales price, ASP, methodology.

However, PPTA also is very sensitive to the concerns of consumers who have experienced difficulties accessing care with the shift to ASP

reimbursement in 2005 in the physician office setting and in 2006 in the hospital outpatient setting. The primary goal of PPTA and its member companies is restoration of patient access to all brands of IVIG in the setting most appropriate for east individual Medicare beneficiary.

PPTA shares these concerns expressed by patients and providers regarding the failure of the present payment rates to reimburse adequately for IVIG under Medicare Part B and the hospital or outpatient setting. Reimbursement methodologies must recognize that plasma protein therapies, IVIG, they are vastly different from traditional pharmaceuticals.

Reimbursement methodologies apply -- unilaterally fail to consider the unique economic and clinical characteristics of IVIG. Acquisition of human plasma, the basic raw material for IVIG, represents a significant investment in resources

before the first manufacturing step can ever take place.

In addition to the enormous up-front capital investigation required by PPTA member companies to bring a therapy to market, there is the seven to 12-month time frame required to manufacture IVIG, the small and fragile patient populations served by this biological therapy, and the robust regulatory environment in which these companies operate.

PPTA believes that the current IVIG reimbursement formula of ASP +6 has proven to be inadequate and is driving complaints regarding IVIG availability and fully explains why patients are experiencing site of service dislocation and access to care.

Let me move to some of the issues with regard to supply. In 2006, more than 19 million grams of IVIG had been distributed by manufacturers in the

first seven months of the year. Nonetheless, even with the record yearly increases in IVIG production and distribution, IVIG stakeholders advised PPTA that it is difficult for some patients and providers to obtain access to IVIG therapies.

PPTA has proposed a comprehensive solution. We have worked with legislators and policymakers. A permanent payment adjustment by CMS to make Medicare payments more reflective of the true cost for providers; separate payment for each brand of IVIG rather than grouping all IVIG therapies together; make permanent the pre-administration code; and recognize IVIG as a high-complexity infusion similar to a biological response modifier.

Thank you and we would also urge ASPI and ERG to ramp up the time frame in finalizing this study. I don't think this issue can wait until First Quarter '07. Thank you.

MS. CONNERY: Thank you very much. I note that there are written copies of your comments, so that for anything that you didn't get to, we'll have that.

MS. BIRKOFER: Okay.

MS. CONNERY: Thank you.

MS. BIRKOFER: You're welcome.

MS. CONNERY: Our next commenter is Mary Jean Peterson. She is the fifth commenter, by the way, and we also -- I just saw the note that the tenth commenter is not going to be commenting, so we'll be moving ahead. Both the ninth and tenth now have told us they won't be here.

Mary Jean is on the phone.

OPERATOR: Ms. Connery, can you spell the last name, please?

MS. CONNERY: That is P-E-T-E-R-S-O-N.

OPERATOR: Thank you. I'm looking. One

moment. If Ms. Peterson is sitting with another party, please press star-zero at this time. One moment. Ms. Connery?

MS. CONNERY: Yes.

OPERATOR: We are having no response that Ms. Peterson has joined.

MS. CONNERY: Okay. Well, it's possible, and I think we can anticipate that a few folks who signed up will not be here. If somebody misses their time and just has miscalculated and comes back in, we'll certainly try to accommodate them towards the end of the day, but we will, at this point, move on.

Our next commenter, which would be Commenter No. 6, who should be in the room with us, is Melissa Schweitzer. Melissa is here.

MS. SCHWEITZER: Good morning. You pronounced it correctly.

MS. CONNERY: Probably the only one so far.

Could you point that just directly towards you so you --

MS. SCHWEITZER: Yes. There -- is that good?

MS. CONNERY: Thank you. That's good, thanks.

MS. SCHWEITZER: I'd first like to thank ASPI and ERG for holding this important meeting and giving us the opportunity to provide comments on the concerns related to IVIG access.

Again, my name is Melissa Schweitzer. I'm with the Washington Strategic Consulting Group, and I'm also a patient with common variable immunodeficiency. As the previous patient advocate for the Immune Deficiency Foundation, I began talking with patients and physicians experiencing problems with IVIG access in January of 2005.

At that time, many patients on Medicare were being told that they could no longer continue their

IVIG infusions in their physicians' offices due to decreased reimbursement of IVIG by Medicare. Most of these patients transferred their care to local hospitals to receive their infusions.

However, as we've heard, this was not always a smooth transition, as it necessitated driving to centers many miles from patients' homes, receiving care from inexperienced providers, and switching from the patients' preferred brands of IVIG. All of these barriers to care created undue hardship on what was already a fragile patient population.

In August 2005, after working with scores of patients and physicians experiencing IVIG access problems, I resigned from IDF in part because of the overwhelming nature of this case work and the personal effect it had on me, as a patient with common variable, for which I receive IVIG on a monthly basis.

However, in April 2006, given the continued

struggle, faced by patients who rely on IVIG as their live-saving therapy, I felt a strong calling to again work on this issue from the patient advocacy standpoint through my current employer, Washington Strategic Consulting.

While I have not personally experienced problems in IVIG access and continue to receive uninterrupted infusions, I live with the fear that if this crisis is not resolved immediately, all patients, regardless of health insurance provider, will experience problems in receiving their IVIG.

This fear is based on many reports from patients on private insurance who are also experiencing IVIG access problems related to reductions in reimbursement rates.

As part of the IVIG patient community, I know firsthand how vital IVIG therapy is to my well-being. By replacing my antibodies and thus reducing

the number of infections I experience, it has allowed me to lead a relatively normal and rewarding life. Because of IVIG, I've enjoyed a successful career as a genetic counselor and patient advocate, working to help educate and support other individuals affected by rare genetic and chronic diseases.

Because of IVIG, I have had the immense fortune of becoming a wife to a wonderful and supportive husband and a mother to two beautiful children, after once wondering if I would ever have the opportunity of becoming a mother at all.

Because of IVIG, I feel that it is my personal and professional mission to help work toward a solution that will restore access to my fellow patients who are not here and can't do this (phonetic). Sorry.

MS. CONNERY: It's okay.

MS. SCHWEITZER: I always thought that if I

had to be born with a rare and chronic condition, at least I was lucky to be born with one for which there is an effective therapy, and I'm sure that this is what many of my fellow patients thought when they were finally diagnosed with their respective conditions, prescribed IVIG therapy, began their recovery, and started to live their lives again.

I can surmise that they did not envision the horrible day when they would be told that their IVIG product was not available, or that they could no longer receive it in their trusted physician's office, because the doctor could not afford to treat them.

What parent should have to imagine that his or her child can no longer receive the one therapy that has saved him from succumbing to life-threatening illnesses? What patient should have to imagine that she will again lose her ability to walk because of lack of access to this life-saving product?

As a step to help restore access to IVIG, a meeting was held on August 28th to discuss the problems faced by patients and providers. This was the first meeting of its kind, as it brought together several organizations that represent various patient communities that rely on IVIG as their life-saving therapy, professional medical societies representing the providers who treat these patients, as well as Congressional staffers from key committees, and ASPI, as well as the Advisory Committee on Blood Safety and Availability.

Regardless of disease state, the participants all expressed similar problems being experienced by patients. While we understand the importance of collecting data to determine all of the underlying causes of the IVIG access issues, we need to take action immediately in order to prevent more suffering and death.

On behalf of patients who rely on IVIG, I again thank you for holding this important meeting.

MS. CONNERY: Thank you very much for sharing your story and that information. I think we're going to hear a lot of personal stories today, and that's part of what this meeting's about. It's a very important part of the picture for the project team, so we really appreciate the folks who are doing that today.

Our next commenter, Commenter No. 7, is Mary Simon, and Mary should be with us by phone.

OPERATOR: Yes, she is.

MS. CONNERY: Okay, great.

OPERATOR: Ms. Simon, your line is now open. You may make your comments.

MS. SIMON: Oh, well, thank you very much. Hi, my name is Mary Simon, and I'm a patient in Orlando, Florida, and I'm also on an HMO Medicare replacement plan. In 1999, I was diagnosed with hypogammaglobulinanemia.

I was (inaudible) non-specific chronic infections and extreme fatigue for most of my life,

but the cause wasn't diagnosed until I was 40 years old. It took the doctors over 20 years to find the cause of my chronic infections, and after I was diagnosed and a treatment plan was given, then the real problems started. I was denied IVIG treatment by one HMO and forced to switch companies.

The second HMO was willing to authorize the treatment, but after trying numerous brands of IVIG, it was discovered that I was allergic to all brands but one. The brand that I ended up needing was too expensive for the reimbursement rate by Medicare. I don't have a choice in what brand I can use, and it's common practice for IVIG administration and for the providers to use the least expensive brand.

I had to start receiving my IVIG in a hospital because the hematologist couldn't afford to purchase it, and after switching to a different hospital because of my HMO plan changing, and that hospital saying they couldn't get the brand I needed, I was then switched to receiving my infusion at the

hematologist's office in their chemo center.

In 2002, I was told by the hematologist's office that they could no longer administer my IVIG. I requested the reason, and this led to extreme grief on my part. I eventually learned that it was the reimbursement rate that was the cause. I never know from one month to the next where or if I will receive my infusions. I was being switched from receiving my treatments in the doctor's office to the hospital and back again.

In 2004 and '5, there were a number of changes to the Medicare reimbursement rate again. This led to a number of financial hardships. There were (inaudible) bills for almost $5,000.00 (inaudible) hematologist's office.

It seems that when the new Medicare reimbursement rate changed in April of 2005, my HMO couldn't -- wouldn't reimburse the doctor's office the cost of my IVIG. The hematologist's office wasn't notified -- or wasn't aware of it before it happened,

and I was getting my infusion at their office.

This resulted in a shortage of reimbursement of $9,000.00 that was passed on to me. With my only income as Social Security Disability, there is no way I could ever afford to pay it. I have been paying them $25.00 a month, but at that rate, it will take almost 30 years for me to pay it off. Also, there is no guarantee that this won't happen again.

To add insult to injury, now, it is getting harder and harder to even get the brand that I require. I've been told there was a shortage of the product, and I never know from one month to the next if I can even get what I need. I was given the choice in June of this year to either forego my infusion, because they didn't have the total amount I needed, or take the decreased amount that they had on hand.

Not only is that physically and psychologically burdening, but a financial burden, as well. If and when the balance of my IVIG became available that month, it would require me to take an

additional visit to the hospital and pay two co-payments in one month. I don't have the money or the energy to do that. Also, it would've been an issue with my HMO. They don't want to pay for two infusions in one month.

As it turned out, the person who receives -- who was to receive the infusion which would've used up the hospital's supply never ended up getting it, and I got the IVIG (inaudible). That's great for me, but what did the other person end up doing?

In addition to the financial hardships of my IVIG infusion, there is the infection factor. I unfortunately (phonetic) receive my infusions at a public site. The chance of my contracting any bacterial or viral infections is very much increased. I have to limit my exposure to the public to keep my infection rate lower. Having to go to the doctor's office or hospital to get my infusions is very stressful because I never know what I could end up contracting.

My HMO does not allow home infusions or subcutaneous infusions. It's cheaper for them to pay a hospital for it because of their contract. When my treatments are delayed because of availability, I physically go downhill very fast. It could take months for my body to build its immunities back up.

I also will inevitably end up on antibiotics. Being on long-term antibiotics has pretty much destroyed my digestive system. Since I have an HMO Medicare replacement plan, I'll never get to see the bills that are sent to my HMO.

MS. CONNERY: Mary, we're at 15 seconds left.

MS. SIMONS: The HMO did all the paperwork with Medicare. The bill was over $23,000.00 two years ago. That was the one-month treatment. If I did not have Medicare, I'd never be able to afford the treatment, something I pray the powers that be understand how crucial it is for people with primary immune deficiencies to be allowed to receive IVIG that their bodies require, and (inaudible) infectious

disease (phonetic) environment. (inaudible) Thank you for allowing me to voice my frustrations.

MS. CONNERY: Thank you very much for taking that time, Mary. I appreciate hearing from you. Our next commenter is Marcia Boyle, who is in the room. I'm just going to remind us, she is -- Marcia is the eighth commenter.

We're skipping over Commenters 9 and 10 because they've they us the won't be here, so our next commenter is going to be Patty Mitzenmacher, who will be on the phone, Marcella, in case you want to queue her up while Marcia is talking.

MS. BOYLE: Okay. How's that?

MS. CONNERY: Good.

MS. BOYLE: Okay?

MS. CONNERY: Great.

MS. BOYLE: Thank you very much. My name is Marcia Boyle. I'm the President of the Immune Deficiency Foundation. I want to thank you for providing me with the opportunity to testify today on

behalf of IDF, founded in 1980 as the national patient organization for primary immune deficiency diseases, or PI.

Through the years, we have advocated tirelessly for PI patients, one of whom is my son, whose life depends on access to IVIG. Today, I'm speaking with the Primary Immune Deficiency Coalition comprised of IDF, the Jeffrey Modell Foundation, the American Academy of Allergy, Asthma, and Immunology, in association with the American College of Allergy, Asthma, and Immunology, and the Clinical Immunology Society.

Access to IVIG is critical to patients with PI. At least seven out of 10 PI patients have diagnoses for which IVIG is the only effective treatment. As a result of age or disability, about 20% of these patients are on Medicare, or about 10,000 PI patients nationwide, who are being treated with IVIG.

Since January 2005, IDF has testified many

times and has provided quantitative and anecdotal information on the problems many of our patients have had with access to IVIG. In order to provide current information, IDF has undertaken three national surveys with the partnership of the (inaudible), a survey of patients with PI, a survey of physicians treating patients with PI, and a survey of hospital pharmacists dispensing IVIG.

Although all three surveys are now underway, today, I'm providing preliminary findings from the patient survey. Three thousand patient surveys were mailed to a random sample of patients drawn from the foundation's database, as well as a supplemental sample of 135 households we believe to include Medicare patients.

My report today is on preliminary findings from the first 763 completed surveys. From our preliminary findings, approximately 70% of the patients are currently being treated with IVIG. To date, we have 532 patients in the sample who are

currently being treated and 206 of whom are Medicare. And of the 41 stopping treatment since the beginning of 2005, of those who stopped receiving treatments, 11 cited inadequate insurance coverage or higher expenses and three mentioned the difficultly obtaining IVIG.

One of the impacts of Medicare reimbursement has forced patients from their usual site of service for infusions to other sites of service where payment rates are higher and/or Medicare patients were still accepted.

More than a third of Medicare patients reported that they are now being treated in a different site since December of 2004, compared to less than a quarter of non-Medicare patients. 38% of Medicare patients said that the change was due to insurance reimbursement reductions, compared to 9% of non-Medicare patients.

More than a quarter of Medicare patients who had changed site of infusion said it was because IVIG was no longer available at the previous site, compared

to 6% of non-Medicare patients.

Patients were asked whether they had less or more trouble getting IVIG, or had there been no change. Almost three times as many Medicare patients, nearly one-third of Medicare patients, encountered more problems getting IVIG treatments compared to non-Medicare patients.

Current users of IVIG were asked whether they had experienced problems related to IVIG since the beginning of 2005. Medicare and non-Medicare patients were about as likely to say that they had to switch to another brand of IVIG. Similarly, both groups are equally likely to say that they had to pay more for IVIG.

These findings suggest that a tight market has affected product availability, choice, and price over the past two years for IVIG users, regardless of type of insurance. However, Medicare patients were twice as likely as non-Medicare patients to report that their treatments had to be postponed since the

beginning of 2005. Medicare patients were also twice as likely as non-Medicare to report that the time intervals between infusions had been increased at the beginning of 2005.

Most dramatically, Medicare patients were seven times as likely as non-Medicare patients to report that their dosage had been reduced since 2005. These differences between Medicare and non-Medicare users of IVIG are statistically significant. Since the main difference between the two populations is their type of insurance, the survey findings demonstrate a serious reimbursement impact on the treatment of Medicare patients needing IVIG.

Medicare patients were nearly three times as likely as non-Medicare patients to report having negative health effects as a result of problems of getting or paying for IVIG since the beginning of 2005. Those on Medicare who experienced problems were more likely to suffer infections and bronchitis, and they were more likely to require increased use of

antibiotics.

For one in nine Medicare patients reporting negative health effects, the health consequences were severe enough to require hospitalization. One of the dilemmas in the discussion of IVIG access has been whether there is an availability or reimbursement problem. The data suggests a substantial minority of patients is experiencing limited product choice and increased product cost, regardless of insurance status.

MS. CONNERY: Fifteen seconds.

MS. BOYLE: Okay. However, the more serious problems of postponed infusions, increased intervals between infusions, and reduced dosage, fall disproportionately on Medicare patients. The significant difference in these treatment experience meant (phonetic) Medicare status, along with higher rates of negative health outcomes, is clearly a reimbursement problem.

The health consequences of older and

disabled patients on Medicare is a government problem and the government needs to tackle this issue immediately, as there's no alternative treatment for PI. Thank you.

MS. CONNERY: Thank you.

MR. EYRAUD: Jan?

MS. CONNERY: Yes?

MR. EYRAUD: One thing.

MS. CONNERY: Go ahead, John.

MR. EYRAUD: Could you just say -- from the mike, please -- when will the survey be finalized?

MS. BOYLE: We will have it finalized by -- within a month, and I will be submitting electronically my testimony, as well as the graphs, and written testimony that includes more the statistics.

MR. EYRAUD: That's the patient survey for the --

MS. BOYLE: This is the patient survey. The other two surveys will be available later in the fall.

MR. EYRAUD: Okay.

MS. BOYLE: Okay?

MR. EYRAUD: Thank you.

MS. BOYLE: Thank you.

MS. CONNERY: Thank you very much. Marcia, did you have written copies that you want us to have of your comments?

MS. BOYLE: Yes. I (inaudible)

MS. CONNERY: Okay. Excellent. Thank you. The next commenter -- as I said, we're skipping over 9 and 10, so we're going to Commenter No. 11, Patty Mitzenmacher, who we hope is on the phone with us.

OPERATOR: Thank you, ma'am. I do have Patricia Mitzenmacher.

MS. CONNERY: Oh, Patricia? Okay.

OPERATOR: Thank you. Ma'am, your line is open.

MS. MITZENMACHER: Hello?

MS. CONNERY: Hello. We can hear you.

MS. MITZENMACHER: Okay, great. Hi.

MS. CONNERY: Hi.

MS. MITZENMACHER: Patty Mitzenmacher, and I am a patient advocate for my child. I draw my experience from all sides of this issue. I have experience working on the providers' side in the medical management, I have experience working with the clinical research with a pharmaceutical company.

The patient side, my father was a heart transplant patient and I have two brothers who are immune deficient, and I'm a breast cancer survivor. And the (inaudible) because I have the opportunity to have (inaudible) over a number of issues that I got devious behaviors on the back side of the insurance companies.

I'm mostly advocating for my son, who has complex medical issues, who is one of the patients getting IVIG on an off-label way, because he had severe Crohn's Disease (inaudible) from his esophagus down to his rectum at the age of eight months. Through all of his medical care, it has produced

systemic lesions (phonetic) in him, and he now has chronic immune deficiency disease.

We went back to Northwestern in Chicago for another -- to get another choice on how to treat him at this point, because he was failing fast, and IVIG was the only answer for him. We came back to California, where we live, and he's been on IVIG for two years.

My first battle with Clark (phonetic) being an off-label patient was with the insurance company, because Medicare sets that standard for what is indicated for IVIG and what isn't. So I did beat that battle, and his insurance company had to cover him, although in the last month, I just found out why they have abandoned his care, for getting his IVIG (inaudible) on -- at the (inaudible) that he gets it at.

Prior to this happening, in July of '05, I had made a phone call to the insurance company when I was questioning the reimbursements to the providers

for the IVIG. I explained to the insurance company that (inaudible) because they weren't being reimbursed for at least half of the drug, and I was told by the insurance company, as long as I had no patient liability, to get out of the middle of it, because it did not concern me. I explained that it did concern me because eventually, it's going to come down to directly affecting my son's health or other people's health, and I am concerned.

A few months after that, when I went to go get my son's IVIG, I was notified that he couldn't get the IVIG that he needed because he had so many severe allergic reactions from the other ones, but now, they needed to switch him to another one. Given the situation with the lupus, I wasn't willing to cough up his kidney -- or knowing that would kill his kidney (inaudible) and the (inaudible).

So gratefully, every time that we walked in the door, I breathed a sigh of relief that he could get (inaudible) doesn't have the reactions or severe

migraines or all the side effects to -- does offer him quality of life.

As time went on, I watched the decline in payment from the insurance company and the delay at which those companies paid the providers. And I feel bad, and knowing, coming from the providers' side, that a person can't keep their doors open if they're taking a huge loss every time a patient walks in the door, and eventually, they're going to have to say that there's a shortage-- when this occurred, there became a shortage of this type of IVIG that (inaudible).

And me being the research person that I am, I went and called the drug company directly and asked them if there's a shortage. They said no, there wasn't a shortage.

So I took it a step further, went to my local pharmacist who (inaudible) for me. He called around to find out if he could acquire IVIG. He found a place in Texas that he could get it, but then he was

told that unless he was a wholesaler, he couldn't obtain IVIG. And then secondly, the facility would not let me bring in my IVIG, because of liability issues.

I then was approached by an insurance company in Culverton (phonetic) for -- (inaudible) the case manager on my son that wanted to come visit me in my house and bring all his medicine to the home. Given my son's severe history of anaphylactic reactions, not just IVIG, but an array of things, it's not a safe environment for him to get his IVIG at home.

The name of the company and the case management which they stuck on me (phonetic) was called Paradigm Health. And when Paradigm Health called me and stated that they wanted to do this, I thought, "You know, I'm going to ask right up front. Are you a patient advocate or are you on the insurance side?" The answer I got was that they were contacted by that insurance company.

MS. CONNERY: Patricia, we're at 15 seconds left.

MS. MITZENMACHER: Okay. Anyway, it did go on, I talked to the local community hospital. They won't give him the IVIG. They said it costs too much. I have to talk to the CEO. And on and on, it kind of goes over what everybody else has said.

But the bottom line is I'm wondering at this point, people have to become -- I don't understand why people have to become experts on all facets of medication, and that they have to become financial geniuses in order to pay for it. That's a lot to expect of someone who needs to take care of a family member, or are concerned with serious medical issues. They shouldn't have to do that.

In a (inaudible) system, the reimbursement (inaudible) problem won't go away, not just from Medicare, but for all insurance companies, since Medicare sets the standard.

MS. CONNERY: Okay. Thank you very much,

Patricia.

MS. MITZENMACHER: Okay.

MS. CONNERY: And I certainly encourage you, if there are more details you'd like us to have, to send that into us.

MS. MITZENMACHER: I would very much.

MS. CONNERY: Okay, thank you.

MS. MITZENMACHER: Thank you.

MS. CONNERY: All right. Our next commenter, who should be in the room with us, is Susan Pappas?

MS. PAPPAS: Good morning. My name is Susan Pappas. I'm a Certified Nurse Practitioner. I'm the Director of Operations and Legislative Affairs for Critical Care Systems, a leading provider of speciality infusion therapies in home and other alternate site settings.

We prepared this statement today in conjunction with our national association, the National Home Infusion Association based in Alexandria, Virginia. Thank you for the opportunity

to present these comments to you today.

CCS has 46 branch pharmacies, each of which is accredited by the Joint Commission on Accreditation of Healthcare Organizations. CCS has a long-standing speciality in-home IVIG treatment. Today, we have 560 home IVIG patients on census nationwide. This census has increased more than 100 percent in recent years, but this growth has definitely not been in the Medicare population, despite clear medical necessity in many Medicare-eligible patients.

IVIG is a promising therapy for a wide rage of indications, and CCS supports expanded Medicare coverage of home IVIG by allowing Medicare beneficiaries greater access to these life-saving therapies.

We believe that from a clinical and cost perspective, home IVIG is the preferred treatment setting. Unfortunately, however, the passage of new Medicare Part B coverage for home IVIG in 2003 did not increase access to home IVIG under Medicare. In fact,

we've seen no additional Medicare utilization of home IVIG since the passage of this provision.

The implementation of the new Medicare Part B home IVIG benefit coincided with significant reductions in Medicare reimbursement for IVIG administered in physician offices and outpatient clinics. Consequently, physicians in outpatient clinics are generally unwilling to serve these patients. In effect, there are now no outpatient treatment settings available for these patients.

There are three fundamental problems with current Medicare B coverage of home IVIG. Number one, the current Medicare allowable for IVIG product itself is below our acquisition cost, and our acquisition costs are increasing. Policymakers should understand that not all health care entities have access to the same pricing.

Under an average sales price plus 6% methodology, home care providers have difficulty covering their acquisition costs, not including

inventory handling and other product management and dispensing costs.

While it could be conjectured that as the larger nationwide provider, CCS would have sufficient marketplace leverage to obtain more favorable IVIG pricing, this is simply not the case, possibly due to an ongoing IVIG product shortage.

Number two. While in a physician's office or outpatient clinic, Medicare reimburses for administration costs, supplies, and equipment, in addition to the IVIG product itself.

This reimbursement does not exist under Medicare Part B for IVIG administered in the home. For home IVIG, Medicare Part D does not cover the pharmacy, professional services, administration supplies, or equipment, or home nursing visits needed for safely and effectively administering IVIG.

By not covering these essential components of care, Medicare has left a significant proportion of the cost of home IVIG care uncovered. By contrast,

private insurers and state Medicaid programs do cover these costs, and this is a cost-effective coverage decision, as home IVIG administration eliminates the need for administration in more costly treatment settings.

In other words, of the three outpatient settings we are discussing today -- physician, hospital outpatient, and home care -- there are clearly reimbursement issues plaguing all three, but it is clear that Part B coverage for home IVIG is the most lacking and shows the greatest variance for what is provided for privately insured or Medicaid patients.

CCS strongly supports the position of the National Home Infusion Association that these non-drug costs should not be covered under a drug spread between acquisition costs and Medicare reimbursement. Rather, these care costs should be explicitly covered, using the same per diem payment methodology used by private insurers that helps to ensure appropriate

access to these therapies.

Number three. The benefit applies only to primary immune deficiency diagnosis. In our experience, PIDD patients represent only a small proportion of the patient population with a medical necessity for IVIG. If Medicare is to truly provide access to patients needing IVIG, Medicare must extend its approved diagnosis beyond PIDD and cover these diagnosis properly and fully, including all the necessary supplies, equipment, and nursing visits needed to administer these therapies safely.

Number four. Medicare D theoretically provides coverage for IVIG products for patients with a diagnosis other than PIDD, but unfortunately Medicare D is essentially a drug retail benefit, not a home infusion benefit. It provides little or no access to home IVIG because like Part B, it fails to cover these costs of pharmacy services, supplies, and equipment needed to administer these products.

Therefore, we strongly believe that Part D

is not the solution to providing appropriate access to home IVIG for Medicare beneficiaries of any diagnosis. Thank you for allowing me to present these comments.

MS. CONNERY: Thank you. Thank you very much. Our next commenter is Commenter No. 13, is Fred Modell? Fred Modell.

OPERATOR: Ms. Connery, will that be from the room or the phone line-up?

MS. CONNERY: I'm sorry, that is in the room.

OPERATOR: Thank you.

MS. CONNERY: But the next one will be on the phone.

MR. MODELL: Thank you. My name is Fred Modell, together with my wife, Vickie. I'm co-founder and president of the Jeffrey Modell Foundation. Our organization was established in 1987 in memory of our son. Jeffrey passed away at the age of 15 as a result of a primary immunodeficiency disease.

These genetic defects affect more than a million Americans. The face chronic and recurring

infections that significantly impact the quality of their lives.

Now, our familiarity with immunoglobulins go back to the early 1970s, when Jeffrey was first diagnosed. He had to endure extremely painful intramuscular shots of immunoglobulins. In the early 1980s, he participated in the first clinical trials of intravenous immunoglobulins, and then eventually, he was put on a regular regimen of FDA-approved IVIG infusions every three weeks.

I can tell you firsthand how important it is to receive this treatment. IVIG gave our son 15 years of life, 15 years he surely would not have had without this therapy.

Over the past 20 years since we started the foundation, we have heard from thousands of patients going through some of the same problems that Vickie and I have faced, patients who require this critical therapy in order to survive. Without it, they are subject to frequent and serious infections and the

most severe cases, absent some treatment, can be fatal, and quite simply, alternative treatments do not exist.

Now, all of us in this room today know that reimbursement for this therapy must be adequate in order for physicians to deliver the treatment. We also know that our good friends in government, they want to do the right thing, but they need data in order to make that happen.

Over the past several years, Vickie and I have offered testimony before the House Appropriations Subcommittee on Health, and our foundation has worked in close collaboration with the CDC. Government officials have made it very clear to us that we must provide data with supporting documentation and results that can be measured.

Our physician education and public awareness programs with the CDC were developed to identify undiagnosed patients, get them referred to experts at leading academic teaching hospitals, get them properly

diagnosed, and then, appropriately treated.

We surveyed 86 Jeffrey Modell diagnostic and referral centers to measure the effectiveness of that program. The doctors provided us with baseline and subsequent data from their patient records, and here's what they reported: a 79% annual increase in the number of diagnosed patients, a 57% increase in the number of patient referrals, and a 54% increase in the number of patients receiving treatment.

Now, surely, we can all agree that these efforts by the foundation and the CDC and supported by Congress to identify patients and get them properly referred and diagnosed makes no sense if treatment is not accessible or if the physician cannot deliver the treatment because of reimbursement.

Now, there are some who might say does it really matter if we do identify, diagnose, and treat these patients, does it matter to our health care system, and might these programs negatively impact upon budget contractors at Medicare, Medicaid, into

the third-party payers.

Is there a real difference that can be measured, the quality of life for diagnosed and undiagnosed patients. Well, we went back to our expert physicians at the diagnostic and referral centers and this time, 76 centers provided data from their patient records. They go a long way to answering those questions.

We've compiled the information and now we want to share it with you for the first time. Here's what the physicians told us. Undiagnosed patients with primary (phonetic) immune deficiencies spend an average of 19 days in the hospital annually, compared to six days if diagnosed and treated. They suffer with an average of three pneumonias a year, compared to less than one if diagnosed and treated. They endure an average of 45 days a year with chronic infections, compared to 13 if diagnosed and treated.

It goes on and on. Seventy-one visits to emergency rooms and doctors' offices compared to only

12 when diagnosed and treated. How can we wait? How can we wait? How can we stand by in anticipation of more reports, more data, more hearings, while patients endure a quality of life for which none of us would trade places.

There was no way we could help Jeffrey 20 years ago, but we can help thousands of primary immune deficient patients who are relying on all of us, all of us in this room, to allow them to go on and have a fair chance at a quality of life.

Let us act on what we know. We have heard from expert physicians. Let us do what we can do. There are existing statutes that allow us to act. Let us assure our patients that they will receive the treatment they need to survive. We can do no less. We should do no less. We thank you for this opportunity.

MS. CONNERY: Thank you very much, Mr. Modell. Yes, question? Question?

DR. SERTKAYA: Yes, just a quick question.

Are the two studies available?

MR. MODELL: Yes. I submitted written testimony, and then I have the raw data at the foundation offices.

DR. SERTKAYA: Okay. Thank you.

MS. CONNERY: Okay. Our next commentor is Dominick Spatafora, and he's on the phone. If you need the spelling of that, it's S-P-A-T-A-F-O-R-A.

OPERATOR: One moment. You may make your comments.

MR. SPATAFORA: Thank you. Good morning. My name is Dominick Spatafora and I'm the President of (inaudible).

MS. CONNERY: Excuse me, can you get a little closer to the phone or speak a little more loudly?

MR. SPATAFORA: Sure. Is this better?

MS. CONNERY: That is better, yes.

MR. SPATAFORA: Okay. A full-service public affairs firm based in San Francisco, with a strong presence in Arizona, Nevada, and New Mexico, as well.

Also President of the newly created Neuropathy Action Foundation.

Most importantly, though, I'm also an IVIG patient. I was diagnosed with immune-mediated motor neuropathy in September of 2003. I received my first IVIG infusion one month later, in October. IVIG was an absolute miracle drug for me, basically getting rid of all of my symptoms, other than my neuropathy.

I continued receiving this treatment every five to seven weeks until April 2005, when my neurologist called me and told me that there was a national shortage. I conducted significant research to find out to find out if, in fact, there was a national shortage, and I contacted a lot of groups that are on this call today -- at this meeting today; the Immune Deficiency Foundation, PPTA, several California hospitals and health systems, as well as elected officials at a state and federal level.

There was clearly no shortage. In fact, I talked to Mayo Clinic in Scottsdale, who had a very

large supply of IVIG and offered some to me. Unfortunately, my insurance company would not cover it because it was out of state.

I did find out, however, Mayo Clinic purchased their IVIG from a San Francisco Bay area company called Acredo Therapeutics. This is a company about 15 minutes from my home. Acredo had a very large supply at the time, with no shortage. My health plan ended up purchasing 10,000 grams of IVIG from Acredo at the time.

I couldn't get 35 grams out of 10,000 grams that was shipped to my health plan because my name wasn't on it, and because my name wasn't on it, the IVIG was sent to the general population and therefore, it only went to people in (inaudible) situation.

I fought with my insurance company and the Department of Managed Heath Care for three months, until one Sunday morning, I woke up and I was paralyzed in my right hand. Ultimately, it just drove me crazy. I contacted the Governor's office and the

World Health Chairs of the Senate and the assembly in California, and I won my appeal, and I started receiving treatments again, and the use of my hand was fully restored.

There were two things, however, that troubled me about the letters I received from my health plan, which prompted me to start the Neuropathy Action Foundation this year. The first comment stated, "There's currently an acute nationwide shortage of IVIG due to marketing (phonetic), manufacturing (inaudible) shortages. IVIG is used to treat a variety of conditions. Some conditions do not have sufficient evidence of efficacy to justify continued use during this critical shortage period. Your condition falls into this category."

The second statement, from a letter I received from my insurance company, said "Please understand that although the committee made a favorable exception to the terms and conditions of your benefit, we are not required to make the same or

similar exceptions for you or any other member in the future.

Now, for the last year, I have been receiving my IVIG treatments every month since I won this appeal. However, the first four months of 2006, I was unable to get the brand of IVIG that works the best for me as an individual. I was receiving an alternate brand, which caused very severe side effects and did not work as well. It took me four months to win that battle, as well.

In conclusion, I am a young, high-energy, successful professional who happens to be very well-connected, and I understand how to navigate the complex health care system, but what about others?

What about my 60-something year-old parents who are not as educated as myself or not as connected as myself? What about poor Medicaid recipients? What about the elderly, who can barely take their medications on a daily basis?

My opinion of the IVIG access issue shortage

is -- are not the fault of the manufacturers or Part D, 100% the fault of health plans. There's a term called "evidence-based medicine" which, if used correctly, is a very valuable tool for physicians. Evidence-based medicine is typically based on the evidence out there, the physician's personal knowledge and observation, and the individual patient needs at that time.

Health care decisions must be made between the doctor and the patient on an individual basis. This sacred relationship is in jeopardy because insurance companies have hijacked evidence-based medicine and have turned it into cost-based evidence-based medicine.

This type of cookie-cutter medicine is dangerous and more expensive in the long term.

MS. CONNERY: Dominick, we've got 15 seconds left.

MR. SPATAFORA: Something has to be done so that people like myself can actually function and live

better lives, as we've heard today.

MS. CONNERY: Okay. Thank you. Thank you very much. We are at about 11:30, which is the time for our first break, our lunch break. We -- Dominick was Commenter No. 14. Commenter No. 15 is Joseph Bailes. Is Joseph in the room?

DR. BAILES: Yes.

MS. CONNERY: Oh, good. Okay. So we'll take you after lunch, so I just wanted you to know that you will be our first commenter after lunch. However, before that, when we come back from lunch at 12:45 -- and we encourage you all to be here then -- Congressman Tom Foley will be here, and will be speaking, so we'll probably get to you around 1:00, Joseph.

For folks on the phone, you're -- you can stay on the line, but there won't be anything to hear. We probably recommend that you just dial back in close to 12:45.

(Off the record at 11:27 a.m.)

(On the record at 12:46 p.m.)

MS. CONNERY: It's just a little bit after 12:45, so we would like to get started again. We were expecting to be joined by Congressman Tom Foley. Is he in the room? Sorry, Mark Foley. I guess he's not here with us yet, so we are going to proceed with commenters, and then if we do -- if he does come, we will adjust accordingly when that happens.

Now, I did have a message that one of our earlier commenters was confused about the time, and so wasn't there when we called her. That's Mary Jean [sic] Peterson, and she's on the phone, so what I'd like to do is put her back in the queue right now and have her be our next commenter.

OPERATOR: Thank you, ma'am. I will open her line.

MS. CONNERY: Okay.

OPERATOR: Ms. Peterson, your line is open, ma'am. You may begin your comments.

MS. PETERSON: (inaudible)

MS. CONNERY: Oh, I'm sorry. We are having a very hard time hearing you. Is it possible to get closer to your phone, or --

MS. PETERSON: I'm right on my phone.

MS. CONNERY: You're right on your phone? Okay.

OPERATOR: Or maybe increase her volume?

MS. CONNERY: Okay. Yes, just speak up as much as you can. That will be a help for us. Thank you. Go right ahead.

MS. PETERSON: My name is MerleJean Peterson and I'm a primary immune deficiency patient, and my body does not fight bacterial infections. For this reason, I need IVIG treatment. January 2005, I had to change the site of treatment from doctor's office to outpatient services at the hospital.

Because of Medicare's low reimbursement for gamma and the cost of administering it, the hospital gave me all kinds of excuses why they could not give my treatment, and delayed me for hours. By December

2005 to January 2006, my doctor was told verbally by the hospital not to send any more Medicare IVIG patients. February and March, I receive no treatment. Had three bouts of upper respiratory infections that should've required antibiotics.

For years, I had severe skin and other bacterial infections, and the IVIG treatment has kept me well and not having to be hospitalized for IV antibiotics that I don't tolerate well.

Without this treatment, I have had infections, body, joint pain, complete fatigue, and my scalp psoriasis is much worse. Because of the bad reaction to my home infusion in July, my doctor ordered blood work to check my kidney function and lowered the IV rate in August. The rate had been previously increased to lower the cost of giving it.

Medicare reimbursement programs (inaudible) adversely affected my care, and the actions of my secondary insurance company followed Medicare policy. We fully expect our secondary insurance company to

follow Medicare's refusal to pay for any -- for my treatment, as they usually do so. It's only a matter of time.

I've been told by my home health care that if getting my home infusions that Medicare would refuse to pay, my secondary insurance would pay 100%. I recently found out they will only pay 20%, if Medicare pays for my home infusion, which they do not.

To save money, my nurse mixes my gamma at home. Medicare paid for my April and May 2006 infusions, and that must be refunded because of their change in policy and that mine is a non-specific immune deficiency, which they have covered in the past.

My question is, why has Medicare cancelled their coverage for my illness? Is this tweaking of the rules the administration was talking about when it comes to Medicare? What do I do when a hospital has refused to give me my treatment because of Medicare's reimbursement. I've heard that Medicare says they do

not receive any complaints about the IVIG treatment policy.

In February 2006, I received a letter from Medicare, after I tried to make an appointment. It was 12 pages of civil rights complaints after trying unsuccessfully to verbally lodge this complaint. So by sending letters to my local politicians and making phone calls to their offices, I received no letter or one telling me that to be sure, Medicare was following up on my complaint.

Politicians did not sign the letter to Medicare asking for an emergency to be declared to change their policy to give us our (inaudible). I did not fill out these papers -- these civil rights papers -- at this time, as I felt so -- I felt like what needed -- "What can I do without getting a lawyer?" I've talked to getting the needle and many different agencies and I have different answers for them all.

I will try and make a special effort to get these civil rights papers filled out and send in a

complaint to Medicare. I get very upset when I hear the illegal aliens need Medicare and Medicaid coverage, when mine has been denied and my life is at risk if I don't get my IVIG treatment.

I feel like a ball being tossed about with no answer to date. They keep playing with our health care coverage. Thank you for your attention.

MS. CONNERY: Thank you very much, MerleJean, and I'm sorry for the difficulty you've been having. Our project team has been listening carefully as we've heard your comments. We thank you for taking the time to be with us.

For those who are in the queue to comment this afternoon, I'll just note that we've had a few more cancellations, Commenters No. 32, 34, 39, 42, and 54 have all let us know that they won't be taking their time, so at those points, we'll be going forward to the next commentor.

I have heard that Congressman Mark Foley has been a little bit delayed by a need to vote on

something, but he is expected probably in 10 or 15 minutes, so what we'll do is keep going with the comments until he arrives, and then we'll pause to hear him speak to us.

If the next commenter is in the room -- and I realize we're a little bit earlier than I had indicated previously, but we'll take him -- is Joseph Bailes. Okay, great. Thank you.

DR. BAILES: Thank you. I'm Dr. Joseph Bailes, the Executive Vice President of the American Society of Clinical Oncology, or ASCO. We're the national organization which represents physicians who specialize in cancer.

IVIG is typically used by an oncologist, widely in a supportive care role for individuals with chronic lymphocytic leukemia who have low immunoglobulin levels. Also used to treat idiopathic thrombocytopenic purpura, when platelet counts need a rapid rise and in some bone marrow transplant situations.

In response to the notice of this meeting, ASCO conducted a survey of its members to identify access and health problems related to IVIG. I've provided a copy of these comments to your staff. Sixty-eight practices that reported administering IVIG over the last six months responded and provided a significant amount of information that we believe you studied in probably some of the issues.

First, there continues to be a shortage of IVIG. Half of the survey respondents reported that in recent months, their practices had not been able to purchase the full quantity of IVIG that they desire to purchase. In addition, most practices reported there were significant delays in obtaining the IVIG.

Second, which you've heard previously, inadequate Medicare reimbursement for IVIG is a serious problem. There was a wide range of prices paid for IVIG by practices but those prices were generally substantially in excess of the Medicare claim and amount. The average price paid by our

survey respondents in the last six months was about $40.00 per 500 milligrams for lyophilized IVIG, and about $50.00 for non-lyophilized IVIG.

The current Medicare allowable amounts are $25.00 for lyophilized IVIG and $30.00 for the non-lyophilized version. Our survey also indicates that the add-on payment that Medicare made for IVIG acquisition has not been a solution for most practices. They have not viewed it as such.

Third, as a result of this, many practices are referring patients to hospitals for IVIG therapy. In fact, about half of the survey respondents stated that that is their current practice. Some of these referrals, as in the qualitative discussion by respondents, require patients to travel long distances.

Fourth, the respondents indicate that the shortage of IVIG has altered treatments. 42% of respondents said they give patients less than a full dose because of the amount available, and 31% said

that they have decreased the number of doses given to IVIG patients.

Finally, in the qualitative or comment part of our survey, there were a number of adverse effects on patient health mentioned by the respondents: delayed treatment, in some situations, increased bleeding episodes, bruising, infections, hospitalizations. And also, the intermittent availability of IVIG, especially in relation to idiopathic thrombocytopenic purpura, has increased spleenectomies and transfusions in some practices.

Patients also sometimes have to be switched from one manufacturer's IVIG to another, and side effects, including the allergic reactions that did not occur with the initial IVIG, can result and have resulted from a different version.

ASCO thanks HHS for its work and for the opportunity to present these comments, and we look forward to working with HHS to resolve the access and patient health problems caused by the inadequate

reimbursement and product availability. Thank you.

MS. CONNERY: Thank you very much. Our next commenter, who would be someone on the phone, is Jackie Liles, L-I-L-E-S.

OPERATOR: Thank you, one moment. Ma'am, do you have the spelling of her first name?

MS. CONNERY: The first name, I've just got, I think it's Jackie, J-A-C-K-I-E.

OPERATOR: Thank you. I'm currently not seeing her name on the screen. If on line with someone else, please press star-zero so an operator can open your line. I'm receiving no response, Ms. Connery.

MS. CONNERY: Okay. Okay. No -- if she comes in later, we can take her comment later.

OPERATOR: Thank you.

MS. CONNERY: Our next commenter is -- would be in the room, and Ronald Hartmann, is he with us? Yes, okay, great. That's Commenter No. 17.

MR. HARTMANN: Good afternoon. My name is

Ron Hartmann and I am Vice President of Pharmacy MedAssets Supply Chain Systems. We're a health care purchasing organization. We're the third largest GPO in the country and have been fortunate to have been the fastest growing, as well, over the past four or five years. We currently represent over 1,400 hospital members, as well as 23,000-plus non-acute providers across the country.

My comments today, I'm representing just MedAssets. I'm not representing the industry. May make some general comments about the industry, but I just wanted to be clear that I'm basically just representing MedAssets here.

The group purchasing industry plays sort of a very important role in this entire equation. The group purchasing organizations are one of the groups that secure contracts with manufacturers on behalf of our members and have a significant role in determining allocation of product, where that product goes on a monthly basis, in terms of not only specific product,

but quantity in product.

Talking also about albumin here, not just IV immunoglobulin. They're very much needed by our members, and the albumin is allocated here similarly to the way that the IVIG is allocated. In fact, in today's market, the albumin is more of a challenge for us than IVIG. IVIG certainly has some challenges in terms of securing an adequate supply, and the dynamics of the market have changed dramatically over the past couple of years. Even more recently, albumin has become an even greater challenge for us.

The manufacturers generally base their allocations, the amount of product that they set aside for a specific contract holder, specific, in our case, group purchasing organization, based on historical needs. As we have heard this morning from several of the presenters, patients have shifted from one location to another to receive those allocations.

Another factor in this, the one that more directly impacts us in our industry, is that health

care providers can choose and do choose to move from one group purchasing organization to the next. The groups have acquired and secured allocations of product for their members based on that member's historical purchases.

The current supply system in the current market does not support the movement of a member from one GPO, from one allocation, from one place where that supply has been secured, to another, causing certainly difficulties in the course of movement of hospitals and health systems, and in our case, inability to secure additional product to take care of them.

The point that we would certainly like to make and the challenge that we would like to make to the industry is to support a system whereby the product moves with the customer should the customer choose to change, in our case, their GPO affiliation. There certainly are going to be challenges in that, we understand that, some logistic issues, but we are

certainly more than happy to sit down and work with the manufacturers and distributors to help facilitate.

But in addition to movement of product from a patient office to a hospital, it's our hospitals that are receiving those patients and truly have a limited ability to acquire the product that they carry.

That's further complicated by, in a larger sense, an entire health system moving from where their historical allocation was located to a different place, and in our case, from moving from another group purchasing organization to MedAssets.

What we would certainly like to help keep in mind is in our focus, certainly, we're patient advocates, as well. The patient care needs to be the number-one priority and needs to override other issues that may influence positions that certain groups may take on this.

I'd like to thank the HHS, as well as ERG, for the efforts here and the opportunity to address

this and I certainly look forward to some continued dialogue. Thank you.

MS. CONNERY: Thank you. Thank you very much, Ron. Our next commenter will be in the room, and that's Edith Marshall. She is with us. Great.

MS. MARSHALL: Good afternoon. I'm Edith Marshall and I'm speaking today on behalf of the Public Hospital Pharmacy Coalition, known as the PHPC, an association of close to 400 disproportionate share, or DSH hospitals, that participate in the so-called 340(b) drug discount program.

Under the 340(b) program, companies that manufacture drugs covered by Medicaid or Medicare Part B are obligated to afford significant discounts on the purchase of covered drugs to qualifying safety net providers, such as DSH hospitals and other qualified facilities. 340(b) prices are subject to a statutorily defined ceiling.

Charging a 340(b) covered entity a price for a drug that is above the 340(b) ceiling price violates

formal written agreements manufacturers must execute with the Secretary of HHS, as well as the legislative mandate of Section 340(b) of the Public Health Service Act.

In other words, our member hospitals are where many people who need IVIG, but can't pay for it, go, and the 340(b) discounts are an important part of what enables these hospitals to provide that care.

340(b) hospitals and their patients, like many other health care providers and the individuals they serve, have been experiencing severe difficulties in obtaining adequate supplies of IVIG. Indeed, based on a survey of its members conducted by PHPC earlier this year, only about half of our member hospitals are able to obtain enough IVIG to fulfill the treatment needs of their patients. We don't know if there's a shortage. We don't know exactly what could be the cause of the problem, but we do know that there appears to be a crisis situation.

The 340(b) covered hospitals we represent,

however, also face special problems with regard to IVIG access that are distinct from the generalized problems of product access and availability that we have been hearing about today.

Specifically, because our members serve large numbers of indigent and often uninsured patients who can't pay for their health care, or who can only pay for a small percentage of its costs, these hospitals rely heavily on the discounts they are entitled to receive under the 340(b) program to enable them to stretch their limited resources and provide pharmaceutical and other care to a vulnerable population.

Despite the legal obligation of drug manufacturers to offer IVIG for purchase by 340(b) covered entities at or below the discounted 340(b) price, manufacturers are only infrequently offering IVIG for purchase at the 340(b) price. Almost 80% of the hospitals in our survey sample, in fact, supported -- I'm sorry, almost 80% of our hospitals reported

being unable to obtain any amount of IVIG at the 340(b) prices, to which they're supposed to be entitled under the law, even though close to 70% of the same sample reported being able to obtain IVIG at higher prices through regular wholesale and distribution channels.

The result is that the 340(b) hospitals, which are under restrictions even from using GPOs to buy outpatient drugs because of their participation in 340(b), are forced to pay prices for IVIG far in excess of what they can afford, and at what applicable laws intend them to pay.

We've been told that representatives of the manufacturers, at least in the field, characteristically cite a shortage of IVIG as the reason 340(b) pricing is unavailable, but the data gathered in our recent member survey seems to belie that explanation. A shortage doesn't explain the frequency with which the product is indeed available, just not in a 340(b) price.

It appears that what is going on is something resembling a shell game. We have been assured by manufacturers that they do indeed offer IVIG at the 340(b) price as the law requires, but they also demand, unlike for other outpatient drugs, that IVIG has to be purchased -- this is usually what manufacturers insist -- they must be purchased directly from the manufacturer.

Then when a 340(b) hospital goes to the manufacturer and says, "Okay, I want to buy some product under at 340(b) contract," they're told, "Sorry, but all of that product has already been allocated to other purchasers of a commercial contract, and we have to honor those contracts." So go and try to get the product elsewhere on the commercial market.

Then, when the 340(b) hospital goes to one of the speciality distributors or wholesalers, who are the entities that bought the product from the manufacturer, they're told "We can't give you a 340(b)

price. That's not our obligation; it's the manufacturer's obligation." And the manufacturers, although they will reimburse -- it's called a charge back system -- they will reimburse wholesalers and distributors for the amount of the discount, generally, on a 340(b) product, they are not permitting any charge backs on IVIG.

So in other words, it really appears that, at least from the special perspective of the 340(b) hospital community, there's more going on here than a simple mismatch of supply and demand. Nobody, not manufacturers, not distributors of IVIG, seems to be willing to put in writing an explanation of what is really going on and why it's becoming impossible to purchase IVIG under the 340(b) program.

But it just all doesn't make sense. It doesn't make sense why allocations are based on two thousand and -- I'm sorry, 204 purchasing levels when clearly, the distribution of supply has changed. It doesn't make sense to say there's a shortage as the

reason we can't get 340(b) prices if indeed, the product is out there to buy.

We applaud the government's efforts to look further into this entire situation and we are hopeful, for the sake of not only 340(b) providers and their patients, but all the providers and patients that desperately need adequate supplies of this product, that efforts that are being made here today will yield significant changes in the way IVIG is allocated, distributed, and priced within market. Thank you.

MS. CONNERY: Thank you very much. Our next commenter is Jean Sifingo, and she would be on the phone. The last name is spelled S-I-F-I-N-G-O.

OPERATOR: Okay. One moment, please. I'm sorry, I'm not showing that participant at this time.

MS. CONNERY: Okay. Well, again, if she does run in later, let me know. We'll go then to the next commenter, which would be Commenter No. 20, also would be on the phone. That's Tessa Gehardt, G-E-H-A-R-D-T.

OPERATOR: She has disconnected from the

conference.

MS. CONNERY: Okay. Then we'll go to the next commenter who is also on the phone, Margie Pride, P-R-I-D-E.

OPERATOR: Okay. I'm not showing Ms. Pride on the phone.

MS. CONNERY: Okay. Well, let's try somebody in the room. Our Commenter No. 22 is Mary Kruczynski. Mary's with us. Okay. Glad you're here.

MS. KRUCZYNSKI: Thank you for the opportunity afforded me to witness to the experiences that I and others have experienced nationwide as a result to the pricing and availability of IVIG. I will go so far as to say the distributors are also having the same supply issues and sadly, demand is ever present.

I am also a member of Community Oncology Alliance, an organization aimed at preserving community cancer care, where 84% of cancer care therapies are delivered and among them, we treat a lot

of patients with immune deficiencies.

I have experienced first hand the problems associated with securing and administering immunoglobulin, and I can see down the road a similar problem on the horizon with chemotherapy drugs and the associated drug therapies stemming from the reimbursement issues with MMA, and I'm frightened.

As a practice administrator, the challenge of not only finding, but affording IVIG product, rises above pre-authorization (inaudible) administration of a product, which is something we all need to do now. So I thought I'd give you the perspective of what happens in a physician office when a patient requires this drug.

The normal course of action in an oncology clinic is to seek approval from the patient's insurance carrier to administer the drug for the specific patient diagnosis because, as you know, many times, this drug is given off-label. Some insurance companies pay for it, some do not.

Once that hurdle is achieved, we tackle the rate of reimbursement, but with IVIG, we actually have to reimburse our entire process. First, we have to call our distributor or speciality group to find out what product is even available; that is, Gammagard, Flebogamma, Gamunex, Octagam, etc., and what quantity will I be allocated that month? And then the next, the million-dollar question is how much is it going to cost me?

That number is then multiplied out by the number of grams required for that specific patient, which we then compare to the allowables from the carrier of that patient, be it Medicare or private pay, to determine if we are even going to make whole on the raw product.

Our decision to treat, as you can see, is a truncated one, and also a very time-consuming one, because once we have the answer as to what product and what quantity is available and whether or not we can afford it, we have to go back to the treating

physician and explain to he or she what product we have, do we need to adjust the dose because of this product, can we even use this product for Mary Jo.

Oftentimes, this is not the first dose of IVIG that the patient has received, but due to proclaimed shortages of products which may be made for this life-saving treatment, regardless of the risk of reaction with this patient. This is a tough decision that we have to make.

Thereafter, we need to call the insurance company and review local or national coverage determinations in an attempt to get that final approval to treat now that we know that we have the drug. That doesn't always occur. If we get a positive, we proceed to our internal scheduler to find out when we can fit a five-hour infusion in in our very busy infusion suite.

This is a long infusion and it cannot be rushed and the patient needs to be monitored, and we use certified chemotherapy infusion nurses, and I

don't have to tell you how in short supply they are, or perhaps I do have to tell you. They are in short supply and they demand a high salary and they're worth every penny.

If we are unable to secure the IVIG or be made whole on the purchase of it, then we have to explain to the patient why he or she needs to go to the hospital for this treatment. This is usually followed by questions, anxiety, and oftentimes, tears. Of course, those patients have been shifted to me after the doctor gives them this news because I'm supposed to pull a rabbit out of a hat and find this product, which I cannot.

If the patient is being outsourced, we have to call the hospital outpatient department. We have to schedule a date and time for the patient. We have to write physician orders, patient demographics, and pertinent medical records and fax all that over. That takes a lot of staff time.

Then we have to go back to the patient and

communicate what we've done and invariably explain once again why they cannot receive this treatment that they used to receive in our office, oftentimes for years, and it's not an easy task.

In today's technologically advanced society, it's amazing that this is what we have to go through (inaudible) just telling you about it, and may I also mention that most times, we cannot treat the patient, and we've already expended hours of time in an effort to do that, with zero remuneration by Medicare or any other carrier, yet but we tried to administer their policies, essentially for free.

MS. CONNERY: You have 15 seconds.

MS. KRUCZYNSKI: Oh. We are contacted from time to time by home care companies offering to take our IVIG patients off the market -- off the market -- off our hands. A recent call (inaudible) revealed that they had no supply difficulty with IVIG and in our area, they were treating 17 patients an hour (phonetic). When I asked why we couldn't get the IVIG

and they could, she said "Because we have special arrangements. We're very large."

Well, as a member of a GPO, we thought we were very large also, and we wonder, could this be a planned relocation of place of service for this very expensive blood product? Are there separate contracting arrangements between manufacturers, insurers, home infusion companies, limiting the very position to prescribe their care?

Could the shortage then be contrived rather than actual? Are these entities profiting from these transactions? Human life is at stake here. I have just one last quote, if I could just squeeze it in.

MS. CONNERY: Go ahead.

MS. KRUCZYNSKI: In February 2006, Congressman Mark Foley, supported by Congresswoman Nancy Johnson and Nathan Deal, Chairman of Energy and Commerce, had a meeting, and they said "We need to get to the bottom of this" -- and I quote -- "and find a fix to this problem before someone dies."

Regrettably, at the Ways and Means Hearing in July '06, someone did die. We've missed our deadline.

MS. CONNERY: Thank you very much, Mary. Well, that quote provides an excellent segue, because we are joined now by Congressman Mark Foley, and we're very grateful that you could take the time to be here. We are joined not only by the folks in the room, but several folks who are on the phone, as well, who will be able to hear very clearly, as long as you use the microphone. We can -- would you like to -- here, let's do this. That way you can --

MR. FOLEY: Well, then I can do an Oprah. Hello, everybody. Let's take questions from the audience. No, this is obviously -- I am Mark Foley from the 16th Congressional District, which is in Florida. I represent the fifth largest Medicare population in America. This is a critical issue. I don't want to underestimate the impact this has had on constituents in my community and people that I've met

with throughout the entirety of both patients and patient advocates.

You know what the topic is, so I don't need to read that portion, but about two years ago, I started to hear from my local immunologists, other providers, and patients that doctors were not going to be able to continue providing IVIG in the office setting because the doctors claimed their Medicare reimbursements were too low. As a result, patients would have to seek treatment in a hospital outpatient setting, something that would be devastating for this patient group because of their susceptibility to catching other illnesses in those settings.

It was at that point that I, along with several of my colleagues, began taking a very close look at the problem. We began to meet with manufacturers, distributors, GPOs, providers, patient groups, to get their input on what they were experiencing in the marketplace. However, despite our best efforts, there was no consensus as to what was

causing the problem. Soon after, I began to hear from hospitals that they would be cutting off services entirely, leaving countless patients without this life-saving therapy.

With a newly found sense of urgency, Congress turned to CMS, FDA, and HHS for their input and asked them to develop a solution to this crisis. However, we were quick to discover that no one in official Washington could tell us what the cause was and thus, could not offer a solution.

We then asked the U.S. Department of Health and Human Services Inspector General to do a study of the problem. Again, regrettably, that won't be done until next year, and people are dying without their remedy.

During an earlier hearing this year, Congressmen Jim McCreary, Nancy Johnson, Clay Shaw, and I asked Health and Human Service Secretary Leavitt to immediately look into the problem and provide Congress recommendations on how we can solve it.

That's why we're here today.

After several years of looking at this problem, there's a general consensus on Capitol Hill that there are three factors causing the problem. First, reimbursement. 2003, Congress changed the way CMS paid for Part B drugs because the spread -- the difference between the amount of money CMS was paying and the actual cost of administering the drug was enormous in causing the Medicare program financing hardship.

As a result, we required payments to be made using the average sales price formula and not the widely used, but invented, average wholesale price formula. One of the biggest problems with ASP is that it requires CMS to use months-old data to determine pricing, not to mention that it doesn't take into account final acquisition costs. I think that by requiring CMS to require a one-quarter lag in data, it may help.

Second, is there a product shortage? While

pricing the product may be a factor, the fact is that many hospitals are not able to get product at all. Part of the reason for this is because the treatment is a victim of its own success. I've heard from countless doctors across the country that IVIG is a miracle drug.

Hospitals all across the country had very off-label uses, and the amount of non-PIDD patients receiving the drug are on the rise. This will be a very difficult issue to deal with, but we must triage our patients and give IVIG to those that need it most.

Third, and what has been colloquially called "channel conflict", when the patient shift from physician setting to hospital settings occurred, we discovered in most cases, the product was not following the patient to the new setting.

This is extremely important because of the way contracts are entered into for the purchasing of this treatment. Amounts are based on the providers' previous year usage. Therefore, if a hospital has

contracted for a certain amount of grams, it is difficult for them to get more at contracted prices.

We need to take a look at how these contracts are done and revisit whether federal law and other regulations need to be changed.

In conclusion -- which is always the happiest word for panelists to hear -- the fact that we need to find an answer and quickly. As of yesterday, according to the Florida Hospital Association, no hospital -- no hospital -- is offering IVIG any longer in their outpatient setting. We are going to see patients die, and this is simply unacceptable.

You here have been charged with finding an answer, and as someone who is responsible in overseeing Medicare, I am telling you we need an answer now.

In the meantime, I wanted to let you all know that I'm continuing to work with Chairman Bill Thomas, Congressman McCreary, on several options, and

we are hoping to have something soon. While I can't discuss what we have been talking about, I can tell you that we do not plan on moving a reimbursement-only bill, as some may want. No one is without some responsibility for what has happened here. Any responses that we take will reflect that fact.

Again, I want to thank you for allowing me to appear before you today, and thank you for your consideration of this very important population.

MS. CONNERY: Thank you. Is this anything that you would take a couple of questions on, if people have questions about your activities? Do you have time for -- yes?

MR. FOLEY: Yes.

MS. CONNERY: Okay.

MR. FOLEY: I may have to turn the mike --

MS. CONNERY: Well, and I'm going to have to --

MR. FOLEY: (inaudible)

MS. CONNERY: Right, because we do have to

get everything on the mike. And what we'll do is we'll alternate between a question in the room and a question on the phone, and maybe you could discuss the procedure for folks on the phone, if they have a question? Is it press star-one? Operator?

OPERATOR: Yes.

MS. CONNERY: Is it press star-one?

OPERATOR: Press star-one if you'd like to ask a question.

MS. CONNERY: Okay.

PARTICIPANT: What vehicle would you use to move that solution that you and Chairman Thomas and the like are working through? How would you get that vehicle -- how would you get that through? Are you tacking that onto a bill, or --

MR. FOLEY: Again, the first is to come up with a solution, and then find a vehicle that would be appropriate. It could be an omnibus (phonetic), it could be in special session. It certainly won't be before we adjourn Friday, but there will be some

vehicle we can tack that to.

I know physicians are looking at reimbursement issues. There are a number of outside and outstanding issues that we have to tackle. If we come up with a solution, it would probably be melded into one of those vehicles.

PARTICIPANT: So it would be not before the end of the year?

MR. FOLEY: It could possibly be before the end of the year. I wouldn't want to give anybody that close assurance, because I'm not telling you what we're going to get done, unfortunately.

PARTICIPANT: Right.

MR. FOLEY: But we are going to be back here on November 13th for a week. We're going to be back here at least two weeks in December. There are a lot of outstanding issues, so things may move a little bit more quickly once the election season's finished.

MS. CONNERY: Is it -- Marcella still with us as the operator on the phone, or somebody new?

OPERATOR: Yes, I'm here.

MS. CONNERY: Oh, okay. Still Marcella. Do we have anyone on the phone who wanted to ask a question?

OPERATOR: By hitting star-one, we have no other parties in queue.

MS. CONNERY: Okay. We have a couple of others in the room, so we'll go to those.

MS. BIRKOFER: Thank you, Congressman Foley. I'm Julie Birkofer with the Plasma Protein Therapeutics Association, representing the manufacturers of IVIG.

First, I'd like to thank you and Bradley for your leadership on this issue, and let you know that the companies are committed to finding the solutions, and we've been working tirelessly with many in the community, and we're talking about things substantiated by data by the Lewin Group, as well as external data from the Office of Inspector General, and any ASPI findings to support a payment adjustment.

We're also advocating for separating out the (inaudible) codes brand specific reimbursement, as well as maintaining the pre-administration code, and identifying IVIG as a complex infusion similar to a biological response modifier.

We're working with some of your colleagues in Congress and we'd like to work with you, of course, sir, and we have some draft legislation I'd like to give to (inaudible). I just want to thank you so much for your leadership, you and Congressman McCreary and Israel (phonetic). We've been working with Congressman Pitts (phonetic).

The bottom line is we're all working for the same end goal, to restore access for IVIG, so I just wanted to thank you, sir.

MR. FOLEY: Thank you. I'll take your compliment and (inaudible). That's a lot to do, but we have it.

MS. CONNERY: Well, we have another question over here.

PARTICIPANT: Hi, Congressman. First of all, again, I ditto what Julie Birkofer said. You've been an incredible advocate for our community and your remarks have been wonderful and I know what your constituency's going through, and I know that there are constituents from your district right now listening on the phone, so you've been great.

But you've also taken a leadership role in doing two letters to the Secretary requesting that he declare a public health emergency, which would get us out of this mess right now. Would you consider requesting a member-level meeting with your colleagues, McCreary and Israel (phonetic), with your -- with members of the community to sit down with the Secretary and discuss what could be done to get some relief?

MR. FOLEY: Yes. Bradley -- and you mentioned that to me when I entered. There's no question we would like to facilitate a meeting and urge him. I know we've spoken to him repeatedly on

it, sent him letters. We testified before the Ways and Means Committee. We brought that, as did Mr. McCreary and others, to his attention.

I'm delighted to work with the Representative Israel (phonetic) on this issue, as well, and he and I will coordinate the formation of a letter seeing if we can (inaudible) a meeting.

PARTICIPANT: Thank you.

MS. CONNERY: Marcella, is anyone queued I[by pressing star-one with a question on the phone?

OPERATOR: Yes, we have Tessa Gehardt. Your line is open.

MS. CONNERY: Okay.

MS. GEHARDT: Hi. My name's Tessa Gehardt. I'm a patient.

MR. FOLEY: Yes, ma'am?

MS. GEHARDT: Do you hear me?

MR. FOLEY: Yes, I can, please.

MS. GEHARDT: Okay. My question is, also with the insurance companies, there is a cutoff limit

with lifetime capabilities and getting treatment. Is there any way that the Congress can deal with this issue where -- this is a lifetime treatment for me, and at the rate the cost of it is, it will cut me off at the age of 60.

I am 44 years old right now, and my insurance company, if I stay with the one I have, will cut me off around age 60, so what am I to do if I live beyond that and I still need treatment?

MR. FOLEY: That's a very, very important question, and that's one of the concerns we have in a multitude of areas where they have caps on coverage, because you can't -- in fact, it's actually a waste of money to continue to fund and provide it if you're not going to sustain it to the lifetime of the individual.

So we want to be very careful. I don't have an instant solution, but much like we've worked on issues of organ transplants, it was ironic that we do an organ transplant and not have Medicare reimburse for the anti-rejection drugs. It seems a very

expensive and devastating procedure to put a person through when you're not going to provide the very relief that will sustain the organ living in the new body.

And so these are the same questions we're going to be challenged with in the reimbursement caps that are in some insurance policies. So I'll ask Bradley to look into that further.

MS. CONNERY: Thank you. We'll go the next commenter -- I mean, sorry, questioner in the room.

MS. BOYLE: Hi. I'm Marcia Boyle from the Immune Deficiency Foundation. I just wanted to reiterate and thank you for your leadership. Many of our patients have been in touch with your office, and they know that you're a member of Congress who really cares.

Earlier today, I gave some preliminary data from a survey we've done of patients and the impact of Medicare reimbursement. I'd like to be able to send that to the office and sit down with you and Bradley

at a time of convenience, because we do have data now that is current stat that certainly shows what's happening disproportionately to Medicare patients.

So I know that one of the things you need is data at all times, so we're happy to provide it and we just want to thank you from the bottom of our hearts.

MR. FOLEY: Well, there's no question, I mean, there are so many stress points on Medicare right now, and we mentioned reimbursements, hospital reimbursements, home health visits, and all kinds of things, physical therapy caps. We have got to do a major restructuring of how Medicare works.

It seems like the only answers we find in Washington cut reimbursement and hope it stops the hemorrhaging of money. But oftentimes, it leads to greater illnesses, which then exacerbate the expenses.

We've been trying to, and I know I worked with Senator Graham and Carl Levin and others on wellness models -- John Lewis -- trying to find ways to enhance Medicare as a wellness model, not just a

sickness model. For it to be a wellness model, reimbursements have to provide this type of therapy so we can keep people healthy.

So this is going to be an inherent struggle, but unfortunately, the response we seem to get from the administration, or at least CMS and others, is just flatline physician fees, take a nick or a cut here, find ways to do things differently, and ultimately, it's leading, in my view, to deterioration of human health, which then again exacerbates the system, puts them in either intensive care units or long-term care units well in advance of when they could've or should've been admitted to these facilities.

So we will continue to work on it. I'm hopeful. Both sides of the aisle -- and I think both sides are clearly interested, and this isn't a partisan issue -- both sides need to tackle this, and not simply just wish it away, because these things won't go away.

MS. CONNERY: Okay. Marcella, is there anyone else queued up on the phone by pressing star-one to ask a question?

OPERATOR: Yes. Peggy Hassel, your line is open.

MS. HASSEL: First, I would like to thank you, Senator Foley, because you have helped both Ken Bennis and myself immensely many times. (Inaudible) please into your (inaudible) facility layer doctors' fees, because if we moved our doctors, we will not be able to get treatment, no matter what you come up with, and then you have our doctors, as well as (inaudible) their practices.

MR. FOLEY: First, let me thank you for the promotion to Senator. That was so wonderful without even having to go through election. Best victory of my life.

There is no question that physicians have to be equitably treated. I think that's when this problem seems to have spiraled out of control, when we

moved it from physician practice settings into hospitals, then changed reimbursements, then made it hard for hospitals, then changed the utilization of it for other reasons.

So it's a cumulative effect, but I want, out of my heart, the doctors to be intimately involved in this issue, because they are the closest to the patient, they have to monitor and deal with the side effects and after effects, and you can't simply push them into a third party facility and hope somebody there is going to be able to give the continuity of care that your own physician has been able to do knowing your case management and the things that you had to experience. So I am all for trying to resolve that, including the physicians back in the system.

MS. BOYLE: Okay, thank you.

MS. CONNERY: Okay, thanks. Anyone else in the room have any questions? There's one over there. Let me -- I'll walk your mike over.

MR. FOLEY: Then this will be the last

question.

MS. CONNERY: The last question? Okay.

MR. FOLEY: I don't want to miss folks. I'll leave my -- that's all right. Yes?

MR. SCHLEIS: Hi. Tom Schleis, Octapharma. Do you feel you have the necessary information at this point to come up with a plan and implement it?

MR. FOLEY: Well, the information -- we're not sure we have everything. People have been very good. I must say, the manufacturers have come in -- there's nobody that hasn't been willing to share data points, and I think that's encouraging. So there's nobody that -- we're not casting a blame and saying there's one side holding supply out of the corner. We don't know why these things are occurring, but we have been very, very pleased that whether they be manufacturers, patient groups, hospitals, doctors, they've all come forward, because they're all under the same duress as each other.

So I -- so far, Bradley, do you have any

thoughts on additional information?

BRADLEY: Yes, I mean, as far as specifics why this issue has arisen and how we can prevent it in the future, we don't have that pinpointed. That's why these folks are here and that's what they're charged with by ASPI.

We do, however, have a great deal of concern, if you look at the universe of what's out there, how the contracts are entered into, the chain of custody of that product, making sure it's not being siphoned off into the gray market where there seems to be a ton of product right now at double, maybe sometimes triple, the prices.

But there -- I mean, while we can't necessarily say whatever we're going to do is going to be a silver bullet, if there is anything done, it certainly can address some of these other concerns that we've been made aware of over the past two years.

MR. FOLEY: My lawyer probably just got the sound bite of the conference "been siphoned off to a

gray market". But that is, it's true. It's one of the concerns that we're facing. But thank you.

Let me thank everybody for attending and for your interest in this, and again, we've shared accolades with our colleagues who have been very, very vigorous in this issue, so it's not me alone. There are a number of people on both sides of the aisle that are taking this very seriously and they're trying to help. Thank you.

MS. CONNERY: Thank you, Congressman.

[Applause]

MS. CONNERY: Thank you very much, Congressman Foley. Okay. We will go back to taking the public comments. Our next commenter -- actually, our next three commenters are with us via the phone line, so let's hope they're there. First is Christine Butler, who is Commenter No. 23.

OPERATOR: Ms. Butler, your line is open.

MS. BUTLER: Okay. What do I do now?

MS. CONNERY: We can hear you.

MS. BUTLER: Okay. This is Christine Butler from Montgomery, Alabama. I became a patient of Dr. Harry Burns in 1985. I was having pneumonia every other month and coughing up blood, and so I had (inaudible) and took antibiotics every other week without any improvement. Dr. Burns referred me to the University of Alabama Medical School in Birmingham to be evaluated.

I made many trips over several months and (inaudible). The doctors diagnosed me as having a compromised immune system. This concurred with Dr. Burns' diagnosis. This doctor recommended taking gamma globulin with an IV every month under Dr. Burns' supervision. I started the treatment in 1990. I was not making much progress with the monthly treatment of gamma, so then, I was increased to 35 grams every three weeks.

The instructions (phonetic) weren't clear from (inaudible), but it takes five hours (inaudible) the medicine. Over these years, a few times, the

gamma was not available, because the cancer center said (inaudible) and let's reschedule in the next few days. This happened at the early years of treatment and (inaudible) gamma.

As you well know, gamma is very expensive. It (inaudible) Medicare (inaudible) Blue Cross with Alabama (inaudible) all covers for me. Dr. Burns was taking the reduced cost (phonetic) of IVIG, and I appreciate that.

I know there are (inaudible) not have the benefit of Medicare and Blue Cross coverage. I could not financially afford these treatments without them. The reason that I will continue with doses of (inaudible) antibiotics, it'll keep my lungs clear.

I believe that if I fail to get these treatments, my life will be in danger because this (inaudible) is very essential. With this treatment, I take very few antibiotics and my quality of life is much better. I have not been hospitalized for lung problems for many years. Dr. Burns has a great

facility for these treatments. Hospitals could not furnish what he offers to his patients. Many qualified (inaudible) and and at least one of the oncologist/hematologist is always in the building. Thank you so much.

MS. CONNERY: Ms. Butler, thank you for taking the time to comment today.

MS. BUTLER: Thank you.

MS. CONNERY: Our next commentor is Commentor No. 24, also on the phone, Peggy Hassel, H-A-S-S-E-L.

OPERATOR: Ms. Hassel, your line is open.

MS. HASSEL: Yes, my name is Peggy Hassel and I work for the Sheriff's Department in Palm Beach County. I was sprayed with a chemical back in '89 which triggered (phonetic) my immune system. I was diagnosed with common variable immune deficiency, neutropenia, and ITT.

I hope you are aware that all three of these illnesses combined with each other (inaudible) gamma globulin to survive. I was then taken to the

University of Miami Hospital. I was (inaudible) because I had lost 40 pounds and I had infections and (inaudible) my body.

I tried various gamma globulin (inaudible) price and we wound up at that time getting the gamma (phonetic). I have been on that pump (phonetic) since 1990. Just let me give you a few experiences of what happened when the rule (phonetic) changed for gamma for Medicare. I then had a lump in my breast. My doctor had scheduled me to get an IV of gamma with an IV antibiotics before the (inaudible). The day before this was to happen -- and at this time, I was getting that at the hospital. Up to this point, I was still (inaudible) for the procedure, per Medicare's decision.

The day before, I was told I would not be able get my gamma, nor my IV antibiotics, in the morning when I was scheduled to have the breast biopsy the day after (inaudible). You cannot have (inaudible). I (inaudible) took place. After that,

of course, I was without a home, (inaudible), because that's before we (inaudible) getting in the same facility.

We were put out of the hospital. We didn't know where to go. I needed another dose of gamma globulin before the procedure with the breast, and (inaudible) had not received it, but all that (inaudible). We wound up having to purchase it out of our own money (inaudible). At that point, we could show that because we had (inaudible) that we could get in the hospital (inaudible) medical? (inaudible) this week that I would no longer be able to get my gamma at the hospital.

My question to you is what does a patient do (inaudible). We have no (inaudible) and we are blessed to have Medicaid or (inaudible), but we need to have access to our regular treatment. And because these things happening, I have taken IV antibiotics and (inaudible), which is costing Medicare probably more money than if they had given me a dose of gamma

globulin, and, of course, antibiotics (inaudible) orally.

The other problem that you have is the doctor is completely out of the loop. While you're in the doctor's office, you had the ability to go to the doctor, and he saw -- he could see that you had an eye infection. He can tell that you had an infection wherever it was, and would immediately give us what we needed. This way, you're in a hospital. (Inaudible. You don't know what the (inaudible) level is when you're walking in. You don't know if you're going to get the product, and (inaudible).

(Inaudible) of course with (inaudible) and a quality of life and that we will live and be able to enjoy life, just like everyone else who is sitting in the room and on the telephone (inaudible) their life.

My other problem, too, is if Medicare does not come up and meet the needs at a cost where these companies can afford to provide, they will sell this product out of the country, and Americans are donating

their blood for us to survive, whether they get paid a small amount or not. Once it leaves this country, patients like myself will die.

I want to thank, first of all, the IDF, Congressman Wexler (inaudible), especially Michelle (inaudible), those kinds of people who go out of their way to keep us alive, and help (inaudible) with improving our doctors.

I also want to thank my friend Ken Bennis, who we had lunch (inaudible). He had statements over phone calls (inaudible) and vice-versa. And these people do not have the support of a friend or someone who (inaudible).

We plead for our lives today. I know if you are not affected with this illness, you don't really understand this, but we do have a right to live, and pray in our hearts that you will listen and that you will think of the people who have died because we have not done anything yet.

MS. CONNERY: Peggy, we're at about five

minutes.

MS. HASSEL: Thank you.

MS. CONNERY: Okay. Thanks so much. Our next commenter, also joining by phone, is Betty Gordon. Betty is Commenter No. 25.

OPERATOR: One moment, please. Ms. Gordon, your line is open. You may make your comments.

MS. GORDON: Hello. My name is Betty Gordon. I live in Warwick, Rhode Island in the New England area. I am a patient with IG decrease deficiency (phonetic), and I receive IVIG infusions at Kent Hospital here in Warwick. I'm happy today to give testimony on behalf of myself and (inaudible) Immune Disease Foundation.

I have two concerns: product choice/availability and (inaudible). Just a brief personal history. After 13 years of misdiagnoses of sinus, bronchitis, or six pneumonias (inaudible) the whole year, I was forced to retire at age 49 from (inaudible).

At 56, by the time (inaudible) after the unsuccessful sinus surgery, and I was finally correctly diagnosed with hypogammaglobulinanemia, IG decrease deficiency (phonetic). With this diagnose came a miracle, outside my medication that had slowly helped me regain my life. I had received 35 grams of Gamunex every three weeks (inaudible). If I had a problem (inaudible) product choice/availability.

I began my IGIV in February of 2004 with first, my (inaudible). And then that product, I believe, was discontinued and without forewarning, (inaudible). Within the next six months, again, with no forewarning, I found that I would be given Octapharma because the hospital's infusion unit did not have enough of the Gamunex. I refused the Octapharma and they found enough of the Gamunex by 1:00 that same day.

(Inaudible) this year, I (inaudible) someone in the emergency room and after frantic phone calls to my doctor, my Immune Disease Foundation mentor, the

hospital (inaudible), I agreed to have the antibiotic just that day.

(inaudible) as most you know who have this disease, the (inaudible) has given side effects, and it took my body two months to return to previous health levels.

At the next month, after preparing for the (inaudible) Hospital's administration in pharmacy, I was after Gamunex, but I (inaudible) pharmaceuticals. (Inaudible) having patients scheduled for this product and I heard -- one of the comments that Dominick and Tara say, that (inaudible) that IVIG is divided by locks and not by gates, and he's correct.

So mine was given to another patient and it has not happened since and hopefully, it won't happen again.

My other aim is reimbursement. Plus, location of the infusion seems to be an issue when it comes to this. So in 2004, I decided having IVIG in the hospital rather than in the doctor's office, and

here's the reason. My Blue Cross would only say 80% if I had IVIG in the doctor's office, but it would pay 100% if I had hospital outpatient treatment.

Second -- and I hope you can follow me through this catch-22 -- Medicare reimbursement has created a huge problem (inaudible) Medicare. Last fall, as soon as I was eligible for disability, I applied, was rejected twice, and was up for appeal at the (inaudible) level.

But in January of 2006, my hospital, the Kent Hospital in Warwick, began testing IDG level of all patients, both on Medicare and so as not to be accused of discrimination, both, like myself, on Blue Cross. The reason not enough reimbursement, the Medicare patient and the hospital has to find a way to (inaudible) specific (inaudible) average IDG levels. This has come off as an invalid and discriminatory test. It's like testing someone for low blood count after a blood transfusion.

Also, my insurance does pay fully for this

treatment. I am not yet on Medicare. Plus, I have IDG-3 deficiency, which is a specific problem. The trial level was invalid to me, and so I should not be tested. But if I refuse testing, Kent Hospital will not treat me.

Go back to bullet Social Security and Medicare Part A. After e-mailing my (inaudible) State Senator, Senator Lee, and the (inaudible) Foundation, I wondered if I refused Medicare Part A, I will be denied Social Security Disability, which is what I need, as I retired on a small pension.

So here's the catch-22. If I get Social Security Disability, I cannot refuse Medicare Part A and keep my own Blue Cross. But if I take Medicare Part A, the hospital will not treat me.

So I notified my attorney with a number of the (inaudible), and here's what I'm hoping, that sooner than five years, when I turn 65, this will all be resolved, because while I need it in a facility (inaudible) we need IVIG to stay alive.

I'd also add that I e-mail an IVIG patient in California who is on Social Security Disability and Medicare and has had **no problems with either access or reimbursement, so there must be in equality, and it must be regionally.**

MS. CONNERY: Ms. Gordon, we're at about five minutes.

MS. GORDON: Okay. My last comment, Medicare has to return to previous levels of reimbursement, again recognize plasma (phonetic) as a life-saving blood product, and access to IVIG must be the same all over the United States. Medicare reimbursement levels and all the (inaudible) levels should be the same all over the United States.

Lastly, I know without this product, I would become sick again and eventually, it will kill me. I ask that you recognize IVIG as a life-saving blood product. It gives me some type of normal, better health, so perhaps I can see my grandchildren grow up. I would never want to go back to where I was health-

wise a few years ago. Thank you very much for all you're doing for us.

MS. CONNERY: Thank you very much for your comment. Our next commenter is in the room, and that is Michael Rigas, and he is Commenter No. 26.

MR. RIGAS: Good afternoon. Thank you for allowing me to speak. I am a pharmacist. I'm the Senior Vice President of Clinical Affairs for a company called Crescent Healthcare based in California. We are an alternate site infusion provider with about 3,000 patients on service every month in 36 states. About 500 of those are IVIG patients.

What I've provided today is two different spreadsheets. I'd like to talk about them just for a minute. I'm not going to get into details. I think Susan Pappas said it nicely for our industry. I'm going to concur with what she said, but I want to talk about our patients now.

As a practicing expert clinician in the

subject, I'm quite disturbed. What I've given you, the first one is in color. It is a chart that shows the beginning of the year of 2003, going off to the right, 2006.

The different sites of care that some part of Medicare wouldn't pay for, whether it be A, B, C, or D, if you like that alphabet soup. Then I have what's happened with reimbursement. If the reimbursement's in black, that means it's at or above the level of acquisition of the drug. If it's in red, it's below the acquisition of the drug.

Now, at the bottom, I have what the average acquisition cost is to our company during those years, and I have below that what the gross profit would be; that is, what's left over after you pay for the drug. If you look on the bottom line, lower right-hand corner, you can see that we're about a negative $1.00 per gram gross profit. Obviously, that isn't going to help -- you can't make that up in volume.

If you look over to the right at the

results, what that describes is what I think is happening with our group of patients that we like to call the IVIG gypsies. Those are the folks that I've been working with for over five years who are on their fourth and fifth site of care right now since I've been taking care of them.

They started off in 2003 with a doctor's office. The reimbursement was sufficient. In 2004, that was lowered. They went to hospital outpatient in 2005. That was lowered. They moved out of that and into the home care under Part D in 2006, doing them, and as a result of that, now many of them are receiving it back in the hospital because they couldn't afford the co-pay and the catastrophic piece of Part D, which even at 5%, can result in a $10,000.00 fee per patient per year, above the other $7,000.00 they pay for their part of the co-pay and the insurance itself.

I did think I was going to be educated as a clinician. I didn't know I'd know so much about

reimbursement at this point in my career. The next spreadsheet I have for you is the impact of Medicare changes from 2005 to 2006. Right now, we have a total of 111 Medicare patients on service, 10 of them Part B; 101 of them Part D.

As you can see in the graph, the number there is the percent of patients affected by what I've listed. So switching IVIG product due to allocation, 25%. Switching due to access issues at the particular facility, 50%. Changes in administration, location, 100%. Every one of our patients has had to change the site of care since I've taken over their care within the last five years.

Okay. 20%, patients needing to become hospital inpatients to receive care. 10%, patients needing to have us supply the drug to the hospital because they can't get enough, so every Friday night, that's when my phone starts to ring. Can I spare 200 grams? Can I spare 500 grams? Can I spare 1,000 grams?

This is for hospitals whose annual budget dwarfs ours by 10 times. (inaudible) IVIG because they don't have it and they don't know how to get it.

Patients receiving fewer treatments, 10%. 15%, patients receiving lesser dosages. 35%, patients with worsened health status due to any of the above. Patients with payers who deny Part D coverage, saying that it's Part B, for non-PID diagnosis, 20%. We also have to deal with them. 20% stopped therapy altogether.

So as far as our company goes, I would consider this a health care emergency. Of these 500 IVIG patients (inaudible) our service, representing 100 of them that were Medicare, are feeling quite affected and quite put out, as well as our company -- as you can see from the first page, anything to do with Medicare right now, the gross profit is below cost. So right now, unless they have a second (inaudible) or somebody else to pay the difference, they'll either have to pay cash or they'll have to

find some other place to get it.

So I appreciate the fact that you have a large task to do, but I think this is clear evidence of a great travesty that's happening in these patients right now. Thank you.

MR. EYRAUD: Could I just ask, while you're up there, in this spreadsheet, is this an actual -- just so I know, make sure I know what I'm looking at -- is this an actual census, or your estimates of the percentages?

MR. RIGAS: This is actual as of yesterday.

MR. EYRAUD: Actual census of the patients involved. Okay, great.

MR. RIGAS: Thank you.

MR. EYRAUD: Yes, thank you.

MS. CONNERY: Thank you, Mr. Rigas. The next commenter is joining by phone, and her name is Rosa Luna, L-U-N-A. (inaudible) to take those.

OPERATOR: Ms. Luna?

MS. LUNA: Yes?

OPERATOR: Your line is open. You may make your comments.

MS. LUNA: Okay. Hi, my name is Rosa Luna, RN, and I work at Clinical Neuroscience, P.A., which is located in De Soto, Texas, and we service the Dallas/Fort Worth area. There are approximately 10 neurologists in our group.

We see patients who drive in from up to two hours away to receive IVIG, and I do have one patient in particular who wanted to change location that would be closer to her home since she moved closer to Fort Worth, and she was told that the drug was not available in any clinic, any outpatient setting at all. So pretty much, she was locked into our clinic due to the allocation or the limit that you can receive.

Our IVIG patients we see at our clinic have CIDP, which is chronic inflammatory demyelinating polyneuropathy. We also see some Guillain-Barre patients, myasthenia gravis, polyneuropathy, and

multiple sclerosis. Our clinic opened in about 2003 and at that time, the amount of IVIG that we wanted to purchase was pretty much limitless and cost-effective.

We are currently are able to service about 50 patients a month on a regular basis. We have been able to offset the cost of the administration of IVIG since the reimbursement changes of Medicare formed the reimbursement of the other insurance companies.

But now, this is getting much tighter in our clinic. Many other clinics have had to follow, and that is to shut down because of reimbursement.

I have a chart -- I don't know if y'all have that in there, but I did e-mail a chart with the tolerance with the insurance companies that our clinic receives reimbursement from, which includes Medicare, which is also PacifiCare, the HMO's Medicare, Blue Cross and Blue Shield of Texas, of Illinois, Oklahoma, and Kentucky. Also, United Healthcare and Cigna and other insurance companies.

I will focus on Medicare, as I believe they

are the driving force for all the other insurance companies. Many patients are diagnoses with (inaudible) diseases and pretty much have to go on Medicare after one to two years. Currently, we are reimbursed about $50.31 per gram from the powder IVIG, which is procedure coded J1566, and we're reimbursed $64.20 per gram for the liquid IVIG, which is code J1567.

We're also reimbursed for a few other things. The infusion, for the first hour, we get $81.68, and then for each additional hour, we get $27.01. That's also a code that was added -- it's a G code -- and we get $69.00 for that. We get no reimbursement for any of the supplies that we use at our office.

It costs us anywhere from $60.00 to $100.00 a day just to infuse one IVIG patient, depending on what kind of IV (inaudible) to use, and we have to pay our nurses anywhere from $25.00 to $50.00 an hour, and, I mean, that just doesn't -- the cost of what

we're having to (inaudible) just doesn't -- and what we're getting reimbursed. And I feel that Medicare drives the market, and because of the Medicare reimbursement, I also believe that all the other insurance companies are following.

The reimbursement from one of the insurance companies is $44.34 a gram, and that's just way below what we're having to pay for it. Like I said, pretty much all of the other insurance companies are following.

Our cost that we're paying right now for our powder IVIG is $46.00 a gram, approximately, and our cost for the liquid is approximately $60.00 a gram, and all the other insurance companies follow the reimbursement practices of Medicare. Again, as stated before, our clinic will have to shut down, and we just can't sustain the cost of administering IVIG when the cost of the drug is more than the reimbursement we are receiving.

In the last quarter, if I'm not mistaken, I

believe Medicare was also reimbursing about $44.00 per gram.

MS. CONNERY: Ms. Luna, you've got about 15 seconds.

MS. LUNA: And like Senator Foley said earlier, I do like what he said. He said we need to do human health and not let the insurance companies be the doctors for our patients. I have a couple of other things here. I recently had a patient with myasthenia gravis who had no benefits for his IVIG in the outpatient clinic, so he had to get his in the hospital. The patient was admitted --

MS. CONNERY: Ms. Luna? Ms. Luna?

MS. LUNA: -- and he did receive IVIG at 9:00 in the morning --

MS. CONNERY: Ms. Luna?

MS. LUNA: -- and he had a second shift come in, and they gave him another dose of the IVIG, and that really should've been spread out into two days. Anyway, it's just that the nurses there in the

hospital have no experience with IVIG, and he did --

MS. CONNERY: Ms. Luna, can you hear me?

MS. LUNA: -- get two days' (inaudible) in one day. These kind of things were very common, because the hospital setting is just not the best place for IVIG. These kinds of mistakes can cause a patient to go into kidney failure.

The other issue is the allocations. Due to the limitation of purchasing IVIG, pretty much we cannot take any patients that are (phonetic) in great need of it. It's just not there. Also, because of the delay in getting the IVIG from the distributor, it has caused the patients to have to be cancelled --

MS. CONNERY: Marcella, can you hear us?

MS. LUNA: -- for a couple of days, or even a week until we get the drug, and this can also compromise --

MS. CONNERY: Marcella?

MS. LUNA: -- the disease process in the patient. Some patients are having to be changed to a

different product, and this also increases the risk of an allergic reaction, so we try to keep the patient on the same product. Basically, our clinic --

MS. CONNERY: Marcella, can you hear us?

MS. LUNA: Hello?

MS. CONNERY: Hi, Ms. Luna?

MS. LUNA: Yes?

MS. CONNERY: I'm sorry, this is Jan Connery, the facilitator. We were having trouble reaching you, but you're well past the five minutes. I'm afraid -- I'm sorry to interrupt, but you'll need to wrap it up.

MS. LUNA: Okay. That's fine. Again, like I said, we just try to provide the best safe care for our clinic. And that's it.

MS. CONNERY: All right.

MS. LUNA: Thank you.

MS. CONNERY: Thank you so much. Thank you. A little technical difficulties there. Marcella?

OPERATOR: Yes, ma'am?

MS. CONNERY: You indicated there were some

people queued up to comment. How many -- or questions. How many do you have?

OPERATOR: I have five.

MS. CONNERY: Five? Okay. I would note that Congressman Foley is no longer with us. That is the period where we were taking questions. He left the room several minutes ago, so --

OPERATOR: All right. I understand that one of the questioners got disconnected after asking a first question and had a second question.

MS. CONNERY: Oh, well, yes, and unfortunately, I -- we had a limited time for questions, so I think not everyone who wanted to ask a question had that opportunity. We took as many as we could, so --

OPERATOR: All right. Thank you.

MS. CONNERY: Okay. All right. Our next commenter is in the room with us, Jenny Peckenpaugh. Okay. We -- somebody is live right now, Marcella. Could you make sure everyone's on mute except our room

here?

OPERATOR: Yes, one moment.

MS. CONNERY: Thank you.

OPERATOR: All right, that line has been muted.

MS. CONNERY: Okay, excellent. Thank you. And we are going to have our next commenter, Jenny Peckenpaugh.

MS. PECKENPAUGH: As much fun as this has been, I should not be here today. I should be out living my life. But mine is a life made possible by replacement gamma globulin, and today, it is a life lived in fear. To understand that fear, you have to understand what I went through beginning in 1998 at the age of 23.

I was the healthy kid growing up, sick once per year. But that fall, I became ill with a sinus infection requiring multiple courses of antibiotics. I did not recover until January. The infections became more frequent, lasting for months at a time,

and even when the doctor said they were gone, I still experienced terrible fatigue as if I were sick.

By 2002, the ENT was telling me "All we can do is keep you comfortable." I felt something was terribly wrong. I had sinus infections, not cancer. In another year, I was diagnosed with common variable immune deficiency and put on IVIG. It took five and a half years of sickness and (inaudible) for that to happen.

The summer before I began getting sick, I worked 60 hours a week, seven days a week, at two jobs. By the time I began IVIG in February of 2004, I was rarely able to work my scheduled 12 hours a week. I could not get through the day without a nap. The antibiotics I was on made me so sick to my stomach. I could only work in the evening, after taking the antibiotic early in the day, allowing it the full time to absorb, and then, taking several Imodiums to stop the horrible diarrhea.

I did not have the energy to walk across

campus to go to class, so I would park illegally and get tickets every day that I was healthy enough to attend. I suffered severe joint pain, like many CVID patients do, particularly in my right knee. I moved like a 70-year-old at the age of 25. My weight shot up.

Many nights, I could not sleep due to the pain. My life was on autopilot. I was so sick, it was as if I were gone. A zombie remained, trying to keep myself in school and marginally employed, because I felt that I would come back sometime and I would be upset if I had lost those things.

I registered for classes and dropped them when I became ill later in the semester, but I never knew that I was going to become ill. It was very unpredictable, except that it kept happening. While I was getting sicker, the University of Maryland's academic policies tightened. I could no longer withdraw from entire semesters, so when I did become ill, I ended up with incompletes or poor grades. This

has destroyed my prospects to attend law school, and I feel I would be a very good lawyer.

When I began IVIG in February of 2004, I thought I would be better right away, but today, I have not fully regained my health. Many patients have this experience, where it takes a year, two years, feeling perhaps worse than before they began IVIG, as their body uses the donated antibodies to fight infections it before ignored.

I know I'm not going to be healthy like I was before CVID, but my doctor indicates that I would be able to work 40 hours a week and live a normal life, as long as I receive immunoglobulin replacement. But in January 2006, my pharmacist had trouble obtaining any Gamunex for me. I need 45 grams per month.

He could not get it from his wholesaler or another branch of his company. He spent hours phoning, eventually forced to borrow from colleagues in other companies. His company switched to a

wholesaler that received a large amount of Gamunex sometime in February of this year. That was supposed to fix the problem.

I began to participate actively in Immune Deficiency Foundation forums online, discovering others were also having difficulty getting different brands of IVIG. Different states, different doctors, different locations of care, different brands of IVIG. I decided to get to the bottom of the situation.

My doctor told me there was a shortage and a priority allocation system, and hospitals were looking to (inaudible) doctors' offices. When I talked to the manufacturer of the drug, the representative told me that was not true, but that in January of this year, because of increased demand for IVIG, they reallocated supply and cut some wholesalers' amounts in order that everyone could get some.

Since switching wholesalers, my pharmacy still has had problems getting my Gamunex. This

month, it was late. Patients are panicking. I've heard rumors that people are unable to get IVIG because desperate people pay cash to use it for off-label devious purposes. I don't like dealing with rumors. This is my life. I want facts.

But we don't know what percent of IVIG is being diverted because there's no tracking of where it goes by diagnosis. When I researched more, I found disturbing testimony about -- from the last shortage of IVIG.

Let me be clear. I believe there is a shortage. If I can't get my IVIG, my insurance paying a high price for it, and hospitals are putting patients on waiting lists, so every month, they're unsure if they're going to get their IVIG on time, logic is telling me there is some kind of shortage.

On August 14, 1998, Miriam O'Day of IDF testified at a CDER stakeholders' meeting. It was surprising to us and others the difficulty FDA had in determining distribution and supply in the

marketplace.

In that same year, the Advisory Committee on Blood Safety and Availability recommended HHS explore 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. I do not see that HHS has done that.

On August 23, 1999, a memo from Miriam O'Day of IDF states: "Prioritization protocols and distribution strategies have not been 100% successful."

MS. CONNERY: Jenny, you've got about 15 seconds.

MS. PECKENPAUGH: The result for patients is the same as it is during a shortage, whether there's a shortage today or not: less dosage, switching brands, going too long between treatments. Patient health ultimately suffers. The system is broken. We cannot

rely on manufacturers such as the manufacturer of (inaudible) and the manufacturer of Gamunex, to register patients in order that they can get it.

Every time I've switched location of care or insurance companies, I've had a delay and I've become sick because of that. I am now afraid, even though I would save approximately $400.00 a month, to transfer insurances, because I'm afraid I won't get my treatment. That's a lot of money to pay just because we can't think of a better way to do things.

MS. CONNERY: Thank you very much for your comment, Jenny. Our next commenter is Joanne LaDouceur, and she is joining us by phone, and the spelling is L-A-D-O-U-C-E-U-R.

OPERATOR: Thank you. I'm looking for her, ma'am.

MS. CONNERY: Okay.

OPERATOR: If Ms. LaDouceur is on line with another party, please press star-zero, we will open your line, if you are on line with another party.

MS. CONNERY: I'm anticipating that perhaps she isn't on the line. Our next commenter after her would be Jonathan Katz, so we'll just wait a moment and see whether anyone joins on the phone.

OPERATOR: There is no response, ma'am.

MS. CONNERY: Okay. Very good. We'll move on to Jonathan Katz, then, Commentor No. 30.

DR. KATZ: Hi. I'm a physician in neurology from San Francisco, California. I'm affiliated with (inaudible) Health Care Systems, where I run a large neuropathy clinic. I was previously an Associate Professor at Stanford.

I also am a member of the Guillain-Barre Foundation International, which is one of the largest patient support groups for individuals with immune responsive neuropathies. I also work with Crescent Healthcare. You heard Mike Rigas talk a few minutes ago.

I've also authored the criteria for IVIG used in neuropathy in the State of California for

Medicare. I'm a published author on the use of IVIG in neuropathy in several peer review journals, and I'm a member of the CID (phonetic) validation study group, which is a large group -- a group of 13 worldwide physicians that are trying to better understand the diagnosis and use of IVIG treatment in neuropathy.

OPERATOR: Excuse me, sir. This is the operator. If you could, speak up just a little bit, please.

DR. KATZ: Okay. Is that better?

OPERATOR: Yes, thank you.

DR. KATZ: I'll start off by agreeing with everybody here that through my experience in my clinic, there is a gigantic problem right now with access to IVIG.

The reasons for this have been elucidated by many speakers before me, including inadequate payments to MDs and infusion clinics, difficulty admitting patients to hospitals who don't find profit incentives and have a hard time admitting patients with chronic

diseases, a lack of FDA approval for many of the treatments that we want to use neuropathy [sic] for. It's a good excuse to push back against therapy. Payment delays and payment risks.

You've heard all about this as the day's gone on. But I wanted to say that within the segment of our clinic, it's a gigantic difficulty finding time for these patients, answering their phone calls, and explaining to them that even though they have weak limbs, weak arms, numbness, whatever, we can't treat them. There's nothing we can do right now. And it's a real issue.

I think it's worth reflecting, though, for a second, how we got here in the first place. We've heard a lot of advocacy so far today, but there's questions that I've seen in my experience in the last four or five years of working in IVIG that need to be looked at carefully before a pendulum swings back in the other direction and we begin to ask the same questions all over again about the reimbursement.

For one, within the field of neurology and in the field of neuropathy, the high cost of IVIG is truly an issue for Medicare, and there's always going to be pushback. There's reasons for it. One is we've seen issues regarding the fairness of physicians profiting from the idea of (inaudible) medicine, as opposed to hands-on therapies, like surgeries or whatnot.

In my experience, it's hard to find support, even from physician groups, for this sort of treatment because the doctors who make money in hands-on care don't see it as fair for other doctors to be making money in infusion, and for that matter, for anybody else to. That needs to be considered.

There's an issue of what I call diagnosis drift, and I think people have the tendency to underestimate the complexity of a diagnosis in the area of neuropathy. What I mean by the complexity is we don't really know, like you would expect with a case of cancer, who has peripheral neuropathy that's

treatable.

We're taking a guess a lot of the time. We're relying on pattern recognitions. We're relying on people who have an extreme amount of expertise in this area to tell us who's going to respond to therapy. We also don't know things like what represents a therapeutic response? Is a little improvement in numbness a therapeutic response, or a slight improvement in weakness of a limb a therapeutic response, or do we need complete recovery?

What matters is a big question, and we don't have answers to these questions. What that'll ask (phonetic), to a degree, is for physicians who run infusion centers to create a conflict of interest where you can say anybody's responding to therapy and you could say anybody has an immune treatable neuropathy. When you have to infuse these patients once a month, it's a burden to the patient, but for a clinic with the wrong approach, this could be seen as a conflict of interest.

Another thing that's happened that's caused some pushback in the recent years is growth. These diseases didn't really exist before 1995, I mean, immune treatable neuropathies, and the idea of treating with IVIG.

What happened was gradually, we became accustomed to patients actually responding to therapy. With that response to therapy, we became more and more interested in treating more patients, and we were more willing to treat patients who just might have the disease than just treat patients who have to have the disease. So with that, there was an actual tendency for the amount of patients who were (inaudible) to grow.

Then there's finally this issue of criteria. Who's going to draw up the criteria? Is it going to be people with an interest in these diseases, or is it going to be among doctors who may not have any interest in profiting from infusions? So who are we going to listen to is an important question.

So those are just some MD oriented issues that I could think of that explains to us how we got here in the first place that need to be dealt with as we go forward. Now, with that being said, I do think the pendulum from 1999, 2000, 2001, where there was big issues with the cost of these medicines, has now swung too far back in the other direction, and the reimbursement issue is enormous.

So a short-term approach to solving this is simply to fix the reimbursement issue, which will at least open up the door to these patients again. The long-term issues are very important to think about also, so we don't go back to square one.

We have to think about how payers are going to become involved, not just in paying for these treatments, but in helping physicians understand these disorders, getting us access to data, so over time, we can better understand which patients respond to therapy, and which of these clinical patterns are meaningful, and which patients should be treated.

Thank you.

MS. CONNERY: Thank you very much, and if you did have more that you didn't get to, please let us -- hand that into us in writing. Just send it after the meeting.

Our next commenter is Elaine Hill, and Elaine is joining us by phone, I believe?

OPERATOR: Checking. One moment.

MS. CONNERY: She's Commentor No. 31.

OPERATOR: Elaine Hill, I've opened your line. You may make your comments.

MS. HILL: Thank you. (inaudible) Elaine Hill, and I'm a patient.

MS. CONNERY: Elaine, can you get a little closer to your phone, or speak just a little -- speak up a little bit for us?

MS. HILL: Well, I'm trying, but ironically, right now, I have laryngitis from a throat infection.

MS. CONNERY: Oh. Okay, well, we can hear you.

MS. HILL: I'm a patient diagnosed with common variable immune deficiency, and I wanted to comment, first of all, that Ms. Peckenpaugh's life, physically (phonetic), that she indicated, sounds a lot like mine. I have been receiving gamma globulins for 10 years. My treatment has (inaudibly) surely as any patient sees, dialysis, (inaudible) hernia, or (inaudible) treatment.

I am a daughter, a mother, and grandmother. I was diagnosed when living in Miami and working as Assistant State Attorney; in other words, a prosecutor. With treatment, I was able to work as a prosecutor for an additional seven years. However, after I was diagnosed, it took four months to get approval through the insurance company before I could begin my treatment.

Before (inaudible) childhood, I had numerous upper respiratory infections, pneumonia, (inaudible), a tonsillectomy, two sinus surgeries, gallbladder surgery, diverticulitis, and finally, typhlitis, and

that is an extremely rare bacterial infection. It was this rare infection that led to my diagnosis finally, at the age of 47. I held my job and worked through all of this, and I haven't even mentioned the fatigue that goes along with the (inaudible) and the numerous infections.

Because I was sick so often, I missed a lot of work, and paid. The cost of the treatments and (inaudible). Yet I want to live. (Inaudible) to live. And even though I had never smoked, I had prominent lung disease with fibrosis, a paralyzed left diaphragm, a partially collapsed lung, and bronchiectasis.

I had gastrointestinal diseases, which include the (inaudible) diverticulitis, gastritis, and irritable bowel syndrome. (Inaudible) diagnosed for so long. Yes, I still want to live. (Inaudible) I'm more susceptible to infection, and even with the treatment, I have been hospitalized with pneumonia at least once a year for the last five years.

Yet, I struggle and I want to live. Please keep treatment and product options available. I'm now a diabetic also, so specific products are needed. I need to have that product (inaudible). I am on (inaudible) and I'm dependent upon Medicare to help pay for my health care.

My life is literally in your hands. My children want their mother to live and be around, and my grandchildren love their grandma and they need me. My father loves me and he needs me. Please recognize that you hold all of this in your hands. I want to continue to live.

(Inaudible) If I offered you a million dollars to trade places with me -- give me your health and you take mine -- would you take that, or would it take $10 million or $1 billion or $10 billion?

And then ask yourselves, what would it take to give up your life entirely? These lives are worth it. We are productive in a large part, even when we're disabled. We do (inaudible). My previous

employer was there twice a month and worked as a prosecutor. I loved it. I loved when he worked, and I wish I could do it still. I cried so hard when I had to give that up.

In the mid-1990s, when I was -- or the last 1990s, when I was just starting on IVIG, we had a shortage in Southern Florida at that time, and it was because so much was shipped out of the United States to (inaudible) other countries. We need to keep that here at home.

As indicated, these are American people giving their blood to treat Americans, and Americans need it. If we don't need it, fine. Let's give it to other people. But you have a very needy group (inaudible) that can stand several (inaudible) in all legislative areas. Please help (inaudible).

MS. CONNERY: Okay. Thank you very much, Elaine. It is just about 2:30 Eastern Time right now, and that's the time for a mid-afternoon break here, so we are going to take it. That'll be a 15-minute

break, so let's start up again right at 2:45. The next commenter that I have lined up is Patricia McHugh, who will be joining us by phone, so we'll go to her then.

(Off the record at 2:24 p.m.)

(On the record at 2:45 p.m.)

MS. CONNERY: Marcella?

OPERATOR: Yes?

MS. CONNERY: The next commenter will be joining by phone, so you could get that line open as people take their seats. It's Patricia McHugh, M-C-H-U-G-H.

OPERATOR: (inaudible) right now.

MS. CONNERY: Okay, thank you.

OPERATOR: You're welcome.

MS. CONNERY: We'll just take a moment as everyone is taking their seats, and our next commenter is ready to join us by phone. Folks who are in the halls, I'm just going to close the doors over here. I'm sure we've got everybody's attention now. Would

you like to begin?

MS. MCHUGH: Certainly. I'm Patricia McHugh, a Medicare patient requiring IVIG treatment for chronic inflammatory demyelinated polyneuropathy, an autoimmune disease which attacks the peripheral nervous system, causes numbness in the feet and legs, and difficulty walking, fatigue, muscle weakness, and balance problems. Left untreated, severe disability and permanent nerve damage can occur.

In the two-year period prior to my diagnosis in January 2004, I had gone from being able to lift a 25-pound television set and carry it from one room to another to having difficulty lifting a jar of peanut butter.

Because of the severity of my symptoms, I was started on a monthly IVIG treatment within a week of diagnosis. These treatments were given at the neurologist's office. A pattern emerged such that in January, the day of the treatment, I began to experience improvement in my condition. As I

approached the next treatment, I began to feel worsening symptoms.

With each successive treatment, improvement was greater, the worsening less. By September (phonetic) 2004, after 11 treatments, while it's not (inaudible) it was markedly improved, and while I couldn't lit a 25-pound TV, I could lift a bag of groceries.

Then, in January of 2005, I began to experience difficulty getting my treatments because of Medicare reimbursement issues. My January treatment was delayed two weeks and after my February treatment, my treatment was (inaudible).

Another provider could not locate it until late June, 2005. Again, my condition had worsened considerably.

(Inaudible) the local hospital, which gave me the IVIG as an outpatient. However, that hospital could not always get the IVIG, so I had to wait eight weeks for my next treatment and then another six weeks

for a treatment that consisted of only half my required dose. My condition worsened.

In September 2005, (inaudible) and my current provider, the clinic that has just opened 20 miles from my home, and I have been receiving my treatments on schedule and have made considerable process.

I can't adequately express the gratitude I feel that I can still receive my IVIG on a consistent basis, but because I am well aware that there are still availability and reimbursement issues, I carry a fear that at any moment, my current provider will decide they can no longer afford to treat Medicare patients. If they stop my treatments, there are no other (inaudible) available to me.

I've learned that without consistent IVIG treatment, my future is bleak, because without consistent treatment, my condition (inaudible) treatments (inaudible), btu not stop, and I don't want to find out what happens if my treatments could stop

permanently.

I've also learned another emotion strikes me here, and that's that I find (inaudible) doesn't seem to care what happens to me or other IVIG patients. Here's one example. In the Spring of 2005, I repeatedly made calls to Medicare's 1-800 number, trying to let somebody know the urgency of the situation.

Each time, the person taking my call told me to change my doctor or contact my Congressional representative. And further no, there was no person (inaudible) at Medicare I could speak to about the issue.

Then I read, in an article dated July 19, 2005, that Herb Kuhn of Medicare was quoted saying "We're not seeing prices that others have referred to." Imagine my frustration with the system and the wall that exists between it and patients (inaudible) and extremely vulnerable. There are certainly people who do care, my neurologist, my IVIG provider, and my

Congressman (inaudible), but the system seems to be such that (inaudible) in a timely fashion (inaudible) required.

I realize the IVIG issues are very complex, and that there is no simple long-term solution, but for IVIG patients, the short-term solution must expand to allow us to receive IVIG and to receive it on the schedule prescribed by our physicians. This short-term solution is needed quickly, because, as I found out, (inaudible) time is not time for IVIG patients who are not receiving their IVIG.

I thank you for your work and for (inaudible) this opportunity to say my piece. Thank you.

MS. CONNERY: Thank you very much, Patricia. We can hear you clearly here and we can hear how difficult it's been for you. Thank you for sharing your experience with us.

The next commenter is also on the phone, and that is Steve Bailey, B-A-I-L-E-Y.

OPERATOR: One moment, please. I'm sorry, I'm not finding him. Let me check one more time. If Mr. Bailey is on line with another person, please press star-zero. At this time, I am not seeing his name.

MS. CONNERY: Okay. While we wait to see if anyone will press star-zero, the commenter who would be after him and may, in fact, be our next commenter, is in the room with us, we hope, Ann Walton. Ann is here, wearing a beautiful purple shirt. Okay. Well, we're not hearing anything, Marcella, from --

OPERATOR: That's correct.

MS. CONNERY: Okay. Then let's move on to Ann, and Ann is Commenter No. 36.

MS. WALTON: Can you hear me?

MS. CONNERY: We can. You'll just need to stay as close as you can to the mike.

MS. WALTON: Okay. My name is Ann Walton, and I appreciate this opportunity to speak on behalf of the Immune Deficiency Foundation. I became

completely disabled before my disease had been diagnosed, so I'm eligible for Medicare benefits for IVIG. My treatment is covered by my husband's insurance at his job presently, until he retires, and after that, I will be at the mercy of Medicare. His retirement is looming.

I lost most of my adult life to this disease. Even though I've always had health insurance and I've always been under the care of a physician, I was bedfast and housebound for years at a time, so sick with infections on a daily basis that I could not even walk to my own mailbox.

IVIG treatment is so effective that in 16 months of treatment, I am now completely recovered from total disability. I am now able to work a full-time job. Until I'm overtaken by old age, I will probably remain well, as long as my IVIG treatment is not interrupted or terminated.

Because I am able to exercise, I am now -- my incipient osteoporosis has reversed, and my bones

have normal strength. I no longer suffer from angina from ischemic heart disease, that my cardiologist said had been caused by deposition of infected cells on my capillary walls.

So I am building a life for myself for the very first time, starting at age 59. Yet without a fully functional immune system of my own, I fall ill again with infections whenever my infusions are delayed, even by a few days. Without IVIG, I'll be back in bed.

I cannot support myself on part-time work at entry-level wages. I need to know now that IVIG will be available after I go on Medicare without interruptions for bureaucratic and administrative reasons. Legal protections for disabled workers will not apply to me until and unless I can demonstrate to an employer that I am able to successfully perform the job, including meeting attendance requirements for whatever probationary period my employer specifies.

I cannot give myself subcutaneous IG

infusions at home because of my dosage and treatment intervals, so I need to receive infusions at night and on weekends, but I can't get them on Medicare. No IVIG infusion service providers in my area work on nights and weekends, except for the home infusion services, and they don't take Medicare patients.

So unless something happens to solve the access problems for IVIG on Medicare, my last chance to earn my own living will come to an abrupt halt as soon as Medicare rules my treatment.

As you have heard, Medicare doesn't pay for the nursing services necessary to make home infusions a reality for Medicare patients unless they are homebound by Medicare's definition, even though this is the least costly type of IV infusion to receive, and the safest in terms of exposure to infection.

Since I'm now able to work full-time, I'm not homebound by any definition, but I will be when I can't get treatment as a Medicare beneficiary and then, I will be homebound, and then I'll be eligible

for Medicare home health nursing. And then, I would recover again, as soon as I get back on IVIG treatment, but at that time, the untreated disease and consequent illness will have destroyed my employability again, and it will be too late for me to start over with a new career.

Having been sidelined my entire life from the working world, I am heartbroken that I am finally well, but I am still unable to count on living a full and complete life because of contradictions in government policies and rules. Medicare agrees IVIG is a covered service and medically necessary.

When taxpayers provide a treatment that restores disabled patients enough to work, Medicare should create conditions for the formerly disabled to return to employment and contribute to the cost of their care. Thank you for listening to my story.

MS. CONNERY: Thank you very much, Ann, for telling us your story. Our next commenter is Imogene Moore, and she, we hope, is on the phone, and that's

spelled M-O-O-R-E.

OPERATOR: Thank you. Ms. Moore, your line is open. You may make your comment.

MS. MOORE: Thank you. My name is Imogene Moore. I live in Gibsonia, Pennsylvania. I am an 84-year-old female and I have chronic inflammatory demyelinated polyperipheralneuropathy. It has slowly progressed above the knees. I need to use a walker or a cane when outside of our home.

The first diagnosis by Dr. Steven Semanski (phonetic) and Mayo Brothers (phonetic) was in 2001. I was fortunate to be in an area where my doctors made a quick diagnosis. My first infusion was done with one of the cheaper gamma globulins. The first day, it resulted in hives. Dr. Semanski (phonetic) switched to Gamunex, and these infusions have caused no problems physically.

There was such a dramatic change in my strength and overall improvement that I felt that the doctor had found the right answer. Gamunex put the

(inaudible) on hold for three weeks and three days, and severe pain occurs less often.

Then, a human element entered the picture. Medicare informed me that they would not reimburse for the treatment, using the reason that my disease (phonetic) did not cure. That meant that my secondary insurance was not put in, either. My response to them was Medicare pays for diabetes, AIDS, and cancer, none of which have a cure, and (inaudible) numbers, we hurt also.

With a cost of over $1,500.00 every three to four weeks, I resigned myself to whatever nature handed out, because with an upper middle class retirement income and a declining stock market, I couldn't leave my husband with the eventual outcome. Medicare slowly relented, but during that time, the CIDP moved up from the ankles to the knees.

There are constant billing problems. Reimbursement is so low and the price so high, my doctor could no longer afford to have it done in his

office. I was passed to a hospital medical unit as an inpatient. There have been three occasions when the pharmacy there had tried to switch to a cheaper form, to which I had allergic reactions. Fortunately, either the nurse or I have caught it. I do have a fear that it will be mislabeled at some time.

Once, I had to sit in the medical unit several hours while a messenger service brought the syrup (phonetic) from a warehouse elsewhere in Pittsburgh, and I had given her (inaudible) it would be needed.

There have been times when the product is not available in Pittsburgh at all, and the delays have been as long as two weeks. During those times, the CIDP has progressed farther up the legs, and I have less strength and I tend to (inaudible) from one side to the other when I walk.

Constant pain uses a lot of strength. To me, and to those around me, it seems unfair that I should have to live with the idea that perhaps the

IVIG will not be available the next time. For me, as a patient, I feel that my doctor's office had put together a great team for scheduling, financing, and administering these drugs, and that seems to be a better way to go.

Since the use of IVIG, I am much stronger and my husband and I are able to live independently. We prepare our food, do our laundry, and drive ourselves for errands, and enjoy our family. This is a big savings for United States citizens.

Thank you for listening.

MS. CONNERY: Thank you very much, Imogene. Our next commenter is also joining by phone. Her name is Adele Kirkpatrick, K-I-R-K-P-A-T-R-I-C-K, and she is Commenter No. 38.

OPERATOR: One moment.

MS. KIRKPATRICK: Hello?

OPERATOR: Ms. Kirkpatrick, your line is open.

MS. KIRKPATRICK: Thank you. I'm speaking

today on behalf of the primary immune deficiency community and at the invitation of IDF. I have common variable hypergammaglobulin anemia, which was diagnosed late in 1990, after having been ill for well over a year from infections that triggered severe asthma.

I was barely functional. Today, I lead a functional life only with IVs. IVs were started in March 1991, 15 years ago. I had IVs in Dr. (Inaudible) office or at home until January 31, 1999, when I turned 65. We generally used Gammagard SD, 40 grams, five grams an hour for eight hours. Shorter time (inaudible) headaches for 24 hours, and other brands caused bad side effects and allergies. IVs are preceded with premeds of Tylenol, Benadryl, fenaden (phonetic), and solucortez (phonetic) to curb side effects.

My husband's blind, so I have to drive myself down to the location, then take premeds, whcih preclude driving until they've worn off. In '97, I

tried to get off of the IVs and skipped three IVs and caught an infection that -- complicated by asthma and lasted four months.

Under Medicare, since August 1999 through March 2005, I had IVs at my doctor's office (inaudible) if something was available. I always had bad side effects with everything except Gammagard. IVs for Medicare patients in doctors' offices stopped March the 31st. April 2005, local hospitals didn't use Gammagard, so I (inaudible) in Medical Center, 25 miles from home via I-95 under construction.

The center's protocol was to infuse at 10 grams an hour for four hours, no exceptions. The first IV was on April 27th. The nurse treated me very badly. I'll skip most of the details, though so she did tell me to put (inaudible) on my left arm myself and (inaudible) after blood was drawn, because I can't use adhesive tape or paper tape, and she placed a person with staph within three feet of my chair.

Premeds made it difficult to focus my eyes

when en route home, so I had many near accidents. I returned two more times, but stopped due to the close accidents.

July and August 2005, I had no access to Gammagard. September 2005 through January 2006, I had it at Palm Beach Gardens Medical Center, 11 miles from home, when they used Gammagard SD as a backup.

After January the 31st, they only ordered (inaudible), to which I've had severe reactions of confusion and headaches for three days. February and March 2006, no source for Gammagard. April 2006, Walgreens Home Care say they could provide it at home. April through July, home care with Gammagard liquid, and it was possible on the liquid to stop premeds, except for solucortez (phonetic). Infusion time was reduced to six hours, and no side effects at all.

August of 2006, Walgreens was told that I did not qualify for home care, as I was ambulatory. They provided interim home care in August. September, Walgreens provided Gammagard liquid to the doctor's

office where I received an IV. Walgreens submitted a bill for Gammagard to Medicare Part B and this was rejected. They were going to submit it to my Part D provider, Signature RX, which has Gammagard on its formulary. If this didn't work, I was to pay for the Gammagard myself. On October the 3rd, next week, I will receive another Gammagard IV in the doctor's office, but it will be the SD, so I have to take premeds. Medicare hasn't paid for my Gammagard since April the 27th. Thus, after October the 3rd, I'll be personally liable for $24,000.00, assuming it costs $75.00 a gram, and I really can't afford it.

The consequences of missing the IVs or irregular -- when they're irregular or missed (inaudible) three months, I catch infections going around, have difficulty getting well without strong antibiotics that don't contain penicillin. These illnesses last one to four months, depending upon the numbers of IVs missed.

I thank you for the opportunity to relate the problems I've encountered in recent years, and I do think it's a crime that Medicare pays an average of two and a half million dollars for terminally ill patients to spend their last two weeks of life in a hospital ICU, but can't pay for treatment that enables people to lead functional lives. And that two and a half million dollar quote is from the newspaper. Thank you very much.

MS. CONNERY: Thank you. Thank you, Ms. Kirkpatrick. Our next commenter is in the room with us. It's Natasha Pires.

MS. PIRES: Good afternoon. My name is Natasha Pires and I am here today to represent and speak on behalf of the Neuropathy Association. The Neuropathy Association is a public, charitable, nonprofit organization that was established in 1995 by people with neuropathy and their families and friends to help those who suffer from disorders that affect the peripheral nerves.

It is estimated that in the United States alone, neuropathy sufferers number upwards of 20 million. Neuropathy challenges patients, not only with the pain they experience, but also, with the lack of appropriate treatments for its different variations.

However, except for one specific class of neuropathies, autoimmune neuropathy. IVIG products have made a significant difference. Controlled clinical trials have demonstrated that IVIG is an effective treatment for autoimmune neuropathy which, as a class, includes chronic inflammatory demyleinating polyneuropathy and Guillain-Barre Syndrome.

Autoimmune neuropathy is a debilitating condition that can leave people unable to work or care for themselves. To some patients, IVIG is the only effective treatment. Without it, the neuropathy progresses, leaving patients unable to walk, unable to function, and often paralyzed.

Alternative therapies like steroids and chemotherapeutics work for some patients, but not without severe side effects, side effects like diabetes, hypertension, osteoporosis, bone fractures, or life-threatening infections, to name a few.

The inadequacy of the current Medicare reimbursement rates have made it impossible for patients to obtain IVIG treatment outside of hospitals, which are not always able to provide treatments. This has resulted in our members suffering adverse health effects because of increased time intervals between infusions, switched brands of IVIG, and/or decreased dosage per infusion.

If access inadequacies continue, some of our patients may be confronted with returning to the alternative therapies at greater cost to their health and ultimately, to the health care system.

The reimbursements provided to health care providers of IVIG often do not cover the cost of acquiring this critical medication. In addition, when

addressing the costs involved, one must also consider the hidden and unaccounted for costs. They include the administration, maintenance, and inventory and billing, to name a few.

Switching to a hospital setting for treatment has also been a (inaudible) Medicare. Hospital outpatient clinics add a substantial facility charge that is not added in the office setting, and sometimes, patients have to be admitted for treatment. This greatly increases the overall fee. One of our members recently brought in a hospital bill for $17,000.00 for treatment that would have cost no more than $4,000.00 in the office setting.

IVIG is a life-saving therapy with no better substitute. Patients who rely on IVIG need to have access to all types of IVIG and all care sites restored. This will reduce the burden in the hospitals, improve the quality of care systemwide, and decrease the potential for morbidity and mortality associated with delays in treatment with IVIG, or the

lack of treatment altogether.

Inadequate reimbursements have resulted in shifting costs to hospitals and consequently, to the patients and taxpayers.

Thank you for allowing me to speak on behalf of the patients we represent, and to voice the Neuropathy Association's concerns about what we see as a looming crisis.

MS. CONNERY: Thank you, Natasha. Our next commenter is on the phone, and that is Iman Tanzey, T-A-N-Z-E-Y.

OPERATOR: Ma'am, is the first letter T as in Thomas?

MS. CONNERY: T as in Thomas, yes.

OPERATOR: Thank you.

MS. CONNERY: He is Commenter No. 41.

OPERATOR: I do not believe he has joined.

MS. CONNERY: Okay. Do you want to ask if he's joined with another party?

OPERATOR: Certainly. Again, if Mr. Tanzey

is on line with another participant, you can press star-zero and indicate what line you're on. We will be able to open the line for you.

MS. CONNERY: While we're seeing if anything comes through that way, let's -- the next commenter after that, we're going to skip over Commenter 42 because he let us know that he wouldn't be commenting, and go to 43, which -- who also, we hope is on line, and her name is Susan Pentlin, P-E-N-T-L-I-N.

OPERATOR: There's no response from Mr. Tanzey, but we do have Susan Pentlin on line.

MS. CONNERY: Okay. Let's go ahead, then.

OPERATOR: Ms. Pentlin, you may make your comments.

MS. PENTLIN: Thank you. I'm registered with the Immune Deficiency Foundation as a patient with common variable immunodeficiency. I'm an ameritus professor in Warrensburg, Missouri. I have my PhD from the University of Kansas and I'm a patient in the University of Kansas Medical Center in Kansas

City, Kansas.

As a child, I had unusual skin infections and in college, I began to have frequent sinus (phonetic) infections and bronchitis, which hung on for months. In 1976, my health worsened after I had a reaction to a wasp sting. In 1978, I found Dr. Daniel (inaudible), Director of Neurology, Arthritis, and Immunology at the Med Center (inaudible). He understood that I had primary immune deficiency, and in 1986, I began gamma globulin treatment.

Dr. (Inaudible) caring and (inaudible). He has given me excellent care for 28 years, and the nursing staff indicated that they were (inaudible) and have provided high-quality care.

IVIG has made a tremendous impact on my health. For the past 20 years, I've gone to the Med Center every two or three weeks to get an infusion. It has been a lifesaver to me several times, once when I had a ruptured tubal ovarian abscess, another time, pneumonia, and another, osteomyelitis. Whatever

infections I had began to improve almost immediately after an infusion.

Everything began to change in January 2006. Medicare patients getting IVIG were required to be admitted to the hospital. The brands they got there were different and several had reactions. It sometimes took up to nine hours instead of three to get treatment. I am not on Medicare and my private insurance policy approved my IVIG for 2006, so I thought I was okay.

I had always believed that at the medical center, my health was their concern, that they would care for me when I needed help. At the end of April, I learned that those assumptions were not wise ones. The internal medicine clinic cancelled my next infusion with no forewarning, and the individual patients received unsigned letters saying they would no longer provide IVIG therapy after May 1. You could make appointments at the cancer center or the hospital, where they are still scheduled (inaudible).

Dr. (Inaudible) did not know about the changes any sooner than I did. When patients called the cancer (inaudible). In fact, the center did not begin to process any necessary papers for my insurance until the day I was originally scheduled for my next treatment. I asked if I could get IVIG in the hospital, but that was no longer possible.

This was the first time in 20 years I had gone over one or two days late to get my infusion, except once, when there was a shortage in products a few years ago. That time, my infusion was delayed a week, and I ended up hospitalized with pneumonia.

I did not get an appointment in the cancer center for 10 days past the due date for my infusion. I'm still trying to recover from colitis, skin infection, (inaudible) joint inflamation, which flared (inaudible), and only now, after four months, am I able -- am I almost back to where I was (inaudible).

When I contracted administrators at K.U. Med Center about the transfer to the cancer, they told me

this was necessary because of Medicare reimbursements. They considered stopping treatments altogether, so I should be happy about being transferred to the cancer center.

Insurance companies that follow Medicare (inaudible) were not paying even the actual cost of gamma globulin, and my insurance company was no longer paying what they had to pay. A year ago, I (inaudible) they no longer give it, because of Medicare changes. I know the immune deficient patients in Kansas City (inaudible) diagnosed cannot find any (inaudible) gamma globulin.

Recently, this cancer center stopped giving gamma globulin to immune patients whose insurance requires them to purchase (inaudible) the hospital. The cancer center is not a good place for immune patients to be.

We are exposed to seriously ill patients. The nurses are not accustomed to the protocols from (inaudible) or we can make appointments (inaudible)

physical. This is really hard for me in a cancer setting, because my sister died at age 38 from cancer.

Now, (inaudible) my cancer. When I go for treatment, everyone assumes I have cancer. I'm concerned that there's a lack of quality control and consistency of care which affects most primary immune deficient patients at (inaudible). Dr. (Inaudible) comes to see me at the cancer center, but my charts are not usually available. Home health is an option, but I fear I would not be permitted to return to the medical care center for treatment should the reimbursement issue resolve or the home health care companies stop giving IVIG.

I'm aware of the (inaudible), but I have a history of skin reactions and infections, and the rate of skin infections is over 30%.

MS. CONNERY: Ms. Pentlin, you have about 15 seconds.

MS. PENTLIN: Okay. I was at the medical center yesterday. When I arrived, the cancer center

told me there's a shortage of gamma globulin, and I could only get half my dose. The primary immune deficient population in the United States is estimated at about 50,000 people.

We are so (inaudible) number (inaudible) by their government for a situation. A democracy's only as strong, because it takes time and resources, until we have those (inaudible). I believe that (inaudible).

MS. CONNERY: Thank you very much for your comment. I'll just note that we heard Commenter No. 45 won't be joining us, and also, that we actually have an additional four people on the list. They were signed up after we went to press with the list, so there are actually 60 people here on my list, four more than you probably have on yours, and we will be getting to them today, as well.

We'll move on to our next commenter, and she should be in the room with us. Melinda Haffron?

MS. HAFFRON: I want to thank all of you for

the opportunity to come and talk with you now. I want to just point out that patients diagnosed with immunodeficiency diseases require the regular infusions. It's not a treatment that's supplemental or extra. It is required and it is for life. For life, both for long-term and for daily living.

I want to tell you that I've been on both sides of this issue. I'm the parent of a patient with immunodeficiency disease. She's got chronic variable immunodeficiency. And I work for an immunologist who treats primary immunodeficiency and secondary immunodeficiency.

I want to talk about both sides, since I've been on that aspect. As a patient, when you find -- well, as you see your child sicker and sicker and sicker and you go from specialist to specialist to specialist with no answer, and you just see them declining, we need to finally find that physician who goes, "Have you been tested for immunodeficiency?"

That had never come up before. Immediately,

it was very obvious what it was. Began to receive treatment. It took -- in his practice, we are able to use all the different products. It took trial and error of about five different products before we found the one that worked for her, but the results were amazing.

She went from missing 40 days of school a year to being a normal child on the playground. Her life changed. But that, in itself, was not the biggest battle. The biggest battle that I want to talk about, for both myself and the physician I work for, is the reimbursement and the managed care. I work for a physician in Denver, Dr. Isaac Melmed (phonetic), and his primary focus is immunodeficiency, primary and secondary. I have seen the battles on his part and our part before managed care.

When you first get the diagnosis of needing IVIG because you have primary immunodeficiency, it takes months to go through the process.

When you finally are approved, you get the

pre-auth, and then get the treatment, and then the doctors have to submit efficacy paperwork -- "Oh, they lost this, they lost that," and then you realize that it's taken the insurance company up to six months to cover one treatment when sometimes, patients that we work with can require bi-weekly, three-weekly -- or every three weeks, every month, and you have -- that physician has to cover and carry that cost while you're waiting for reimbursement.

With the Medicaid changes, the reduction in reimbursement level, we're barely breaking even, and then these patients are not able to get the product that they need.

The other issue we have is sometimes like for my daughter during the beginning of the school year in the fall, she gets sick more often, she needs increased dosage. You increase the dosage, she carries through, we don't need hospitalization, we don't need IV antibiotics. But to get that covered, they -- I think it's almost easier to go to a hospital

to get that IV treatment because you then could get your IVIG.

One time, the switch between -- we've always had private insurance. We had to switch because of my husband's employment change. He had a new policy. We had to wait three months because of a preexisting condition. She missed four treatments before we could actually get her covered, which she ended up in the hospital for.

There needs to be some way to get these patients with these preexisting conditions that are life-threatening, even though when you see her, you would not recognize that she has anything wrong. But without these treatments, her life is at risk.

Then from the clinic perspective, I'd like to talk briefly on that. Managed care's lack of knowledge on treating primary immunodeficiency is tremendous. They don't understand the replacement, the need, you need to change doses, the cost reimbursement, all of that. Product differences.

Luckily, we've been able to keep that change and keep up with it a little bit, but our reimbursement levels were really, really struggling at this point.

The other thing is the extensive paperwork for every infusion that we have to do. We have to employ two people to deal with the paperwork, to get the coverage, and to make sure that we have the number of patients and the product that we need per month. And then when we have new patients, to get your allocation to start covering those is nearly impossible. Somebody -- it's give and take all of the time.

And then the being compared as a physician, real quick, an immunologist who was trained in allergy versus immunodeficiency, I don't think they make that designation. These physicians are constantly being hassled and harassed about "You're high cost." They were told to lower IVIG usage. How can we do that? That's the only way to treat these patients.

So I guess I want to thank you for being

able to express the issues, the reimbursement issues, Medicaid, all of that. (Inaudible) Thank you.

MS. CONNERY: Thank you for those perspectives. Our next commenter is Robert Sugerman, S-U-G-E-R-M-A-N, and we hope he's on the phone.

OPERATOR: Ma'am, we have just heard from him, while the previous commenter was speaking, that he is unavailable to comment today.

MS. CONNERY: Okay, okay. Thank you. Then we'll move on to Commenter No. 47, and that is Jennifer Reed-Hack. According to my notes, you should be in the room with us? Could -- I don't see her in the rom, so would you mind checking on the phone and seeing if she may have phoned in? It's R-E-E-D, hyphen, H-A-C-K.

OPERATOR: Thank you, one moment. No, I'm not seeing her. If --

MS. CONNERY: Okay.

OPERATOR: If she is sitting with someone, she can press star-zero.

MS. CONNERY: All right. Then let's move on and see if the next commenter is on the phone. That is Sarah Lazarus, L-A-Z-A-R-U-S.

OPERATOR: Yes, we do have Ms. Lazarus.

MS. CONNERY: Okay.

OPERATOR: Ms. Lazarus, your line is open. You may make your comment.

MS. LAZARUS: Thank you. My name is Sarah Beth Lazarus. I am a patient. I'm 63 years old. I'm disabled (inaudible). I have not taken gamma globulin since January 2005 because of Medicare not paying the doctor the right amount. I mean, Dr. Sugerman that wasn't on the line a minute ago, he is one of the doctors where I go for my IV gamma.

My (inaudible) level has gotten a lot lower since I had to take it. I am an asthmatic and I have severe arthritis. The arthritis I have is inflammation of (inaudible) standards of living. Also, it deteriorated both of my knees, and they told me I need knee replacement, but because I'm not taking

gamma globulin, I'm very scared of getting a major infection (inaudible).

In the early '80s, I started getting sinus infections, bronchitis, pneumonia, constantly. Towards the latter part of the '80s and the early '90s, I had seven different sinus surgeries for infected sinuses (phonetic). In '92, I had my frontal sinuses removed. In fact, (inaudible). This was a very major surgery, but they told me it would be the answer to all my problems.

If I didn't have the frontal, the rest of my sinuses couldn't get infected and therefore, I wouldn't get sick (phonetic). Well, that was a good theory, but it didn't help me. Less than a month after surgery, two weeks without antibiotics, I had a sinus infection again. Within a few months of surgery, I was back on the IV antibiotics for two months at a time.

After this surgery, I spent the next two years at my ear, nose, and throat doctor's office at

least two to three times a day -- I mean, two to three times a week, having my sinuses cleaned out, and just (inaudible).

He was trying to convince me that these infections would get into my brain and kill me, so he decided to find a reason for my sickness. He sent me to other ear, nose, and throat doctors, and between all of them, they found out I was immune deficient. So then, I went to an immunologist in '94 and started taking gamma globulin (inaudible) every four weeks.

(Inaudible) immune deficient, I had so many sinus infections, it seemed like one long infection, never ending. I was on oral antibiotics 14 days -- I'd be on oral antibiotics for 14 days, and then I'd be off maybe seven or 10 days, and the infections would come back. Back on the oral antibiotics I'd go.

Sometimes oral antibiotics would not work, and I'd have to go to my doctor's office for shots of antibiotics. Sometimes that wouldn't work, so I'd go back on the IV antibiotics at home for up to three

months at a time. I took (inaudible) for about six months before I could see a real improvement. I -- well, just gradually, I got better and better through the years.

I still got infections, but (inaudible) oral antibiotics for six weeks before I get an infection. (Inaudible). I know that doesn't sound like a long time, but compared to seven to 14 days and back on the oral antibiotics, that was (inaudible). My quality of life was better.

Another (inaudible) with gamma globulin, I have not had to take IV antibiotics at home since I've been taking gamma globulin. When I was first diagnosed as immune deficient, I thought my life was pretty well over. And as sick as I had been, I really didn't want to live with no quality of life. But with gamma globulin treatment, my quality of life changed, and I thought I could manage my life with its help.

Since February, I think February was the first month in 2005 that I was not allowed to take

gamma because of Medicare's price reduction. (Inaudible) because I had my hope of getting better, and once I (inaudible), and getting better was really important.

Last year's reduction in price per gram did not even cover the cost my doctor was paying for it, so therefore, he couldn't continue to give it to the Medicare patients. So in February of 2005, my quality of life was (inaudible) on a downward slope. Every day, week, month, I'd get a little sicker. (Inaudible) taking gamma, gamma helps inflammation of the body. I didn't know (inaudible)

MS. CONNERY: Ms. Lazarus?

MS. LAZARUS: So that most of the time -- I'm only 63 years old, but when I get up from a sitting or laying position, I walk like I'm about 90, from the pain. I now take oral antibiotics every day and still get infections, and then I have to switch to a more powerful antibiotic for 21 days, and then I go back on my (inaudible) antibiotics.

MS. CONNERY: Ms. Lazarus, you've got about 15 seconds.

MS. LAZARUS: All right. Since stopping gamma, I have increased my prednisone from five milligrams to 20 milligrams. My bones (inaudible) in the last couple of years. I need (inaudible) prednisone level back then, and without gamma, I'm never going to get there.

I just want everybody to know that they include cancer, diabetes, other things that are not curable (inaudible). Thank you very much.

MS. CONNERY: Thank you for your comment. Our next commenter is Commenter No. 49, and that's Bruce Bunyan, and we -- yes, he's with us here in the room.

MR. BUNYAN: Thank you, Jan. Good afternoon, everyone. My name's Bruce Bunyan. I'm the Vice President of Corporate Communications and Public Policy for Talecris Biotherapeutics. We manufacture Gamunex, a product, as you have heard today, is

critically important for many patients.

Talecris looks forward to being part of the review of this IVIG access process in more political outlets. Our approach to patient care is simple. We support giving each patient and his or her physician access to the IVIG brand that's effective for them in the setting best suited for his or her individual needs.

We're committed to working openly with ASPI, because your work will have such an important effect on access to IVIG therapies for thousands of Medicare beneficiaries, just like those that we've heard from here today. We are dedicated to ensuring access to this life-saving therapy. We continue to take reports of IG access issues very seriously.

Although some appear to be inclined to see the access issues as supply-driven and not reimbursement related, we do not believe that this is correct, particularly when we exam the evidence related to our product. Specifically, over the last

five years, we have increased the amount of IVIG that we make available in the United States by over 75%.

Talecris has dedicated significant resources to meet the needs of the IVIG community. Finally, we have invested more than $250 million to build a highly efficient, state-of-the-art manufacturing facility in Clayton, North Carolina, the only facility of its size dedicated to IGIV production.

In addition to our dramatic efforts to increase production, we have established the Gamunex Emergency Supply Program for patients who might be facing a critical or urgent situation related to their IGIV therapy. This program provides Gamunex on a first-come, first-served basis to patients in emergency situations, and we have never come close to exhausting our emergency supply.

We have heard from a few patients today who have experienced access issues with our product. We encourage them to utilize this program or through their physician.

Further, our price increases have been quite limited, despite the increased production costs, significant investments in additional manufacturing capacity, and large investments in producing a new IGIV product. Since 2000, Talecris has not increased prices at a rate that keeps place with the rate of inflation.

Finally, we have sold Gamunex to both the VA and 340(b) programs at the required prices since inception of both of these programs without interruption.

The chronology of the IGIV access issue clearly shows our opinion, its fundamental (inaudible) to changes in Medicare reimbursement policy. Access issues were largely localized initially in physicians' office settings, when those providers migrated to the ASP methodology in 2005 without separate J codes, and only spreading to the hospital outpatient setting in 2006, when that setting switched to the ASP methodology.

We are also committed to preventing gray market activity from becoming a significant issue with respect to our product. Our reduction in the number of distributors and wholesalers, our work to increase substantially the proportion of encumbered product sales, and our audits of distributors and their sales, are ways of restricting our product being moved to this gray market.

We think CMS can meaningfully address the IGIV access issue in a manner that is entirely consistent with the average sales price methodology by (1) providing separate J codes to the quite distinct IGIV products used by Medicare patients and (2) providing more accurate administrative service fee reimbursements to providers.

IVIG products are treated differently than most drugs under the ASP methodology, although different IGIV products have different characteristics and according to the FDA, are not bioequivalent, they are lumped together under a single ASP. This should

not be the case. IGIV products should have a separate J code like other single source products.

Attempts to improve the IGIV access problem that are temporary or that fail to address need for separate J codes and more accurate administration service fees, will actually create additional problems by discouraging the significant investigation necessary to maintain adequate supply of this life-saving therapy.

To the extent that CMS wishes to explore certain coverage issues for particular indications, it should do so, as in the past, through its contractors and local coverage determinations.

Talecris thanks you again for this opportunity to provide input to a review of this patient and physician -- both patient and physician concerns and access to this therapy, and more importantly, look forward to working with you continually as we try to solve this access problem for patients. Thank you.

MS. CONNERY: Our next commenter, we hope will be with us by phone, and she is, and that is Martha [sic] Bond, B-O-N-D. She is Commenter No. 50. Marcella, do you have Marsha Bond --

OPERATOR: Marsha, your line is open. Thank you.

MS. BOND: Hi, this is, it's actually Marsha Bond.

MS. CONNERY: Okay.

MS. BOND: I'm 39 years old and I have common variable immunodeficiency disease. Before I was diagnosed, I was medically disabled for about three years and bedridden for two years of that, and then they finally figured out what was going on.

It's taken me two years on IVIG therapy to get to this point to where I'm very hopeful that I'll get to return to work in the spring, and that's all based on how I do this fall, as far as catching viruses and (inaudible) and how bad they are, but I'm very hopeful that that will happen.

What I'm talking about are various things. Basically, I'm going to attest to all of the things that you've asked about, which is we no longer are able -- I haven't been able to go to my doctor's office -- it's been -- February of 2005. We were received by every (inaudible) or hospital in Texas to even consider treatment, so for five months, we didn't get any treatment at all because we couldn't find someplace to have it done.

Then they were finally able to get an infusion clinic that was not a private hospital (inaudible) take it on, but every month, we have delays. We oftentimes have no idea what product we're getting. Our delays can be anywhere from two weeks to two months, and like I said, every month, we get a different product. We can never get the same product hardly two times in a row.

I know what the -- I talked to the director of the infusion clinic, and she said basically it's an allocation issue. They cannot get an allocation from

the distributor or the manufacturer, because they don't have enough patients, and they've been trying since 2005 to get an allocation, or if they get allocation, it's not to cover enough of us.

So then it's like, okay, what do you do? Do you get an allocation for two people and let 10 people go? I mean, it's a real -- I'm sure (inaudible) answer. Also, I know there are 15 patients out of the doctor's office that I come from that are all on Medicare, and I have not noticed -- I have not experienced a (inaudible) reaction to the changing of the product, other than minor migraines and stuff like that, things that (inaudible).

But I do know that there were others who had severe reactions, so they had to actually stop their treatment because they had such severe reactions that it was just worse off.

I also know that the reimbursement problem is 99% of the problem. When I talked to the distributor -- the district -- excuse me, I cannot

talk. When I talked to the manager of the infusion clinic, I asked her, "Is it because you can't find my product, or you can't find product at our price?" She always tells me she cannot find product at the price. You can buy lots of product, but it's all way above the reimbursement level.

I do know that there are cases in our group, as well, that are receiving (inaudible) treatment -- about half of our patients, if they get treatment, (inaudible) two to three weeks (inaudible) every month, and I know that they are no longer getting that (inaudible) once a month or not at all.

I believe as far as my health consequences, and I've already gone into that, I do know that there have been other people that have (inaudible) had not heard of any deaths at this point, but I do know that, like I said, we suffer every day.

And then when we're a day late on getting this product, I feel it. I mean, everybody feels it. It -- I mean, and I'm scared to death. I don't want

to go back to being bedridden. And right now, with the way the situation is, I (inaudible) playing Russian roulette with my life (inaudible) because I don't know. Am I going to get my treatment this month? Is it going to be late? How late is it going to be? And this has a direct impact on obviously my future goal of wanting to go back to work. I don't want to be disabled. I want to work and take care of myself.

I just -- I'm really frustrated, too, because I've contacted my senators, my -- all the Congress, all the local media, national media. I've written every talk show host that there is. Not one of them, did they want to give us any time of day, and I think that's how it is, because we're too small. There's only 50,000 people who have common variable immune deficiency. (Inaudible) write the law into that.

Whereas I know I heard that other lady say that neuropathy has a million patients. There's a big

difference in there of people using it for off-label versus label, and I can quickly, with (inaudible) treatment with the fact that they (inaudible).

If you're going to use it for off-label use, then you should have to pay this price. If you're going to use it for on-label use, then you should be able to pay this price, because it is widespread for us. It's not life-threatening for people with neuropathy; at least, I've never heard of anyone with neuropathy that has actually died.

I just want to say thank you for listening to me and letting me (inaudible) and I would pray that you guys (inaudible).

MS. CONNERY: Thank you very much, Marsha. Our next commenter is, we hope, in the room with us, David Elkayam.

OPERATOR: David, your line's open.

DR. ELKAYAM: Okay. Can you hear me?

MS. CONNERY: Yes. Yes, we can.

DR. ELKAYAM: I'm a physician in private

practice in Bellingham, Washington. I'm near the coast. I'm an allergist and immunologist by training and (inaudible) I treat the folks, like the lady that we just heard from very eloquently described the dilemma and the problems that we're having treating our patients with primary immunodeficiency.

My comments are directed specifically at those individuals who are often productive individuals in society. These are not people who are at the tail end of their lives. They're often very productive members of society.

My comments not only include the several patients that I have who have had Medicare coverage, but extend to all the patients that I've had. In the years that I've been in practice, I have treated approximately 35 patients with primary immune deficiency , and that goes back 18 years now.

I put into effect training that I received as a fellow in a certified allergy/immunology program in Denver, Colorado, which is very well-respected in

this regard, so I feel that the treatment needs to be defined and supervised by somebody with adequate training. That may be something that you can look at.

I also agree with the prior speaker that there needs to be a definition of who is the best candidate for receiving this therapy, primary immune deficiency patient versus off-label uses that have less treatment benefits for neuropathy and other neurologic conditions, and help to define the (inaudible) population.

I think (inaudible) outline the results that have occurred at the beginning of this year, which has been primarily in the record (inaudible) regarding IVIG (inaudible) last year. You may well be aware that in the other third-party insurance companies (inaudible) IVIG (inaudible). There's been a very important consequence (inaudible) of that (inaudible) policy.

For example, there's one clinic that has had experience with IVIG now for about 18 years, and as

recently as September of 2006 [sic], a year ago, I was treating 22 patients with (inaudible) various forms of primary immune deficiency (inaudible) versus IV (inaudible) globulin.

Since that time, I have (inaudible) direct care and supervision of IVIG therapy for 12 of these patients. I currently am treating (inaudible) and it is highly likely that I will be treating few to none of these patients by the end of the calendar year. The (inaudible) care of these patients does the (inaudible) end of last year that did not (inaudible) January.

This resulted in a very significant negative financial burden on (inaudible) and one that we can try very hard to contend with and one that we cannot simply sustain. The methodology of ASP +6% does not take into account that the indications (inaudible) IVIG product (inaudible) the reimbursement allowed, as the previous speaker just outlined. The problems that they're having (inaudible) the problems that we're

having in Washington State.

The reimbursement has always been unfairly low with respect to the nursing services and the time commitment, and you may or may not be aware that the provision of IVIG is nearly a one to one nursing commitment for a period of three to five hours at a time.

As a practical consequence of what has happened during this past year, we've had to eliminate two full-time nursing positions from our clinic staff. These are not only lost wage-earners in our community, but their speciality expertise has been very hard to lose and will be very hard to replace if we're ever able to (inaudible) IVIG (inaudible) the future.

In addition, the lack of more direct supervision of the care for these patients (inaudible) immunologist out of the loop. I did all the (inaudible) every three and four weeks for their infusions. Typically, this would've been what we consider a curbside consult and typically does not

involve any additional billing.

Now, these patients are seen on a much more periodic basis. They have to be scheduled in. And I can't even (inaudible) pick up on the more subtle or early signs of their disease conditions, and this is not only with respect to infectious diseases.

For example, in the past year, I've diagnosed a deep vein thrombosis, which is an immediate life-threatening condition in a patient who presented for IVIG, and fairly recently, I referred a patient who was found to have bacteremia directly to the hospital, because of appropriate (phonetic) signs and symptoms that she presented with in a "routine office visit."

MS. CONNERY: Dr. Elkayam, you have about 15 seconds.

DR. ELKAYAM: These types of events will (inaudible). In closing, we need the support of CMS of a permanent add-on payment to cover the gap between the cost of the drug and the reimbursement. We need

creation of separate (inaudible) codes for each brand of IVIG (inaudible) separately. Finally, we need to pay physicians at a higher level (inaudible). Thank you.

MS. CONNERY: Thank you very much. I would like to check at this point if Joanne LaDouceur is on the phone lines with us. That's spelled L-A-D-O-U-C-E-U-R. She was someone who was scheduled to come in earlier and missed the time, and I think would like to -- I heard would like to do so, so I just want to see if she's --

OPERATOR: Joanne, your line is open.

MS. LADOUCEUR: Yes, I am here.

MS. CONNERY: Okay, great. We can hear you.

MS. LAUDOUCEUR: Thank you for being so patient. Yes, I'll tell you a little bit about my story. I've been on -- I was diagnosed four years ago, I believe it was, with CVID, and I have had numerous serious infections requiring hospitalization and home (inaudible). I think I had PICC lines like

four or five times.

So I had been very sick, and so I was diagnosed and I started IVIG in an infusion clinic, and at that time, they had venoglobulin (phonetic), which is now off the market, and I had the first infusion, mild side effects. I mean, it was a lower dose.

The second infusion, I developed (inaudible) meningitis, and I was quite sick with that. And it was kind of scary, you know. You wonder, "Well, should I have even started this?" But they were certain that it seemed to be rate related, and so they said that the next infusion had to be at least six hours.

At the infusion clinic, it was very difficult for them to do an infusion that long, but they tried to, and I was developing a thrombocybitas (phonetic) with every infusion. So a couple months later, I switched to a different infusion clinic, and then I at least have a different brand. They don't

have the same brand. You get whatever they happen to have that day.

So then I had more problems with severe side effects, body aches, severe headaches, and it was difficult to get them, again, to run the infusion over six hours. Thrombocybitas again. Then the doctor wrote orders that it had to be at least six hours, and they had to change the IV site midway through the infusion. Because of my numerous infections and my history, they would not do a port, so I was -- I had to -- through IV.

So the year went through and they changed brands a couple times. They tried to keep the same brand, but I continued with multiple side effects. Even though the infusion was every four weeks, after the infusion, I was sick for a week, and prior to the infusion, I was run down and not feeling well, so I was feeling crummy half the time, and the other half of the time, I seemed okay.

My infection rate went way down, so that was

a good thing, but with my insurance, they refused to do it subcu (phonetic). However, a year later, the year after I was into this, my insurance changed and I was able to start subcu (phonetic). So I did that at home. The nurse helped me the first one or two times, and it seemed to go smoothly. However, I was infusing into one site, and that was a problem. Then we went to two sites and two pumps, and the big backpack instead of a little fanny pack. That seemed okay.

I still had some side effects, and when gamma globulin went off the market, I changed to Gammagard, and I did have fewer side effects with that, fewer headaches, because -- well, I take that back. I had headaches, severe headaches, for about six months, and they were always worried about getting meningitis again. Then, it was discovered that I had these problems whenever I changed lot numbers. So the company that I worked with, Accudo (phonetic), would kind of horde as much as they could of one lot number, put it aside for me, and if it lasted six months or a

year, I would at least be able to stick with the same lot number.

At that time, during the course of this time, I should say, I started to lose weight. I went from, let's say, 140 pounds to 110, and finding infusion sites was difficult. We changed from a soft set (phonetic) to a silhouette, which is a very shallow needle that goes in, needle comes out, the catheter remains, so it's very shallow. You can put it in just under the skin, and I was running my infusions 24 hours, but I seemed to get better.

I had fewer infections, no more infections that required hospitalizations, a couple of sinus infections a year. Still working with the same people. But some time in the middle here, it was discovered that my headaches were probably related to the IDA content, and then, we were able to get the Gammagard low IDA, which is what I still receive, and just about let's say four -- a couple months ago, three months ago, I found out that I could use

something, a different kind of topical anesthetic (inaudible), which they usually use for (inaudible) patients, so I could use that. It's kind of icky (phonetic) to use. It's sticky. You have to put some kind of dressing on it and you keep applying it every couple of hours, and --

MS. CONNERY: Joanne, you've got about 15 seconds.

MS. LADOUCEUR: Okay. So I was able to cut down my infusion time, but then I had reactions to that. So I'm back to the 24-hour infusions. I must have the low IDA, and subcu (phonetic), for me, is the best thing to do. I had a couple of hospitalizations this spring and they had a hard time getting it at the hospital, but I ended up getting IV, and they did it over six hours.

But that's the best thing for me, and I cannot change brands. If I had to, I would probably just resign myself and quit. And thank you very much for your time.

MS. CONNERY: Thank you for joining us, Joanne, with the comment. Our next commenter is also, we hope, joining us by phone, Commenter No. 52, and that is Ken Bennis, B-E-N-N-I-S.

OPERATOR: Thank you.

MR. BENNIS: Yes, I'm here.

OPERATOR: Mr. Bennis, your line is open.

MR. BENNIS: Hi. I want to thank all of you for listening to me today. I'm an injured (phonetic) firefighter from Fort Lauderdale. As Peggy Hassel said today earlier talking, her and I have both been tossed out of doctors' offices and many hospitals. We've had to pay for this gamma on our own. And sitting here listening to all these people speak today, it seems to be just one common thing. Medicare has cut back so much on paying for this, and this is a necessary drug for everybody.

I myself, they cut me back -- I'm 170 pounds -- they cut me back to 15 grams a month. I'm back walking with a cane, in pain constantly, and I just

hooked up with the VA, and the VA doctors there said to me that "They're not even giving you the proper amount that the product calls for, which with your weight, has to be 30 grams."

Again, being Medicare seems to be the bullet here that's hurting everybody. They've taken away the doctors' care. They're putting doctors out of business by not paying enough. They're putting patients out of hospitals by not paying enough. Something has to change in Medicare.

These companies say there's no shortage. Every time I go to a hospital or doctor's office, they say, "Oh, there's a shortage of the product." I've called Talecris. I've called the other companies. There is no shortage of the product. They have it here in the United States. But the problem is Medicare won't pay, and there's too many middle people making a profit off of us. Something has to stop here, because this product is needed for all of us to live. Without it, oh, there's a lot of patients that

are dying, and it's not necessary. Thank you for all your time.

MS. CONNERY: Thank you very much. Our next commenter is, we hope, in the room with us. Mark Ballow? Okay, great.

DR. BALLOW: Good afternoon. I am Dr. Mark Ballow. I'm Chief of the Allergy and Immunology Division at University of New York, at Buffalo School of Medicine, and also at Women's and Children's Hospital. But today, I'm representing the Primary Immune Deficiency Committee of the American Academy of Asthma, Allergy, and Immunology, which is the largest professional medical specialty organization in the United States, representing allergists and clinical immunologists.

We have over 6,000 members in the United States, plus 600 members in other countries. I am also a member, and with my comments today, I have the backing of other organizations of clinical immunologists, including the American College of

Allergy, Asthma, and Immunology and the Clinical Immunology Society.

I myself, and the clinical immunologists of these professional organizations, are part of the Primary Immune Deficiency Coalition, along with our partners of patient support groups, the Immune Deficiency Foundation, and the Jeffrey Modell Foundation, whom I think we've heard earlier from, represent some of these views. I'd like to cover four points, many of which you've heard already in detail.

One is that IVIG is life-threatening for patients with primary immunodeficiency disease. Two, IVIG is a complex biologic product. It should be a biologic response modifier, classified as such. Reimbursement issues, you've heard a lot about today, and I just cover a couple of points related to that.

Lastly, utilization, and we believe that long-term, we'll need to address appropriate utilization of IVIG. With regard to the first point, IVIG is the only therapy for patients with primary

immunodeficiency disease. It is life-threatening. Can you imagine with a diabetic, telling them that they can only have their insulin two days a week? I mean, I think that's unacceptable.

Plus it's also unacceptable to tell a patient with primary immunodeficiency disease that they have to deal with six weeks, seven weeks, eight weeks. They have to reduce their dose from 30 grams down to 10 grams. It's the same issue.

Although (inaudible) is purified IGG, there are differences in the purification process and antiviral steps that make each product somewhat unique with regard to tolerability. Again, you've heard this a lot today from the callers calling in today on the phone, in whcih they switched brands and clearly, they have difference in tolerability. There needs to be access to different IGIV products to ensure patient safety, and this is really critical.

Second, IGIV is a complex biological product. It should be classified as a biological

response modifier. If you look at the package inserts of these products, it very clearly outlines that there are a number of adverse events associated with the administration of this product, and I refer you to these product inserts. I won't go over the data at this point.

Somehow, IGIV has been classified as a simple administrative agent, like saline or antibiotics. This is not the case. Vigilance needs to be maintained for detecting and managing these adverse events and I think we've heard many examples of that today, in different -- when patients have told their stories.

The risk of these adverse events are magnified by the decrease in availability of products and therefore, a limitation in the selection of products which may be more appropriate in some patients, with regard to tolerability and with regard to some of these adverse events.

Third, because IGIV is a complex biological

product with adverse events, there are inherent increases in cost incurred in the infusion of this product, and again, we've heard a lot about this today. Nursing on a one to one or at most, one to two, the length of infusions of anywhere from three hours to eight hours, depending if there was a patient with autoimmune disease or a patient who had primary immune deficiency disease, and the list goes on and on.

There are up-front costs in acquisition, determining what the appropriate product is, and of course, costs associated with the administration. We've heard -- again, a lot -- that reimbursement is just totally inadequate for the administration of this biological response modifier.

MS. CONNERY: You've got just a few seconds left.

DR. BALLOW: Finally, the last point is that -- utilization. 70% of IVIG is for off-label, and even with that 70%, surely, there is a lot of true

indications of IGIV outside of patients with primary immune deficiency disease, and I don't belittle that at all.

In fact, our committee, the Primary Immune Deficiency Committee, has published a utilization document where we have looked at evidence-based medicine to try to prioritize where IVIG is best utilized for patient care. It's also posted on our Internet (inaudible).

So as a community of physicians, clinical immunologists, together with our allied health providers, together with some of our lay organizations, we are certainly here to help governmental agencies address this issue of not only short-term issues of reimbursement and allocation of product (inaudible) pricing of product, but the long-term utilization of IVIG in a cross-section of patients outside of patients with primary immune deficiency disease. Thank you.

MS. CONNERY: Thank you. Our next and last

six commentors -- again, I have four more names that aren't on the list in your packets because of late registration -- are all joining us by phone. So we'll go to our 55th commenter, who is Jason Slotnik, S-L-O-T-N-I-K.

OPERATOR: Thank you, one moment.

MR. SLOTNIK: I'm actually here in the room.

MS. CONNERY: Oh, he's here in the room. Okay.

MR. SLOTNIK: I could call in on my cell phone.

MS. CONNERY: Oh, no, it's nice to see you.

MR. SLOTNIK: I just want to thank you. My name is Jason Slotnik, and I'm Director for Medicare Reimbursement and Economic Policy at the Biotechnology Industry Organization, and I thank you very much for hosting this open-door forum today. I have some brief comments that focus on two particular aspects of this challenging situation.

The Biotechnology Industry Organization,

like I just said, appreciates the opportunity to speak at this town hall meeting organized by the Department of Health and Human Services, the Office of the Assistant Secretary for Planning and Evaluation.

BIO is the largest trade organization to serve and represent the biotechnology industry in the United States and around the globe. We represent over 1,100 biotechnology companies, academic institutions, biotechnology centers, and related organizations in the United States.

We represent an industry that is deeply devoted to discovering new therapies and ensuring patient access to them. We are pleased to see the continued focus on the need to ensure adequate access to IVIG. We appreciate the Department's willingness to support and maintain an ongoing dialogue on this issue, and are hopeful that these discussions will result in solutions that will increase reimbursement and restore access to all IVIG therapies.

As we have heard numerous times today,

Medicare beneficiaries face serious and sometimes insurmountable barriers to IVIG access. These challenges have coincided with and are a direct result of the reimbursement revisions that occurred on January 1, 2005.

While BIO is fully support of efforts to ensure that the Medicare program does not overpay for drugs and biologics, appropriate reimbursement is critical to ensure patient access to treatment. Current reimbursement for IVIG and its administration is not adequate, unfortunately, to ensure access to all brands of IVIG.

In addition to the need for increased reimbursement for IVIG, unique codes should be established for each brand. Each brand should get their own code. IVIG is one of a very limited number of biological therapies with mixed (inaudible) codes. Both of the codes for IVIG contain products with differing characteristics and value. For example, some products contain less immunoglobulin-A, also

known as IgA, which may prevent or lessen reactions for patients with IgA deficiencies, while others contain no sugars and are often prescribed for individuals with diabetes.

Despite the clinical reasons that one brand of IVIG may be preferred over another, reimbursement is based on the volume weighted average of all products in that code, rather than the average selling price of each product. The result is further under-reimbursement for some therapies, creating a barrier to the therapy which may be best suited for that beneficiary's specific medical need.

We urge you to correct this problem by establishing separate codes for each brand of IVIG, while I was hopeful that the wide variety of comments provided today will demonstrate the need to restore beneficiary access to all IVIG therapies, through both increased reimbursement and brand-specific coding.

Thank you again for this opportunity to testify. See you later.

MS. CONNERY: Thank you. Well, I guess I need to qualify and say just according to my notes, the next five commentors are on the phone, but we're happy to take the comment whether you're on the phone or here in person.

So we'll move on to our 56th commenter, Judy Woody, W-O-O-D-Y. I don't see anyone standing up in the room, so hopefully, she is with us on the phone.

OPERATOR: One moment, I'm looking. And that's W-O-O-D-Y?

MS. CONNERY: Yes.

OPERATOR: Thank you. I'm not finding Ms. Woody on line. If you have connected with someone else at their location, press star-zero.

MS. CONNERY: Okay. While we're waiting to see if that works, could you check for our next commenter, Patrick Schmidt, S-C-H-M-I-D-T?

OPERATOR: Mr. Schmidt was online earlier. He's no longer connected.

MS. CONNERY: Okay. All right. Let's check

for Dolores Hanson, H-A-N-S-O-N.

OPERATOR: Thank you. I also am not finding her.

MS. CONNERY: All right. Well, we have two more folks who had indicated they would like to comment, so we'll check for them. The next is Eugene Richardson.

OPERATOR: Thank you. Yes, he is on line. Mr. Richardson, you may make your comments.

MR. RICHARDSON: All right, thank you. This is Lieutenant Colonel Eugene Richardson. I'm retired from the U.S. Army with 27 years' active service. I have had the experience of having been diagnosed with chronic inflammatory demyelinating neuropathy and peripheral autonomic neuropathy.

I have gone 34 years without diagnosis in a total nightmare until, in 1987, when I was forced to retire from a promising career and (inaudible) because things really had gotten -- were really out of hand. But I thought if I started a new career, which I did,

and I worked for 14 years, but my condition, in a typical relapsing and remitting fashion, continued to get worse.

Basically, I hid from everybody so no one would know what I was going to until the '90s, when breathing became very difficult. I was put on steroids, but unfortunately, in two years, my eyesight was destroyed. I had surgery. Then later, after that, my back came apart from osteoporosis. I had major surgery. Again, having heart problems.

Then, in 2000, had to retire from this second great career, and went on Social Security Disability, literally beaten by this disease. I then was finally diagnosed with having a peripheral neuropathy, and then in 2004, was diagnosed with CIDP, and they gave me a trial of CIDT, and I got out of my wheelchair, I stopped spinning around the room like I had been all the time now, and I could breathe and talk at the same time, and pain was less, and I thought maybe I could live now.

I then was given this infusion at a doctor's office when all of the sudden, they told me that Medicare was not reimbursing them, and besides, I was on a brand where the fluid volume was high, and I kept drowning in it, because they gave it to me too fast.

I then was sent to Holy Cross Hospital in Fort Lauderdale, where they changed me to Gammagard brand, and even though I had a lot of problems with that, and again, the problem with fluid, I then all of the sudden, in February of '05, was told that they no longer had the product, and no one seemed to know why.

My wife and I called all over the place in desperation, as I was getting sicker and sicker, and by the eighth of March, I was in the emergency room at Imperial Point Hospital. I couldn't breathe and talk. I was back in the wheelchair. I couldn't walk. I was now spinning and going around the rink 24/7.

I couldn't sleep. The pain and the electric shocks were beyond anyone's imagination. Again, I was in a body of torture, almost wishing that I would just

die. I then changed to the new brand of Gammagard -- no Gamunex -- at Imperial Point and the next day, they gave me this, and I got out of the wheelchair, and I could breathe now, and all my symptoms started going down.

I now am very anxious that that will stop, because Imperial Point says they're losing $10.00 a gram, and that they will no longer give it to any new patients. I have called Holy Cross and other hospitals in the area and they no longer will offer it at all.

I know that those who are desperate with immune deficiency mean well when they talk about those of us with CIDP not dying, but people do die and I just hope this does not become some kind of game in which who is worse off, but rather to (inaudible) look at the issue, as the one doctor, I think, was suggesting they have done.

Anyway, I want to thank you very much for doing this, and I want to thank Congressman Clay Shaw

and the Neuropathy Association, especially Dr. (inaudible) and the GBS Foundation International and the (inaudible) center, because if it wasn't for them, I don't think I would have made it this far. Thank you very much.

MS. CONNERY: Thank you very much, Mr. Richardson, for sharing your story with us. We wish you the best with the challenges that you're facing. Our last commenter on my list -- also, I believe, joining us by phone -- is Maryann Ostrowski, O-S-T-R-O-W-S-K-I.

OPERATOR: One moment. Ms. Ostrowski was on line, but is no longer connected to the call.

MS. CONNERY: Okay. So I want to ask the folks who are on the phone if there was anyone who was scheduled to comment earlier who may have missed their time, but is on the line now, we could take them, and you could indicate that by pressing star-one. Marcella, is that correct; star-one?

OPERATOR: That is correct.

MS. CONNERY: Okay. Can you tell us if you're getting any signals?

OPERATOR: It will take a moment for them to queue up.

MS. CONNERY: Okay. I'll just check in the room if there is anyone we may have missed who was scheduled to go earlier.

OPERATOR: No -- oh, I have just two -- just a moment.

MS. CONNERY: All right.

OPERATOR: Mr. Reice?

MR. REICE: It's me.

OPERATOR: Go ahead, sir. You may make your comments.

MR. REICE: Thank you. I heard the Colonel, and this is a coincidence, because -- my name is Gerry Reice. I'm a (inaudible) United States Army Reserve. I've always learned that medical care is a right, not a privilege, and I learned that many years ago in the service. We have a right to this medical care.

I never thought I was a patient. My ego got in my way. For a number of -- seven years, eight years, I've been taking gamma globulin, taking it and gaining benefits from it. Again, my ego got in my way. Never a patient. Always taking the gamma globulin because it was prescribed.

Now, a little while ago, we lost gamma globulin as a prescription through Medicare. The VA told me they would give it to me if I was close to death. My pain is in my hands. My sons help me. I think it is very cruel that our government is not funding this properly.

There is a responsibility somewhere up the ladder, and listening to this program as long as I have, I, as a layman, gained more knowledge than I have in many years because as I said, my ego got in my way, and I will call on Senators Clinton and Schumer (phonetic) and on Congressmen as long as my sons are able to carry me in their offices.

Thank you again for teaching someone

something that his ego did not allow him to learn.

MS. CONNERY: Thank you for your comment. Marcella, did anyone else response?

OPERATOR: No, Ms. Connery.

MS. CONNERY: Okay.

OPERATOR: We have no one else in the queue.

MS. CONNERY: Okay. Well, that is all that I have on my list, so I'd like to close out the comment period and just end with a few remarks.

OPERATOR: We do have one more, ma'am.

MS. CONNERY: Oh, okay.

OPERATOR: That's just come up.

MS. CONNERY: All right.

OPERATOR: One moment. Donald Davies, your line is open. You may make your comments.

MR. DAVIES: Thank you. I've had the opportunity to hear everybody from all different areas of the health care, and I really appreciate that. I am a value analyst for a pharmacy. I've been doing this for 17 years, and I've gone through the ups and

downs for many product shortages throughout the United States.

I am seeing some significant issues for the past couple of years. I know usage is going up, but also, we need to take a look at the total output of the product coming from the manufacturers versus the demand. I know that American Red Cross went off the market. I know that Baxter shut down one of their plants that was producing their product.

I know that raw material collection sites across the United States have been reduced over the last five years. (Inaudible) where we used to get raw material and blood from Europe, it's almost at a standstill because of the mad cow disease.

(Inaudible) all the (inaudible) that I haven't heard today? That's all I have to say.

MS. CONNERY: Okay. All right. Thank you, Mr. Davies. Marcella, any other participants?

OPERATOR: No, no. That was the last question in the queue.

MS. CONNERY: Okay. I think some of those latter folks were folks who were not signed up earlier, so if you want to make that same offer, if there's someone here in the room who didn't sign up to comment that you'd like a few minutes right now, we do have a little time left, if anyone would like to do that. Okay. Go ahead.

MS. VOGEL: Thank you. My name's Michelle Vogel and I work for Washington Strategic Consulting and work with a number of patient groups. I work for the Immune Deficiency Foundation and currently work with myositis and the Neuropathy Association, so I've had, I like to say the privilege, but also, have experienced the hardship of all patients going through this, both as we've seen what people have stated on-label and off-label.

The one statement I'm going to make is a concern to me greatly. You should never see one patient put against another. This product is needed for many, many patients, and I know that there's a

limited amount and it's a scarce resource and it's a miracle drug. We've heard all of that today and we're trying to decipher all of the problems.

We know for the primary immune deficiency, this is the only product that works and these patients need it. But also, for the myositis community, for the CIDP community, for ITP, for so many other diseases, this therapy, for many of those patients, is the only product that works and they need it.

So I'd like to make sure that at no time do I see one patient being put against another, and I see all the patients working together and making sure that access is restored for all patients who need this product as a life-saving therapy.

I want to say thank you to ERG, to ASPI, and all of you. To put together a meeting like this, over the last years, we've all been working in the whole IVIG community to get the stories out for patients to be able to tell their stories, and physicians who haven't been able to come to D.C., but to be able to

call in today and tell these stories.

It's been tough listening to every single story, but for them to finally have a voice and to be heard, you don't know how much that means to those people, because they really feel that people now care. And so I'm just hoping that all of us, continuing to work together, that we are going to get to a solution, and it's going to happen hopefully quickly, because we are running out of time, as you've heard from a lot of the devastating comments that came forward.

But thank you. Thank you for opening it up.

MS. CONNERY: Thank you, Michelle. Anyone else in the room who had not commented today who would wish to do so? Marcella, do we have anyone on the phone?

OPERATOR: No, I do not.

MS. CONNERY: All right. Well, it looks like, then, we are at the end, so let me make just a few closing remarks.

As Michelle noted, we've heard a lot of

personal stories today and it's clear that some of them are very hard for people to tell, and even harder, as we can all imagine, for folks to live those stories. So our hearts go out to all the people we've heard from today that are struggling with those medical difficulties, and we wish you the very best with your health, and we're very grateful for those stories, because that was the main purpose of this meeting, was to provide that opportunity, to get those stories, to get that input, as part of this project.

I'm grateful, also, to everyone else who was speaking from other perspectives, for an organization. All that information is valuable.

Just a few reminders, that for those who spoke today, it's possible some of you will be getting a follow-up call. We didn't have time for our project team to go into sort of detailed questioning, but I'm sure for at least some, there's more information they're going to want to get, and so some of you may be getting a follow-up call.

Also, as I mentioned earlier, there will be a transcript available of this meeting, and also a summary report that ERG is producing. We expect both of those to be available within the month, and we will be very happy to send them to anyone who is interested in getting them. On the handout marked "Additional Information" in the packets, or in the e-mail that we sent to people on the phone, there is information, basically telling you to contact Laurie Stamatatos at ERG. She will keep track of who's interested and will get those to you as soon as they are available.

Then, as I mentioned earlier, the analysis report that ERG will be producing will be available to the public in early 2007, and almost certainly, put up on a portion of the Department of Health and Human Services' web site. I could not find the URL, but what I did talk to DHHS about was the idea that you all would receive a notification when that's available, so that you will know that it is available and know at that time how to get it.

We, of course, have the contact information of everyone who attended this information or indicated an interest, so we can work with DHHS to make sure that you get that notification.

Let me ask my colleagues here if you have any closing remarks that you would like to make. Could you draw that close to you, Aylin?

DR. SERTKAYA: I'll just be very brief. I just want to thank all of you for being here today and sharing your experiences with us. We luckily received quite a lot of information, which will be highly useful for our analysis.

Again, as Jan noted, I just want to encourage you to submit any additional comments, reports, studies, or other documentation you might have to us before October 15th and preferably earlier, if possible.

Again, I would like to conclude by reminding you that as we go through all this information, you might get a call or an e-mail from our project team to

clarify any lingering questions we might have on your comments. Also again, thank you very much.

MS. CONNERY: Yes, and instructions for how to get us those written comments -- again, by October 15th, please, to be considered in the project -- are on this handout.

So with that, I'd like to thank everyone for being here and the project team will be getting to work (inaudible).

(Off the record at 4:25 p.m.)