COMMISSIONER ASTRUE : Okay. For our next panel, we're honored to have three distinguished experts. We have from the Department of Veterans affairs, Dr. Jerome Herbers, who is a medical consultant in the office of the inspector general. We have John Sharpe, who is a service-connected veteran with the TBI. And we have Dr. Ali Rezai, who is director of the center for neurological restoration and a professor of neurosurgery at the Cleveland clinic. Thank you all for coming. Why don't we start with Dr. Herbers.

JEROME HERBERS, JR. MBA, MD: Okay, Good Morning. Thank you, Mr. Commissioner and distinguished panel.

COMMISSIONER ASTRUE: Move the mic a little bit.

JEROME HERBERS, JR. MBA, MD: Maybe I can get it a little bit higher. Let's see if that works a little better. I hope my comments will be complimentary to what you heard a little while ago. I hope that's the case. I think I may have some additional information to provide. I'd like to first comment briefly on what's known about prognosis and TBI, at least from what I've garnered, and then present some of the findings from our published reports. Now, predicting which patients with TBI will have severe disabilities years later is, as you've heard, quite difficult. Patients with even devastating injuries, regularly show substantial improvement over time. However, I just want to stress that from a population perspective, certain variables at initial presentation do reliably indicate a poor prognosis. And these variables you've heard include older age, poor level of functioning prior to injury, and substance abuse. Now, the additional factors that show up as the patient progresses in their course are also important, as some of these were mentioned, some more or less important, but the key ones are the presence of intracranial hemorrhage, skull fracture, duration of coma. Now, predictive models have been developed that use multiple variables together, not just one. These models are not readily applicable for use of individual cases right now. But I want you to know that the data is there. To be useful in predicting long-term recovery for individuals, specific cutoffs would have to be derived from the data. These are not available in the published reports, but there are a number of published reports which I think quite accurately display that the information available from population information could be very easily used. We can say some more about that in a few minutes. In particular, I just want to make mention for the record of the model systems of care program that's been a collaboration of 18 to 20 of the country's best private sector rehabilitation centers. They've been pooling their data for quite a long time. This is a federally funded program. Data is available. It's not packaged in the way that's readily available for the kind of use you want. But I'm just suggesting that it could be. So while we're waiting for the exciting research developments you've heard described, I think the information is already there for you. Now, in practice, rehabilitation experts have used a wide range of measurement tools to assess how patients progress over time and to tailor their rehabilitation. Some of these tools have been used for decades. Because they're usually applied as patients are making the transition from acute care to rehabilitative care, usually some weeks after the traumatic event, these assessments may be particularly useful predicting -- for predicting long-term disability. Now, among the most consistently-applied measures is one that's called the functional independence measure, known as the FIM. It consists of 18 items that look at motor

function and some relevant cognitive function; these include comprehension, expression, social interaction, problem solving and memory. In VA rehabilitation units, polytrauma patients, including those with TBI, are categorized on admission and at discharge based on the FIM. Now, my office, the office of the inspector general for the Department of Veterans Affairs, evaluated the medical care provided for a group of service members who had suffered TBI during or after service in Afghanistan or Iraq. All of these individuals had been transferred to one of VA's four polytrauma rehabilitation centers. Just want to mention, those are in Tampa, Richmond, Minneapolis and Palo Alto, California. Injured service members typically receive approximately one month of inpatient treatment during their initial period of rehabilitation. While there, the VA specialists measure the functional capacity for each of those individuals when they're admitted, just prior to discharge, both times. We identified a group of patients who had completed initial inpatient rehabilitation in 2004. Our healthcare inspectors, most of whom are registered nurses, completed comprehensive in- person assessment of 52 of these patients, one to two years after discharge, to assess their functional status and their continuing need for supportive services. Our inspectors conducted interviews in 23 states and the District of Columbia. Two years after those interviews, we tried to contact all those 52 patients and were able to obtain follow-up information on all but one. We're, therefore, able to comment for you on the status of this group of injured service members at three points in time over a three to four-year period. As expected, most of these 52 patients were young adult men. Somewhat surprising, however, was that most of the injuries occurred after these service members had returned from combat zones. I want to stress that we're talking about 52 people, all of whom had been in Iraq or Afghanistan. Most of the TBI's occurred after they returned. Most of those TBI cases resulted from motor vehicle accidents. To a large degree, therefore, the experience of these service members reflects that of many unfortunate people throughout American society. I mentioned that on transfer to initial rehabilitation, these 52 patients had been categorized according to the extent of their functional independence. When we examined them in follow-up one to two years later, we used the same measurement instruments in order to estimate their progress. Almost all of these patients, showed significant improvement over time. For the purpose of this hearing, I'd like to focus on the eight persons who showed the least functional independence at the time they began. These individuals required assistance with all of the aspects of motor functions that are measured. When we visited them at follow-up, all were substantially improved. However, none was fully independent, and three remained institutionalized. Earlier this year, now more than three years after their initial TBI rehabilitation at a VA hospital, we interviewed 41 of those original 52 patients or their families. Focusing again on those eight who started out with the most severe disabilities, one remains institutionalized; five continue to require major support at home, certainly not employable. One veteran was living with his family on an Indian reservation. Now, I'll just mention that he reported that he was attending school full time. But he also told us that he had been fired from several jobs in the last year because he was, quote, too slow. Only one patient, a man who was attending school full time and planning to become a teacher, was living independently. Now, I'm highlighting the experience of the eight service members initially considered to have the worst injuries but many of the other patients suffered catastrophic losses in their ability to think, work and carry on with their lives. Only 17 of the 41 veterans we interviewed this year were

working or attending school full time. Many of these patients present tremendous challenges to healthcare providers and their families. Just to give you one example, we talked to a 29-year-old soldier who suffered a traumatic brain injury when a large tire exploded at a military post after he got back from Iraq. At our initial visit, his wife described times when he was up all night punching the walls, his kids all avoided him, he had assaulted one of them. They had plans at that time to move to another state where they both had extended families. But unfortunately when we went back to see the service member early this year, he was divorced, he was frequently staying in shelters, he had visited VA hospitals in three different states around the country, and they had a terrible time establishing continuity of care. He often missed appointments and failed to take prescribed medication. Now, the toll on families has been particularly tragic. We learned of wives and mothers who had to quit their jobs to take care of their injured loved ones, and of children sent to distant states to live with relatives while a wife provided care for her husband at home. We didn't collect information on receipt of social security benefits. But information about VA disability, I think, is instructive. By early this year, 40 of these 52 patients were receiving monthly compensation payments for service-connected disabilities. 25 had 100% service-connected ratings, and eight of these had been found to be impaired enough to require the VA terms aid and attendance or house-bound support, and that's severely impaired. Five patients had been awarded compensation benefits prior to discharge from inpatient rehabilitation quite quickly. But for all of the remaining patients, the median time from discharge to inpatient rehabilitation from the time they left inpatient rehabilitation to the time they got their initial compensation award was 53 weeks. That's the median time. So in conclusion, the long-term outcome for patients with TBI can be difficult to predict. But patients and families clearly need extensive support in the early weeks and months of recovery. I think it's actually quite possible, based on information we have, to make accurate determinations of those individuals who are very unlikely to have -- to be employable in the first year. Even if you can't predict what's going to happen in three to five years. Numerous readily available data sources could be used to gauge those expected long-term and short-term effects of employability. But the timing of the measurement, as was mentioned this morning, is key. The use of which demographic and clinical variables, the cutoff points for which outcome predictions you want to use, all these need to be specified, and I think they can be specified from available data. Now, these large databases already exist, and I think the time is right to establish ways for providing much needed support early on when it's so critically needed, with recognition that support for families is critical to the recovery of patients and for the well-being of their children. Thank you once again for the opportunity to address this panel and to talk about the challenges faced by these patients with TBI and their families. And I'll try to address any questions you might have in a few minutes.

COMMISSIONER ASTRUE: Thank you. John?

JOHN SHARPE, MBA,MS,PT: Commissioner, panel members, ladies and gentlemen, thank you for the opportunity to share with you my story of someone who has sustained a severe traumatic brain injury while in the military. I typically have the audience sit back and take a journey with me as I tell you my story. But I'm not sure I can tell of 18 and a half years in ten minutes. So I'm going to try to condense as best I can. First of all, let me

say I want to echo a lot of things that were mentioned today already. All the signs and symptoms that everyone has talked about, I have experienced every single one of them. I'm going to share with you some of the things I think are very important to me and some of the discoveries I had along the journey as I went through the process. First of all, my -- I had a frontal lobe injury; I had a subdural hematoma in a motor vehicle accident coming back from a training exercise. I spent approximately 40-some days in intensive care in a comatose state. And then once I was stabilized, I was transferred to the Richmond VA medical center. My first memory was waking up at that Richmond VA Medical Center. But I can't tell you when or what day it was. I just found out a little while ago that Dr. Helmick may have been one of my physicians at the time. So I'm glad I came today. But anyway, the signs and symptoms they talked about, short-term memory, behavioral changes, slow rate of processing, irritability, fear, humiliation, not knowing what had happened. I experienced all of those things. The biggest obstacle I had initially was the humiliation when I lost -- didn't have any control over bowel and bladder. I couldn't balance myself. I couldn't stand. I basically had to go through all the developmental sequences of a newborn child all over again. And that's the way I looked at it, and that's the way I've approached it ever since. Throughout the rehab, I was able to memorize my therapy routine and my schedule and I was very -- functioning very independently while I was in the hospital. So much so that I thought I was good as gold. I was 99.9% and I was going back into the air force. That wasn't the case. The medical team thought that I should go through a transitional living facility. Of course, I displayed all the inappropriate behaviors, and was kicking and screaming that I did not want to go. However, looking back, that was probably the best thing that ever happened to me. Being in the structured environment in the hospital setting and memorizing my routine, I was able to function and do the things that I needed to do. But when I went to the transitional living facility and had to function in the completely different setting in a complicated society, I ran into a brick wall. It was the most difficult, frustrating experience I ever had the first month and a half. Looking back now, I know it was the best thing that ever happened to me. I wasn't ready to leave the hospital and go back into the community when I was finished with the rehab. I think, personally, we need to have much more transitional living facility and community integration with patients that experience traumatic brain injury. Some of the things that I experienced there may sound trivial to you. We take it for granted. But, you know, if I wanted to do something, like I was big in working out and taking care of myself. Well, they told me I had to find a gym. I had to get the yellow pages, find out where it was. Once I found out where it was, I had to find out how much it cost, then I had to locate the bus schedule, find out how I was going to get there, all these things that you have to do if you live in a community. I struggled with that for three weeks before I got it right. So simple things that we take for granted in the community, I was struggling with. Some of the other behaviors that I had is, and I still have, I have a hard time noticing when I say something that I feel is appropriate to say or I think is common sense in my view may be very offensive or hurtful to someone else. I'm completely oblivious to that. Even to this day I'm still oblivious to that. I try to focus as much as I can on nonverbal cues to help me, but I still struggle with that. So I have a disclaimer in the very beginning, I let them know that they may get offended, so Please let me know if I offended you, because I know it's going to happen. But one of the things that was very valuable to me during my transitional experience was they videotaped our

community outings. And when we all came back from our community outings, we could watch the videotapes and sort of debrief what we went through and actually see with my eyes the inappropriate things I was doing or that I was saying. To me, that was a big help. To not only send it back to my mind for me to think about it in the future, but you always bring it up and think about it. So I try to focus on a little bit more to help me be as appropriate as I can when I'm in a community setting. I was eventually discharged from transitional living facility a total of eight months after my initial injury. So I spent eight months going through various forms of rehab. The air force put me on temporary disability retirement list, which meant that I had to go back home and live with my parents, and I was wondering what am I going to do now? All I had was the training that I had in the military. And I didn't know if I could go back and do that job or not. I tried a couple other local jobs working as a laborer in construction, different things. And those didn't pan out very well because of my slow rate of processing. I was more of a safety risk than I was appropriate for their jobs. So those jobs didn't work out. The VA came through; VBA did and offered me a chance to go to school. And I took them up on that And I started going back to school. I did the one-class-a-semester routine because I did not have the self-confidence that I would be able to succeed. The first three classes I took, I got D's in. And it wasn't until then that I realized that I have some serious problems that I need to work on. I was able to work with disability services there and talking to the vocational rehabilitation counselor, and I realized that there are certain things that I can ask for because of my deficits. So I was able to tape record my lectures in college and -- which meant that, lucky for me, I was single so I could spend the extra five or six hours a night for class to relisten to the tapes again, write them all over again. But what I found out in the long run was that by doing it that way, I was getting more senses involved. I could hear it the second time, I could also write it and see what I was writing and had my vision involved. So the more senses I got involved, the easier it was for me to retain the information. And I was able to go through undergrad, apply to pre-physical therapy program. I applied to Thomas Jefferson University and I got accepted and in March of 1999 I graduated with a master of science in physical therapy. Now, here's some of the things that's going to contradict some of the things that were said today. 11 – 10 to 11 years after my injury and this is a tribute to my wife and her health. She's an occupational therapist, so she fits the role pretty well. But I had a huge issue with inattention or attention deficit problems that I was unaware of. And my relationship was suffering with my wife. But with her work and her understanding and me trying to understand that and doing some additional research, I realized that I was having basic forms of attention deficit disorder. And I realized that I probably had those same things as a child that was undiagnosed. But because I was at the stage ten years later to finally have some insight and some more self-awareness to accept that, I started doing some additional research and went to seek a mental health professional within the VA system, got the proper type of medication, and my wife said that it's been 180 degree turnaround with my attention and my ability to focus on her. The other part about that is when I was driving before I got that medication, I had five tickets in one year because I was so focused on the road and things around me, I was not paying attention to the speedometer. You know, and if I looked down at that, I wasn't paying attention to the road. So I had a hard time doing both tasks. Now that I've had the medication, I have zero tickets. So something is working. [laughter]

My insurance company likes me too, for that. But it was already mentioned earlier about family members are very important. I think families are instrumental in helping anyone with a traumatic brain injury recover. It's going to be the family members or the people closest to that veteran or that person that's going to pick up the things that they're lacking, the deficits that they have. I did not have the insight or self-awareness until 11 years after my accident. And that's a long time. There's some things today that I feel like that are coming back. But I'm fortunate that I was blessed with a no-quit attitude and I have the energy to not be depressed and keep moving forward. I'm very fortunate in that respect. In closing, I want to thank you for the opportunity to condense this as much as I can. The best analogy that I can give you as an audience, and I didn't realize this until I had my son and daughter, but that my three-year-old son, who is a miniature Tasmanian devil, a lot of his behaviors mainly reflect and see myself in him as I was going through my rehab phase. And it's a developmental sequence. You got to go through all the stages that a young child has to do to sit up, to crawl, to walk. I had to do the same thing in the beginning. And if it takes 18 years for a person to become an adult, it's going to take at least that long or longer for someone with a TBI to be able to make it back if they have that opportunity. So thank you for the opportunity to tell my story, and I hope I helped.

COMMISSIONER ASTRUE: Thank you. Dr. Rezai.

ALI REZAI, MD: Thank you. Thank you, commissioner, the panel for inviting me here, to be here, and Diane Bronstein and her staff. Thank you all. Traumatic brain injury is among the most common neurological disorder afflicting Americans. There are 1.4 million new cases of traumatic brain injury each year in the United States. The vast majority are mild. However, unfortunately, 20% of them can be moderate to severe traumatic brain injury resulting in significant impairment. In fact, over five million people in the U.S. are living with traumatic brain injury and impairment. And approximately 80,000 patients each year come up with traumatic brain injury unfortunately and the resulting impairments. So clearly, it's a major issue for the society. Traumatic brain injury, as discussed this morning, can be acute, or immediate or sub acute. And that usually is within the first three months of the injury, whether you're in the intensive care unit, in the hospital, or in the rehab unit. Subsequently, from 3 to 6 months, and then for the rest of your life, you're in the chronic phase of traumatic brain injury. And that's the group that's the subject of relevance for today. The chronic brain injury patient, the impairment in functioning, independence and ability to be employed needs to be measured for this large group of patients. We need -- in order to do that, I think it's important to understand the frontal lobe, which is the largest part of your brain in the front that controls so many functions that result in TBI impairment. And frontal lobe is very vulnerable; it sits in the skull in the front part. So any damage, acceleration, deceleration, other damages can damage the frontal lobe. So what happens? Depending on the location and the extent of the injury to your frontal lobes, you can have damage resulting in problems with attention as john was alluding to. Concentration. Awareness of yourself and your environment. Processing of information can be impaired. Planning your daily tasks, routines, job performance. Performing sequences can be impaired. Communication, understanding and expressing yourself. Involvement of the memory parts, and not only just memory, remembering things, but your working memory, the

computer part of your brain that requires a ram. Imagine in a computer you turn it on and you press the buttons and not responding to you. Or it would take several commands before your e-mail comes up. So the working memory is impaired in chronic TBI patients in the moderate to severe category. The behavioral problems, anxiety, mood, impulsivity, judgment problems. All of these that are underlying the function of the frontal lobe that's the most common area damaged in traumatic brain injury impact disabilityand ability to work. So how do we quantify that? Dr. Herbers outlined the traumatic brain injury model. I think it's outstanding. And there are several other models in this country and groups that have worked very hard to quantify these patients. The assessments should be done with clinical assessments and also imaging that's coming very rapidly. Clinical assessments, there is no single test that can magically prognosticate traumatic brain injury or determine if you can work or not. Rather, there are a number of tests that need to be investigated and integrated as a comprehensive assessment of each patient with respect to their physician, pm and r physical medicine rehabilitation doctors, neuropsychologists, case workers and the family. These clinical tests, as outlined by Dr. Herbers, for example, the functional independence measures, and I have a two-page list of tests here that can be employed, These are neuropsychological tests and others that are measuring attention, Working memory, judgment, decision-making, behavior, mood, anxiety, impulsivity and other components of frontal lobe function. And these tests can be categorized together as in the case of the international classification of function, disability, or the TBI system. So these are very important. They're already out here. We just need to put them on paper and integrate them and streamline those tests to be provided. The tests need to also provide an objective measure of the patient, as well as a subjective measure of the patients, asking the patient about what you're feeling, what you're going through, As well as asking the family or caretakers. Only by combining these objective measures, subjective measures for the patient and the family and caretakers and integrating these tests together, we can come up with an overall best assessment of an individual's lack of functioning, impairment and ability to work. These tests also should not be administered in a one-time snapshot. They need to be administered at multiple times and correlated over time. And these have been integrated into classification systems that are providing an organized framework that is looking at neuropsychological assessments and clinical assessments, sort of a logical framework in systemic and organized evaluation of TBI impairment and frontal lobe function. I want to talk a few minutes about imaging. It's a very powerful tool that's evolving and becoming more and more common. Imaging, for example, magnetic resonance imaging, or MRI, as you all have heard of, it assesses damage. It can assess damage to the structural aspects of the brain and the function of the brain. You heard about functional MRI. So MRI, you can do a standard high resolution MRI where you're assessing the structure of the brain the extent of damage to your frontal lobes, damage to other parts of your brain, whether it's local, in one area, or diffuse, widespread damage. Damage to the cortex, the surface of the brain, or damage to deep parts of the brain, damage to the buildings or the homes involved in the cortex brain, or damage to the highways that interconnect information. There are billions of highways in your brain that connect various parts of your brain that make you a conscious, self-aware human being. Structural MRI can help us understand that degree of damage and quantify it. Additionally, functional MRI was discussed this morning. I think it's very important. Functional MRI, pet scanning and magnetoencephalography are very important tools that

allow us to, beyond looking at the structural damage to the brain, look at the functional assessment of brain in terms of speech, language, behavior, mood, anxiety, judgment and cognitive processes. So imaging is fundamentally important for assessment of structural and functional damage. And by combining imaging studies with clinical assessment, neuropsychological assessments, neurological assessments, we can get a more cohesive picture of TBI impairment and the ability to work. Finally, I'd like to say a few words about treatment. There are no F.D.A approved medications or other therapies for treating patients with traumatic brain injury. The goal is to improve functioning of the frontal lobe so the patients can go back to work and be independent and interact with their surroundings. Standard therapy is physical therapy, occupational therapy. Cognitive rehabilitation is very important. Cognitive rehab is designed to improve attention, self-awareness, motivation, memory, concentration, self-monitoring, emotional well-being. And integrating that with biofeedback and other measures and combining cognitive, physical, occupational, speech and other therapeutic measures, we can help facilitate recovery and functioning. We also need to explore medications. There are a number of activities going on to look at medications that can regulate mood, depression, anxiety disorders. It's a common feature of traumatic brain injury. Medications can regulate the mood in the patients or regulate the anxiety that can help people function better. Medications can help activate the frontal lobes, so you can conduct these different functions. That becomes very important. And finally, there's a new option using surgical therapies or brain pacemaker that has been proven to demonstrate benefit for patients with movement disorders like Parkinson's, or people with severe depression and anxiety disorders, that can help improve some of those disabilities. There are studies now looking at the use of a brain pacemaker to activate the frontal lobe and improve these functionings. So I appreciate inviting me to this panel. And in summary, I think it's a combination of standardized validated clinical assessments and brain imaging that can be put together in the context of a framework of a TBI model system for international classification of function and disability and functional outcome measures that can help us best understand the ability of someone with traumatic brain injury to work. Thank you.

COMMISSIONER ASTRUE: Thank you all. I wanted to kick off with this question. It seems for what we need to do, there's a period of brief coma which is relevant, but not very determinative, someone that has been in a coma for three hours, we're going to have to go through our full process to evaluate everything else that's happened.
It seems to me that there is a point, John mentioned, I think 40 days he was in a coma, that it's highly probable that if you pull out after that length of time, you're going to be going through a very arduous rehab. For our standard, it would be unreasonable to expect someone to work in that 12 months. Is there any kind of consensus in the medical community as to sort of how long a coma would ordinarily extend before you reach a point where the reasonable expectation is that there would be an extremely lengthy rehab?

ALI REZAI, MD: It's a great question, commissioner. With coma, from a moderate or severe or devastating brain injury, typically, you can come out of the coma within four to six weeks and then there's a spectrum of evolution from the initial severe brain damage and coma. Then you go into a vegetative state, which is the next step up. But there's

really no significant function in the vegetative state. These are all reflexive movements and so on. Then the next step of evolution and recovery is the minimally conscious states which is one step better where the patients are severe impairment in their consciousness and arousal. But they have up and down activity and some form of communication. Then there's an evolution to severe and moderate and mild TBI. So there's a spectrum evolution. But typically, within four to six weeks, you come out of the coma and go into the vegetative state where your eyes are open but you're not making a significant interaction. And then if you evolve from a vegetative state or go higher up in the spectrum, you go into a minimally conscious state. So I think it's very important to evaluate one at six months and one year. Really after one year that gives the best time for spontaneous or natural recovery of the brain. So after one year, we can really assess the patients at that time to see what their prognosis will be. Spontaneous natural recovery can occur for up to one year and thereafter, But it's most common within up to one year.

COMMISSIONER ASTRUE: Someone else?

JEROME HERBERS,JR. MBA, MD: I just – to dovetail -- I'd like to comment on that. By the way, I'm an internist, not a rehabilitation specialist or a neurologist or anything like that. I've just been able to work with some of the specialists and learned a little bit. But I just wanted to make a comment about long-term prognosis. It seems from what I've learned about social security disability that one of the tests is employability within 12 months. I could have that a little bit mistaken. But I just want to make a comment that we may be talking about a two tiered sort of approach. I believe that the data will very clearly describe that, given certain variables present within a few weeks of injury, it would be very easy to say, this person is very unlikely to be employable within a year. We don't know what's going to happen long-term, but it is very unlikely this person with this big intracranial bleed and prolonged coma is going to be fully functionally employed in a year. It's a separate question for the long-term employability. I think it might be useful. I'm just suggesting it might be useful to think of it in that way.

COMMISSIONER ASTRUE: It would be useful for us to stimulate that conversation. Because, you know, our statute says 12 months. And we, in fact, have mechanisms where we can mark someone is likely to improve medically and schedule them for review two or three years later. But if we know with a high degree of assurance that someone just isn't going to be able to function within a year, we can make some judgments and create some rules on that basis. So helping us find those would be tremendously helpful to us and obviously more important to the people we're trying to serve.

ALI REZAI, MD: Commissioner, just a follow-up. There are coma recovery scales that are assessing this, so within this one year, called CRS scores that can assess coma. But I agree with you, after one year, if you're still in a minimally conscious state or vegetative state, the likelihood of significant recovery is not there. So they will be disabled for quite some time.

COMMISSIONER ASTRUE: What if you're in six months, wouldn't that be similar? Or do you actually see significant spontaneous complete improvement after six months?

ALI REZAI, MD: It’s rare after six months. But that's why we say up to one year typically. Because you can still get significant recovery up to one year.

COMMISSIONER ASTRUE: Okay.

WALTER KOROSHETZ, MD: I was just going to follow up on the point that you mentioned. That the -- it is oftentimes very clear when someone is not employable in the first 12 months. The difficulty is after that. So the two-tiered system works. I guess the other point I was going to raise, and maybe john could mention is, that in my experience there's actually a price to pay by trying to send somebody back too early. Some of the deficits, and you mentioned that when you're in the hospital, things are fine; you didn't really know there was something wrong. Then you go, and in your instance, it was assisted living and things got tough. The other scenario is people go home, they go back to work and it's -- they're really too early. I've seen things crumble there as well. And because of the interaction between the social network that people have and their eventual recovery, if you get in too early and things start to fall apart, sometimes that's actually a spiral. Which is a lot harder to get out of. So I guess – in commenting on that, can you say more about what is it that you noticed when you moved up to the next level? Was it fatigue and headache? Many people can do any single thing. When you have to do -- we do a hundred things in an hour automatically. We take it for granted. But that seems to be the hard thing.

JOHN SHARPE, MBA,MS,PT: I’ll give you an example. Fatigue, mental fatigue was a big issue in transitional living. Part of my responsibility was I had to plan a meal for lunch and dinner for a whole week and then I had to make the meals. It wasn't until I begged and did as much as I could to try to have them take me back to Andrews Air Force Base so I could work on a part-time basis to gradually get back into work. When I came home one evening and it was my turn to cook, I turned the kitchen into; it looked like Iraq when they were initially bombing over there for the first time. It was disastrous. I dropped a bowl of pasta all over the floor. Busted the bowl. I was just severely fatigued and tired. I couldn't concentrate and focus on what I was doing. I struggled. And that went on probably for the next three to four weeks before I finally got a grasp of it and was able to establish a routine and get a routine down. One of the things that helped me a lot today, besides a lot of the compensatory techniques that I learned along the way is I have to have a very set strict routine so I don't forget anything. My wife calls me a robot sometimes. But I do everything systematically because I know I won't forget it. But if I get into a situation where I’m pressured or I am rushed, I will forget. I'll leave things behind. I was rushing out of the house last week to come up here to work and I knew I was staying overnight a couple of nights. But I rushed out and left my blackberry at home. And I felt like I was naked for the next three days -- naked for the next three days because I couldn't communicate when I needed to. So there's some things when the pressure gets on, and I have to make quick, fast decisions and I’m not able to process and problem solve effectively. I make mistakes and I become very forgetful.

ELLEN EMBREY: Dr. Herbers, you mentioned that data is available. We just haven't done the research to pull it together. Is that what you're saying?

JEROME HERBERS, JR. MBA, MD: I guess I wouldn't characterize it perhaps as research. The researchers have aggregated that data. There's several publications. I gave you just one reference in my testimony report, which is the most recent review, which summarizes all of the other reports. But there are three or four reports in the last five years which pull together information from thousands of patients with TBI. From private sector TBI. Which look at how well the predictive models match the patient's long-term prognosis. So you know the researchers have been able to say, yes, we can predict for a population how well these people will do. What the publications have not attempted to do is to say, what cutoffs could we use for individual patients. What I'm suggesting to you from having talked to a couple of those experts is that the data are there, they actually believe that it's certainly possible. Nobody has really asked them to look at it that way. But you've got this large body of population data from which I think you could extract common points to use. Now I have to say, I don't think they are going to terribly -- they're going to be terribly useful in the mild TBI cases, and they are not going to be terribly useful for long-term prognosis. But I actually think they already are excellent for short-term prognosis. There are other measures, of course. But I think that we should be taking advantage of what we already have.

COMMISSIONER ASTRUE: I wanted to ask a question, I guess, primarily to Dr. Rezai. There was a period of 12 to 14 years ago when I was working the biotech industry where I was looking at a lot of the potential products for stroke and neuro protection generally. The theory being there's damage caused by the original violence, and then there's additional damage by the inflammation that comes afterwards. And I remember being very focused on stroke. But not TBI generally. And I wondered if you could maybe update me a little bit on neuro protection and whether some of the drugs that have been proven to be effective for stroke have been tested in TBI generally, and what the outcome of that has been.

ARI REZAI, MD: That's a great question. So the damage beyond the initial damage, there's a secondary damage that occurs with inflammation and swelling of the brain. So a lot of pharmaceutical efforts to minimize that has been under way. Unfortunately, there's nothing out there for TBI as far as clinical trials or medications that can minimize the secondary damage. Still, the mainstay of therapies is controlling the brain pressure and the swelling and minimizing the overall pressure by taking out the blood clot or putting a tube in the brain to reduce the fluid in the brain to make the brain relaxed. There's no medication out there, unfortunately. We need much more research in this context.

COMMISSIONER ASTRUE: Are there medical reasons why something like TPA, and I forget what The competing product is, Is there a reason with a typical TBI that you would see for instance in a military context or after a severe auto accident, is there some reason TPA would be contraindicated?

ARI REZAI, MD: That has to do with you don’t have enough blood flow going to the brain from the clogging of the arteries. So the mechanism is different of that. That's the lack of oxygen. Whereas, the trauma is just a blow or damage or an acceleration, deceleration, penetrating or a blast injury. So unfortunately, there's nothing out there that, from a medication perspective. Maybe Walter wants to comment on that. But nothing that I know in terms of demonstrating benefit to minimize this secondary damage that occurs early on.

WALTER KOROSHETZ, MD: It has been disappointing. We -- ninds has funded on a regular basis a study after study to try and find something, and so far they have not proved positive. But we continue, and there are new drugs on the horizon. And hypothermia is another very potent effect that people are testing in brain injuries still. So we're -- and I think the experiments that have been done in animals have given us new insights and potentially had combined different therapies. So it's been a hard rock to move, but we're still pushing it.

COMMISSIONER ASTRUE: Thanks. That’s helpful. I appreciate it. Anybody else?

NANCY GRISWOLD: I have a question. One of the things --

COMMISSIONER ASTRUE: Nancy, if you could get closer to the mic.

NANCY GRISWOLD: Sure. Pull it toward me. One of the things that we -- we often see people who are able after this initial recovery phase to go out and obtain work. But what we see is an inability to retain the work that they get, and so we see folks that end up with a succession of short-term jobs. What sort of things would we need to be looking for in order to predict that sort of pattern?

ALI REZAI, MD: It’s a difficult question. And I think we need to quantify the functioning of the frontal lobes that are involved in your -- as I outlined all the components involved in judgment, decision-making, impulsivity, being able to carry out sequential tasks. You were talking about making pasta and you didn't know the components. So it's out of sequence. And I think there's a lot of neuropsychological and cognitive tests that can further quantify frontal lobe function. And there's a lot number of validated tests. If they can be assessed at multiple levels to see if they're being, having a very low level of functioning in those tests, that may provide additional input ,as far as them being able to hold a job down the line. That they have significant compromise in their judgment, decision making, based on these standardized tests.

JOHN SHARPE, MBA, MS, PT: I’d like to comment on that as well. A lot of it depends on the type of job the individual is going to. We know that, I use the term emotional intelligence. My emotional intelligence was shattered. I didn't have the awareness or the ability to know if I said something wrong or did something wrong or if I really offended someone. So if I was going to work in a customer service job, there's no way I could maintain that job. However, if I was going to be a general construction laborer doing rote memorization jobs, I could probably function successfully. But could I deal with the

community in a public setting appropriately? Probably not. So there's a lot of different variables you have to look at. So it's very hard to quantify what you need to do to be able to put a number, saying, what can we do for that? Personally, and this is my own opinion, and even though I do have physical therapy background, I've been a patient; unfortunately, we are going to have to look at each individual by themselves. We are going to have to look at the holistic approach of the whole entire person. What can they do in a community? Do they go through community to reintegration? What things could they do appropriately? What do they need help with? What follow-up do we need? When it comes to job employment, maybe we need to have some sort of a work hardening, work simulation center for them to practice skills, practice parts of a job. See what they're good at, what they are best at. Maybe they would be better at a different job than what they think they want to do, that they are more appropriate for. But those are the things we have to look it at in the future. But those are some challenges that not only you as a social security administration but the patients and families have to deal with as well.

ALI REZAI, MD: If I may make a comment, follow-up. I think I want to underscore that point, that traumatic brain injury is very complex, Depending on what part of the brain is damaged, to what extent, what's the mechanism of the injury, and it can affect all these different functions. It's a very difficult area to quantify.

WALTER KOROSHETZ, MD: I think what you mentioned is that's the sign of starting too early, When you send people back out. You know, so here's a strong guy, he can work construction. What's the problem? But you don't realize, you know, there are all these other aspects which require concentration and multitasking. People developing fatigue, people being slower than the other person. So I think, you know, it's worthwhile testing it, but you can't have somebody go from a minimal conscious state to working. There has to be a credation for it to work well. So the trick is trying to know, you know, how fast you can move somebody through. I think that the vocational therapists and the speech therapists who deal with brain injury patients, they know because they've seen it so many times. This is not an uncommon condition. So I think they have a sense. And you mentioned, you know, the FIM scales. In the rehab they're using scales all the time. So I think we could probably make some progress by looking at the correlation between employability and the scales that are used in the medical practice, like the FIM, To give us kind of clues on who is going to have trouble. But a good vocational therapist, they know.

DAVID RUST: The reason I sort of sound like Johnny one note about anything that gives us some additional insight into how to adjudicate these cases, as the commissioner said in the opening statement, about two and a half million applications a year. There's a large segment of those that are clear denials. People have some impairment but they clearly don't meet the standards of the program. There's another category on the other side of people who clearly meet the standards of the program that are allowed. But there's a gray area in the middle. That's a large gray area where it's very hard to make a definitive decision. And the result is, if we deny that decision at the first level, at the -- many of those people will appeal and go into the appeals process, which is very costly. It's very time consuming. It's very expensive. And if the person legitimately needs benefits, it

stretches it out for a long period of time. So any even tidbits of information that give us some ability to make a more definitive decision earlier in the process, or even later in the process, because the person then will have -- will be several more years removed from the traumatic brain injury, anything along that line is helpful to us. So I'm especially interested in the lists you're going to submit for the record and how those things, maybe not one thing, but maybe interplay of one or two of those things would give us better insights. Timing questions that dr. – I think also -- and others have too, the whole question about not only what tests do you do, but when do you do them and how close together do you do them to get a reading. Anything that can give us some insight would be helpful.

UNIDENTIFIABLE VOICE: Maybe having the two bars, you know, one for the early, where we think we have confidence, and then one for the later where the bar should be higher because we don't --

COMMISSIONER ASTRUE: Let me just do one add-on as we continue to impose on you to try to get some help. We also very specifically under our statute are allowed to consider age as a factor. So as we look at these scales, if there's a significant age factor justified by the medical data, we can incorporate that into our scales as well. I wanted to ask a question. Maybe just slightly off topic. But I think I'll probably be forgiven. Dr. Herbers, you mentioned the homeless veterans. One of the things that we think we will be able to do shortly is have our first on-line forum for applications for title XVI, The SSI program. And that may seem not terribly helpful in lots of ways, but what we found in some pilot testing is that the service providers for the homeless think that this is the greatest thing because they have the same problem we do. There's a huge problem, even when they connect with this population to get them to go through our ordinary process and literally to show up for the appointment. And so they loved the on-line application. When we get this up and running, can you just talk to me for just a moment or two about what kinds of records, what kind of data that the VA has about its homeless population that we might be able to tap in to help find these people and help the VA help these people? Do you know anything about that? Or do you know where we should ask that question?

JEROME HERBERS, JR MBA, MD: Well, I know in our office the inspector general has published a report on homeless care in the VA, and the VA certainly has extensive programs. I think this is a time to make another plug for the electronic medical records that's so effective in the VA. But I can't say much more than that. Except that there is a VA office that's -- that's devoted to -- devoted to homeless care. I can get that information to you.

COMMISSIONER ASTRUE: That would be helpful.

JEROME HERBERS, JR. MBA, MD: Okay.

ELLEN EMBRY: I'm intrigued by the idea of a work competency testing center, actually. Clearly, the criteria for social security is substantive work. But, I wonder if

there's a way in which you could correlate what substantive means in the context of functional capability as it relates to cognitive capability or the person's functioning on a daily basis. Because, you know, I hadn't really thought of it that way. A person could be -- could handle certain things but maybe not others. And evaluating that might be important in coming up with an algorithm for that.

COMMISSIONER ASTRUE: I think that's really important. And one of the things we're trying to do to change the paradigm. We have a little over $30 million a year in r and d money. Which for a long time we've been spending on very similar – worthwhile, but similar tests on work incentives that haven't yielded a lot. And one of the things we're excited about with the M.O.U. that we signed with NIH is, I think we wanted to try to do some different kinds of studies we haven't done before, where we're trying to correlate biomarkers with functionality . And I think that we're going to be able to run these a lot more quickly and inexpensively with a higher likelihood of success in the kinds of studies we've run in the past. Getting going and trying to figure out which are the right ones to do first, I think, we're still in the planning stage on that. But our hope is that, you know, one of the things we're going to be able to do with the partnership with NIH is start running more studies that look like that. It will help us actually answer those questions and give us a basis in our regulations for deciding that we can make some of these cases easy.

WALTER KOROSHETZ MD: One parallel situation, we were just chatting before, is on driving. I don't know if john wants to say anything about that. One big question, when somebody goes out of rehab, they want to know can I drive the car. And so people have tried to figure out ways of evaluating that. There are centers and rehabs that have virtual driving paradigms or basically get somebody on the road. This was an instance where you have to make a decision, go, go go, you drive or you’re not. You have to put in the system, and I think it's pretty effective. It's hard to predict. But you get somebody on the road and drive with them, then you know. What happened with you in the driving?

JOHN SHARPE, MBA,MS,PT: First of all --

WALTER KOROSHETZ MD: You had tickets. Were there any accidents?

JOHN SHARPE, MBA, MS, PT: that was the -- to be honest with you, because I couldn't remember, I mean, my post-traumatic amnesia was greater than two weeks prior to the accident, I couldn't remember anything from the time I was at the community hospital. And when it came time to go to a driver simulation to drive again, that was probably the scariest feeling I’ve ever had, Because I had no idea what to expect or how I was going to handle myself. And even though it was a simulation where I sat in a room with a steering wheel and pretended like I was driving, it was challenging. But again, once I memorized how to work it, and felt comfortable with it, I thought I could drive around the NASCAR track. Then when I got behind the wheel of a real automobile and had to do that, the fear and anxiety set right in right off the bat. And I struggled with that. And I had some challenges initially. And it took a while for me to overcome that. So that's been a challenge. And then once my insight and self-awareness started to improve and I could sense that I was having problems, that's when I realized that my inattention was leading

to my erratic behavior behind the wheel of my speeding tickets, so I was able to seek out the proper mental healthcare and correct that. So it's been challenging. To comment back a little earlier, what we talked about earlier, as a therapist and physician, physicians their job is to make the patients as stable as possible so they can carry on with rehabilitation. From a therapist's standpoint, our focus is on the FIM scores and the functionality. How functional can we make this individual? Can they get out of bed? Can they dress themselves? Can they walk? Can they go to the restroom? Well, that is fine. But we have not talked about any kind of community assessment. How they function in the community. You know, I know that the FIM score does has some cognitive and function and abilities dealing with ideals and different aspects from that avenue. But we look at the community. How well do they function in the community? Can they hold a job? You know, yes, they can go out and work as a construction worker and they're fine. But you know, are they able to talk to the teller at the bank or when they go to the store, are they appropriate? There's a lot of things that we haven't looked at. Maybe there's an opportunity for some additional research and a pilot study on some sort of a new assessment tool dealing with how you function in a community or deal with family members.

DAVID RUST: How would you respond if you were simply on benefits and not challenged to do anything? You got your medical benefits, you got an income, but there was no need for you to work to overcome these deficits?

JOHN SHARPE, MBA,MS,PT: How would I respond? How I would respond? Well, first of all, let me tell you that I had the opportunity to serve as a peer counselor to a lot of patients and families with severe TBI. And as a physical therapist, I refused to work with TBI because I didn't want to conflict the peer counseling with working as a therapist. I didn't think that was appropriate, so I stayed in spinal cord injury. But I know for a fact that no two entities are alike. It's a different mechanism for each individual. So it's very individualistic. With that being said, Some people's pre-morbid coping abilities or their way they function in society is completely different. So if you were the type of person that may not have been very motivated or aggressive and you gave up easily, you might have the tendency to be more depressed after a mild, moderate, severe brain injury. Lucky for me, and I'm attributing this to my parents, but I was blessed with an attitude to not give up and keep on trying. And that has benefited me throughout my recovery process. There's a lot of times I've been knocked down, but each time I've gotten up and dusted myself off. And I've learned to go back and find out what I did wrong or what didn't work. And that's something that I've had to learn. That's helped me along the way. So it's hard for me to say that. I know there's individuals out there who are getting their 100% disability check and they are just going to stay home and do nothing because they don't have to. It's hard to quantify how we can, you know, address that. But some individuals are going to be motivated like myself. I mean, I was initially 100% service connected. But, when I went back to school and became employed, it changed to 60%. I didn't complain about that. I felt with my career being cut short in the military that I deserved the 60%. So I wasn't worried about that. But I'm also the type of person to – well, I'll be honest with you. I was bitter at the air force because they were kicking me

out. So part of my motivation was to prove to the air force they made a mistake. So that's why I got two masters degrees after my head injury. I think that I proved that point.
[laughter]
So – but I'm one of the fortunate ones. I had the opportunity with the attitude and the positive outlook to keep moving forward. Sometimes that's not a good sign, Because it causes difficulty within my family. And I have to -- it takes my wife's help to regroup and sit down and say, wait a minute; I have other priorities that are more important than staying focused. So it's been a challenge, but it's hard to answer that question, Because each individual is completely different. So I can't respond to how someone would answer that question.

WALTER KOROSHETZ, MD: I just say, I think the important point is we don't want to disincentivize trying. That would be really bad. Because just medically, that's how the brain recovers, As I said before. So if you just look at recovery of patients, those who are most active, less sedated, always do the best. So this activity is really important. So you know, again, a short term low bar, which is -- enables people to improve as much as they can in the first year, and then the higher bar after that makes a lot of sense.

COMMISSIONER ASTRUE: Nancy?

NANCY GISWOLD: One more?

COMMISSIONER ASTRUE: Yes. Go ahead.

NANCY GISWOLD: I'm fascinated by some of this newer imaging technology that you've been talking about. But I'm curious, what percentage of cases is that sort of technology actually used? I'm talking about like the functional MRI and the pet scans. Is it --?

ALI REZAI, MD: So with imaging, the structural imaging of a standard MRI is used in standard routine all across the country. And we can look at the structural damages. It's the functional tests that are emerging with a number of paradigms that are specifically assessing cognitive function or specifically assessing speech, language, intentional paradigms. So there's a lot of research going on, but this is an active area of application of these technologies to those with epilepsies, patients with traumatic brain injuries, stroke. And I think it's going to play a much more important role in the next few years. A large number of elements are on the research, but it is being used routinely for clinical practice in certain conditions.

WALTER KOROSHETZ, MD: so the diffusion weighted imaging which you mentioned was so that the white matter, which most of the lesions are, is now pretty wide spread. And the question is: how do you best analyze the data? That's basically developing programs. Once they're developed, they can be used on pretty much any MRI machine throughout the country. I would think that that's going to be a major -- something that you'll see in the next year or two really coming out. But, again, as was mentioned, we're not sure it's going to help the mild. But I was actually involved in the first publication

years ago in severes, and it was really quite remarkable how well it was tracking with recovery. So in the severes, I think it's going to be very important and more work than the milds.

ELLEN EMBREY: Before we go, I'm sorry.

COMMISSIONER ASTRUE: No, no. We've got time for one more.

ELLEN EMBREY: Many of the wounded warriors have highest -- the highest problem that we see folks leaving a service is hearing loss. And it seems to me that hearing is very important in the recovery and rehabilitation of traumatic brain injury because it helps you engage the mind to the therapies that are being offered. So to what extent do you have data that talks about the co-morbidity of hearing loss and traumatic brain injury and its effect on restoration of function within that one-year time frame?

ALI REZAI, MD: I don't have any direct data on that. That's an excellent question. Hearing and visual senses and other senses that can be damaged with traumatic brain injury and are important to the feedback that we need to be aware of our environment. So I don't have an answer. Maybe Dr. Herbers can answer that.

WALTER KOROSHETZ, MD: That's unfortunately, I think going to be pretty specific to the blast. Because they have frequent hearing damage due to the blast injuries. And the civilians don't see that as much. But civilians see the stimulating balance, with dizziness. Imbalance is very common. And it does have a major, can have a major negative impact on your ability to recover, all sorts of -- just moving your head to read sometimes is too much. But the hearing would -- we don't know actually.

ELLEN EMBREY: It's not just blast injury. Hearing loss is the number one disability for veterans. So it's not just blast injuries. So it's a combination of the occupational risk of being around munitions exploding and jet engines and things like that where they fail to do the protective measures. And then that, in combination with a traumatic brain injury affects the individual's ability to recover more rapidly, I would think. That's a postulation.

UNIDENTIFIABLE VOICE: And also, the tinnitus, The ringing in the ears. That's also a major problem that affects over 20 million people in the U.S. And that's very much associated with the veterans coming back, having tinnitus. That's a big problem as well.

JOHN SHARPE MBA, MS, PT: And I'll agree with that as well. As I mentioned earlier, when I got more of my senses involved, as I was re-listening to my tapes and writing them down and again listening to them a second time, it helped increase my memory retention ability. So the hearing aspect was extremely important in my ability to be able to function and learn material and pass tests. So if hearing is removed, you know, with a mild or moderate TBI, it's going to challenge that individual as far as relearning the new task and maintaining their memory.

COMMISSIONER ASTRUE: Well, I’m going to -- I want to thank john for his very brave testimony. And thank our two doctors for really helping us on a lot of points that are very important. So, another great panel. We're going to take a break for lunch. But again, thank you all very much. And I’ll see you all at 1:30. [applause]