SSA HIV Policy Conference

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FEMALE VOICE: Test. Test.

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MR. GLENN SKLAR: …to SSA's conference on HIV and the disability program. I realize many of you have traveled from far and wide to be here. We are extremely appreciative. We think today is a really important day as we begin our journey of looking at the medical criteria with HIV, for determining HIV under SSA's disability programs.

Before I start, I want to introduce a couple of folks who are here that you will see out and about throughout the day, handling the mics, fielding questions; first Dr. Monte Hetland, behind Monte, Barry Eigen our Executive Program Policy Officer, Dr. Desi, our internist, and Paul Scott, Senior Analyst at SSA.

I guess I need to introduce myself. I'm Glenn Sklar, I'm the Associate Commission for the Officer of Disability Programs. We are the policy group at Social Security. We help write the standards for medical criteria for all diseases. And I think what you're witnessing today is a different type of method for coming up with criteria. We really are moving to a more interactive method where before we put pen to paper, before we do anything with any of our disability criteria we go out and find out what's on people's minds. We invite in the very best medical experts we can find, advocates, patients, whoever can really make a contribution to our learning and thought process. We bring them all in. We think it's really important to hear from everybody and we hope today is a really interactive session as well.

I'm going to start with a two-minute overview of the programs that SSA runs, just so everybody starts with the same type of background. SSA has two main disability programs; the social security disability insurance program, and that's funded out of your FICA contributions that you pay every week or every other week out of your paycheck. SSA also runs another disability program, the supplement security income program, or SSI program. That's more of a mean's [phonetic] tested program.

The important thing to realize in the context of HIV, is not only are these potential benefit streams [phonetic] for individuals, they are also gateway programs to other health insurance benefits. Social Security Disability Insurance could be a gateway program to Medicaid, help to Medicare, Supplemental Security Income, it could be a gateway program to Medicaid. So I am sure we will have plenty of discussion today about the implications, not just of the benefit stream [phonetic], but what it means in terms of health insurance as well. Although we are not the keepers of the health insurance program, that is CMS, our cousin, the Centers for Medicare and Medicaid Services. We do realize that there is connectivity, and in particular how folks get on the disability roles and how important it is, particularly in the content, context of HIV.

So where are we in updating our medical criteria at Social Security in terms of disability generally? We're on a five-year plan to update all of our criteria. We really want to keep them as current as possible. Ultimately we'd like to be on a three-year cycle. Unfortunately, not all of our criteria are that up to date right now, including the HIV criteria. Paul will explain that we really haven’t made significant substantive [phonetic] changes to the HIV criteria in over a decade. And that's why today is so important to help us get to the right answer.

A couple of administrative points about today, the proceedings are being transcribed. We have a transcriptionist. So it is important that whenever you come to a mic you identify who you are and that you also speak clearly so that she can transcribe the best way possible. Really we're building a record, and it's a record that we'll use to write the standards. So just so everybody is on notice that today the entire proceeding, anything that is said will be transcribed, so please identify yourself.

We're also going to be fairly careful about staying on time. We have some wonderful practitioners with us, but our obligation to them is to get them back to their practices so they can see patients. Some need to see patients today. So please, if you do have a time slot, please be cognizant of that. And we don't want to insult anybody, but we will be holding up placards, 10 minutes, 5 minutes, just so that we can run the conference on time as well.

Okay, what I would like to do is bring up Paul. Paul is going to talk in detail about the current HIV standard. And again, welcome to the conference. We hope we can be really interactive. And we're going to try to have a dialogue during the various portions on the agenda. Where you see public input we are going to hopefully have a very thoughtful back and forth discussion. So we encourage your participation. Thank you.

MR. PAUL SCOTT: Good morning. My name is Paul Scott. I am a Policy Analyst in the Office of Disability Programs. And I want to thank you for attending our conference today on the HIV infection listings. We are here today to hear your comments on these listings.

We have a number of excellent speakers today who will be presenting information. And we're just very happy to have everyone who is speaking. And we will have two panel discussions, one this morning, one this afternoon, that will give everyone a chance to present information or to participate.

This morning we will be discussing information concerning adults, and by adults we mean individuals age 18 and older, and this afternoon we will be discussing information regarding children, and by children we mean individuals less than age 18. Now even though this is an SSA sponsored event we have received a lot of help in putting this together, especially in regard to finding speakers. I just want to mention a few names of people that we really appreciate their help in finding speakers: Andrea Whettle [phonetic], of the HIV Medicine Association; Dr. Judith Aberg, who is also one of our speakers, a Professor NYU School of Medicine; Mark Delmonte [phonetic] of the American Academy of Pediatrics; Cathy Bowman of the South Brooklyn Legal Services; and, Dr. Marcy Sedlacek of Montefiore Medical Center. And we also spoke to a number of other people and we really appreciate everyone's willingness to help us.

Now we might go through quickly the conference binder, just so I, we can know it's there. The first half, of course, is the agenda, and the second half are speaker presentations. And these are handouts of the PowerPoint slides of our speakers today. So you can follow through there or look at the screen once they do their PowerPoints. And they are in the order of the presentation. Also under handouts we have a glossary of terms that Dr. Nadler will be using in his

presentation. We also have a copy of the Advanced Notice of Proposal we're [phonetic] making that we published in March of this year, asking for comments in regard to our HIV infection listings. And then we have another handout for the adult and child HIV infection listings.

We actually have the complete introductory text for the immune disorders, which HIV infections are a part of. And we have 14-1408 [phonetic] for the adults and 141-1408 for children. Then we have the attendee list. And I'm sure if you look through that and see your name you will agree this is a very impressive list of people attending today. And we have the evaluation form that we would like for everyone to complete before they leave today. We would really appreciate your feedback.

And also, we have a couple of brochures in the front of the binder, Disability Benefits and Benefits for Children with Disabilities. And these brochures provide information concerning our disability process. And we included those for people who might not be that familiar with our process, that's our reference.

Now a brief historical perspective over HIV infection listing. We did publish in July 1993, final [phonetic] rules for the immune body system that included the HIV Infection Listings. Now I didn't participate in that process, so I feel comfortable in saying that over the years we have received supportive statements in regard to the listings. And we actually have an individual here today who participated in that, and that is Barry Eigen, who was introduced earlier.

Now let's go ahead about 10 years to May of 2003. In that time we published an Advanced Notice of Proposed Rule Making for the Immune System Disorders that once again include the HIV infection listings. Then we asked for comments on how we might update or revise them. Then in, also in 2003 and 2004 we held outreach meetings, similar to what we're doing today. In August of 2006 we published a Notice of Proposed Rule Making for the Immune System Disorders. And in March of this year we published Final Rules and they became effective in June.

Now as a result of this process, and Glenn mentioned this earlier, we did actually do significant revision to the introductory text for the HIV listings. That's where we

provide guidance for adjudicators. However in regard [phonetic] to the criteria or the listings, we only made a few changes and primarily those were for clarification. So basically the listings we have today are the listings that we published in 1993.

As a result of the comments that we did receive during the process, and especially on the Notice of Proposed Rule Making, we did publish, on the same day that we published the Final Rules for the immune system, an Advanced Notice of Proposed Rule Making, in which we requested comments on whether and how we might update our HIV listings. We appreciate the comments that we received. And as a result of those comments we are here today to receive expert opinion regarding how we evaluate HIV infection, and opinions on whether and how we might update our listings. So, again, we are here today to listen to your comments. And we are very interested in any suggestions you have on whether and how we might update our HIV infection listings.

Now I just have a few brief slides. This is the beginning. I want you to know the creative genius behind this was Barry Eigen, including the pictures. So I want him to get full credit. Now this is our definition for disability. I'm going to go through these slides really quickly. It's a very strict standard. We require that there must be a medical impairment that causes the inability to work or inability to do substantial gainful activity - - work. And we have a duration requirement. That means we expect for the impairment to last for at least 12 months, either have lasted or will last for 12 months, or result in death. So that is a strict standard.

And this slide provides a little more information, because when we consider whether someone can do any substantial gainful activity we not only consider whether they can do their past work, but we also consider whether they can do other work, considering age, education, and work experience.

Okay, now this is the sequential evaluation process for adults. We have a similar process for children, but to save time we're just going through the adult five steps. It is a series of five steps. And we do stop at any point in which we can make a determination. The first step is we want, we determine if someone is performing substantial gainful activity. And that is primarily a, determined by monthly

earnings. And the earnings for someone who is blind is higher because of that's in the statute [phonetic].

The next step, so if someone is performing SGA we would determine that they are not disabled. But if they are not working they go on to step two, which is, do they have a severe impairment. And that really means do they have more than a slight or minimal, an impairment that has more than slight or minimal impact on their ability to work. So it is a very low threshold, and most people have a severe impairment.

So we go on to step three. This is the most important step for today's discussion, because at step three we determine if an individual has an impairment that meets or equals our listings. Now an important thing I want to mention is that we only use the listings to allow someone, to find that someone is disabled. We never use the listings to deny anyone. If someone has a severe impairment that does not meet or equal the listings then we go on to step four. And actually the standard that we use at step three where the impairments in the listing are severer than the definition require. But that is because at step three we do not consider age, education, or their previous work. And, again, we never use the listings to not deny anyone, just to allow them.

And when we say someone has an impairment that meets the listing, we're saying that in their medical records they have the findings that are in the listings. Now also, it's possible for someone under our rules to, what we call, medically equal listing. And that can occur in different ways. But one way it would occur is if we look at the records and we don't find the findings that are described in the listings, but we find other findings that are of equal severity.

So this is a slide of our body systems for which we have listings. And the listings are divided into two parts. Part A, for individuals aged 18 and over, and sometimes we can use it for children who are less than age 18. And then the Part B listings are only for children less than 18 years of age. Okay. So if someone has a severe impairment that does not meet or equal a listing then we do assess their residual functional capacity. And that basically means we assess what they can do on a sustained basis.

Then we would consider whether they can do past relevant work. If they can do their past relevant work based on their RFC then we would find that they are not disabled. But if they can't do their past work then we go on to other work. And in deciding whether someone can do other work, we do consider their RFC, what they can do, their age, education, and work experience. And we do have medical vocational guidelines that we use at step five to determine if they can do other work.

And then the next slide is my favorite because that means I'm done. So thank you for your time. Again, we appreciate you being here today. Our masters, Master of Ceremony is Dr. Monte Hetland, so I will go ahead and hand it over to Monte. Thanks.

DR. MONTE HETLAND: Good morning.

SPEAKERS: Good morning.

DR. MONTE HETLAND: I'd like to introduce our first speaker, who is Dr. Jeffrey Nadler. He is the Acting Director of Therapeutics Research in the Division of AIDS at the National Institute of Allergy and Infectious Diseases. Dr. Nadler.

DR. JEFFREY NADLER: Good morning to you. So my job today is really to keep us on time as the first speaker. That's the introduction. And what I wanted to do was talk a little bit about historically, I was asked to address HIV from 2003, which was to the present. And there have been huge and very consequential changes in our medical approach to this illness. So historically let's look back at it.

Remember the disease was first described in 1981 officially, although some of the first cases were reported in the fall of 1980. Life expectancy at that point was six to nine months. When you were diagnosed with AIDS you were basically not expected to live. And the defining characteristics that were limiting were really laid out pretty well, even in that first definition. Terms of the opportunistic infections, and again you have some of the definitions in the handout. If anybody is not sure what that means just put a hand up.

We had no antiviral therapy. We didn't even have diagnostic tests. So our diagnosis was clinical. And we only recognized it in general when people presented with advanced disease. So the diagnosis was not only clinical, but delayed. And we had no surrogate laboratory markers. We

think automatically today of CD4 counts and viral loads and things of that nature. They didn't exist. In the early 1980s lymphocydenumeration [phonetic] was an expensive laboratory test that had not been validated for use in essentially any clinical situation.

And so we did see some early improvement as, especially those of us in the infectious disease community, became really better at recognizing the earlier stages of these very severe illnesses. And also as we came to understand that we could use preventive therapy, prophylaxis for some of them. And, boy, was that controversial in the early to mid-80s. And treatment, which could be applied, was improved with better diagnosis. We could start treating early enough. And so life expectancy hugely increased to two to three years. Now put it in the perspective of the average 25- to 35-year-old who is being diagnosed with this illness. Two to three years of life expectancy is still pretty crummy.

So opportunistic infections are often severe illnesses that are rarely encountered unless the immune system is considerably compromised. One of the most common causes of immune system compromise in adults is HIV. - - can be certain types of malignancies, cancers. Medical advances have substantially improved the prognosis of many, but not all of these opportunity infections. Some still really remain untreatable or minimally treatable at best.

And so we can see persistent illness or death unless there is significant immune improvement. And that's something that today we often see in HIV with the use of highly active antiviral therapy, which is really only fairly active, but that's not as polite an acronym.

Now the immune restoration doesn't occur uniformly. It is in some instances not predictable and it's not an overnight process. It's a process that can take years in order to see it, if it occurs. Now our first big breakthrough was 1987. That was the dawn of antiviral therapy, antiretroviral therapy and zidovudine, or AZT, ZDV, became available. Some of us that had been involved in antiviral research developing some of the anti-herpes agents were kind of co-opted into this other disease that we were trying to manage clinically and worked to develop these new drugs.

We had one drug, AZT. Then we had DDI and DDC and D4T and 3TC, and we used them one after another as the benefit wore

off. So a serial monotherapy. It had very limited effect. I mean we knew when we were developing these drugs that individually their potency was quite limited. So some of us in the early 90s proposed combination therapy, as was being used in, for instance, tuberculosis and cancer treatment. The combination therapy was studied and originally we looked at two drug combination therapy and then three drug combination therapies. And in the earliest years of the 1990s the third drug was really interferon, and that was not very active.

So even with combination therapy we had better effects 'cause of greater potency. But the benefit was limited because of adverse effects of the therapy directly. And that's all we had. So for many patients it was, well, how many pills can I swallow before I get so sick that I can't take any more. That's not a good approach. And it was still applied in those patients with the most advanced HIV disease. So you're taking someone who is basically pre-terminally ill and trying to bring them back from the brink of death with a toxic, inconvenient therapy, suboptimal.

A major advance was the availability of what became called HAART, Highly Active Antiviral Therapy. In 1995 and 1996 protease inhibitors became available. It was actually Thanksgiving of 1995, kind of appropriate, when saquinavir became the first available protease inhibitor. Challenging, you know, a handful of pills, two, three, times a day. Limitations in terms of how much food you had to eat and when regarding with timing of the doses and so on.

And then our further development in early 1996 was indinavir [phonetic] and ritonavir. And as one of my patients said to me, well you've got me on combination therapy and now I have to walk around looking at my watch constantly because I have to figure out, is this the two-hour period where I have to eat or is the four-hour period where I can't eat so that I can try to take my next dose on schedule. And it was really challenging because with multiple pills as well. So we knew we had to do better.

So in 1996 and in to 1997 we really developed the non-nucleoside reverse transcriptase [phonetic] inhibitors, navirapine and efavirenz were the leaders, if you will, in that, although there were others that we used in the clinic. And the result of using these combinations was a huge decrease in mortality and morbidity that followed the

initiation of therapy. But it was very difficult for patients to sustain these regimens. And it was challenging for us as providers to try to figure out how do we deal with the complications.

In addition to this at about the same time, actually a little bit before, we had new laboratory diagnostics. And we were able to diagnose and monitor the disease better. So the original 1987 approval of the HIV ELIZA [phonetic] test, which was developed for screening blood. It was widely applied in the late 80s. When I think back, I believe that was only the second clinical use of ELIZA technology. The first was in the diagnosis of hepatitis B.

Then in 1989 and in to '90 this technique of polymerase chain reaction was developed by crazy Kerry [phonetic] and we rapidly applied that for quantitating the HIV viral burden. In addition, in the late 80s we had really achieved a pretty good standardization of our monoclonal antibody technique for quantitating the different components, at least the gross components of the immune system, the CD4, and CD8. And so we were able to apply that as well.

And so now we had quantitative measures telling us how rapidly the immune system was becoming impaired, how severely, and how improved it was becoming with therapy. And we also understood the flux of that in relation to the amount of virus using the PCR technology. It's fascinating to me, having been in medicine since the mid-1970s actually, that monoclonal antibody technology led to a Nobel Prize some years after it was originally described, in 1986, '87, excuse me, '76, '77, '78. And then we applied it in clinical practice 10 years later.

And the same thing, PCR took two to three years to come from the discovery end, publishing of that test to application in clinical medicine. And CD4 counts, and CD8 enumeration had been cooking for awhile using that new technology of monoclonal antibodies. But it was 10 years into the disease where we were able to say we've got enough standardization to be able to apply them in management.

Here's the consequence of what we saw. So the 1993 definition, which is what SSA largely uses, what we saw was the number of deaths as we moved into the early 90s to mid-90s with dual combination therapy stabilized. But with the introduction of HAART we had a huge decrease. Okay. And the

number of cases also stabilized and began to decrease. These are the cases of AIDS, because we were able to diagnose the disease earlier, before full-blown AIDS developed, and treat it.

The consequence, however, is that people are living with HIV now. And this line of the prevalence of HIV infection, and this is actually the prevalence of AIDS in the United States, indicates one of the consequences of early diagnosis and better therapy. People live with it and they live longer with it. And we actually know that the prevalence of HIV infection is well over a million in the United States today. And from the latest CDC figures, which they did another re-estimate, if you will, of the number of cases that they've been reporting of 40,000 per year new cases since 1990, and we know that that represents probably at least a 40% undercount. So add a lot more to some of the published figures.

So what are the issues that we have with HAART, with Highly Active Antiviral Therapy? So we've seen incremental improvements from 1996. What we don't with [phonetic], and this can be disabling as well, is the prominent adverse effects of therapy, gastrointestinal intolerance, diarrhea in particular, and it's chronic. Anemia, largely associated with AZT but not exclusively. Disfigurement, that fat redistribution syndrome that we call lipodystrophy, which is a bad term to a clinical. It can be that loss in the periphery, which can make the muscles and veins look much more prominent. I had a patient in clinic last week who said, oh, is that why my legs look this way? And he refused to get off his D4T when I offered him an alternative. And also fat accumulation around the mid-section, buffalo humps, et cetera, and there are lumpy fat deposits that can occur as well.

So wasting is also a characteristic, and it's more than just the fat loss. And a lot of these things we now understand are a toxicity that really hadn't been well characterized before. And it's what we call mitochondrial toxicity. And that some of our drugs, in particular the thymidine based nucleoside inhibitors, AZT and D4T and to a lesser extent DDI, which is not a thymidine, were causing abnormalities of the mitochondria of the cells. Mitochondria are the energy powerhouses. And if those get sick there's a finite ability for recovery. And so you may have some individuals who are

exposed to some drugs that cause this toxicity who are left with a permanent impairment.

So we needed better drugs. And starting at about 2000, 2001 we started seeing some major improvements in the drugs that were available to us as HAART. These drugs had reduced toxicity. They had much better tolerability, and most of them also were a lot more convenient, in fact, to the point where today we have one drug, which represents a combination of three in a single pill, which can be taken once a day. And it's probably the most commonly prescribed initial therapy in the United States.

So we developed more potent agents, with improved durability of response. So we were getting better suppression of the virus. And then depending on the immune systems' ability to repopulate itself we may or may not get improved immune recovery. And also, because these drugs are more tolerable, letting patients take them more regularly with fewer side effects, as well as more convenient we're seeing durability of the response.

And we've had further improvements in laboratory monitoring, the ability, for instance, to measure the quantity of virus, which was initially 10,000 copies, then 1,000 copies, then 400 copies, and now 50 copies is widely available as the commercial standard. And in research we have single copy assays that we use. I'm not sure that those are likely to come into clinical use, but in research they are.

And then we also have some disease issues that we have to consider. Unfortunately, the virus mutates very rapidly. And many of these mutations can cause resistance to develop, and that in turn can compromise the response. We also, as people live longer, have the emergence of new opportunistic conditions that we may be knew about but didn't worry about, for instance, hepatitis C, chronic hepatitis C in particular. People died before it became manifest before, but now they are living long enough so that liver compromise is overlaid on top of HIV disease. And it's an extremely common problem for us.

We also see premature death, much of which we don't understand. Is it due to HIV and the immune activation of a chronic infectious process? Or what's the contribution of the natural processes involved here? So we have a population that's aging with HIV. Let's see if we can, I'm not, here it

is. So are the elevated lipids, which we know can be caused by some of our medications, lipids meaning cholesterol and triglycerides, et cetera, which we also know are predisposing factors for heart disease. Is that due to the disease? Is that due to the drugs? Or is that due to the aging of the population that's living with HIV? And from a disability perspective, does it matter? If you've got heart disease, you've got heart disease.

Unfortunately, many of the morphologic changes, the mitochondrial toxicity and disfigurement these are not, largely not, reversible. So that disfigurement that may lead to discrimination, et cetera, is a persistent feature we're living with. We also know that some of our drugs can cause abnormalities of glucose regulation. And the consequences of that is intolerance of glucose and a higher rate of diabetes and pre-diabetes. And we're seeing, again, how much of that is due to the disease, how much of that is due to the drugs, how much of that is due to the fact that we're just getting fat and old with HIV infection? And does it matter from the perspective of disability?

Another problem that we're increasingly recognizing is the problem of decreased bone mineral density. Now in the disability world there's a better appreciate, I think, than in most of the clinical world, that if this is severe enough, and if it results in fractures or frailty that there are adverse consequences beyond just the fractures. There's a disability that can occur. We are also seeing some patients who develop neuropathy as a consequence of some of the drugs that they had neuropathies, abnormal peripheral nerve function. And we know that much of this is persistent as well.

Chronic hepatitis C, I already mentioned. We are also seeing an increased rate of malignancy, cancers, both AIDS defining and non-AIDS defining. And the question, again is, is it due to the immune activation of AIDS? Is it due to aging with HIV infection, and does it matter? Perhaps we need to rethink our definition because we include certain lymphomas, but not others which are more common, like Hodgkin's disease is not an AIDS defining condition, and yet it clearly is increased in the HIV population.

And then another important point is that we're seeing subtle, very often, cognitive impairments. Our ability to function intellectually in the sphere around us, we may call this

minor cognitive motor disorder. It's a less severe set of conditions than the original AIDS dementia conditions, per se, but it's definitely a problem. And when you add in depression, and I don't want to get in to the psychiatric aspects, when you add in depression which is due to a stigmatizing disease, et cetera, is that exacerbating the process.

So, let's see, a few other things just to point out here and then I'm going to stop and we'll go forward. We don't have a good estimation, even, of what is the effect of HIV in an aging population. What are the interactions? We certainly know that as people live longer that they are likely to have other medical conditions that need treatment. So polypharmacy, multiple medications become a problem, drug interactions become a problem, management is more complicated, inconvenience and cost are increased, and there's a potential for adverse affects from medication complications.

And so I think there are two key points. One is that there's a disproportionate affect on minorities, which are, in fact, disproportionately infected, with HIV and represented in the epidemic. And there's also a shortage of benefits. More people living with HIV, the pool of resources available is not increasing. How do we triage it most affectively? And the discrimination issues have not gone away. Okay.

[Applause]

DR. MONTE HETLAND: Thank you, Dr. Nadler. It hasn't happened yet, but I was supposed to remind people to turn off their phones, on buzzer, or silent. Okay. Our next speaker is Dr. Judith Aberg, who is the Director of the South Manhattan Health Network at New York City's Health Hospital Corporation at Bellevue Hospital. She is also an Associate Professor of Medicine at NYU School of Medicine.

DR. JUDITH ABERG: Thank you, Monte. I apologize, I have a little bit of allergy going on and hopefully my voice will last the whole day. I'd really like to thank Christine Lubinski and Andrea Whettle at the HIV Medicine Associate and the SSA for inviting me today. Jeff, I want to thank you too. It was a fabulous overview of what's gone on with HIV and how the landscape is changing. And I'm going to spend a little bit of an introduction going over this.

But we've heard how we went from a devastating disease to now one that's more this chronic manageable disease that people can possibly live out their full life time. But that's not why we're here today. We're here today because there are thousands of people that are still living that devastating disease. And as Jeff was hinting upon, I think, is the stigma. That stigma remains such a huge barrier and that's why patients aren't accessing care and being identified earlier on. And I wish if we could find anything it would be a way to cure that stigma so that we could reduce that barrier and get people into care.

So as Jeff mentioned, there have been remarkable advances in HIV treatment. And yet, only 50 to 60 percent of people respond to antiretroviral therapy. In some of the new cherry-picked clinical trials you may see that in selected individuals that at 48 weeks, sure 80% of the people are responding. But we don't see 100% responding. And it comes to the issues that Jeff mentioned. Maybe it has to do with side effects of the medications. There could be drug interactions, et cetera.

Many people in the United States with HIV and AIDS are still diagnosed late in their disease, and I'm going to go over some statistics there. And the Institute of Medicine estimates that nearly 50% of people with HIV and AIDS in need of therapy are not receiving it.

Now this was a presentation given a year ago looking about who really is eligible for therapy. So if you look in the United States, the estimated number of people living with HIV and AIDS is 820,000. And of those that are eligible, meeting criteria set by national standards of being on therapy, 480,000 are eligible, but yet only 340,000 are actually estimated - - in care. And of those in care, only 268,000 are on therapy. So we have a long ways to go here of getting people on appropriate therapy.

The other issue is when you start looking at how late people are presenting and where they are in their stage of the disease at time of diagnosis. This is data collected from 35 states, and you'll notice that 39% are diagnosed with AIDS within 12 months of their HIV diagnosis.

What about when do people start therapy? So if you think about it, here we have all these medications, we have all these programs, the Ryan White Programs for people to access

therapy, but if you look here you'll see what the starting CD4 count is at the time people start therapy. Our guidelines now recommend that individuals start HIV medications at T-cell counts of about 350, 187, that's already an AIDS diagnosis at that time. And you can see compared to the rest of the world we're not that much better, and we should be. Right? We have much more access than Sub-Sahara in Africa. And yet we see numbers increasing here. We still remain here.

And that brings me back to my first point, because I think part of this is the stigma of people not wanting to get tested. They are afraid to get tested, or if they find out that they do have HIV that denial phase and trying to really access care remains difficult. Late diagnoses make a big difference in the outcome of our patients. In one study from South Carolina Health Department they looked at HIV cases from 2001 to 2005 and 41% of individuals progressed to AIDS within 1 year of their diagnosis.

The New York City Department of Health, a Study by Judy Sackoff and David Hanna, they noticed that patients diagnosed with AIDS at the time of the initial presentation were 55% more likely to die of an HIV related cause. And more than 50% of those deaths occurred within 4 months of being diagnosed. So people are entering care very late. It's too late. And trying to turn around and improve in those individuals is difficult. So the listings that you are going to see, that I am going to go over, some of the medical diagnoses, really unfortunately reflect the state of too many individuals that are presenting in the United States.

People are diagnosed late with HIV. They are more difficult to treat. There have been several cohort studies that have shown that individuals who take HIV medicines when their T-cell counts are lower than 200, experience more side effects to those meds. So therefore, they're less likely to take them. They are already very sick, advanced, and then they take these medicines, and as Jeff mentioned, can have neuropathies, diarrhea, and the list goes on and on of these side effects. Yet, if you take these medicines at an early stage people have less side effects. So, again, it's that key of getting people into care earlier.

These individuals experience the same disease as it was in the 1980s. There is no difference. You're coming in late diagnoses. I work at Bellevue, which is one of the city

hospitals. I can tell you, we still have an AIDS ward and that AIDS ward really isn't much different than that AIDS ward was in 1987. People are coming in with pnuemocystis [phonetic], they are coming in with progressive neurologic decline, they are coming in with wasting.

They are less likely to actually receive the full benefit. Again, the studies that I mentioned earlier, have shown again that people that start antiretroviral therapy with T-cell counts less than 200 are less likely to gain that benefit of an increase in CD4 count. So again, it's, you know, you're totally behind the eight ball there if you start therapy when your T-cell counts are less than 200. You can have more side effect to those medicines making it more difficult to adhere to, plus you're not going to get all the benefits of those because we don't see the immune response coming back fully in those cases.

So other factors complicating treatment, as many as 76 to 90 percent of patients in treatment are resistant to at least one drug. Now some of this was all learning experience, as people who were diagnosed years ago and we had limited therapies, people were essentially given sequentially monotherapy. So they were given AZT, if that didn't work we added one on. And now so what we're seeing is people that do have resistant virus that we cannot control effectively with antiretroviral therapy transmit that resistant virus to others.

And in New York City now there have been a few cases of individuals who have required a resistant virus that none of the drug classes were effective in until recently, with the addition of two new classes this year. Effective suppression of HIV requires strict adherence, some people say even greater than 95% adherence. How many people in this room are supposed to be taking a multi-vitamin or a blood pressure medicine and you miss a dose or two? All right, you miss a dose of a vitamin, you're going to be okay. You miss doses of your HIV meds, the virus can mutate and you can wind up with resistance. So it requires that really strict adherence.

And then there is something called the Immune Reconstitution Inflammatory Syndrome which really can complicate therapy. So what is this IRIS? IRIS is a response that you get to a pathogen specific. So that you may have some [phonetic] clinical disease, you might have something like cytomagalo

[phonetic] virus but you don't know it's there. And then what happens when you take these antiretroviral therapy, you're immune system all the sudden comes alive and it goes, oh, there's cytomagalo virus there and they get an inflammatory response. And the next thing this person has visual difficulties. So you can imagine one of the complicating problems is that if a person that, they're not feeling so well but they're not so sick. So now you give them these HIV medicines and they up having the side effects from that, but not only that now all of the sudden they have pneumonia or they have lymph nodes that they didn't have before. And so then you hear, those HIV medicines made me sick. And then you have to try to confront the community about explaining that this was a response of the immune system and it's actually a response signaling that it's getting better. But sometimes with an IRIS event what happens is you actually get worse before you get better.

So let's now go over the actual, some of the actual listings. So bacterial infections, one I think most of the audience is familiar with is tuberculosis. And HIV patients with pulmonary tuberculosis are five times more likely to die during anti-TB treatment than those that are not HIV infected. Now that comes from CDC surveillance data. I'm going back from 1993 to 2005. But those estimates are still true. And certainly what we're seeing in the world internationally, I would even say it was probably higher than five times. That is because patients have weakened immune systems, therefore, they're at increased risks for acquiring TB.

We don't really know what the optimal treatment for TB in HIV infected patients really is. And I find that amazing, but so many of the diseases that we treat among those with HIV are based upon studies that were done in people that did not have HIV. And so there have not been really new treatment strategies looking at what would be the optimal therapy there.

The other that makes it more difficult is that one of the preferred choice drugs for the treatment of TB is a medication called Rifampin, which causes serious drug interactions with HIV medicines. So this complicates it even further. And then TB more than probably any of the other types of infections is one of the most commonly associated with that IRIS that I talked about. And so the whole issue of when can you start antiretroviral therapy in the setting

of TB still remains unknown. And there's a large study through the division of AIDS that's ongoing now trying to address that question. Because there is actually a risk of mortality, increased mortality with one starts antiretroviral therapy at the same time that you start treatment for TB. So that timing is really critical and we still don't know what that actual timing is.

Other bacterial infections can cause significant disability, something kind of new in town. Although, methicillin resistant staph aureus has been around for a long time, we're starting to see more and more reports of this, particularly among men who have sex with men. It requires prolonged antibiotic treatment. This is really difficult to manage. I can't tell you how many patients I have that just keep having, what I think are recurring abscesses but I question whether or not we're actually being able to eradicate that infection.

So rather than really use the word recurrent, I really think in this case, this is one of those persistent, they harbor this methicillin resistant staph aureus and it keeps coming out. And the other danger to this is that it can be transmitted from person to person. So we're seeing clusters of people coming in that have this disease. And it can be difficult to manage, and it frequently requires hospitalization with IV antibiotics.

Clostridium difficile is another pathogen that's associated with antibiotics. Essentially what happens is when you take antibiotics for one thing you wipe out the normal bacteria in the gut, and this one organism called clostridium difficile overgrows and produces a toxin causing this diarrhea. And this is more common among those with HIV. And it's reported now to be one of the most common causes of bacterial diarrhea. And it's been, again, more difficult to treat. You think you have it under control. You stop the therapy and it comes right back again. This also can be transmitted from person to person.

So one of the things is then to consider then changing the terms, and how do you define severe? Severe I think is really difficult, and I think Monte did a great job of going over the definitions and all. But what is severe to one person may not be severe to another. So trying always to objectively classify this is really important. And, again, I think the word recurrent, recurrent really is not commonly

used in HIV because it's not that we ever seemed to be able to get rid of it. It's always there. It's refractory to treatment. You treat it. It seems like it's getting better, but if you ever take that treatment away it's really there. So that's why I actually prefer. And in my notes I use refractory and persistent.

And I think as clinicians this is an important message to get. I think one of the things that's really important with working with SSA is that we have effective communication. We need to know the language that they need to know. And they need to understand the language that the clinicians use. And, you know, source document is everything. And you know years ago physicians weren't so good. I remember when I was in San Francisco, I had one colleague that would write in his note DWNC, and I'd go what is this. And it was, doing well, no complaints. But you can imagine, you know somebody reviewing a chart is not going to know what that means. So as a clinician I need to be really thinking about somebody else is coming in reading that chart that they understand what I'm saying.

Fungal infections are less common but we still see them. Cryptococcal meningitis is a live and well, unfortunately, at Bellevue. We probably see about 30 cases a year. Yet, we keep hearing about how this disease is going away. Cryptococcal meningitis, the last review I read still showed that there's a 15% mortality at 2 weeks. That's about what I'm seeing at Bellevue, unfortunately. Patients that have fungal diseases are just as ill as they were in the 1980s. PCP, pneumocystis pneumonia, is still the most common opportunistic infection.

And 70 to 80 percent of our patients respond to treatment, but we are unable to predict who is going to respond. You know to paraphrase Dan Quayle, you know the problem with predications is that they always occur in the future. So, you know, I don't know looking at somebody who is going to get better. And it is a day to day judgment. And so it gets very difficult in the beginning to say, what is their 12 month outcome. I don't know what their 12 month outcome really is.

What about protozoan and helminthic infections? Again, patients have weakened immune systems, they're more susceptible to parasites that are benign to others. Giardia is a great example, if you remember President Ford had gone

skiing in Colorado and he ate dirty snow and came down with giardia. You know, so he had diarrhea for a few days. Our patients get giardia and it can last for months. And you know what I've found is I, lots of times, have to use even double or triple the doses that you normally would prescribe for somebody that doesn't have HIV. It's very difficult to control for some patients.

And we don't have good medications for many of the intestinal parasites. And, again, you're unable to predict who responds to treatment. So I just saw a gentleman the other day who is 33 years old, he was tested 2 years ago, he was negative. And he came in because he had over a 10% weight loss and has all this chronic diarrhea, and we did all the studies, and the only thing we came up with was something called blastacysis [phonetic]. And blastacysis, for the most part, isn't considered a pathogen.

We decided to treat him for this anyway just to see what will happen. But what he really needs to do is go on HIV medicines, which we just sent off his genotype to see if he has any resistance. But if you asked me right now, what is his outcome. I don't know, this gentleman has actually lost about 20% of his body weight in 6 weeks. Now 10 years ago I would say, probably not. I'm hoping he's going to have a good outcome. I'm hoping we're going to start him on medicines when his genotype comes back and six months from now he's going to look like the man he was a few years ago.

But this is where we get into that, where do you say, what can I say. And it's just kind of a day to day look and we're just going to have to see how he responds on therapy. But I'm sure I'm going to have that phase right now. He can't work. How do I fill out that form? And I think that's what I'd like to see on some discussions about…

[END TAPE MZ000015.MP3]

[START TAPE MZ000016.MP3]

DR. JUDITH ABERG: …how we address those issues.

Viral infections, herpes can still be disabling. I can't tell you how many individuals I see that come in with these super-imposed bacterial infections. They can't even sit down. It's a chore getting up out of bed, having to go to the bathroom. Many of these individuals have gone on course after course of acyclovir and they are resistant to

acyclovir. So they actually have to be hospitalized to get IV medications to treat this.

Another illness that I'm seeing more of, unfortunately, is progressive multifocal leukoencephalopathy, which is a neurologic disease caused by JC virus. The problem is, this is one of those IRIS events. People don't know they have the JC virus. They have low CD4 counts. I start them on antiretroviral therapy. Their T-cell comes up to 200, 300, and all of a sudden they can't walk, their memory is gone. And then we find out, we do the scans, and we find out they have this PML. Well what's the treatment of PML? The treatment of PML has been that you get antiretroviral therapy and you get [phonetic] up the T-cells, and the T-cells then control this virus.

But what happens to these people that get high T-cells and the PML flares as this IRIS event we don't have any treatments for this and it is devastating for these individuals. And everyone I've seen has been dead in a couple of months.

Hepatitis C is, as Jeff has mentioned, you know, about 30, 40 percent of my patients have concomitant hepatitis C. It makes it difficult to treat HIV because they have hepatitis C that affects the liver. All these drugs are metabolized through the liver. So you go kind of in this vicious cycle. And then - - the question, can you treat the hepatitis C first and then get that under control, then you can treat the HIV? Or do you try to treat the HIV and then you can treat the hepatitis C? And, again, we don't have answers to these things. And we have limited therapies.

One of which is, a really difficult drug to treat, give is interferon, which is contraindicated in people that have psychiatric disturbances. So many of our patients that have hepatitis C also have mental health issues and they cannot tolerate the medications for this, and the outcome with this, again, is just increasing. If you look at the number one reason over the past couple of years of people with HIV the number one cause of death has been end stage liver disease, predominantly from hepatitis C co-infection.

So we really are suggesting that there be strong consideration to add hepatitis C to the listing. And, again, I think I've gone through all these reasons of why that should be.

I apologize, this is really hard to read, but I couldn't figure out a way to get this graph out from Annals without all the footnotes attached. But essentially what we're seeing now, as Jeff mentioned, is this increase in non-HIV related malignancies. Of note, the previous study I mentioned with David Hannah and Judy Sackoff was that lung cancer in particular, even when you adjust for smoking it's several times higher in the HIV population compared with the non-HIV population. So we're starting to see the traditional or the common cancers occurring in those individuals. For reasons that are unclear, and how does this relate to their immune systems.

So different ones, again, that I think about. So the non-HIV related malignancies are increasing like lung cancer. We're seeing more and more of the human papillomavirus related cancers and then the side effects from radiation. So people have genital warts, you get a malignant conversion, they now have squamous cell carcinoma of their penis, of their rectum and then you have to get radiation therapy. We're seeing individuals they suffer from what's called radiation proctitis. So essentially what's happening is the skin in the rectum is just sloughing off, which causes, it just unbearable pain with, especially with defecation.

We're seeing more and more malignancies as we're having advancing HIV disease. And now there's this question, even, is it related to IRIS. Could it be in people with advanced disease that when you start antiretroviral therapy are we acting some type of cancer genes or something within the body that's promoting cancer development? So these individuals that have been living with their low T-cells, you know, less than 100 T-cells for 3 years, now all of a sudden we've got more effective therapies, we've put them on these medications, and the next thing we know we're seeing Hodgkin's lymphoma, we're seeing lung cancer, we're seeing these HPV related cancers.

And I've been seeing quite a number of these HPV and you think, oh, well they're just skin cancers. But, again, the complications of treating them have been really impressive. And then again, this questionable association, one of the new medications that just came out, maraviroc, which is a CCR5 inhibitor has not really been seen so much with this. But there is a little bit of a trend with that and another drug, raltegravir, again, of seeing these malignancies. There is an investigational drug, vicriviroc [phonetic] which was more

associated with this. But, again, the question is, is it really the drug or is it the fact again that these are patients that are severely immunocompromised and for the first time their immune system's coming alive and they're recognizing some foreign antigen and then a cancer is coming out.

Conditions of the skin, we talked a little bit about staph aureous already, but we see other skin conditions. I have a gentleman right now that's in the intensive care unit that has psoriasis. He has really bad psoriasis. We have treated his HIV. We got the HIV under control, but he keeps getting super-imposed staph infections with that psoriasis. So he presented again because one of the scales on his legs got a skin infection. And within a matter of 24, 48 hours he was in septic shock and he's in the intensive care unit. So we still continue to see that it's really difficult in some of the immune - - skin conditions like psoriasis. How do we prevent them from getting these recurrent skin infections and ultimately preventing bacteremia, septicemia, and death?

Other conditions, these are the toughies. HIV wasting, what is HIV wasting? The gentleman I told you about before that came in with this big weight loss over six week, the blastocystsis was there, do I think it's real or not? I don't know. I don't really think so. I think it's about his advanced HIV disease. But how do you describe that? You know, what definition should we have? Greater than 10% involuntary weight loss is a good one. You know, but what are the other manifestations? You know, how do you describe loss of muscle, you know, malnutrition? You can look at the total proteins, the albumin content. So there's various ways of looking at wasting. But wasting isn't gone. People say, oh, we never see HIV wasting anymore. That's not true. We still see this.

Diarrhea, what is diarrhea? If I went around the room every person in here would give me a different definition of diarrhea. And what's diarrhea to you, you know maybe it's fine in your particular job because you're sitting there at a desk and you can go to the restroom. But what about, even if it's three loose stools a day? If you're that local truck driver and you're sitting in traffic in the middle of Manhattan and you've got to go, where are you going to go? So you really need to put it into the perspective of the individual. So diarrhea is something, I think as a clinician, it's always hard for me to get a handle on what is

diarrhea to one individual versus another and when does it really affect one's ability to function.

Fungal sinusitis, again, we're not seeing as commonly. But as people are on antibiotics for other conditions they get these super-imposed fungal disease. And if you look in the SSA definitions there is that resistant to treatment. What does that mean? I'm a clinician, I see resistant to treatment, because I'm doing so much HIV, I think resistance is about mutations and so you've got to come up with other drugs. Resistance to treatments meaning that they didn't work? The patient doesn't want to take the therapies? I mean so I think, you know, just a little bit more clear on what do we mean when something doesn't respond to treatment rather than using the word resistant.

And then there's the repeated manifestations. And I think this helps us a lot as clinicians. I see this quite a bit is again these signs and symptoms that are difficult to really qualify and quantify. So patients feel malaise, fatigue, the metabolic syndrome, you have distal sensory polyneuropathy. How does one, again, function with that versus somebody else?

So what's a debilitating fatigue to one individual may not be so to another one. And this is, again, where I think it's really important to have effective communication because seeing fatigue on a chart, just positive fatigue, I don't know what that means. Positive fatigue that it's debilitating, patients not able to stay up for, you know, so many hours, or you know can't even concentrate to read a newspaper. Those are the things that are really helpful to know.

So, therefore, that's why I think it's really important that we recognize the validity of the HIV treating physicians' objective evaluation. I'm sitting there with a patient that I've known, I've seen them, I know what, I got a better sense of what they're capable of performing, how do I put that on paper so somebody else can interpret that? How do you know that there isn't some manipulation one side or the other? You know, and so I think there's always a little bit of blame game. Sometimes people get in, patients get angry with me, you know, I didn't get this. You know, and I have to be honest and say, actually, I don't think you qualify for this. You know? Because I don't see that this really is causing you a change in activities of daily life.

On the other hand, it's very frustrating to me when the reverse happens. When somebody gets denied and I'm like, this person can't work. So, you know, I think, again, this is where the communication comes. How can we better define terms and really getting that trust that you know if such and such person says this is what it is that's what it really is? And I think we need to explore about ways that we can communicate this better.

Mental illness I'm not going to go into a lot because Dr. Cohen is going to be speaking about this. But, boy I tell you, this is a huge problem for us. Mental health illness really complicates matters. It complicates adherence to medication. You know just even apathy, you know, can you get up, can you even take those pills. You know? Looking in the mirror and then you see these pills. Can I get them in my mouth? And so Dr. Cohen's an excellent speaker on this and I am going to differ further comments about mental illness to her.

And finally, with the HIV Medicine Association they define an HIV expert really as those that provide continuous and direct medical care to at least 20 patients with HIV over the past 2 years and complete at least 30 hours of continuing education. And I'd really encourage that there be more dialogue between SSA and the clinicians who are doing this. And have people that are truly HIV experts review those charts to assist in really trying to decide whether or not people qualify for it.

I just want to end about this predicting, because it is very difficult. And I've looked back over the 20 years and I can only think of three times that my predictions really were wrong on how I thought somebody was going to turn around. And it just recently happened to me. So does everybody recall the movie with Mel Gibson, "Forever Young"? It's where he's frozen in time, you know, he's frozen and he comes back 50 years later. And he agreed to do this experiment because his fiancé was hit by a bus and he thought she was dead. And when they wake him up he finds out she never died.

And, you know, I've seen this movie 20 times. I still cry each time. It's like one of my favorite movies, and it's a silly movie. But I went in a room the other day, and it wasn't my patient, it was a patient that came in because she had just started therapy. She is recently diagnosed. And she had, quote, unquote a drug rash. And I walked in the

room, she's a Mandarin speaker, and she got this whole glow about her and everything.

And she started chatting away. And the translator said to me, she remembers you're the doctor that took care of her husband. So I proceeded to go over there and I held her hand, and I was like, you know, I'm so sorry that was such a difficult time and all. And in my mind I remember I sent him to a chronic care facility here in the city because I knew he was going to die. So I'm going on. And the translator is going, and then finally the translator looks at me and says, you know her husband's doing much better. So those are the great stories.

So, as a clinician I'd rather have those couple of times that, man, I was wrong and those people flip around and they're doing better. And, although, he's not out of the woods yet, I am so glad for those events. And so I hope you'll understand the few times that myself and others do make that wrong classification. But I think, again, it's better to err on that side than to do the reverse and not have somebody quality and they continue to spiral down. So thank you so much.

[APPLAUSE]

DR. MONTE HETLAND: Our next speaker is Bebe J. Anderson. She's representing the HIV Project as the Director from Lambda Legal Defense and Education Fund, Ms. Anderson.

MS. BEBE ANDERSON: Good morning. I'm happy to be here and I want to thank the Social Security Administration for putting on this program and for inviting me to present information about comments that were actually submitted by a group of organizations that I will talk about those today.

The process has already been mentioned, by Paul Scott earlier, about the original advanced notice sort of proposed rule making and then proposed rules, then final rules, and now this current advanced notice for proposed rule making. And in each instance a group of advocates, layers, others who work with people with HIV who try to get Social Security Disability benefits got together and put combined comments and submitted those to the Social Security Administration. And with the final rules that were issues in March of this year there were some important changes that we were happy to see, that were changes that this group had asked for, which included, of course, retaining the specific HIV listing, but

also some of the reorganization of sections 14.00 and 114.00 reflected some of the comments that were specific to HIV, even those these were general comments applicable to all of the applicants with disability benefits.

And in particular there was an expanded discussion of treatment related topics, including specifically mentioning the variability of individuals' responses to treatment, which is, of course, a very important issue for people living with HIV. The difficulty of distinguishing side effects of medication and treatment from the side effects of the infections, which makes it complicated for people living with HIV applying for benefits. And the fact that side effects of treatment may themselves result in functional limitations. And then also language, specifically mentioning, in reference to difficulty of adhering to treatment, mentioning HIV situations as an example of that. So those were important changes in the final rules, but certainly some further changes are needed in the specific HIV listings.

So, once again, Lambda Legal convened a working group, but the credit, this was really very much a joint effort and the credit goes to all of the groups that worked on it. And so we pulled together a group of, as I said, advocates and others to try to use the knowledge that came from working with people applying for disability benefits and the difficulties seeing those claimants' experience and the responses that Social Security Disability Examiners and Adjudicators have had to claims of disability for people living with HIV. And then also sought to pull together medical references to support the various comments.

The groups in the working group were representatives from the AIDS Law Project of Pennsylvania, AIDS Legal Counsel of Chicago, the Disability Law Center, Gay Men's Health Crisis, Health Advocates, Kendra Kleber & Associates, Lambda Legal, National Law Center of Homeless, on Homelessness and Poverty, National Organization of Society Security Claimants' Representatives, the Center for HIV Law and Policy, the South Brooklyn Legal Services, the Whitman Walker Clinic, and we also received input from the HIV Medical Association, though that organization put in separate comments. I am happy to see that there are representatives from some of the organizations that worked on these comments and specific individuals who were very involved and instrumental in pulling together these comments, which we then circulated for sign on, and 37, national, regional, state, and local

organizations and 8 individuals signed on to these comments, which were then submitted to the Social Security Administration.

And today I'm just going to sort of try to highlight some of the major comments, the main points that were made by the group. I'm still getting used to using PowerPoint. There we go. Okay. We requested further revisions to the HIV Infection Listings beyond what were in the final rules, which were just some very minimal changes to those - - themselves. And these changes are needed to reflect advances in medical knowledge, treatment, and methods of evaluating HIV infection and also to address the problems that, as I mentioned, people actually applying for disability benefits have experienced, in terms of how those applications are reviewed by the Social Security Administration.

We also asked that some important topics be specifically addressed in written guidance and training to Social Security adjudicators. And this is important to make sure that the comments, or actually the issues are fully understood by the people on the ground reviewing the claims. And we also requested that there be some specific changes to the listings, including, for example, these specific changes would reflect the current medical information and also we specifically wanted chronic pancreatitis to be added to the listings and that specific manifestations be added as well to the listings.

With reference to the request for written guidance and training we focused on two major issues that had been addressed in the general comments not specific to HIV, in terms of the general part of the rules, the general rules. In particular the consideration of subjective evidence and the consideration of claimants who are non-responsive to treatment, ‘cause again, these are very important issues for people living with HIV who are seeking Social Security Disability Benefits. And what we've found in terms of the consideration of subjective evidence is that that tends to be heavily discounted by the Social Security Administration in evaluating disability claims.

And that's very inappropriate, we feel, for people with HIV in particular, partly because the advances in medical diagnosis, diagnostic procedures and the progress in understanding the clinical manifestations of HIV disease have often eliminated the necessity for laboratory evidence of

certain HIV related conditions. Also, claimants may experience a combination of symptoms which render them disabled but are not really going to be able to be established by objective data. And treating physicians' evaluations based on subjective symptoms are extremely important, but they are typically discounted by the Social Security Administration in evaluating a claim.

And, therefore, we ask certain changes be made so that the rule specifically state that manifestations of HIV infection may be established in the absence of objective findings based on the claimants treating physician's assessment of the impact of impairments and manifestation of impairments to the claimant. And also that Social Security provide specific guidance and training to Social Security adjudicators on the topics of the symptoms and signs that HIV specialists consider to be reliable evidence of impairments and manifestations of impairments. What other evidence, not specified in the listings, HIV specialists consider to be equivalent to the evidence that is in the listings, and also what other combined manifestations of impairments, which aren't, again, specified in the listings impact a claimants actual functional ability compared to the, what is in the listings.

And of the great needs for this continued training and guidance is that, of course, as already reflected in earlier comments today, HIV disease is relatively new, as diseases go. And there are significant advances continually made in understanding the disease and also in treating the disease, and in the progress that people with the disease experience themselves individually. And the rules, even on a three-year track to change the rules are not likely to be able to keep up with that and so it's very important that there be continual training and guidance to keep Social Security adjudicators up with the evidence, with the understanding, especially of things like subjective findings.

We also ask for additional training and written guidance on this issues of claimants who are not responsive to treatment. And that, as already indicated, it can be a real problem in terms of several things: there could be many, there are many people living with HIV who are resistant to treatment and as a result they end up with fewer treatment options. And then they are more susceptible to complicated illnesses. The physician may have to actually suggest to them that they reduce their functioning in certain ways to avoid possible

exposure to infections. And the claimant may have to sort of restructure their life to reduce the risks of subsequent infection. And that can be at the expense of their ability to engage in activities of daily living. And so that needs to be understood, again, by the Social Security adjudicators and recognized as a complicating factor for people, many people living with HIV.

And so the rules should reflect the importance of having this case-by-case analysis of whether a claimant actually needs the listings. Take in to account the fragile and tenuous position of a person with HIV who has experienced persistence resistance to a medication regimen and also limitations that have been imposed, either specifically at the instruction of the physician or that the claimant themselves has had to, found they need to impose upon themselves in order to avoid the risk of subsequent infection.

We also ask that medical criteria related to co-infection with hepatitis B or C be specifically added to the listings. This problem has already been well addressed by Dr. Aberg and the importance of it is very crucial for people living with HIV. The co-infection can be a significant contributing factor to being disabled. And I'll just mention, there's lots of special problems that exist when you have both diseases and it can't just be evaluated under hepatitis and then under HIV because you've particular treatment problems that relate where you can't take treatment for one infection because of the other infection. And treatment for one infection may exacerbate problems related to the other disease. And symptoms may be hard to distinguish which disease they really relate to.

And so we have requested that in the final rule, the new listings, that sections 14.08 and 114.08 specifically reference hepatitis or a co-infection with both HIV and hepatitis C or B complicate the treatment of both conditions, and specify that the interplay of the two infections needs to be considered on an individualized case-by-case basis.

Mention has already been made of the importance of diarrhea, in terms of the significance of diarrhea for some people living with HIV. In terms of actually the issue of whether or not they're disabled under the meaning of the Social Security Regulations. And you know, the diarrhea associated with HIV can come from a variety of sources. It can from parasitic co-infection. It could be a side effect of the

medication, or it could actually relate to a generalized condition of malabsorption. And in any of those contexts it can, for certain individuals, be creating instability in the patient in making them unable, as already mentioned, to engage in the activities of daily living and having significant functional limitations.

And one of the difficulties here is again the unlikelihood that you'll actually have subjective, or sorry, objective indicators. It's more likely to be subjective information. And, again, this goes to the importance of crediting the treating physicians' information the submitted it in support of a claim.

Therefore, we've asked that the rules specifically specify clinical indicators and not just objective indicators related to diarrhea and more specificity is found in our comments. And that the listing as now constituted isn't quite, we don't think accurate in terms of the objective criteria it does mention. And we have suggested some specific re-wordings to relate to the current medical understanding.

We've also, as I mentioned, asked that chronic pancreatitis be added as a standalone listing under the HIV listings. And this problem is related to the fact that pancreatitis can be a very important marker of HIV related drug toxicities, and it can limit life saving treatment options, or it can add to complications of HIV related opportunistic infections. And this chronic or relapsing pancreatitis among people living with HIV can severely impair their ability to function. And serious life-threatening pancreatitis can actually develop as a side effect of medications used to treat the HIV disease.

And, therefore, we've asked that it be added with, and we've suggested specific wording in terms of subjective evidence and time period of experience of pancreatitis to be used in evaluating individual claims. And that these criteria would apply to individuals who suffer more than just a transient episode of pancreatitis that resolves after a change of medication.

We've also asked that additional manifestations be specifically referenced in 14.08 and 114.08. Now those are written to make it seemingly clear that they're not expected, meant to be an exhaustive list of additional manifestations. I mean that was been true in the original rule, it was true in the final rule, but the language that's used to indicate

that clearly has not been sufficient because people, claimants, are continuing to experience a problem where Social Security adjudicators, despite that caveat, are really using that listing of manifestations in what's now 14.08K and 114.08L as being sort of an exhaustive list.

And so given that resistance to viewing those as non-exhaustive, and given the importance of certain additional manifestations and the recurrence of certain additional manifestations in people living with HIV we requested that there be specific language added to say that special consideration should be given to other conditions, signs, and symptoms deemed by the primary care provider as contributing to substantial, functional, limitations.

Again, this importance of recognizing the very important role of the clinician, the very important information that the person actually treating the claimant has and valuing that and considering that more thoroughly in adjudicating a claim. And also we've asked that specific references be made, and I didn't list all of them here, there's more in the comments. But we flagged, in particular, as particularly important the issues relating to impaired mental functioning, morphological abnormalities, metabolic abnormalities, and infarction, and cardiac problems. And the significance of those problems for people with HIV, Dr. Aberg already touched on. But I do want to say some specifically some more about the important issue of impaired mental functioning, which of course you'll also hear more about from Dr. Cohen.

But one thing that we're trying to get greater recognition of by the Social Security Administration is the extent to which this mental illness interplays with HIV. And for a variety of reasons, including that people living with mental illness, some of them may be more susceptible to getting HIV in the first place for various reasons. There can be reservoirs of HIV accumulating in the brain causing dementia. There's obviously the mental health impact of having an HIV diagnosis itself.

And all of these mental health conditions, from whatever source or combination of sources could clearly interfere with a person's ability to engage in self-care and activities of daily living, and adhere to treatment regimens, and adhere to appointment schedules. And one of the difficulties is that people living with HIV will often receive mental health related care, not from a mental health professional, but from

their infectious disease professional or their general practitioner for a variety of reasons, including access and cost reasons. And including the fact that it is so common to see mental health problems for some people living with HIV that the infectious disease specialists are familiar with those problems and may prescribe medications themselves.

So there's a lack of that type specific mental health related data or information as part of the application. So we've asked for changes related to these issues, and in particular that there be additional language to reflect some of these problems. But, again, this was just a quick overview of some of the issues that we tried to address in more detail in the comments that were submitted that are available on our Lamdba Legal's web site, or, of course, you could email directly to receive them. Also available are the comments we submitted at earlier stages of the review process for the Social Security rules. Thank you.

[APPLAUSE]

DR. MONTE HETLAND: Break time. Okay, we're not doing too bad on timing. I have 10:14. So let's see, let's try and meet back at 10:25. That's 10 minutes, 11 minutes. Bathrooms are, if you walk to where, the check in at the hotel, go to the right and they are down the hallway. Okay, see you back.

[END TAPE MZ000016.MP3]

[START TAPE MZ000017.MP3]

[Crosstalk]

[END TAPE MZ000017.MP3]

[START TAPE MZ000018.MP3]

[Crosstalk]

[END TAPE MZ000018.MP3]

[START TAPE MZ000019.MP3]

DR. MONTE HETLAND: …take their seats again. We're not too far behind schedule, and I would like to stick to that as soon as possible. So if we can take their seats.

[Crosstalk]

DR. MONTE HETLAND: Okay, we're going to get started. Our next speaker is Dr. Mary Ann Cohen. She is Clinical Professor of

Psychiatry at Mount Sinai School of Medicine. She is the Former Director of AIDS Psychiatry at Mount Sinai School Medical Center. Dr. Cohen.

DR. MARY ANN COHEN: Thank you, Monte, and Barry, and Scott for inviting me and for Judy and Jeff for suggesting that I come to this really important meeting. I was thrilled to hear the initial presentations and I hope I can live up to that caliber. Well, so the first thing I want to do is to sort of give you an overview and apologize for the 50 slides that you have of my presentation. And I will try to talk really as fast as I can. But I want to note that we did start late, and it wasn't my fault.

So the first topic is the relevance for disability determination. And that really has to do with five major areas that we're going to cover. The relevance first, the high prevalence of psychiatric disorders in persons with HIV and AIDS, the multifactorial nature of the reasons for psychiatric disability in persons with HIV and AIDS, and the complexity of assessment of psychiatric disorders in people with HIV and AIDS, and finally the role of AIDS psychiatrists in psychiatric disability determination.

So first of all, in terms of relevance AIDS is really, and this was emphasized very clearly by the presentations by Judy and Jeff and Bebe, but complex and severe medical and psychiatric illness is really what characteristic, characterizes the HIV and AIDS epidemic. There's a tremendous amount of illness involved with elements of nearly every other illness involved. And people with AIDS are really vulnerable, medically, psychiatrically, and socially.

So this slide, and I keep trying to fix the slide and add things because there's just so much. It's hard to keep up. But it really summarizes the real need for an integrated biopsychosocial approach to HIV and AIDS. And I won't go through this, but you have it in your handouts.

So the relevance of AIDS psychiatric disability has to do with a number of things. First of all, unrecognized psychiatric disability can lead to non-adherence to medical care and to combination antiretroviral medication. Intermittent adherence to combination therapies can lead to emergence of drug resistance, as we heard, and to illness progression. And, finally, non-adherence to medical care and visits can lead to dangerous medical consequences from both

HIV and its treatments, and medical disability. So AIDS psychiatric disability has meanings for adherence, morbidity, suffering and prevention.

There is a higher prevalence of psychiatric disorders in people with HIV and AIDS. People with HIV and AIDS may have psychiatric disability despite lack of evidence of any immunosuppression, because we know that HIV is harbored in the brain. And psychiatric disability may lead to medical disability due to non-adherence. And there is a high prevalence of HIV in persons with mental illness and a high prevalence of mental illness in persons with HIV and AIDS.

The prevalence has been quoted in many different ways, but a most clear and dramatic concept is that we understand that in the United States HIV prevalence is about 13 times higher in people with, in people with mental illness than in the general population. Blank and others, estimated that the HIV rate is estimated to be much higher in people with untreated serious mental illness, and maybe up to 10 to 20 times higher than that of the general population. And I think it's really about 20 times higher than that, the general population.

I've only put the Ds in, but people with HIV are very vulnerable to mental illness. And those mental illnesses are actually related to the HIV in the brain itself, except for drug dependence: and that is; dementia, delirium, depression, drug dependence, and death by suicide. The one that I left out is P, which is not a D, but is posttraumatic stress disorder, which they are, people with AIDS are also vulnerable to. We've heard before the need for integrated care and the need for changes in the way the rules are written to involve HIV and HCV co-infection. Alcohol dependence doubles the risk of cirrhosis in HIV, HCV co-infection. And people with HIV and HCV are much more vulnerable to depression. And persons on treatment with interferon/ribavirin are vulnerable to depression, suicide, and psychosis.

So this is a listing of the most prevalent psychiatric diagnoses associated with HIV. The cognitive disorders, dementia and delirium, substance related disorders, posttraumatic stress disorder, bereavement, mood disorders, and those can be mood disorders due to medical conditions with depressive features, and mood disorders due to medical condition with manic features, and also major depressive

disorder, and bipolar disorders; and then the psychotic disorders and schizophrenia.

The prevalence of distress in persons with HIV and AIDS is twice as high as that in persons with cancer. So 72.3% of patients in the waiting room at the Mount Sinai AIDS Center had a high prevalence of distress on the distress thermometer. And 70% had anxiety on the hospital anxiety and depression scale, or the HADS. And 45.5% had depression on the hospital anxiety and depression scale. Again this, if you compare that to a study in the Memorial Sloan-Kettering prostate cancer clinic it was twice as high using the same measures.

Thirty to fifty percent of HIV patients meet the criteria for posttraumatic stress disorder. And 60% of those patients go untreated and are severely disabled. And the overlap with depression and other psychiatric disorders is very common, so that PTSD, or posttraumatic stress disorder might actually be overshadowed by other diagnoses and very, very difficult to detect. An early article that came out written by Jeff Friedman [phonetic], and Mary Ausodowd [phonetic] and others, was entitled: "Depression, Dementia, Delirium, Posttraumatic Street Disorder, or All of the Above." And I think that this actually characterizes a lot of the people I've seen over the past 27 years.

HIV and substance use disorders are a very synergistic problem in our population, in many populations of persons with HIV. More than a third of new cases in the United States occur because of intravenous drug use, and 40% of United States AIDS deaths are related to drug use. All alcohol and other drugs of abuse cause intoxication and increase risky sexual behaviors and may be very difficult to diagnosis. There is an increase in the spread of not only HIV, but also hepatitis B and hepatitis C. And the use of substances can be very disabling to patients and extremely frustrating to physicians, who are maybe prescribing antiretrovirals and find their patients are selling those to obtain drugs or diverting them in the street.

The psychiatric vectors of HIV include cognitive disorders, cognitive impairment is associated with disinhibition and poor judgment, maybe indiscriminant sex. Mania is associated with disinhibition and hyper-sexuality. Psychosis is associated with regression and also indiscriminant sexual behaviors. Posttraumatic stress disorder is associated with

a sense of a foreshortened future. So caring for the body, caring for the self is not that important. And depression is associated with problems with self-worth, caring for the self, again. And substance use disorders are associated with intoxication, exchange of sex for drugs, indiscriminant sex.

So what of the causes of psychiatric disability in persons with HIV and AIDS? Again, dementia, delirium, depression and other mood disorders, alcohol and drug dependence, psychosis, and posttraumatic stress disorder. There is a high prevalence of psychiatric disorders in the HIV population, a much higher prevalence than in the general population. There is an increased risk of suicide, an increased risk of dementia because of the involvement in the brain, increased vulnerability to side effects of psychopharmacological agents, and increased vulnerability to the psychiatric side effects of antiretroviral agents.

So the causes of psychiatric disability in persons with HIV and AIDS include a response to the diagnosis, the very first time someone learns that they are HIV positive it can cause terrible psychiatric responses. I have a patient that I've been working with who, strangely enough has absolutely been diagnosed and clearly has long-term, non-progressing HIV. He has never been on antiretrovirals. He has been infected for more than 12 years and he has never been on antiretrovirals and has never had a viral load over 50. And his CD4 count is in the thousands. But he's someone who got so depressed when he learned he was HIV positive that he's been chronically depressed and suicidal ever sense. And he's actually got severe illnesses that are not related to HIV. He has chronic obstructive pulmonary disease, he has pulmonary hypertension, rheumatic heart disease, and was just diagnosed with Paget's disease. And he's really, really more depressed that because it's hampering his ability to walk his dogs because he's having so much severe hip pain and can not tolerate the bisphosphonates.

So here's a man who has HIV. He is a long-term, non-progressor. Many of my patients would be out celebrating about that. But he's really depressed and has been depressed since his diagnosis. So I've begun to do family work with him to try to help him to accept that this is not as depressing a diagnosis as he thinks. Although, right now he's oxygen dependent and he's other diagnoses are very depressing. And he has the worst clubbing I have ever seen in my career actually. So the response to a diagnosis can be

very depressing, a response to a first symptom, to the first illness, to progression of illness, and to end stage illness, so response to illness can be very, very upsetting.

The effect of virus on the brain, the direct effect we talked about a moment ago. The direct effect can be a result in delirium, dementia, depression, mania, and psychosis. The effects of other opportunistic infections can actually do the same thing. So that cryptococcal meningitis can present as mania. The effect of antiretrovirals and other medications on the brain also can produce delirium, dementia, depression, mania, and psychosis. And we've seen people get very depressed on efavirenz, have nightmares on efavirenz, and have psychosis on efavirenz, so, and other antiretrovirals.

Concomitant psychiatric illness and HIV and AIDS: schizophrenia, affective disorders, addictive disorders, and posttraumatic stress disorder. And finally the social stressors: domestic violence, homelessness, job loss, stigma, and ostracism by family. I think my patient, whom I described in the beginning, who is so depressed about having HIV was so embarrassed about his diagnosis that he is only now with family therapy beginning to admit it to some of the members of his family. Assessment of psychiatric disorders in persons with HIV and AIDS. A need for thorough evaluations can't be over-emphasized. A need for understanding of the current psychiatric nomenclature. A need for comprehensive evaluations, and a need for careful cognitive assessments.

Just a quick overview, and I think everyone probably knows, bur organic mental disorders that term is no longer in use. And the diagnostic term in DSM-IV, which was the APA Diagnostic and Statistic Manual IV, which was written in 1994. The term is Cognitive Disorders and that includes the categories of both delirium and dementia. The required level of severity for the disorders, I won't go over all of that but to just say that the first one, disorientation to time and place is not a very relevant criterion for determining HIV dementia until very, very late stage. Although it might be relevant for delirium. Delirium is self-limited, and although it might not resolve and it may lead to death, it isn't something that usually leads to disabilities. So disorientation to time and place usually wouldn't meet the criterion for a 12-month duration, nor lead to disability, per se.

Memory impairment, either short- or long-term certainly can do that. And perceptual or thinking disturbances can change in personality, disturbance in mood and emotional ability [phonetic], as well as the loss in measured intellectual ability. But here's another caveat, using this criterion is difficult because access to neuropsychological testing isn't really that easy even in resource rich places like Mount Sinai, except on a research basis. So that there isn't neuropsychologists ready and waiting in the clinic to get the testing done, which takes many hours and a lot of evaluation and time.

And finally, resulting in at least two of the following, marked restriction of activities, these are certainly very useful but, and then repeated episodes of decompensation. Again, these are valuable. So that what I thought was perhaps missing is recognition of early onset of HIV associated dementia. This is really, I think, an important issue for disability determine and it requires an understanding of the different presentation of HIV dementia from other dementias. This requires a full cognitive assessment, experience in the psychological care of the medically ill, and particularly in the care of persons with HIV.

Early HIV associated dementia, or HAD, can cause disability. And these include slowing of speech, slowing of reaction times, slowing of motor function, psychomotor slowing, reduced speed of informational processing, difficulty performing complex previously learned tasks, dropping things, executive dysfunction, abstraction, attention, and shifting cognitive sets may be impaired. Now those are all early manifestations that wouldn't really be picked up unless you were really looking for them. And it's very easy to test for them. It's part of my routine evaluation, but often these are missed. I mean a patient may complain, you know, a pianist who could play Chopin no longer can play Chopin, but if that's their way of earning a living that's going to be impaired. And so other functions, like someone who could beautifully make wedding gowns can no longer really do that anymore, but maybe could do a hem. So these are important functional concepts.

A recognition of later HIV associated dementia, there you would find in memory impairment, word finding difficulty, paraphasia, apraxias, visuospatial difficulties. They are easier to pick up. And the behavioral signs, of course, are

also easier to pick up, apathy, depression, sleep disturbance, agitation, mania, psychosis.

So, again, for psychiatric disability assessment what's called in your terminology affective disorders, the new term is mood disorders. And what is really useful for evaluating a person with HIV and a mood disorder, appetite disturbance with change in weight, sleep disturbance, psychomotor agitation, or retardation and decreased energy are not as relevant as the following, because you could have any of those because of the illness itself, like feelings of guilt, or worthlessness, difficulty concentrating, thoughts of suicide, hallucinations, delusions, or paranoid thinking, depressed mood, anhedonia [phonetic], crying a lot, guilt, worthlessness, hopelessness, and suicidal ideation are really the important ones recognizing HIV related depression.

Same with mania, so hyperactivity, pressured speech or flight of ideas, or inflated self-esteem are almost never seen in AIDS related mania, while irritability is very common, irritability, impulsivity, and hypersexuality are much more commonly associated with AIDS related mania than what are the usual listings. Recognition of posttraumatic stress disorder in HIV I think is really valuable, insomnia, hyper-vigilance, easy startle, hallucinations of the abuser, nightmares, vulnerability to victimization, vulnerability to abusive relationships, and difficulty with trust and adherence to care.

So these are, I think, all of the changes that I would recommend, the concerns that I have. And finally, the role of a psychiatrist, and I would, I think there were comments in some of the material that I was sent that much of the diagnosis and treatment of persons with AIDS and psychiatric disorders and even psychiatric disability could possibly be left to, in the HIV clinician. And I don't really think that's fair. I think that's, it may be necessary in some places, but I think if there is availability of psychiatrists it would be of great help. Psychiatrists who have experience in the care of persons with HIV and AIDS and have the experience and training in the psychiatric care of the medically ill can recognize and treat in the HIV setting.

Psychiatrists have long-term, non-judgmental, trusting relationships. They routinely take sexual histories. They routinely take drug histories, encourage behavior change, do

crisis intervention, psychotherapy, pharmacotherapy, couple, and family, and group therapy.

I have to say though, after listening to Dr. Aberg's presentation I worried that, yes, it's true when I get a patient sent to me who's not adherent to care I've almost invariably gotten them back on or on to antiretroviral therapy. Now I'm thinking of all the people that I probably got to immune reconstitution inflammatory syndrome. And one that really bothered me, that I felt really guilty about, because I was at Rivington [phonetic] House, which is an AIDS Nursing Home from 1995 to 1999, is it, and, I'm sorry, yeah, from 1995 to 1999. And during that time, as we heard this morning, there was a huge change in mortality, morbidity, and life expectancy and the world of people with HIV was really turned around.

And what we saw when I first got there were people dying every day. When we opened the nursing home, I was there when it opened, shortly after it opened. Actually, there was a memorial almost every other day or every day the first couple of weeks. And then the memorials were a little less frequent, but maybe a couple memorials at the bed sides of patient after patient. And the life expectancy was very short. In fact, one patient was dead on arrival from Bellevue. No kidding, I mean that was really true.

When I started working with people with AIDS before I got to the AIDS Nursing Home at the City Hospital in New York Metropolitan, we would see people come in in the morning and by the afternoon I'd come back to see how they were doing and they were already dead. So the, it was just, 1981 was really a nightmare. I have never seen an illness like that in my career. And I saw that we really needed to get together and work as a team to deal with this.

What I then saw was the introduction of the combination antiretroviral therapies, and all of a sudden things changed very dramatically. And what reminded me of that was one of our patients, who was the Head of the Resident Counsel, they called the residents in the chronic care facility, the President of the Counsel was an extremely effective, talented, young man who came to me one day and said, you know, I think there's something wrong with my handwriting. I can't write anymore. I don't know what's going on, but I can write, but it's different. And he had been started on

antiretroviral therapy combinations and developed PML and two months later he had died.

And I only after your presentation realized what happened to him. And I thought, wow. Now he was not somebody I convinced to go on. There was such an amount of enthusiasm that almost everybody at that time wanted to go on the medications. But I'm thinking of other people, and I'm wondering too, if there isn't an activation of the virus in the brain that may cause depression because I've also seen that after people are restarted or started on new regimens. So something that I'd have to look up and see whether that's the case.

But psychiatrists do encourage behavior change, and sometimes I wonder. So we do crisis intervention therapy, family therapy, and couple, and group therapy. And we can identify and treat distress and treat psychiatric disorders like delirium, dementia, depression, alcohol dependence, drug dependence, and posttraumatic stress disorder. We need to have psychosomatic medicine and AIDS psychiatrists making accurate diagnoses and providing comprehensive integrated treatment and psychotherapy and pharmacotherapy, therapeutic modalities.

There is now an actual text book in the field of AIDS psychiatry and an organization of AIDS psychiatrists and mental health clinicians. So the modalities, again, we heard are crisis intervention, cognitive behavioral therapy, psychodynamic psychotherapy, supportive therapy, bereavement therapy, palliative therapy, couple and family therapy, and group therapy.

The pharmacological modalities include appropriate medication choice, awareness of drug-illness interactions, awareness of, you know, you heard before about the possibilities of developing pancreatitis, the diabetes, some of the medications that are given to people with HIV are dysglycemic. So that we have to be aware that some of the medications that psychiatrics give are also dysglycemic, an awareness of drug-illness interactions, pharmacokinetics, pharmacodynamics, and drug-drug interactions. We need to start very, very low and go very, very, very slow and use appropriate dose ranges.

So the role of a psychiatrist in the AIDS pandemic, we can promote adherence to safe sex, drug treatment, harm

reduction, and needle exchange. We can improve adherence to medical care, antiretrovirals, and hopefully decrease suffering, morbidity, and mortality. The book I was talking about is, "The Comprehensive Textbook of AIDS Psychiatry." It was published in 2008. And our organization now has a web page that you can access on, a web site, it's in your brochures. And I welcome you and thank you very much.

[APPLAUSE]

DR. MONTE HETLAND: Our next speaker is Mr. Brett Smiley, who is going to share some of his own personal experiences. Can we turn this off, please? Or I guess I can.

MR. BRETT SMILEY: Thank you. Hi. My name's Brett Smiley and I want to thank Paul Scott and also Cathy Bowman of South Brooklyn Legal Services, and Dr. Hetland, as well too. I'm actually like, I'm not a clinician or an expert, or, well I'm an expert, that's debatable on that. But I've been living with HIV/AIDS, God, for so long I don't even remember.

I've been very, very lucky, in my opinion. Well I made some notes, but I don't have a presentation, I don't have a PowerPoint thing and all that, but I do have my experience, and sure I've got opinions left and right. And it's a lot of information, especially Dr. Cohen's the last thing there was, it's like mind-boggling some of the information on all that. And, but I was really touched when she was mentioning, you know, when she was at Rivington House and, ‘cause you know I've got friends that were there and then there again, and then on to some place. And where they are now, you know, they're not here anymore, you know, or you, but they are here. I've got to believe that they're with me.

Let's see briefly, let's see on some of the notes, I'll try to follow them here. Well let's see I've been, like I said, I feel like I've been very lucky. I'm from a small town in Indiana. And when I was very young my mom took all of us to come move to New York City. And I grew up in the theater, a musical comedy theater, whatever, I was very, very young. And so I was actually very old at an early age. I mean it was really quite nice. And that evolved into the Pop music world.

So in the 70s I was, I did have a career in show business. And show business, it was always sort of gypsy lifestyle, you know, a lot of improvisation. I love show people and like

the song goes, you know, there's no, you know, they're just always on with the show.

And I attribute some of the reason that I'm still standing here to that, that attitude towards life that, okay, well what are we going to do. And you just, you know, pick yourself up and you go on to the next thing. You just try your best. 'Cause I mean everything I hear, I mean like every time you know the word suicide and all that came up, and sure I've been there, sure I've been there. And it's like, you know, the thought's - - like whoa. It's, you know, someone with a lot of wisdom said, "That's a long-term solution to a short-term problem." You know?

And well briefly let me say, I first tested positive, it must have been about '92 I guess, and I was living in Los Angeles. And I had tested before that and you know totally sure, because of you know my, the people I was involved with they were sick. And quite a few had died actually already. And I came up negative. And I was really surprised. I thought, oh, man I skated, you know I skated. I really though, oh whoa, it's like close people to me were positive and were, you know, some had died and gotten very ill.

And you know later, not long after that I tested again and it was positive. It was a false positive or whatever [phonetic]. I'd had symptoms, shingles, and a few things like that, early symptoms, and I was concerned. And of course, you know my, with… You know my story involves a lot, well substance abuse was a big part of it. In the Pop music world that was like just part of living. And the sexuality, the 70s were actually a very innocent time, in my opinion, very innocent. And you know all I know is I got, I felt immortal. I mean that's how we felt. And it was just like we could just, you know, there was a whole brave new world, and you know, which is a reality because it's like really become a brave new world, I'll tell you that.

But I tested positive in Los Angeles and out there, you know, okay, I was relatively healthy but there were some things. I, like I said, the shingles, I had a pneumonia that was very hard to treat. And out there, there was an organization called AIDS Project Los Angeles. And I remember they had a T-shirt, it was a beautiful, beautiful T-shirt and a slogan. It was a picture of the world, a globe of the world and it said "Be here for the cure." And I still have that T-shirt.

And I didn't bring it ‘cause I have it buried in the bottom of a trunk, but somehow I've held on to it.

But I did bring with me a T-shirt that's more relevant actually. I was feeling a little frivolous and a little devil-may-care, I'll show it to you. And I just had it printed up because it's the slogan that sometimes this is exactly what I feel like I'm walking around like that, okay, a ticking time bomb. Because I've had a lot of medical things, in fact, just yesterday, and the past few weeks it has been a little difficult ‘cause I was on one protease inhibitor that one of the side effects is jaundice and whatnot. And it was creepy up on me and I had just been feeling real ill. And actually just yesterday I had started a new regimens of meds. And that's the way it has sort of been the past I don't know how many years.

I got, in '94 or '95 I got very sick. I was here in New York. I had moved back to New York with the purpose of being near some family. My sister is here today with me and just ‘cause I'd known, I'd watched so many people drop like flies. It's like, you know, I really had a lot of relation to what Dr. Cohen was saying on that. And you know sure I was running scared. And I was in recovery and staying clean and sober for a long time, and really doing my best, but physically really getting ill, and I was terrified, running scared, just running scared. You know, and almost a magical thinking in my life, you know, and like trying every, terrified of the idea of medications then too.

This was like the middle-90s and everybody I'd known had gone on like AZT, et cetera, whatnot, and but still it didn't, you know, they died, and, or they went through miserable, life was really hard. And I was just running scared. But through a series of events, I do have a doctor, Dr. Paul Bellman [phonetic], who's actually very good. And I literally crawled in his office and then I wound up spending a month's in St. Vincent's and I guess I'd had three OIs and, you know, I was a goner for sure. I remember actually they thought I had tuberculosis so they gave me an isolated room. That literally I just really, I had my guitar brought in. I had people come in. I remember, it was really, you know, like all my friends would come in with, they'd have to wear the masks ‘cause they thought I had… Whatever.

And you know I did not have tuberculosis, but I did have to go through the regimen of the medication, which is really,

really wicked. And also though, this was just about the time when all the meds, I guess the HAART and all that were coming in. And it was really like Indiana Jones and the boulder, ‘cause I remember the cover of Time Magazine and there I am taking, and it was like a lot of pills, and they were harsh. And so I had a lot of identification, you know, the identification with the bathroom issues and whatnot. I mean literally I could not, I had to be 20 feet from a bathroom for a long, long time. And it's still, you know, it's not as bad. The treatments have gotten more tolerable.

But then, again, the things, you know I didn't come up here to whine necessarily, but, you know, and I've been hospitalized a few times over the years, quite a, like most recently was a couple years ago, in the ICU for three days, and again I was a goner for good. You know I had intubated and they still don't even know what it was. You know it's like whatever. It's all connected. I mean whether it's this or that, this or that, that's what I really feel and believe.

The thing that, - - got me, you know, I managed, you know like I said I was clean and sober. You know I've spoken at 12 step meetings, you know, and I'm a performer. I've done things like that. I volunteered with theater groups and I'd do little, even little concerts and stuff when I can. But I've never spoken in front of a conference like this. So this is all very new to me ‘cause I'm not, you know - - about expert.

I remember I used to take the subway into town all the time and they'd have an advertisement for some clinic or whatever saying we're experts in depression. And I'd look up at that sign and I'd go, ha, you know. I'm the expert in depression, you know, and it's like really, that's really the truth. And I went through the whole gamut of, I call it the mix, and it's actually a really scary thing ‘cause I know people that get into it of you know a lot of antidepressants, then it goes to the anti-anxiety meds, and then of course there's the painkillers. And it's really hard to come out of that. And it's really, it took me, you know, ‘cause I wound up on, oh, I don't even know how many different ones. I would go from one then I would try to kick one, and I'd end up buying on the street another. And I really hear, and all that I know very, very well.

And I'm very fortunate to be, - - the 12 steps, this is not a meeting but it's really such a big part of my life having

that sort of faith and purpose. And it's like, whoa, you know. And I can step by and look at my life and I go, boy, again it's like I have skated. You know? Just like back in the 90s when I thought I tested negative I skated. And I don't want to have that attitude though that I've skated because it's really, you know there's a friend of mine now, and I was talking with my sister, who was in Rivington House, not once, but twice. And then he'd go back to his apartment and he had worked for the opera and all that. And then he wound up a few times and he just would disappear. And, of course, he went to once place, Cardinal [phonetic] Cooks and now I have not even heard from him. The last time I saw him I went up to visit him.

I can't even get up to where he is now ‘cause the problems I'm having now with the arterial, I guess it's atherosclerosis [phonetic]. I had a minor heart attack and so I've got to take another regimen of meds. And you know I come here and I saw the grapefruit juice back there. And it's like, you know, half of my meds said I can't have grapefruit. So that's been like a big thing with me, the importance of grapefruit has really become, like I am really salivating for a grapefruit. And, you know, but that's something I cannot have because of the acid… You know, I know the science there. And I don't even want to know the science to tell you the truth. But I've learned more about science than I ever cared to know in these past, gosh, 15, 16, 17, I don't know how many years.

It's just, you know, I often tell my doctor, I go see the doctor, you know, and like how, you know, how are you feeling. And it's like, to be honest, I don't know what normal is. I know when it doesn’t hurt. I know when I'm more human than other days. Some days I do not feel human. The stigma that, you know I suffer from both ends of the stigma. You know I have the stigma, again, you know, and then also I suppose I do, I don't feel what's normal.

I've got a lot of friends, but really close relationships are very hard. My friend Peter came here today and, you know, I don't want to disclose - - for anybody else, so I won't do that. But it is so important of developing relationships and yet it's hard because relationships involve certain, well it involves some responsibility. You've got to show up and be there. And some days I'm not able to show up.

You know I didn't want to, you know, I'm living on disability. When I, I remember filling out the forms and I was really, this is when I was in the hospital back in the 90s. And I don't remember much of it because I was just so, you know, on IVs and da-da-da, but I was fortunate where it came through quick. And it has helped me. And I've made little attempts but, to get back to work and it's like, you know.

And then I was putting a band together in 2005, a Rock 'n' Roll band. I had some success in the 70s in England with all that stuff. And there's been real interest ‘cause out of left field some interest in that stuff came back. And I'm giving it my heart and soul. And you know my disability check, is like, you know I'm like not paying the rent and I'm trying to pay the rehearsal rooms and really trying to do something. And then it's like I'm getting the pains in my left shoulder. And you know, I know there's no, maybe, documentation of whatnot, but I know at least five people that died of heart disease that were on the HIV meds, and I, recently I mean. Of course there were other factors, lifestyle and all that, and a life lived in excess, whatever. But that’s when I just did the show anyway, but then I wound up in Saint Vincent's.

And you know attempts to, you know and then what am I going to do, just go home and just stay there and think about, you know, what might have been or think about what could be, which can be pretty grim, actually if I really start thinking. And so it's real mental work for me to stay in the present and one foot in front of the other and keep going on like… You know, it's like, you know, I never, when I was 18 and they had the draft, I was in England and I was like a teen pop star. You know, so you know I never even registered for the draft. But believe me, I've been through war.

All I can say of my war of: A; the drug addition and getting out of that, and especially getting out of that with HIV/AIDS. 'Cause I mean right now I mean if I want, you know, I can come up with a reason to go pick up and all that. But it's like, really, do I want, I, maybe my mom, my faith, I don't know what, but there's been some, I know people that have loved me and cared for me, and maybe some self-love, 'cause that was a big topics today, taking care of ones' self, is a part of it. But there wouldn't be anything if I didn’t have, I've got to have some love and care for other things too.

I mean, just, and you know that's why I often think, I mean my friend, you know, I was overloaded with information coming here. You know, I had a dear friend who was a drummer, psychiatric problems. He couldn't be treated for the hepatitis C and it was so quick. And how quick he got, and I would go and visit him in hospitals. I don't like going to hospitals. But, you know, I went in when his belly was getting fat and I'd joke with him that he was pregnant and blah, blah, blah.

But and the next thing I know I didn't hear from him, and then he's in the ICU. And then they had to put him out and intubate him. And then they tell me that I was his healthcare proxy. And I had never, didn't even know that. And I don't want, you know, God, and he died it was a little over a year, a year ago. And this go was so, he's still with me, 'cause it's like, he's like, Brett we got to do the music, Brett we got to play, we got to get it. And he had so much ambition, which is like, I don't have the ambition I had when I was 16, 17, you know, when I was 18 years old.

I, you know, some days, again, the best I can do is get up and eat and take my meds. And I'll be honest, there are days that it's like, you know, screw that. I mean really it's like, I just, some days I… But you know most of the time, most of the time, and most of the time I do pretty good and I stay grateful for what I got. Although, it's just too, it's an attitude change. I try to, I really try to self-examination. I've got to look at what motivates me. Look at reality, when I, I'm the kind of guy who does not want to live in reality, I'm the kind of guy that wants to…

And I did all that, but I, you know, I'm the kind of, I mean the sexuality. I was thinking right here. I mean, God, what a candidate. You know, I remember having not only the gonorrhea, the Chlamydia, but also syphilis. And then having the gonorrhea that was the penicillin type too, and going to my girlfriend who was actually working on the streets. And she's positive too now, you know. But, and, you know, the Board of Health have, you know I just have a lot of stories. And I can't carry them all here, tell them all here in 15 minutes.

You know and then I skated, see I call it skate and that's maybe giving it an attitude. Like I lived through that and experienced it and I try to put that into, you know one thing I can do, I can write, but some days I can't even do that.

Some days I can just like, you know, on a match book or something I can scribble.

But I'm trying the new protease inhibitor, still got to take the Norvir with it. I asked the doctor, there's a new generation of drugs, I guess the infusion inhibitors or whatever the - - , the science I'm not as up on it as I probably could be. But he said we don't know the long-term effects with the liver, talk well you have hepatitis C too. You know the whole gamut, just lucky, that's the way I look at it. You know, so I'll try the new protease and it's like I've just got to go on. It's like I'm a soldier. Like I'm amazed that I was invited here to speak, and like, I guess my time is about up on that, is that? I haven't been timing myself.

But again I go back to that T-shirt, "Be here for the cure." And so I go, well I'm here, and you know and I'm - - . And like living on, I couldn't get by on disability, 'cause I swear, I walk two blocks my leg cramps up. That's about how, I've got a girlfriend in California who wants me to move there, because A, Social Security Disability is a little higher out there with, the state kicks in more or something, but that's not it and all that. But it's the car life and all that. But you know your car you don't have to walk far. You know and I love New York City 'cause I could walk around, walking and movement, interaction with other people is what keeps my spirits up, other people. It really, really does and that's why I said yes to coming here. This is a real privilege to get to meet you all. And thank you for, I hope I've been a service. All right. Thank you much.

[APPLAUSE]

DR. MONTE HETLAND: Thank you, Mr. Smiley. Okay, our crew is going to come and put the table up in front. We're going to ask our speakers to come up and be part of a panel discussion. While I'm, before I forget, those of you who drove here, we do have some help with parking. Speak to Reese who was, I'm sorry… Oh, this is Reese. Don't talk to her right this instant. Can I ask our speakers to come up? Did you want to come up too?

VOICE: [Off mic] Yeah.

DR. MONTE HETLAND: Just bring your chair. Yeah. I think we're short of chairs. We will have some floating microphones out in the room. I'm going to ask you to compulsively identify

yourself and if you're with an organization. It's really for the benefit of our transcriptionist, otherwise you're just going to be anonymous, et cetera. First of all, I do want to thank our speakers. And I should introduce Dr. Wiznia, who is going to be speaking this afternoon, as well as Dr. Flynn. And Mr. Glenn Sklar wanted to make some comments.

MR. SKLAR: Usually we wait 'til the end of the panel to thank the panel. But I think given what we heard this morning, the incredible thoughtfulness, the preparation of the actual speakers, the comments of Mr. Smiley, I think we have a really good feel for where we need to go as the Social Security Administration. We've done a lot of these sessions over the last couple years. And I have to say, I can't think of one that's been as efficient, in terms of bringing information forward and giving us an idea of what needs to happen next. So thank you so much.

The second comment also is about compassion and it's very clear there's just a tremendous amount of compassion in this room. I think a lot of folks are here, not because they have to be here, but because they thought it was important to be here. So we're incredibly grateful and incredibly thankful.

If I can kickoff with one question on a theme that I've heard recurrently, it's how do we communicate better? It's obvious that there's tremendous expertise out there, often from the Social Security Administration perspective it's difficult to get to the right person with the right question. So the specific question I would love the panel to think about is, is there any way you can help us come up with the right set of questions that we should be asking practitioners? And, the subpart of that is, how do we get it in your hands? You are very busy people. We're a fully electronic agency. Maybe there are other solutions. Maybe there's a web site we could put it on. But the idea of mailing a piece of paper to a really busy place where there's total chaos and commotion because you all lead very busy lives, it's not working. So if you can, any type of commentary on how we can get the right questions asked of the right person to get the right answer we'd be incredibly appreciative. Thank you.

DR: MONTE HETLAND: Am I on now?

FEMALE VOICE: [Off mic] Yes.

DR. MONTE HETLAND: Can you hear me if I, - - do I have to shout? Okay. Who would like to answer that first question? Grab a microphone, please.

MALE VOICE: So I think that the HIV Medical Association definition of who is an HIV specialist is very important, but we know that there aren't enough of us in the country to satisfy those needs. So I think for SSA, perhaps it's a question of triaging the cases. So one of the issues that we talked about already and sort of on the side was, rather than giving a negative, the positives are easy. We'll, you know, there's documentation, you're happy, et cetera.

The negatives, instead of giving an automatic negative, if there's a question of whether there might be more information that's the one to try to refer. Now how do you access that referral database? The HIVMA has an electronic listing of specialists. So that may be one thing to look at. And also in an efficient manner communicate, as best you can, what your question is about making the determination.

So the problem from the practitioner's side. First of all there aren't enough HIV specialists in the country. And our reimbursement is basically nearly non-existent. So that's somewhat of a problem. If it's bounced back from SSA, could there be at least a nominal fee associated with doing an additional assessment? How do we do that? So that's one of the issues that I would throw out to you.

DR. ABERG: You know so the flow is a really big problem because there's so many different settings. So like, myself, that's in an academic institution it's a little bit better if you know the patients come and they bring their forms. They usually give the forms actually to the case managers or the social workers. And the social workers really keep on the docs. I mean you know, I look at it and I'm fortunate because I am at an academic center where it's a team approach and I'm just one opponent. So, you know, I have all these other people that help me and we can really, you know, really focus on the patient. So, actually, though having the case managers kind of be in charge of that really helps me. And that can help us with some of the social assessments that are needed.

The problem is that all of us are just getting buried under paperwork. We have to pre-authorize prescriptions. You know, everything we do now it's paperwork coming back. And I

think, one, the electronic medical records are getting better, but your point can you send something through email. The problem is that firewall. It's okay within an organization, but once you go from one organization to another you might be protected, I might be protected, but as soon as it goes out there it's free. And we've got to think about the patients' privacies. And we certainly don't want a form that's about HIV floating out in space that somebody can acquire. So I think having a generic form is all right, but how do you do that link through?

And one of the things that I do think is working, is some of the managed care facilities now, the managed care companies actually have a way to contact us and give us this information. And that's really helpful for me, because I get, actually in New York for Metro Plus, we're affiliated with. I get this email from the Director at Metro Plus saying this is what's needed.

And so key things like that. But the forms themselves, if you just have checkboxes, I'm busy, alls I'm going to do is I'm going to check, check, check, check. And again that descriptor, what I was talking about, it's the detail that you need. So if I check off and I just say, yeah, there's fatigue, malaise, you know you give that, it's a…

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DR. ABERG: …question, right, and it says other symptoms? Fine, I just check it. It doesn't really ask you, it says, you know, please detail, but, hey, I'm busy. I see I can check and so you're going to get an incomplete form. And I think depending on the busy-ness of the practice. So I think it really needs to be specific like if fatigue then check, you know, decreased 50% of ADLs or whatever it is that's the requirements. It needs to be as specific but as simple as possible, if that's such a thing.

MALE VOICE: Yeah, I was just going to say, I'm thinking to myself, doctors are not in the habit of writing in their notes, this patient's fatigue is so severe that he cannot work 8 hours a day, 40 hours a week, and yet, that's what we need.

MALE VOICE: [Off mic] Right.

DR. MARY ANN COHEN: I was just going to stress a very simple thing in reference to your question. And that is that the organization of AIDS Psychiatry that I mentioned really has access to nearly all the mental health clinicians who are working in the field of HIV/psychiatry, throughout the United States and some internationally, so that you would have access to a lot of people on that web site. And now we have an actual web page.

And one of the things that the organization has done this year is to have sent out an expert consensus survey. And we're working on getting those results together. So that's on, ‘cause we really don't know what the best psychiatric treatments are for persons with HIV. There has been, I mean, we all have experience, I have a 27-year experience with it, but to really find out, well what are the best treatments, what is the best way of approaching a person whose newly diagnosed and on new antiretroviral regimen. What is the best approach in someone who is not on an antiretroviral regimen? What's the best of approach with this class of medications, with that class of medications? So we have, we're just done a survey and we're looking at that and we're going to be writing it up. So those are the things you might have access to as we move on.

DR. MONTE HETLAND: Dr. Wiznia?

DR. ANDREW A. WIZNIA: I've been quiet 'til now, but I'll, I'm not that quiet. So I actually want to go back to Judy's comments about busy-ness and time for clinicians. So any time that I'm given, so I come from this from the - - perspective. So I have some children who have congenital immunodeficiencies who need gamma globulin, they need monthly infusions, every six months, this is life long. Every six months I need to write another letter, which I have to change because they tell me that it's the same letter, so I have to change it, so that this can continue on a therapy that they're going to need for their whole life even though I've written in the thing that there is, this is never going to change. This child is just born with - - that's it.

And what happens is that sometimes their gamma globulins, you know, they don't have the recertification and their treatment is getting delayed at home because I'm being asked just to take a letter out and change a couple words and change the date. But that's enough of a disincentive, it's enough of an obstacle to effect the care. So when I look at these blank

boxes and it asks, provide additional information, first of all, no one can read my handwriting. I can't read my handwriting. And it's probably the major marital issue I have with my wife. She thinks it's passive aggressive, I think it's just fine motor. Maybe you can help me Dr. Cohen. My gross motor's okay, I'm still playing basketball.

So then I write this because I don't have time to type this. I work in a city hospital. We're the largest pediatric HIV program on-site in one site in the country. We're caring for 3,000 adults. I'm the director for all of HIV services. And we have a half [phonetic] a psychiatrist that's how it - - . We have maybe 1 case manager for 400 patients. Okay. So when we get these things and it takes time, yeah we can do forms all the time but we're going to provide no services.

So it sometimes becomes this balancing act that we'll fill out the forms but really some of it is a myth. And I'd rather be having my case managers providing either services or some type of supportive care. So boxes with yes and no and just, and - - it is just to believe us, okay, as opposed to, can you document. I can't tell you how many times I'll get a call from someone from SSA saying, Dr. Wiznia, I just want to verify da-da-da-da-da-da.

So I get a lot of these verification phone calls. And then I've got to call back. And the person I'm calling back, guess what, they're not sitting and waiting for me. They're on the phone with somebody else. So now I have a voice thing. So then I - - all right, and then it's back and forth. And I don't, just to say, yes to a person, but I need to verify it with me not by voicemail but they have to hear me say yes and answer one or two peripherally related questions. All right, and that can take a week. That could take a week, and that could be six or seven back and forth. So that's got to stop. I don't know how you stop that. And I understand the concept about firewalls, but maybe a form saying you've said this, we want you to re-verify, do you believe yes, that this… That would help. If you asked me write text and to write, give us five examples of X, Y, and Z.

And I'm going to be talking about soft science [phonetic]. I think Dr. Cohen talked about soft science and disability all you have to do is come to my pediatric HIV clinic, which is mostly 16-year-old infected adolescents who've had the virus for 16 years and everything's soft. But it's, they're

disabled. They can't go out into the world and function when they're hitting 18. It's not happening. There's 70% have mental illnesses, have a DSM-IV diagnosis. That's a high risk of failure. So if you just throw them out there that's a problem, and that's… Well I'm going to talk about that so here's a prelude.

But I think that anything that, so the bottom line is, anything that you're asking us to do more is a real problem. As a matter of fact, I'm going to make a comment about electronic medical records, because this seems to be in vogue. So the city has done this and we're part of the health and hospital corporation. And I understand why we need that, but I can tell you the quality of notes that I'm seeing in the electronic medical records from house staff to us, everyone is under pressure. And if I, I can take a history and write stuff down and I'd be looking at my patients. I can't really type and look at a patient and ask a question. Okay. And certainly, and then their response would be by the IT people, good, we're going to give you boxes to check off. So I got to find the clicker. I've got to match up my mouse with what I'm looking at the screen. And, by the way the screens are always on the left, the patients on the right. So I'm going like this and I'm getting vertigo. But it hasn't helped.

So what electronic medical record recording to me is every patient is another 10 minutes just to get it down there. And then those probably aren't as good. So if you start looking for that. But take any short cuts, Monte's exactly write, I'm never, I've never written this person can't go this, this and 40 hours a week. Please, you know, yes, I'm hoping that I can meet some of the HIV quality assurance measures from the state because they come in and they look at us also. You have to realize, this group is getting, HIV was a novel illness and that creates an opportunity for people to look over the shoulder's of everyone.

And they do. Okay. I get Icrow [phonetic], I get people coming out for three days looking, you know. It didn't say that you talked about adherence, Dr. Wiznia. I'm like, I've written three grants on adherence and HIV infected ‘cause of course I'm talking about that. Well it doesn't say that yet. Well it does over here. Yes, but we like to have these parameters marked over here. I'm saying, you know, so that's us. So anything that can be very quick and verifiable that would work. Okay.

FEMALE VOICE: And I just want to underline the trust me part of that, and trust the clinician wherever, and you know also take into account that people throughout the country are applying for these disability benefits and they don't all have access, necessarily to the same level of doctors for a variety of reasons. And I think also Social Security Administration, in terms of their end of things has to be not so hung up on the magic words appearing somewhere on a form or in the records, but really going through those records to see what is the situation with a particular claimant, and to be very receptive to the clinician's evaluation of their own patient and some of the subjective information in there without the detailed data, objective findings that ideally you would have, but you're not going to have in every case.

MALE VOICE: And one other point, and that is, I don't know what percentage of care is delivered through academic institutions, as represented here, where for better or worse there's some level of administrative support. What do you do at the private practice setting? I mean have a friend who was an HIV provider who supported his nurses in his clinic by taking out a second mortgage on his house. And then his practice closed and he lost his house. He thinks working for the airlines right now is great because he gets a regular paycheck. So you know we represent kind of the lunatic fringe of the business, if you will, and a lot of the requests for disability determinations are going to docs in the community who have no support whatsoever.

DR. HETLAND: Mr. Sklar, you're on.

MR. SKLAR: Actually, at the moment I'm speechless. Thank you. We have a lot of challenges here, and again, we look forward to working with many of you. This obviously isn't going to be easy, but it doesn't mean we shouldn’t go there, in really trying to find a more efficient way to do this that everybody could live with. And obviously that requires some flexibility on our part as well. So I guess in short measure, we get it. So we'll be back in touch.

DR. EDWARD HANDELSMAN: Hi. I'm Ed Handelsman from the Division of AIDS and I want to ask a question about adherence and how would adherence be, or difficulty adhering be addressed in terms of a disability. I mean in some ways you can think of an opportunistic infection is easy to code, even a psychiatric diagnosis or even the softer signs are earlier to code. How would you get at someone who, let's say, needs to

sit for three hours to try to get his or her medications down and that would really impact their ability to continue to work?

MALE VOICE: Is that a question to me or to them?

DR. HANDELSMAN: I guess, both.

MR. SKLAR: You first. Okay, Dr. Flynn?

DR. PAT FLYNN: I guess being a pediatrician, as Ed is, it's easier for Andy and I to answer that question, because I think as adults, as much as they complain about ritonavir they should try, they don't even have to taste it, they can just smell liquid ritonavir to see whether or not they'd be able to comply with that regimen. And so, and also as pediatricians it's not necessarily the time that it takes the young infant or a child to swallow their medications, but often times you're having the parent having to do it, and if it does take three hours, which it sometimes does, that really impairs, not only the child's ability to go to school, but also the parent's ability to work and support them.

And, not only that, but there are other limitations that are brought about by poor adherence. For instance, our patients when you don't take your medications we see you more frequently. So particularly in adolescent patients we may have them coming to clinic every week so that we can count their pills and check their medications. We may have directly observed therapy regimens that require them to go somewhere or to meet somebody twice a day to take their medications so that we can assure that they're adherence [phonetic]. We may also have them come into the hospital and do pharmacokinetic studies so we can determine that. We may have people calling them all the time. So it is a major impact.

And, you know, it's easy to look at who's non-adherent. You can get that again from Andy's, trust me. But when you have patients on their third, fourth, and fifth medication regimen I think that's also a very good marker of who has had struggles and difficulties with adherence.

MR. SMILEY: I could address that on the adherence thing ‘cause I have had trouble with that. I've been through a lot of meds. And so many of the medications, you know, have to be taken with a meal. A lot of the PIs, well no, actually all of them are better or easier to tolerate with a meal. And then for

me personally there's all the other, you know mendacities [phonetic] of life, you know, dealing with them. But just my day quite often you know revolves around, okay, where is my main meal, and it's got to be within a certain time thing. And sometimes that becomes such a big monumental mountain of…

When I was, actually until very recently I was getting food, when I couldn't walk, God's Love, We Deliver and all that. And, which I was ever so grateful for and all that, but still I'm not, I don't want to be the shut in. But you, one Wednesday night, I relate a lot to music and there was a line in a Bob Dylan song, of all things, said that, it's an idiot wind, and it goes, "we're idiots, babe, it's a wonder we can even feed ourselves." And it's not for lack of food, it's just the mental thing of composing a meal, you know putting a meal together. Or there are services to go get them, but it's like I've got to go from A to B and if I'm not walking good that's an hour extra, literally for me, it's like I have to plan an hour to get to the GMAC if I want lunch there, you know, or go to the market.

Now, I'm doing better, but it's like, it was hard to carry stuff back. I can't carry two big bags. I can carry one thing over the shoulder, you know. It's just living with it, something else that you know is cyclic for me. I'm on a regimen where I get like a steroid, a testosterone injection and a vitamin injection like every two weeks. So for the first few days I'm feeling really good and whole. For the rest of the week it's like a down hill slide. And then it's like, you know, both mentally and physically. I was like, oh, gosh, I got to get up and it's sort of really a football pep rally in my own mind to get up and get on with life. So it is so cyclic and it's unpredictable. I mean it's almost predictably unpredictable. There we go.

DR. WIZNIA: I'll take a whack, actually I'll give it a real life experience. I don't know how to answer Ed's question with how it relates to SSA. So this always comes back and you guys are assessing us, I'm supposed to do that, but, and I'm a clinician. So I just admitted a 20-year-old perinatally infected child or young adult who has a baby. The baby is about 8 months of age. The baby is not infected. She has been in the foster care system in New York City since she was two. She's been in abusive foster homes. She's had to live with her HIV. She hasn't graduated high school. She's in a reasonable foster home now, except that there's a, maybe a little too many foster children.

So they're supposed to sit and hold her hand when she takes her meds. And she told me she was taking her meds, and of course the viral load was 300,000 and her CD4 is a 10. And this is the third time she's been down there. And we had, I took, I actually had the whole dysfunctional family come, the dysfunctional family of her care providers come in to the - - clinic, and that included the agency, the foster care agency that never talks to us, it also included, she's got a legal guardian, the legal advocate, it also included our staff who I think are semi-functional, and her.

And I asked to someone I'd been trying to get DOT, which is direct observational therapy. She basically said, I just need someone to hold my hand when I take my meds. So I'm trying to get that in to her home in Staten Island twice a day. So they call the AIDS task force out there we can go. That was in, the referral was made in mid-August and so far I have an evaluation, but they never called me. And the evaluation is, we can do twice a week.

Okay, so that's probably detrimental to her health because that means that she'll take her meds twice a week and that's a good way, she's almost PAN [phonetic] resistant, but that's a good way to cement her in total resistance. And she's on every available antiretroviral in every class. So we have, there's nothing even down the line to give her.

So I asked her the important question, I said, what time, I said you wake up in the morning, now you've got to take your dose in the evening, what time, when do you start during the day thinking about taking your dose, which she basically looks at but thinks about. So I said, what time during the day do you start to think, she says, the minute I wake up. The minute I wake up I start thinking about taking my medications. And in the last three weeks when I asked her that question she had taken no medicines.

So it's always present, and you know Dr. Cohen talked about posttraumatic distress disorder, I think that's my clinic, my clinical population, my practice. I don't like the word clinic. So I don't know how that goes in to disability. But if she can get services that can do that where I can have someone go out, and I can tell you that I've spent hours and hours and hours trying to work a way, back to a way of getting this done. That would work. So I'm not sure if the disability part can come into this, and that may be how - - , but I think that a lot of the…

And actually we put her in the hospital. And she's been there for about five or six days. And I went in and I saw her and her smile was back. I said your smile is back. She says, I'm feeling better. Of course you're feeling better, you don't have a viral load of 300,000 anymore. You know if you have, think of, it's a virus, so when you have the flu that's a virus. You don't feel that but there's this background yuck. And she's feeling better 'cause that background noise in her immune system and - - is better.

So somehow it's sort of like, it goes back to adherence. So how do you get people to take their medications? It's not to explain to her, so you know you need to take your medicines because if you don't take your medicines you're going to die. You know she feeds it back to me. She can even give you a discussion on pharmacokinetics like why if I miss a dose I'm dropping below but an important - - level of my drug. She can give that talk fairly well. So she understands. It's just the act of getting it. So somehow if this can help, and I guess goes back to whatever the checklist is. Have you discussed adherence with the patient? You know, of course we have. You know, just assume it. I'll stop.

DR. ABERG: You know, just building upon that, Andy, I think, and you'll probably agree is that, you know, adherence comes up looking like a blame to the patient. And I think that's one of the worst things that anybody can do. But adherence doesn't mean that somebody doesn't want to or they're refusing something. You know, we got away from the word compliance because we said, oh, that was putting the blame on patients. But that's what people do. They say, oh, you're non-adherent that's why you're failing.

There could be many reasons why people are feeling. And it, they could be somebody that is actually taking their meds all the time. You know we're not all the same. We have different metabolizing enzymes. We don't know all the differences between genders and race, ethnicity. So there can be reasons or drug interactions why some of these medications aren't working. There are things over the counter, we don't necessarily know how they may interact with some of these medications. But, you know, the automatic assumption is if somebody is not doing well and their disease is progressing well then they're non-adherent.

And I think when you look at a form, and I look at a form, and it asks me, is this patient, you know that if you say no,

then it's that, oh, well this is the person's fault. And we need to get away from that, that it's not the person's fault. And there are so many factors that play in to adherence that Andy was mentioning. But even, you know, there was one study that looked at directly observed therapy compared with people taking their meds on their own. And while people where on that DOT it's true they had great adherence, but after six months after they dropped it, people went in, back into the routine of missing doses. So it wasn't that you get so much the routine.

But the other thing to remember is, just like chemotherapy, just the thought of having to take these meds sometimes make people nauseous. They get sick and worried just doing it. And when I made that comment before about the face in the mirror, I've, I have friends who are colleagues that practice in HIV and they say that's one of the hardest things, is you know you get up in the morning, you've got to take your own meds and then you have to go and you have to deal with this constantly all day. You know, and so you think about it that first thing, like Andy just said, you wake up in the morning, it's the first thing on their mind, oh my God, I got to take these meds. And I think we need to have some forgiveness with a patient.

So what does it mean for adherence? It's really difficult. We all know, you know, lots of times people are going to have a doctor's visit, that's exactly the time when they're the most adherent. Why do we ask, have you missed any drugs in the past three days. Well no, so then you're 100% adherent. I mean that's what's on our computer that Andy was talking about. It has a calculator to calculate what your percent of adherence is, but it's based on a three-day recall. And how, you know, it's, so there's all these missing things and I don't know necessarily how to interpret that. But I certainly don't know how to interpret it as far as saying it's the associate with disability. The reason why there may be non-adherence could be because it could lead to, like we were talking about, mental illness or other reasons why people aren't adhering. And those are the things that you need to get at to, not whether or not somebody is adherent.

DR. NADLER: And along those lines, one of the things that I did with our clinic in Tampa, Jane you know about this, I kept a big bottle of liquid ritonavir. And at the beginning of every year the new fellows were required to dip their tongue into a partial teaspoon of liquid ritonavir. And then we

didn't provide them with anything to try to disguise the taste for the next couple of hours. So they could understand the kinds of challenges that the patients face trying to take the medications.

But what do you do when you've got a newly diagnosed demented 87-year-old who shows up in your clinic, like I had 2 weeks ago? What's the dementia due to? What's his functional capacity? And his daughter says he can't even button his shirt and his trousers in the morning and that's why I want him moved into a nursing home. Is he an appropriate candidate for antiviral therapy? These are tough decisions. But this is a man who is disabled. He cannot perform activities of daily living.

And another point about the chemotherapy thing, at least with chemotherapy it's time limited, either you die or you respond. This noxious stuff is stuff that the patients have to take for the rest of their lives. And they're going to go through periods where they're able to do it and periods where they may not be for an assortment of reasons. And those are tough calls. And I don't think any of our electronic record systems, as good or as bad as they may be, are adequate to addressing those issues.

DR. COHEN: Just a real quick comment on two things that you said about the 87-year-old and about something that Mr. Smiley talked about in his presentation. And that is that, this really doesn't pertain exactly to disability, but the concept of talking about advanced directives with patients long before they become ill, while they're still healthy is really an important one because then Mr. Smiley wouldn't have learned in the intensive care unit that he was the designated healthcare representative for his friend.

And in addition, Dr. Nadler wouldn't have learned that he was faced with an 87-year-old, and it was unclear what to do if that gentleman had actually talked with his daughter, appointed her as his healthcare agent, discussed his wishes, should he became, should he become unable to make decisions for himself. And maybe, even though he's 87 and can't button his shirt maybe he still can make decisions and the question would be, how would you like to feel better, if you got a lot of difficult to take medications then maybe you would be able to get some of your function back and see what he answers.

MALE VOICE: I'm going to say something that I kind of feel like the big bad wolf in that much of what you're talking about is coordination of care. That's not SSA's job, unfortunately. Our job is, does someone meet the legal definition of being disabled. Can anybody say that more subtly?

DR. WIZNIA: I guess the retort would be, so if you look at your medicine and you cognitively know that you need to take this and that this is good for you in the long term and you don't, is that a disability.

MALE VOICE: Mr. Eigen? We can't possibly have an outreach without Mr. Eigen weighing in.

MR. EIGEN: Yes and no. It could, the answer is it could be.

DR. WIZNIA: We'll just take a yes.

MR. EIGEN: The reason I put it this way and the way I wrote it in my notes, I always think of translating what you guys say into instructions to our adjudicators. And what I took away from this discussion is there are two issues that are associated with failure to follow the treatment that's prescribed for you, either at all or the way you're supposed to. One is, if you actually are disabled, where we say, you know you can't work, and there's a treatment that's been prescribed for you that could, that is likely to make you better and you willfully failed to follow it we can deny the claim on that basis. From what you've said the clarification I think we need to make to our adjudicators is that that could never occur, or it would be so rare that for this population that they shouldn't even be considering that.

The second way it comes up is, and this is the trickier one, is when the person doesn't have one of these kind of frank manifestations of HIV infection that automatically meets a listing, one of those earlier things that you all addressed this morning and where we have to consider the person's limitations. And I suspect that one of the things that might be happening is when you're getting, first I was taken aback when somebody said that you're getting questions about whether the person is complying with treatment.

And I was trying to figure out why one of our adjudicators would even ask that. And I suspect that what they may be thinking is it goes to, what we call, the creditability of the person's complaints. That somebody is translating that or some people are translating that to, well the person

appears to be very limited, but they're not following their medicine so maybe it's because they don't need to. Maybe they feel okay and they're just not following it for that reason. And that's another translation I made in my head to an instruction we have to make to people to say actually that's very unlikely. That there's far more likely reasons why people would not be following their treatment. So I'm not sure if that answers it directly. But the point is, if we give out instructions that explain that people who appear to be disabled but who are not following their treatment have very good reasons for not following their treatment the answer to your question is yes.

DR. WIZNIA: So I guess what I didn't hear in that, or maybe I missed it, is what if the reason is that there's an underlying compilation, 'cause I'm an immunologist so I apologize Dr. Cohen, so there's an underlying compilation of mental health issues. So the patient's knows they can physically but emotionally or mentally they can't because they have a combination of - - posttraumatic, depression, anxiety, whatever.

MR. EIGEN: Same answer, it's just that's an example of a reason that a person with a mental disorder or a combination of mental disorders, a good reason for not taking the medicine. So, and we would, and we would and should be taking that into account even now.

DR. WIZNIA: Okay. So if that could be manifested in a checkbox with a verification, as opposed to text. Then someone going back and saying, can you show me in the medical record because the electronic medical records that we're defining, that are being defined by us by other sources isn't capturing that. And we don't, at our program, which is a huge intercity, it's the Bronx. It's the large, it's the large, it's the public, it's the municipal hospital system in the Bronx, okay. We don't have, I'd love to have Dr. Cohen come up three days a week and see patients.

Okay. And in a world of pediatrics and adolescents there are not that many adolescents psychiatrists. And what you find is that if we can find somebody who wants to do it they're looking to start a private practice to do pediatric and adolescent psychiatry. So their open time is during the day. Okay, at night they're seen in private practice. So I can find someone to hire them half time equivalent, but they want to work in the morning. Well that population needs to be in

school. So I don't want to pull kids out of school to meet the schedule of a highly sought clinician who may be a great practitioner. So we don't have that. You know there's a disconnect between what we would like to do, the reality, and then getting you that definition or that verifying it, so.

MALE VOICE: We heard you loud and clear on that in the office - - —

DR. WIZNIA: [Interposing] Okay. - - medical school—

MALE VOICE: —we ought to think of that.

DR. WIZNIA: Yeah. In medical school anything that was important they told you three times. Okay, the first time was during the crossword puzzle, the second time was sleeping, the third time someone said, you better listen. Okay, so.

MALE VOICE: Please, I see a hand in the back.

MS. MICHELLE SPADAFORE: Michelle Spadafore, AIDS Center of Queens County. I'd like to talk about fatigue both to you guys and to our SSA representative. I have a lot of clients that have fatigue. And their fatigue might not be serious enough that they're bedridden seven days a week, but it's certainly serious enough that they cannot go work five days a week, eight hours a day.

And, you know, especially in regards to 14.08K, personally I've got really bad back pain. I don't talk to my doctor about my back pain. When I go to see my doctor I talk about whatever I came in for. I never talk about my back pain ‘cause my doctor can't do anything about my back pain. But I've got these clients that have HIV and depression, HIV and you know hep C or just plain HIV and they've got this serious fatigue. They don't go in and tell their doctor every time they have fatigue. They don't, you know, and so not every piece of the medical records in the treatment notes are going to say, patient complains of fatigue, patient complains of fatigue. Maybe twice a year it get's noted. That doesn't mean they don't have it every day. It means there's no point in talking about it because there's nothing that can be done.

And then when I go and I try to make, you know, an argument to the judges, my patient has serious fatigue, he's like, well I don't see that in the record. It's not on the doctor's notes, just ‘cause he says it doesn't mean it's true, too bad. So, you know, how if at all can that be

addressed in the medical community and is there anything you can do to make the judges listen to my clients when they actually say they have fatigue even though it's not always noted in the record?

MALE VOICE: Something we struggle with all the time.

DR. COHEN: Well it is actually a symptom that has been well documented as very much a part of HIV infection and it is multifactorial. So that, you know, it could be due to HIV, it could be due to depression, it could be due to substance use disorders, it could be due to psychosis, and it could be due to the other thing that's very closely associated with HIV, which is insomnia. Apparently there is a connection between the reticular activating formation and sleeping and not being able to sleep in HIV infection.

So, you know, I think that there is definitely good reason for fatigue and yet some people are able to deal with it better than others, some people talk about it and some people don't. And I've worked with patients. I invite patients to talk about it so they do talk about it.

DR. NADLER: Yeah, I mean there's a certain reality that a practitioner faces. So you've got 15 minutes allotted for your intervention with the patient. Six minutes of that is taken up by the front desk personnel who check the patient in and try to get the patient to your room. Another six minutes of that is taken up with your post evaluation, electronic notation, or not electronic notation, the what you did. So in the remaining three minutes you're supposed to speak to the patient, examine the patient, provide them with any medications or other interventions that may be necessary so that you can then do the documentation.

That's just not a reality. So I think, for instance, a symptom like fatigue, which is the same, visit, after visit, after visit is not going to get noted in the medical note on a regular basis, visit by visit by visit unless there's an active change or intervention that is sought. So there is a communication issue, if you will, with the people, with the judge who's making that legal determination and the availability of source documentation. That's just not a reality. And, you know, the next law that comes down from congress, such as the ones that we've received, that say we have to now document that we've counseled them about smoking cessation, about safer sex practices, we go through the

annual drill about have you had your influenza vaccination, et cetera. Hey, what am I going to do in all that luxurious 30 seconds that remains to me as the provider in the clinic? And that's a real problem.

MR. SMILEY: I could say something on fatigue. Yeah, on fatigue, I could say something definitely on fatigue. The way I, it just comes with the territory. It's just part of the deal. I mean it's, I look at, it's a given, some days are better than others. It's sort of what I meant like it's totally unpredictable and the thing is I wish there was, in my case, in my personal case, I wish there was a pill or a drug but you know that's like something that I just don't do anymore. But that's - - a lot of times I'll fix it with a get high and that's only going to, you know - - that's going to give me a lot more than just fatigue, I'll tell you that. You know it's like I can't fight it.

It's almost I got to just surrender and just, okay, I have it so what, okay. The mail, I'll get it out of the box tomorrow. You know? It's like I just got to like stop, live basically on my own, it's a drag but live, you know, to myself. You know, myself, you know people always said, Brett, you know you got to live, you know life goes on, you got to live a good life. But a lot of things are really, it's my life and I got to live according to Brett. And that's really the way it is. So it just comes with the territory. Fatigue, lately my fatigue has graduated to malaise.

DR. HETLAND: Other questions? Surely there are questions.

MS. ERIN LOUBIER: I'm Erin Loubier from Whitman-Walker Clinic. I think what, the comments about fatigue and what my colleagues said are really about the givens that any disease has that are things that a disease or, you know, illness you live with. And I think what a guidance that you could give to adjudicators would be is that the absence of objective evidence that support the givens isn't a credibility issue for the client. And I think that's the connection that needs to be made that consistently we don't see.

DR. HETLAND: Dr. Desi?

DR. LAURENCE DESI, SR.: Dr. Desi, Social Security Administration. To try to hit maybe, perhaps something a little more pragmatic, we're not the only disability insurance that I think at least some of your patients may see. Is anybody

else doing a better job of collecting medical information to make disability determination benefits better than Social Security?

DR. COHEN: I mean I don't have, as I told Dr. Hetland and Dr. Eigen when I started with this, I have had no experience with disability except as a clinician until now. But I have to say that it seems to me that the Social Security Administration actually has the best approach that I've seen relative to private insurers and other systems. So I don't have that much experience, but I think it seems like it's the best. I mean I think it works, usually when I, I mean in terms of my psychiatric patients, when I apply for disability my patients get it and I can't really say that it's ever been denied. So, you know, it seems to work, at least from my standpoint.

DR. ABERG: You know it's a little bit different system. I haven't seen that many. I mean I actually, probably if I had to think of another disability it'd be workman's comp, but in the few private insurers I've had by the time the patient comes to me they've had an evaluation through the private insurance and it's almost like for me just to confirm that I agree. So I'm not doing that form like, you know that one that asks you, how many pounds can the person carry for, you know, and they can bend for this many hours or whatever. I don't, the private insurers, it's like, this is what was found, do you agree, anything missing, or you want to add, kind of thing.

DR. NADLER: Yeah, and I agree with Judy that in the private setting there is usually someone who is reimbursed for doing that evaluation specifically. That's a big difference. But the other thing is that until that evaluation gets done, in the private sector the answer is, this person is not perceived to be disabled, what information can you provide that can make us change our mind. And I think that's totally inappropriate, but that's the response.

DR. WIZNIA: And I've had one or two, maybe even a couple more where I think some of our pediatric population has been sent out to an independent clinician to verify this. It's someone who never calls me up and then they're turned down. And I'm saying, first of all I'm upset that my patient is being dragged somewhere else, okay, and out of school, again, ‘cause that's what their job should be, you know, if it's an adult. And then I'm just thinking to myself, who is this

person, well maybe it's you Monica [phonetic], I'm hoping not, okay, foot in mouth disease, but who is this person who's evaluating an HIV infected individual that I've cared for 16 years, who's not calling me.

And what is there, you know there aren't that many pediatric HIV experts in the country. And what is their expertise that is - - that is going against my impression of my patient. And I, personally I find that not beneficial. It's sort of like blaming everyone and it's certainly not helping the patient. So if somebody wants verification it's got to be with somebody with some credibility and credentials, and it's not just that they're certified in pediatrics, that they're board certified in peds. They need to have some expertise in HIV and pediatric HIV so they know what they're doing because the stuff that I'm giving back from both the patients and the rejections I know is nonsense.

MALE VOICE: I'll let you answer that in one second. I do want to say though that the request for a consultative exam, where we send somebody out, is because we have not received sufficient records if any. Okay. That's what prompts sending somebody out. And often times, I used to say it when I was in practice and doing QA work in Chicago where the person would identify one particular site as this is my doctor but then when, which was in an outpatient setting, but when the request went in the hospital and inpatient records are kept by somebody else. And so, you know, and the two systems don't communicate. So we get a fraction of the information back, but we don't get it from the hospital and we're trying to get a complete record. Most of the time it's like we haven't gotten anything. But I will turn it over to Mr. Sklar.

MR. SKLAR: No, that's exactly right, it's back to the asking the right question of the right clinician. But often we just don't mesh. And it's not a trivial point that it's really hard to get the right question to the right person in a really busy setting for us. We're processing 2.5 million initial disability claims a year, obviously thousands of patients in your practice. And it's just that sinking it up is, it sounds like in that case they probably, assuming that was us, us being Social Security, that they came looking for a consultation from your office, or from you, or from somebody there and it just didn't happen for whatever reason, and then they went to a source. Which in our, first of all, in our opinion it's deficient. It's not a great outcome from

us. We want to hear from you. So it's just really trying to get that relationship of how to move that information back and forth that's challenging.

MALE VOICE: And actually it goes back to email in a sense of—

MALE VOICE: Can you speak into the mic, please?

DR. WIZNIA: Yes, sorry. Can we go back to sort of readdress that - - . I see where it comes in, so we, we're the pediatric HIV program and I get mail from pediatric endocrine, I get all these other people's mail from the hospital mail system. So I'm always trying to advocate for my patients but then I see them going. So sometimes it doesn't actually hit me. So the question is, can there be a dual notification, you know, we sent this out? You know, because I may not be getting these. And some of the problem also might be that we're looking at the adult form and I'm being asked on a 16-year-old can they carry 40 pounds, and I'm looking and saying, - - . As a clinician I understand where you're coming from, but as a clinician I'm saying what does these questions that are in front of me have to do with this individual who I think is disabled. And there isn't a box. And then I'm not smart enough to try to check some other box and then have them come back ‘cause I am sitting - - can you write comments. So I probably write comments and then they can't see what I'm writing and I'm trying to mesh, it's sort of a, it's putting a square in a round hole.

But then the other part is when they go to the verifier, so what information is that person looking at? Right, so they're getting even less information ‘cause no one's talked to me. So now they're getting the information about the illness from a 14-year-old.

MALE VOICE: If I could just comment, we just put on a series of hearings on rare diseases, some of them very rare genetic diseases, which are by definition rare. So our adjudicators virtually never see them, or never see them so they're not sure what questions to ask. And then they go out to other clinicians who aren't familiar with the disease. So essentially how we've begun to solve that problem is trying to go out to the groups and get assistance on, what is the right series of questions to ask of a kid, of an adult, come up with a better template and then do our very best throwing the hail Mary pass trying to get it to the right person. But clearly it's not great to be asking adult questions of a

pediatrician. And perhaps Monte would, I've heard him make this comment before about his experiences in Chicago, so I'm going to give him the mic.

DR. HETLAND: When I was in practice when I would get the questionnaires from Social Security I threw them away. And I did that because I would be asked questions, my child with congenital heart disease, how far can he walk before he has chest pain, what are his cardiac enzymes. And I said any, you know, agency that's stupid enough to ask me questions like this, I'm busy and I threw them away. So I guess my patients didn't get disability or they got sent elsewhere. But I mean I've been on the receiving end. Yeah, we get it. Dr. Flynn.

DR. FLYNN: I just wanted to mention, you know, I know a lot of this is regionally and locally based, but I have never been called by an SSA person to clarify or ask any questions about a form that I submitted and never get any feedback about whether or not the patient is granted SSA or not. And you know I think that that's a deficiency and I think a dialogue in understanding would improve the available resources for, at least my patients.

DR. ABERG: I wanted to comment about the two things with the forms. One is that we get the forms and it requires the patients to sign so that we can do release of information and that's never signed. And we really shouldn't be filling out those forms. And so you have to wait 'til the patient does come in and you get that signature before you could do those forms. So that would be like really key.

And then the other is about the phone calls, ‘cause we have gotten phone calls. And we're getting a little bit of a stickler now with the corporation that the compliance officer doesn't want us giving any information over the phone because you don't know who that person really is that's calling you. You don't have an established relationship with them. You don't know that's voice. And how do you know it's not somebody else who just wants to find out what somebody's HIV status is.

So there's this caution against now that we shouldn't be doing, releasing any information over the phone. So when somebody calls me I have to then say, I'm sorry, will you please fax me the patient release form so I can talk to you. And they go, well I don't have that. And I go, well then I

can't talk to you. So we have to wait until they can get that signed release faxed to you with a number that then I can call them at. So it's getting more complicated to establish that communication.

MALE VOICE: [Off mic] - - if the fax machine is working.

MALE VOICE: I've seen some hands in the back.

MS. DIANE LAGAMMA: I've got the mic back here. I'm Diane LaGamma with the Legal Aid Society. I think you hit on a really good point that's really kind of a bureaucratic problem that has to do with the obtaining of medical records. In about 20 years of representing people in New York City with HIV I don't think I've ever found a complete record when I've gone to look at the file. Part of what we do is help get that record put together, but most people aren't represented by advocates at these hearings. And I think that something as simple as trying to streamline the process of requesting those records, 'cause lots of times the information is in that file. You may not even need doctors filling out additional forms.

For many of our clients they are very hooked up to the medical care system. They get consistent medical care. They see their doctors once a month, every three months. The information is in the records. The records are just not at the Social Security Administration. And if you could figure out a way of streamlining that process and getting your hands on those records before the hearings I think there might be elimination of a lot of problems.

MALE VOICE: I'm going to take a couple more questions 'cause we're at the, almost at the end of our time. I saw a hand back here, did you have your hand up? Everybody must be total hypoglycemic. Okay, I want to thank our panel very, very much for - - .

[APPLAUSE]

MALE VOICE: Okay, Reese, where do people go now?

REESE: [Interposing] We're going to go right downstairs below this room to the - - room for lunch. - -

MALE VOICE: She said lunch is being served downstairs. I think if you had valuables you should take them with you.

[Crosstalk]

[END TAPE MZ000020.MP3]

[START TAPE MZ000021.MP3]

[Crosstalk]

[END TAPE MZ000021.MP3]

[START TAPE MZ000022]

[Background, off mic]

DR. HETLAND: People would you please sit down? I'd like to get started.

[Background, off mic]

DR. HETLAND: Okay, this afternoon we are dedicated to talking about how we evaluate individuals up to the age of 18. And those people, once they hit 18, are classified as adults, under our system. Our first speaker is Dr. Andrea, Andrew Wiznia who is the director of pediatric and adult HIV services at the North Bronx Healthcare Network. He's also a professor of pediatrics at Albert Einstein College of Medicine. Dr. Wiznia.

[Background off mic]

DR. WIZNIA: It doesn't matter? Okay. All right, thank you Monte for the introduction. Thank you for inviting me to talk. My—just on my first comments, I'm very excited to be coming to - - .

[Laughter]

DR. WIZNIA: I'm actually from Queens. And I'm sure that the reason that this place was chosen is that it's only a mile or two away from Chase Stadiums, so, and that's - - a good - - . So that's why you're all here. You're all Mets fans for the moment.

[Laughter]

DR. WIZNIA: I'm mostly a Yankee fan. I date back to before—I actually have dirt at home from the 1969 when the Mets won. I actually ran out into the stadium and grabbed some—

FEMALE VOICE: [Interposing] dirt.

DR. WIZNIA: Well grass at the time. My mother threw it out 'cause she couldn't understand why there was another pile of

dirt in my room when I was in medical school. Anyway, but that, that's where my comments—I'm just - - --my comments are going to be presented--I've been doing pediatric HIV since 1985 so I'm, my comments are based on 23 years of experience. And so they're going to be - - . And I'm also not an ID person. I'm allergist immunologist. So when Dr, Dr. - - was talking about early days of how did we diagnosis HIV before we had antibody test. We looked at - - . When we were in the lab we were stimulating lymphocytes and looking what your lymphocyte response would be to different antigens that you would throw into the laboratory. And that's how we were diagnosing HIV. So I go back a long time.

So let me just start. And I'm going to try to focus on what's unique to pediatric. So a lot of what you've heard this morning in the excellent speeches we had this morning are apropos [phonetic] to children. So they may be little, but they get many of the same illnesses. We use many of the drugs. But I'm going to highlight what's uniquely pediatric and - - professions.

So who are my populations? So who are we talking about? There are really three different components. The largest group is the 90% of the children. Those are the children who were born to HIV infected moms. The virus is transmitted mostly at the time of delivery. And these babies are born as HIV infected. There are now many of them are adolescent. And I'll show you were - - population. So that's what we call vertically infected or perinatally acquired. So these are children who got the virus from their moms. The moms may have been in high risk and maybe have acquired the virus themselves through sex with their husbands or significant others not knowing the significant others were involved in high risk activity either. So that's where we are.

Then there are the adolescents who get infected through high risk activity or through actives. So that could be, that could range anywhere from a 16 year old who is a male prostitute, has multiple exposures, to a 16 year old girl who has sex with a boy, as we've seen in politics recently.

[Laughter]

DR. WIZNIA: No comments, right. That's that saying, no comment. Don't type that please.

[Laughter]

DR. WIZNIA: Keep that off the official record. I'll have people visiting me at home. Anyway, so those are people, adolescents who are infected through activity. And then there's a small little group and that's people who've been, children who've been infected through accidental needle sticks, accidental exposures, the group of children who got infected before we were screening bloods for HIV, blood products for HIV. Many of those children are still alive. In our, in our program we are actually caring for three, three, three young adults who acquired their infection by being premature babies and got infected through contaminated blood in the neonatal ICU. So there's a small group out there.

There's a small group though, that group tends to act like the perinatally infected group. The high risk adolescents tend to act like, you know, they're getting the virus at 16, 17, they tend to have more of an adult course, clinically, okay. Not maybe emotionally, okay. So the US, the maternal/infant transmission rate now is about 1%. Back in the early days it was 25%. And that's because we use drugs to treat pregnant women and we prevent transmission of the virus to the baby. So in 1990 in New York State there were about 1,000 infected babies. Last year there were about 10. So the transmission rate is really around 1%. So that's the great success in HIV.

And the other comment is that the, the aging population of vertically infected children, then they're all having children, okay. So you need to think about that. I'm sitting there caring for people; I'm caring for all their children.

And then as we talk about when you think about this, everything's dynamic--and I think people hinted to that this morning--meaning that the natural history of HIV is very different now than it was then. Many of the issues are the same and there are a whole host of new issues. And there are some of the clinical entities that we used to see we don't see anymore like lymposetic infestation laminitis [phonetic] was something that we saw commonly, we just don't see very much. We see it a little bit. It just burned out - - discard. But we don't see new cases of the lymposetic - - . And I'll talk about these people in a second.

The other part about pediatrics—and if you're an adult - - , and there are thousands and thousands of adults in large

databases and you want to know what is the incidence of cancer XYZ, whether it be Hodgkins, non-Hodgkins. It can go into a database and get that. Our database is relatively small, few kids, the epidemic has changed. So it's hard to come up with hard concrete numbers. There are a couple of longitudinal studies that were going on. One was PACTG, Pediatric Aids - - . That ended. So then there was a whole database. Then there was another study started which is capturing part of the database.

The CDC tried to put a group together called Legacy. And now the funding for that left. So it's hard to get these large databases one would rely on for what is incidence and severity. They're really lacking in pediatrics. And we may be, they may not be able to be recreated [phonetic]. So you may have to guesstimate - - .

So this is our population of - - Jacobi Medical center. That's in the Bronx, New York. It's part of Albert Einstein College of Medicine. There are, there are three columns: orange, whatever that is, and green, okay. And they represent different years, 2002, 2005, 2008. So I wanted to show it. And these are the ages of the children of the - - population. So you can see back in 2002 there was still a small - - group of children who were less than 2-2. And when you looked at kids who were over 15 the numbers about 6 - - 16, 3 year ago it was 120. And now it's almost 200 of our population, and these are infect, are over 15 years of age. So you can see that - - babies and a population that's aging. So as they age there are different issues that arise.

And I'll just tell you kind of quickly. I can, I can tell a five year old. If I have a good parent I can get a five or six year old to take anything bravely, okay. When I look at a 16 year old and I say you need to take your medicine twice a day—we talked about adherence this morning—I get comments like when did you get so old? And I say what do you mean? They say well you sound like those old people telling me you have to do something. I say I haven't changed. They say yeah, you have. Well some of these kids, fortunately, have hit 22 and 23, they told me know I'm still young and I'm not as stupid as I used to be five or six years ago because now we're on the same wavelength.

So it's a—that's a point in pediatric. There's a developmental stage, which are moving. It's the same patient, but they're moving through different developmental

stages. That's - - pediatrics, okay. So as far as treatment, okay, - - talked about how we used to give - - therapy, ACT, and then a new drug would come and, DDI and then it would be AZTBI, which was better. And then it was AZT3TC. So the population that I just showed you, the - - , they've been through the history of drugs that we had. So many of them initially—which is good because I see us - - because it's important that we're going to keep mentioning.

So initially anyone treated with mono-therapy and duel-therapy before we had HAART. Then HAART became available in the adult population somewhere in 1997, '96-'97. When you think about kids it's always two to three years later because the development of these drugs trailed, in pediatrics, always trailed the development of these therapies in adults. So these kids have been exposed to longer courses of non-suppressive anti - - therapy, virus therapy against the virus. And what that does is it selects out the resistance. So if you're resistance to one - - inhibitor you may be resistant to, depending on immunization, all of them. If you develop resistance to Neviapine, which is a non-nucleoside, well people are resistant to all the future drugs. So when we, when we first used the non-nucs it was in the sickest children. But it was adding one new drug to a failing regiment and that wasn't potent enough so you so - - resistant. So classes start popping, start dropping out as far as effective therapy.

And finally as newer agents developed the lag of, there was always a lag in pediatric formulations. What did it taste like? People talk about Raltegravir liquid. Dr. Nadler said he made all his fellows taste it. I can tell you we were giving that to children and then we were actually, initially there were tablets. I think there were tablets, capsules maybe. And then there was a common formulation. So the adults didn't have Raltegravir in the tablets so they had to take the liquid. All of a sudden I became the most popular person in New York because I knew how to give liquid to kids. And there were different tricks that one could do. But this is a very nasty drug. So we would be using drugs with - - . And someone talked about that, that smell like I smell that drug and I can't swallow it. That's real. This is a real drug. It's sort of like my mother had cancer. She had chemotherapy. When I'd walked with her—I'd go to the hospital—and as she'd walk down the hall she'd say, "I smell those poisons." And I would say, "I don't smell anything."

And she made a comment of my inability to acknowledge the rest of the world.

[Laughter]

DR. WIZNIA: - - play a lot of baseball. Anyway, so it's true. But this has a memory. This has an amnesic [phonetic]. And in immunology we talk about the immune system becoming learning. Once you had these medicines and they taste bad there - - six months later just the thought of it makes me nauseous, okay.

And then the issues that happen is we don't know what the dosing is. So when you talk about this morphology, so adult takes so much. A kid half the size takes that much? Or maybe that much is not good enough. And in most cases the children metabolize or break down the drugs faster than adults. So if you took half an adult I'll give half a dose. They're usually under-dosed, the children. They selected out for resistance more quickly than one would do - - an adult. So pediatricians, as the drugs came along we used them. We didn't know much about dosing.

And then there's a question about safety. And what if you're a population where you're over-dosing? Because the pill, the drug, is only available in 300 mg in the tablet. And I got a kid who's 2/3 size of an adult. Well I can't break it in half 'cause I don't know why. Maybe the whole thing crumbles. So I'll give you the whole pill. And that can cause more drug toxicity 'cause now you're over-dosing. And we're seeing that, okay. I think that we're seeing that. It's hard to - - , quantitate [phonetic], but I think that we're going on. How's that?

So and the last thing is despite the lack of pediatric indication—that's when the FDA says this is the right doses—and without the data that even supports what the dose is, people use these drugs. So we're putting, we just put together an abstract for one of the scientific meetings coming up. And it's about 35% of children who, in this large database, are prescribed drugs which don't have a pediatric indication. And when did we start doing—it looks like somewhere between one and two months after the drug got approved by the FDA to use in adults. So that does have complications. So the question is at what cost are we treating our patients who have a chronic illness that,

without treatment, will lead to death. So you sit there and you go like that.

Okay. Okay, there we go. Okay. So, and some of this we talked about. Consistent coherence to regimens is a constant challenge. And it evolves over the age of the child in their developmental stages. And the obstacles—I'm just putting some of them but I can give five slides in obstacles—developmental stage, school, peers. So a lot of our children, our patients, yeah they look fine. And a lot of them might have medical symptoms. I say I cared for that kid for 17 years. They say oh my God, he looks great. That child, their perception is they got a big A on their forehead. They have the Aids. Look at me; I have them.

And you look at them and they don't. So it's a perception, so they're concerned about how do I look to all my peers. And that's certainly an issue about, that's an obstacle to taking medication because every time I take this drug I remember that I am different. And I don't really want to be different. I'll have different color hair or I'll put different pieces of jewelry through different orifices of my body, but at least everyone else has a ring through their nose or through their eyelid or somewhere. So I got three, they got two, some are different. But I'm not that different, but having HIV, that's really different. And that's scary, okay.

So disclosure, who do they tell? Okay, it's not just their friends. It's sort of like if you work in an institution you have a secret. You want no one to know. You don't tell anyone. If you want everyone to know you tell one person I've got a really important secret, all right. 'Cause then everyone knows. It's important some people know. But the more important is this is really an important thing. So they—we've had certain patients who've had to move out of schools because they disclosed to their sexual partner and then they broke up. And that creates a lot of noise, okay. So disclosure is always an issue. So it's a secret.

Toxicity, palatability these drugs, okay. So we end up with a population that's at extensive resistance and have fewer options. So when you're ready to take your medication what can we use? There are fewer options. And that makes treating harder. So I'm treating in a continuum. So I know this talk is less than 18, but I'm treating beyond 18. But it starts earlier, alright.

And salvage, about half our patients are on salvage. That means that they've failed a lot of regimens already and we're using more drugs and more potent drugs which may have more toxicity, sometimes less toxicity. Some of the new drugs are better, okay. And frequently we don't suppress their virus. So they're sort of walking around, they have virus, not that high, we're hoping. So we actually do a lot of negotiations. So we have some children who we backed off on their therapies 'cause we know that if taking a little bit consistently of less may be better so that in two years when you, when we reach a range, an agreement where you'll take everything, I'll preserve some options. I'll watch you very closely in the middle, okay.

And that's different than the adolescence affected through high risk activity. Their, their treatment is potentially simpler. Dr. Aberg talked about there's one drug, one pill, that's got three drugs in it. So if you are infected with a virus that's sensitive that's pretty easy. The problem with one of those drugs is that if you're a female and you're in the childbearing age it's probably not the best drug to take. And that would be Efavirenz. So it's simple, if I'm a male give me one pill. But a female there's a whole host of considerations that we, we, we think about, okay.

I'm just going to talk— because I showed you that my populations are adolescents. So I'm glad Dr. Cohen's not here so I can—I'm an immunologist talking about brain development and sight.

[Laughter]

DR. WIZNIA: So as far as we—well breaking down into simpler: there are two parts of the brain. There's the limbic part, the limbic system, and the cerebral cortex, the cortex is the part of you that - - judgment center. Don't do this, it's not good. The limbic part is like I really want this and I want it now and I just want to get thrilled. And that's the part—and in adolescence the balance is such that the limbic is really ahead of the cerebral. So here's - - so in Queens, where we grew up, there were railroads over here. There used to be people in my high school who used to go down and play a game of dare with the railroad. Dare was you stood on a railroad track, you waited for - - railroad train to come. And you would, the goal of the game was to be the last one to jump off the track before you got hit. So if you jumped off first you're, you're, you're a coward. You really jumped

off, your reflexes were bad and you actually did get hit—and there always, once a year, couple times a year, there'd be somebody hit by the train—that was the kid who lost the dare, okay. And adolescence play dare. I know I shouldn't do it, that's why I'm jumping. But it's great to win. And it's a balance. And in essence that undermines, that sort of defines what we're seeing in clinic.

And that leads to you're an adolescent, I can't die; I'm immortal, right. That's where this comes from. So this is physiologic. So they may be big. They may be able to understand for the moment. But really to integrate that into my day-to-day living experience is really hard. Because the limbic part says I'm not going to die at my age of Aids and I don't really want to take those medicines though I can tell you why I need to when you ask me. But—and while you're there - - love you. I'm getting a hug every time. I'm going to do it and oh you're not around tomorrow then the limbic system's in overtime. So it's very hard, okay. So this is where we are, we are, we treat.

So, and the thing—so what else is unique? So the psychosocial, so this is where the majority of kids are born in urban areas so there are children throughout the country. So SSA needs to consider that. This is my world. This is mostly urban. And the urban population has a lot of obstacles or things to overcome. Their lack of resources, school's don't have tutorial programs, mentors, friends, stable home environments. About 50% of our population ended up in a foster care system at some point in their life. Many of them ended up in multiple foster homes. And that says something about permanency and loss and how they view the world. You don't walk out of the foster care system unscarred, okay. Who's the nurturer, okay?

We're familiar with generational HIV. The mother's have died. Many of the mothers have died. So these children are, or the adolescences, young adults, they sort of know they're infected and they watched family members die. And it's a very hard question to say am I going to die like my mother of this illness. That's really hard. So you get this point of silence. So it's hard to begin to address it. - - come directly it doesn't happen that well. We've actually had some of our best breakthroughs taking kids to an amusement park and putting them on a ride, one of those super roller coasters, with a social worker. And they survive together. And then they start yapping about death, which didn't happen

in the clinical environment. So it's wherever you can get a breakthrough. So we'll use that. Familiar loss, so we've talked about that. And the kids - - . And they've also watched their other siblings or other kids in the clinic, the - - population, have now survived their HIV. So it's now present, okay.

So if you had to use one word it's a life characterized by loss. What have they lost? They've lost a childhood. They are not normal. They're sick. And when they were younger we thought you were sick with an illness that we couldn't really treat. So we treated you differently. So we didn't really have expectations that you are going, you need to go to school. You actually need to do your homework because someday, in high school, those grades are going to mean something. So in the earlier days people as me is there, do you think these children are going to live to adolescence. 'Cause we didn't have any therapy. And so they're growing up in that environment, so there was a lot of - - poor child. If they don't want to do their homework it's okay, you know. So we've been permissive. And then all of a sudden we can't be so permissive because now you're healthy. You're 17, 18; go out, get a job, 40 hours a week, and become part of society. Well where was the developmental stages that enabled me to do that because no one ever really forced me to do what other kids are doing, okay.

So they're overprotected, lack of consistency, who's the parent, and their loss of ability to experiment. Don't have sex because if you have sex with somebody you actually may kill them. Wow. I thought we only had to worry about STD's. but you're telling me, doctor, if I have sex and I don't take my medicines I'm going to kill someone. That's, that's hard. And you know they experiment. And some of these drugs you shouldn't drink. You shouldn't do, you know pot and stuff like that. That's part of adolescence. I'll just tell you we, we, we had a tutorial going on for our children trying to anticipate this. So we hooked up with a couple local colleges. So everyone had to go through the volunteer office of the hospital. They did a urine screen. Half the kids from college, college kids, failed out because their urine turned out dirty. And I'm getting called by the hospital saying, "What kind of children are you—what kind of college students are you bringing in?" I said, "The motivated ones."

[Laughter]

DR. WIZNIA: All right, then there's this concept of loss of being or looking like normal, okay. And so, and then they always have to think about what is, what is—so these, and I mentioned the adolescence. Typical adolescence has a pimple. All right we look at it as an adult and we say a pimple. But they're sitting there and every time they go by a mirror they'll look over here. They'll go like that because that pimple is not really a pimple. That may be the worst, most grotesque lesion ever on anyone's face ever or maybe this year, someday. And everyone, they think everyone's looking. So our population actually believes everyone is looking at them and sees a big A. That's always in the bad of their mind. And that certainly impacts their function.

So our task is transitioning to being defined by a poorly treated illness that's progressive with a short life expectancy--that's when many of them where born—and we have few expectations, to okay now you got a chronic illness. It's treatable. I don't know how long you can live, but I think you can live fairly long. And I think you can be fairly healthy. We can minimize the toxicity. So now I want you to redefine yourself from being defined by HIV to you're so-and-so and, by the way, have HIV. That takes time if one can do that. And a lack of mental health resources it's very hard 'cause you're talking about therapy for years and years and years. You know people who are in therapy--I, myself--you have to get over your parents. Why did my parents do that to me? And I'm scarred for the next 20 years. And why am I acting this way? And I have someone to talk to. We don't really have that clinical service. It's sort of that type of deeper therapy that I think it starts to be important. So that's my environment, okay.

So I'm going to go through these. These are comments on, on the, on the different criteria. And they're in there. And they're pretty self-explanatory. I sort of made this so it would be - - . So MA—micro bacteria, MPB, we see it. It's not that common even in the Bronx. We see an increase in the immigrant population from epidemic areas. So that's starting to become more a pediatric population 'cause that's what we're seeing the younger kids from. So you have to worry about multi-drug resistant or extreme drug resistant TB, not, but it's always possible there. And then when we go to treat that then the question is what's the drug dose for treating these drugs? And these drugs have interactions with the HIV drugs. So how do we treat that? And I tell you that is

certainly a huge issue in a less developed world. We don't have that as a major problem, but I'm sure we may.

So Nocardia's uncommon. It's in there. I don't know what the relevance is. We still see Salmonella Bacteremia. It's recurrent. It's still relevant. MRSA, multi-resistant staff and - - resistant - - . It's probably likely to become more, more problematic as these children get older their - - decrease in CD4, - - more hospitalizations. They're getting it in the community. What that means long-term I'm not so sure. But I would imagine that we'll see some, some multi-resistant organisms that are going to be difficult to treat.

Recurrent bacteremia, which was something we used to see a lot of, we still see. It's not CD4 dependent. So if your CD4 count is 800 that doesn't mean you're not going to get it. The current guidelines say write this down for less than 13 years of age. I don't see why, okay. I would just sort of take away the age thing. And the other thing I've been thinking about is adding chronic skin infections. 'Cause I think that we're seeing that. So - - define that as a skin infection where you treat and instead of not getting better it's like an - - type of thing. So I think that would make sense.

We see candidiasis. And the current guidelines include pharyngeal, esophageal, vulvovaginal and others. And most of them are now well controlled. And I sort of said there and I said maybe you don't want to just have that as a diagnosis because you can treat that. So maybe you want to add a time limit. So if someone comes in and they got a little esophageal candidiasis I give you some anti-fungal and you're better within a week, it doesn't happen. That's probably not, being fair, probably not a disability. But if you stop having more than two episodes each for a period of time—I wrote 15 days, someone want to argue with 10 days? Okay, I'm good with 10 days. And if you wanted to throw in something about weight loss I'm not that excited about that but I put that in there, okay.

And then if, and then the other thing I would add is that if you do treat, and you're unable to swallow your pills, food, or your medication, that would be a disability. If they have enclasia [phonetic], which means your esophagus stops working, and the pills are getting stuck, that's sort of not in here. So if you have canadidasis, presume canadidasis, you get treated—you still can swallow; these meds sort of get

hung up in your esophagus and you just feel like they're there—that might be enough of to meet that criteria.

Pneumocystis pneumonia, we still see this. We don't see it in infants anymore because there are fewer infants and we are, we are using prophylaxis. But as this population gets older I think that we're going to start seeing more. And I'll tell you, I'll tell you, when I'm sitting and negotiating with a 16 or 17 year old about taking their medications and their CD4's are 100 or 50 and I should be giving them Vatrim [phonetic] to prevent them from getting pneumocystis pneumonia. And what I'm really trying to do is to take your HIV meds because that can make you better and your CD4 counts are going to go up. And the Vatrim makes them nauseous. I write notes like discussed it with them, but concentrating on the anti-retro viral, 'cause you have to pick your battles. So what is - - so far having been burned. But I think the potential is there because I think when you're approaching a 16 year old it's very difficult. You have to pick your battles. It's not like, I'm not going to battle you on everything. But if you take your anti-retro viral everything gets better. It's the virus. And we've had a lot of success doing that, okay.

There are many other fungal infections that happen infrequently aspergillosis, coccidioidomycosis, mucormyosis. I have no comment, okay. Because I don't have any data. Okay, cryptosporidium, still not that common. It's a hard, it's a hard—posses chronic diarrhea. If you're in school—I can tell you I went to school in the New York City public health system, the public school system, going to the bathroom in high school is very scary, really, really scary. So if I have diarrhea and I'm in high school that's not a good place to have to run to 'cause you never know what you were going to see when you walked into the bathroom. So that's something that concerns—I don't know how to put that into your guidelines, but that could be disabling.

[Laughter]

DR. WIZNIA: Or a disability. Okay, maybe we want to get home schooling. It's certainly an issue. And I think that we're probably going to see that as this population gets more and more, you know, deficient, okay. So I would add that.

Herpes virus, and varicella, we do see kids developing recurrences of vosta [phonetic] or shingles. And if it's, if

it's visible and it's chronic that's something that you don't want to go to school with because your perception of what you have is different from the real world. And you're not going to go to school. So I've had kids that just won't go to school because they have these things. I say no one's looking. Oh no, they're all looking. That meets the criteria. You're not doing what you should be doing.

And the definition of—so we will see some resistance to—the definition is probably that it won't respond to therapy. And this—I put this comment, "The threshold for disfigurement for adolescence may be different than that for adults." And how long? One month may be excessive so they, so maybe two weeks. If it doesn't get better in two weeks, you know, that may mean that.

This doesn't show up well. This is a 12 year old. And he was my patient. I do have medical release. This is a child with lymphaticopocy [phonetic]. So his face should end sort of going here. This, everything in here, is swollen nodes. He came in, he was referred, when he was 12 years of age, this year, about nine months ago. When you looked at him from the back there's no - - . He looked like a bat and he was smaller. And I said, "Well, how has, how's school?" He said, "They call me bat boy." I said, "Oh," and I said, "What else?" And he said, "No one talks to me." So he was pretty brave and he kept going to school. But that, to him this is a disfigurement, I didn't know where this would - - a disability. But that would be a disability because to go out there in public, I could tell you, five years before he actually had surgical reception [phonetic]. Of these lymph nodes on this side to try to de-bulk them and they came right back. The good news, here's the good news. He went on a—he was the second child on an experimental drug and within about three weeks, three months, he went undetectable. So the next picture looks like oh my God, same kid. He doesn't even look the same. He's all better. He came in about two months after we started therapy and says, "Look at me." I look at him and I say, "Yeah." He says, "I'm beautiful." He says, "Look at my neck." I said, "Well your neck looks a lot better. You're still ugly."

[Laughter]

DR. WIZNIA: He jumped on my lap and we played some Nintendo or something. So anyways, so, so that needs to be in the consideration.

Neoplasia, the literature is still sparse. And - - , who's going to speak, is more of an oncology expert than I. But the data was that a ten fold increase in neoplasian kids across the spectrum of CD4 counts. And every time you have an immunodeficiency that's a greater chance of having, developing cancer. And there are going to be rare neoplasias. We're just going to see them and somehow I think they need to be in there.

Carcinoma of the cervix, so remember these kids are aging. They are having sex. So we are seeing this. We are seeing abnormal pap smears and significantly. The neurological manifestations as written, it really dealt with the younger kids, you know, the loss of development. So they're able to walk, they're not able to walk. So if I only have four children out of a population of 300 who's under the age of five, that's really what these are, okay, sudden onset of a new learning disability, okay. We don't do those evaluations to - - anymore because the population's really aged. So it's like what is the, what is your inability to learn at school? And how do I quantitate that? And there's, there's a harder test. And they're not widely available, okay. And obviously if you have motor dysfunction that's bad.

Grow failure, I wouldn't change anything. The diarrhea, looked okay, but - - may have a comment about that. I mentioned that we don't see any LIP anymore. We see the consequences of that chronic lung disease. So somewhere in there is a kid who may have had LIP and who's got normal pulmonary function test and is unable to participate in full working, full work. So we'll talk about that. I think I'd like to throw that in there.

Something new, bone integrity, so osteoporosis, osteopenia, we're seeing it in children. There are recent reports of large numbers of children and adolescents who have abnormal bone DEXA scans. So that's how dense your bones are. And we're seeing that. We're seeing a lot with two to three standard deviations below the norm. That's a lot. We're beginning to see papologic [phonetic] fractures. Many people aren't doing this as a screening test. But you're going to see this. It's a consequence of the therapies, we believe, that may have to do with some other issues. And it may have to do with HIV itself. Certain agents, some of the more commonly used anti-retro vials they are very concerned about affecting bone integrity, okay. So I think this is going to become a potential disability.

Mental health, okay so this is where I go into—how much time do I have? Okay.

MALE VOICE: [Off mic] you're doing okay.

DR. WIZNIA: I'm doing okay. So mental health, so I'm talking mostly about the perinatal infected adolescence. So we're beginning to get more and more data about this group. About half of them—we were involved in a four site study. It's about 300 at risk, infected adolescents with an at risk population. Those are the children born to infected moms who didn't get the virus. And what we're finding is that about half those still living with their birth parent. The average age is about 14. If you go higher it's going to be less, obviously. About 2/3 have a DSM IV diagnosis. So that's 2/3 of our population had a psychiatric diagnosis. That's massive. That's unbelievable. And you're putting that on top of needing to take your medications, where they've been, the issue of - - , this issue of disclosure, peers. That is overwhelming. That's just the word I'm using. Okay, and we'll find about half the kids who are not affected also. So they're coming out scarred. This is a scarred population.

The major diagnosis depression. - - very interesting looking at Dr. Cohen's 'cause I - - pretty much. It's depression, anxiety, behavioral problems, impulse control, all right. Just - - a child last week because he's 16, 17—he's 18 now—who has been in probation twice. And they got into—he was at the wrong place at the wrong time and someone said something to him and he cut them. And I said, "What happened?" He said, "Well they ran away" and dah-dah-dah-dah-dah. - - are you out of control? He says, "Yeah" he says, "I did much better when I was on my Zyprexa." I said, "How long does it take you to feel better?" He says, "About six days." I put in him the hospital for six days and start him on Zyprexa. Yesterday morning he calls me at 8:30, "I'm much better. I'm ready to deal with the world, Dr. Wiznia." So he has an impulse control problem. We have ADHD, Attention Deficit, cognitive delay. So this is—early on we didn't know that the mean IQ's were, were the average scores were 85-90. That's not 100, which is what the - - . You throw this stuff on top of it that adds to the problem. Plus all the extra. So most of our population was seven, eight, nine, ten, we saw them frequently. So they were out of school. So you've got some cognitive delay. And we're really not pushing them in school and we're keeping you out of school. And now we're saying perform in school. We're pretty far behind.

So we started a tutoring program ‘cause one of my patients came and says, “I’m having trouble in math.” I says, “What’s going on in math?” He says, “I’m having trouble going from fractions to decimals.” And I said, and I do, I write 2/8. And she divides it. She does it perfectly. I said, “Great, you know how to do this.” I said, then I said 4 over 17. She didn’t know how to divide 17 into 4 - - because she didn’t know her division tables. So she’s failing eighth grade math because she missed third grade math or fourth grade math.

And post traumatic stress disorder, I think I’m see a lot of post traumatic stress disorder. I’m seeing it’s just there. And we also identified in our studies depression and anxiety in the parents, so the health of the caretakers in this population. Many of the foster parents who’ve adopted these children sort of thought that they were in this for a short term, right, you know I’m helping out poor babies. They’re AIDS babies. They were living in a hospital. And, you know, I’m loving and I’ll take care of them. And now they’re 20 and all over the place.

So the consequences, high risk for poor outcome through young adulthood and having difficulties functioning independently—and I want to come back to that—and advancing in life. They drop out of school. There’s substance use, incarceration, probation, not prepared for employment. Where are they, where have I learned the task to get a job? They’re engaged in a high risk activity, which affects their own health, the risk of transmitting it to others, pregnancies, yes, and further maternal-infant transmission. They are infecting. This is a population that multi-drug resistant virus, okay. And if you do transmit the virus to other people that’s a problem. Or if you’re multi-drug resistant and you get pregnant, how do I interrupt maternal-infant transmission? And it’s getting harder. We haven’t had any, any, any infected babies in the last couple years. But the last one I—through a new drug that got FDA approved a month before she was going to deliver. And I gave it to her not knowing anything about dosing during pregnancy. But all I saw was a CD$ count of 15 and a viral load 500,000. And that’s 25%. We got her undetectable, which was great. But it’s getting harder, okay.

What else? Where are we going here? So I’m proposing, I’m making a proposal to add a new standard into the adult guidelines and the pediatric guidelines that allows—so for

the adult guideline, so what happens is I'm talking about children from 0-18. But then when they hit 18 they go into the adult guidelines. They need to be reevaluated. So they're loosing their—if they've had SSA then they go here and guess what? They're getting turned down. Meanwhile we're trying to move them into becoming independent, okay. And whatever was supporting them is now gone.

So I have, I personally, have a 19 year old who lost her SSA. She had it. Her mother died of the virus. She was cared for by her sister who's also infected. She's done fairly well. She graduated high school, did a lot of summer school. And now—and then her sister beat her up. There's a massive fight and her sister beat her up. And all of her belongings were stolen. When her sister threw her out of the apartment she threw all her personal stuff out. Someone came along the street and took it. So we got her housing, she's lost her SSA, and she's sitting in an empty apartment. We bought her a bed, but she has no pictures, she has no music, no TV, nothing. And we're trying to get her into college. And she comes in and she says, "I am so depressed. I don't know what to do. I think I'm going to hurt myself."

Okay, and so there's a hole here where they have coverage and then they don't. And this is the hardest time because they're really not set up. I mean not all, I mean a large number of our population aren't set up to succeed in an adult world. So we need to figure out some type of transition plan. It doesn't have to be—in transition to adult you're going to have this forever. But let us set up some goals and some criteria where you need to achieve. So we'll give it to you for say disability for three years. And in three years we want you to get in to live with your virus, hopefully mature. I'd like to see you either in a vocational program or in college or in something that will move you forward. Because you do have all this mental health. You do have anxiety. 2/3 have a DSM IV diagnosis, but it's a soft diagnosis. But it's present and it's enough to, to, to hinder your, your movement.

And then we constantly incorporate this into a Continuing Disability Review that's performed every three years. I learned a new term so I put it into my slide. I think that's good.

[Laughter]

DR. WIZNIA: The benefit is that you can have a successful transition. Because the way we're set up we are setting these kids up for failure. They've had disability and they become 18, they loose everything. You're just setting up for total abandonment and failure. And the goal is we've done a lot of work already; let's see if we can set you up for success. And success would have conduct your life, maintain your health, no need for long-term SSA benefits, stay out of jail, take your medications, don't infect everyone else—anyone else. And we have some of our older young adults, some young adults, who are actually planning pregnancies. That's pretty responsible. When they were 17 they weren't planning pregnancies, but at 23 yes, all right.

And then there's this whole thing that's in my world about transition. So I've been caring for these children for 23 years and when do you move? When do you go see an adult doctor. As - - I used to take care of adults during my training. So we are semi trained in that. But the systems say after 21, after 24. Of course you're a pediatrician you can't be taking care of people. So I say just go to an adult doctor and I'm going to sort of work—so this is the goal is this is what the public health goal is that yeah, you're supposed to do this and plan for it. But that, on top of HIV, and we sort of have poorly defined roles. I'm not just a doctor to these children, this population. I'm dad. I'm somewhere between friend, dad, doc. You know you've always been there for me. In many cases I'm the longest stable individual in their life. And okay, let's just throw that out the window and you're 24, go to an adult doctor. And their clinics tend to be more, for them to be busier. And forget all our history. That's hard. We're wrestling with that. I tell you we are, at different sites, wrestling with that.

I can tell you sites that just try to do this have been uniformly not successful. And when they tell you that they can do this it's usually the high risk adolescent. They don't have a three year experience and relationship with the program. It's not that hard to transition. Some of the other sites that have been good at transitioning actually are set up so they transition from pediatric clinics, adolescent clinics—different set of doctors and clinicians—to adult clinics. You've done that. But many of our programs are set up we start treating you as a baby and now you're 21.

Now that's much harder. And especially go back to the comment about loss. I'm characterized by loss.

Okay so, bring us to this crisis that we talked about, 18 you need to reapply. So it's important. I'm mentioning it twice. You need to reapply for your benefits, your current therapies. Most 18 year olds are relatively healthy and they don't meet their current criteria, but they're not emotionally equipped to do this. And we really need to Shepard them, you know. Just say go, call this number and get a GED, sign up for class. That doesn't happen. Okay, they really need to be more hand held.

And the abrupt termination of benefits is another episode of abandonment and leaves few options. This is a poem that one of my 15 year olds wrote back in 1999. She actually just died this year, unfortunately. And it sort of describes—if you read it you can sort of see an adolescent it's very flowy. And then you get this thing, the last line: "It's a stupid disease called AIDS." It's not like a complex illness. It's like ah, stupid. And so I leave you with that.

[Applause]

DR. HETLAND: Trying to turn the slides off. Our next speaker is Dr. Patricia Flynn. She is the director of clinical research and infectious disease at St. Jude's Children's Hospital. She's also the chair of the committee on pediatric AIDS. She's here representing the American Academy of Pediatrics. Dr. Flynn. There is, there is not a Power Point for this one.

MALE VOICE: Okay.

DR. PATRICIA FLYNN: Thanks Monte. This will be hard for me 'cause I usually don't talk without slides to use as a crutch. So please bear with me. But first off I want to thank you for the opportunity to come and speak on behalf of infants, children, and adolescents with HIV infection and AIDS. As Monte said, I'm Pat Flynn and I'm here representing the American Academy of Pediatrics. And I currently chair of the committee on pediatric AIDS. In my day job I also direct the pediatric HIV clinic at St. Jude in Memphis. And through that clinic—I've been there since 1988—and we cared for probably over 300 children, infants, and adolescents who have had HIV and AIDS. And so I feel like I've had a first

hand witness to the impact that HIV infection has had on the lives of my patients.

As we've just heard from Dr. Wiznia, HIV AIDS is a very different disease today than it was in 1995 when we both started taking care of these unusual children that had this new disease that we were still trying to figure out what was going on. I think the remarkable transformation has been brought about through the development and the testing of new anti-retro viral agents and the development of highly active anti-retro viral therapy or HAART.

I think it's also important to know that, very different from the adult population, that many of the children and the adolescents that we are caring for today are those individuals who actually participated in the clinical trials that make these medications available to others in the United States and also across the world.

Although the agents of Highly Active Anti Retro-viral Therapy, or HAART, have brought about this decreased mortality, they have not been without their problems. In fact, it's often the side effects of these medications that are most problematic for children and adolescents with HIV infestation. Many of these regiments have special dietary requirements. And I think as we heard from Bret this morning, when you start your day planning when you can eat around when you can eat around when you can take your medications and when you're going to feel bad and have to go to the bathroom from taking them, you can see how this can impact your day-to-day life. So add to this the complexity that you have to take these medications at school and that you want to maintain confidentiality. You don't want the kids to know that you're taking medications because you have HIV. And if you're the mother or the parent of this child who is also infected with HIV infection, they'll know that you probably have the infection too. And you all that together and you have what is the day-to-day experience of many of our children and their families.

As I mentioned, these medications are not without side effects that impact the daily life. And perhaps the most debilitating that we see is the chronic nausea that results from some of the medications. And this nausea may interfere with medication inherence, which as you've already heard several times, can result in a vicious cycle of medication failure requiring new and more complex regimens with their

own side effects that can lead to further medication avoidant behaviors. The medications also have these metabolic side effects that are pretentially [phonetic] disfiguring in the aging up child. Fat redistribution syndrome, which we heard about this morning, can be related both to the HIV infection itself as well as to the HAART regimen that they may be taking.

We also know that in the, in the children it tends to be most prominent in the adolescent population. So thus in the midst of trying to develop your independence, when you're concerned about that zit that's on your face and how you look to your peers, now you have these abnormal disfiguration caused by the fat redistribution syndrome. And we also I think, as Dr. Wiznia pointed out, have a lot more information about the natural history of HIV infection in growing children. We know that they have a greater chance of being diagnosed with several mental health disorders including Attention Deficit Hyperactivity Disorder or ADHD. In addition to the ones that Andy showed we also see a lot of anxiety. We see patients with very low self-esteem. And we see a very high rate of conduct disorders. We know that our children are four times more likely to be hospitalized for mental health problems compared with uninfected children. And we know that they're more likely to be receiving medication for mental health disorders than in other children.

I thought that maybe the best way to give you a picture or a little bit of insight into the daily lives of children with HIV, I thought I would present some vignettes of patients that I have managed over the years. I'll tell you that these are real patients. I have changed their names and mortified a little bit of their story. But I think they bring home some of the important things that we see on a day-to-day basis.

The first patient I want to tell you about is a little boy name Boo. He's now 12 years old. And he's been living with HIV infection since birth. He was the third child and the second HIV infected child of his HIV infected mother. Although he was diagnosed in started on anti retro viral medications by seven months of age, he was hospitalized 42 times within the first six years of his life. For the most part these were very brief hospitalizations when he had fever and suspected infection, lasting about two to three days. However, at age seven months, shortly after we started him on therapy, he developed infection with cryptosporidiosis, an

intestinal parasite. And this required a hospitalization of three months. It also required placement of a long-term central Venus catheter to provide hyper-alimentation for his nutrition because he really couldn't get enough calories.

It was a dramatic moment in my life when I walked in his room and realized that the hair that was growing was white, much like you see the children in Biafra and other areas across the world with - - and malnutrition. He was also diagnosed with developmental delay at this time. Also, before the age of six he had eight episodes of sepsis. He had one episode of meningitis and five cases of pneumonia. And he had persistent, almost continuous, middle ear infections that resulted in diagnosed hearing. Now because of these multiple bacterial infections we treated him with gamma globulins every month. And because he tended to get admitted every Saturday—don't tell my friends in infectious diseases—but we used to give him inject of Chphtriaxon once a week on Friday so he'd make it through to the week.

He was no longer able to walk distances and he preferred to be carried around in a wagon. He was fitted for braces but his mother wasn't able to help him use them. And he developed chronic pain in his left jaw that we thought was related to his chronic ear infections. Eventually we could feel a palpitable [phonetic] mass in his left jaw muscle. And at age six and a half he was diagnosed with a cancer called leiomyosarcoma, a very unusual cancer that occurs in children with HIV infection. Further workup showed that he had multiple tumors around his spine as well. He was treated with radiation therapy and chemotherapy. And by this time his mother had very advanced HIV disease and just couldn't get him there at nine o'clock every morning of the week to get the radiation therapy that he needed. Because of this he was reported to the Department of Children Services in Memphis and he was removed from his family and placed in foster care.

He completed his therapy and he still has ongoing, but stable, leimyosarcoma. And at this point he was unable to walk at all and was basically wheelchair bound. By age eight he had new findings in his chest that look different from the first malignancy that we saw. He had a biopsy performed and now he was diagnosed with Hodgkin 's disease. Again, he went to undergo chemotherapy and his disease is now in remission.

Shortly after this diagnosis his mother, whom he'd only been seeing intermittently because he was in foster care, died. And today he remains with chronic pain related to his residual leimyosarcoma and is wheelchair bound. He requires narcotic medications…

[END TAPE MZ000022]

[START TAPE MZ000023]

DR. FLYNN: …for the pain that he has. And usually the pain is very brief and responds to therapy. But none the less, because he cries out and is disruptive he's sent home from school several times a week. His HIV infection is in control for the first time on his fourth regimen of HAART. And he remains wheelchair bound and routinely makes at least weekly trips to the clinic for either medical care or rehabilitation therapy. And Boo has been receiving SSA since his infancy.

Then next patient I want to tell you about is Kenya. And she's 15 years old now. I first met her when she was five. She had recently relocated to Memphis with her father who had completed his tour of duty in the military. He had been married to Kenya's mother who had recently died of AIDS. And it was only through the mother's end-stage illness that they found out that HIV infection had impacted their family. Kenya was diagnosed shortly after this. She did very well on anti retro viral medications until the age of about 11 when she began to have uncontrolled HIV replication and very high viral loads.

Over the next four years she was switched regimens four times, each to a more complex regimen, including one that would require twice daily injections. With each failing regimen her CD4 count fell more. Most alarming though is that she began to loose weight and did not look at all like the child we knew. You could put your hand on her shoulder and feel her shoulder blade protruding. Combined with an increase in her height because she was still growing taller, she appeared visibly wasted compared to her previous experiences. We began to suspect, because of these rapidly failing medications, that she wasn't taking her meds at all or that she had poor adherence, something that we often see about this age in teenagers. Both Kenya and her father assured us that this wasn't the case. We still didn't believe it so we admitted them to the hospital to measure the

amount of medication in her blood after we had had the nurses administer the doses.

It was only during the stay in the hospital that we learned about the significant problems that Kenya was having with nausea when she took her medications. Whenever they would bring her medications in she would just look at them and say they just make me sick. Kenya's father quit his job to take a minimum wage position at the school that Kenya attends so that he could be there when she had to take her medications, which took her entire lunch period. So with this help and some mental health counseling she's doing better; taking her medications, but still has to deal with the increased nausea.

It is a daily struggle for Kenya knowing that each day when she takes her medication she's going to feel sick. And like Andy mentioned, it's the first thing she thinks about when she wakes up in the morning and the last thing she thinks about when she goes to bed. Also because her CD4 count has fallen so much, in addition to the six anti retro viral medications she's taking she also receives two other medications for prophylaxis for opportunistic infection. She continues to loose weight and she's had a drop in grades in school. And Kenya has applied for and been denied disability benefits twice. She and her father are very frustrated by this disconnect between us facing them in clinic and telling them how sick she is and how fragile her medical condition and her HIV status is, and the fact that they've been denied.

The third patient is Marcus. He's two years old and his mother was known to be HIV infected prior to her pregnancy, but she sought no prenatal care. He was born prematurely at seven and a half months and spend the first six weeks of life in the newborn nursery. When he was four months old he was hospitalized with pneumonia and respiratory failure and was also noted to have failure to thrive. He was also found to have, during this hospitalization, a very large liver, a very large spleen, low platelet counts, and sever oral candidiasis, or thrush. He had a few brief seizures that they thought were related to electrolyte abnormalities. And also during this admission of one month they put it together and decided that they should test him for HIV. And certainly that's what he had.

He was begun on HAART therapy, but had significant problems tolerating the HAART. Again, this nasty tasting medication that Andy mentioned is all we have to use in these very young

babies. He also developed hepatitis as a side effect of the medication. And he continues to have frequent ear infections. He's seen in the clinic now at least twice monthly. And he has an improving but not yet undetectable viral load. And Marcus applied and was denied twice for social security benefits. But on appeal was approved on this last go round.

So in summary, I think the changes that have occurred in pediatric HIV infection over the past 15 years are remarkable. No longer do children develop these severe opportunistic infections and die within the first year of life. Indeed, it's due to the advances of HIV treatment that we have seen come about. And we now have these patients that are alive to face the difficult limitations that are imposed by HIV as a lifelong illness. These children are still distinctly different from their peers. They're behind them in school. They're frequently ill. And they miss a considerable amount of school to attend their medical appointments. Whether it's the developmental delays that are related to the HIV infection, the presence of the mental health disorders that necessitate medications and/or hospitalization, the struggle to keep the secret of HIV infection, the disruption of their family that may be caused by the illness or the death of their mother, their father, or their siblings, or the debilitating side effects of HAART therapy, many of these children have significant limitations in functioning for whom social security remains a lifeline.

I want to thank you for listening to me. And I believe that my patients, as Andy does, are wonderful and brave. And we'll be happy to answer any questions for you.

[Applause]

DR. HETLAND: Our last speaker before the break is Ms. Soraya Pares, who is going to share her story.

MS. SORAYA PARES: Good afternoon everybody. I am Soraya. And thank you for inviting me here to hear my story [sigh]. This happens to me all the time. I [sigh]—sorry—I was diagnosed through my child. My child was born HIV positive. At three months old she got sick. I went to the hospital. I never thought this would happen to me, but it did. And she was diagnosed. I also was diagnosed with HIV. At the time they told me that my child was—did not have HIV had AIDS. She had PCP, her spleen was enlarged, her liver was enlarged. They

did a lot of testing. My child like maybe a couple of months in the hospital, I didn't not know how to deal with this situation. I have other three children who are not affected. I had a husband who I never thought, you know, would bring this home. So that broke our home, my children, my mother. I'm an only child so my mother took my children away from the house on the fact that now I have AIDS and she didn't want my children to catch AIDS. This was in 1991. And then I became, I came, I, I kept going to the hospital. I became this person that wanted to know everything about HIV and how to protect my, my child, my family, myself.

Today my child is 18 years old. She knows she's infected. She's known since she was six, seven years old. We have a wonderful team at—back then it was Bronx Lebanon Hospital—with Dr. Wiznia, Dr. Lambert, other doctors. And then we went to Jacoby Hospital where I got involved with a lot of advocacy and consumer, client and advisory board. And every single conference there was I wanted to be there. And I always would take my child with me. And I always thought, you know, this is the way that I need to introduce her into what she has. And I'm classified and my daughter is classified in the clinic as the model patient 'cause I've never gotten sick. And I'm the model mom because I do what I'm told. And I take care of my kids, whatever.

Just to let you know, we go through everything that was said here. I go through my own issues because I have to deal with my own HIV. And I was receiving HASA [phonetic], welfare, SSA. And then I decided that I didn't need those things. I wanted to transition. I wanted to go back to work. I wanted to do something. And I did. And then the transition was very smoothly. I have to say that if you listened and do what most people advocate for you for, like the case manager, the social worker, the people that know. I did those things. Now I'm working. I'm fine.

Now my child will turn 18 in November. And I receive a letter from SSA telling me that she needs to reapply. She wants to. She just graduated from high school. She got accepted to go to SUNY Albany 'cause she wants to do nursing. She decided not to go after she got accepted because she was like, "Oh my God, Mom, I'm moving away from home. But I can't. But I'm going to leave you. But I don't know how to take my medication by myself. I don't know if I can do this." So we decided okay, if you want to stay home, you go to community college. We'll work it out. It doesn't, you

know, it's not that bad. "But I want to be independent. I want to have my own apartment. I want to have a job." "So yeah, go ahead. Go get a job." She got a job. She is going to go to community college. She was supposed to be here today and she went to take a placement test at Bronx Community College.

I don't know. What can I say? It's been, it's been a ride, a roller coaster ride. It has taught me a lot of things. In turn I have put all this data into this little 18 year old that's going to be 18 but she's going on 35. Yeah. And sometimes she amazes me and sometimes I'm afraid. And I just want you to know that they go through—at 13 Samantha went through I don't work right, the Combivir is making, doing this and that to me and I'm not taking it. She was giving it to the dog. We have to—she was giving it to the dog. The dog was taking her Kaletra at that time, Laletra with Norvir. Yeah. Then she was stuffing it in the sofa. And I'm actually giving this medication to the child look at her, her mouth. "Show me. Did you swallow it?" "Yes, Mom." Medication is not working. Suddenly we're getting a little sick. I don't know what's going on. We go to the doctor. We're getting skinny. I don't know what's going on. And then she admits to the doctor, "Mommy gives it to me, but I give it to the dog or I put it in the sofa. I don't want to go bald. I don't want to go to school. People make fun of me. I look like the skeleton girl." 'Cause she's very tall and skinny.

And she became having issues at 13. We took her out of school for a year to, you know, home schooling. She did a little bit of a year of home school and, and, and I helped her out and then she went back to high school. And then that was another issue. "Do I disclose when I have a boyfriend? What, what should I do? I want to have sex." I'm an open mother. I talk about everything and I'm very raw. This is nice.

[Laughter]

MS. PARES: Yeah. I live in the south Bronx. I was raised in the south Bronx. So this is the nice me. I don't talk to my child like that. I talk to her raw, the way you're supposed to be like you go out there and you're going to encounter guns and drugs and this and that and you must say no, no that's not the, that's not the point. The point is that you can't do it 'cause I'm going to kick your…

[Laughter]

MS. PARES: …and you're not going to have a life. So AIDS is not going to kill you. I am.

[Laughter]

MS. PARES: So we go through everything, everything that has been said here. Talking about medication, yeah, we tried that Norvir in liquid form. Samantha would—she was a trooper; she did it for a year. We used to mix it with Kool-Aid. I used to make syrup. You know Kool-Aid, you take the little pack, you put a cup of sugar, and—well I used to put three cups of sugar, make it into a little syrup and mix the Norvir with the medication. And that was a trip, but we did it.

So we're here and now they're telling me that Samantha needs to reapply. She can not become independent right now because HASA, HASA will harp her. HASA is, you know HASA, welfare, New York City for those who are from New York State. HASA is the welfare for people who are infected, which you need an eligibility criteria to go into that program. So I'm not HASA eligible, but my child was at some point. And we, I get help. So if she becomes independent even though I am a working person now and I make enough to pay for rent, not enough to go into $1,000 or 1,200 rent apartment when I'm not eligible for HASA. So Samantha wants to become independent. I want to give her that independence, but money wise we're not going to make it.

So anyway, Social Security Administration, listen to the doctors. I'm also a service provider. I work in a program, I manage a program, which is Access to Healthcare. And there I get referrals from the Department of Health of newly, newly infections. Some of them are newly, some of them they knew but they out of care. So anyway, they get referred to me. And in order for somebody to have some type of help they have to be dying or a whole bunch of stuff. And, and it's frustrating when you're sitting at the end of the table and the doctor received a letter, "Oh this Social Security, again, Social Security sends me this stuff. I got to answer, check this box." - - can you just do—there's the case manager, fill out the other narrative and, and then the social worker, the psychosocial. And then, you know, there's a whole bunch of people that have to go through this paperwork. It's fine. It's part of life. But then it's not just checking the boxes, it's writing the information in a

way that it's acceptable for Social Security when ultimately they need to be, you know, they need to get some help.

Anyway, not too much drama in my life. But I'm blessed to be here. And I am very blessed, very blessed to have a wonderful team that works with my daughter, that works with me to go over these little lumps and these little humps in life. Transition, oh hell no I am not going to another doctor. Dr. Wiznia's going to have to do something. I'm 18 but no, I'm not going to see no—I'm not going to your clinic. What is that? Are you crazy? You know it's not happening. She decided that she's going to keep continuing to go to the pediatrics. And don't talk to me about transitioning.

She also serves. My daughter serves in the AIDS Institute Consumer Advisory Council. And she told them straight up, "Transitioning, who are you kidding? I have been with the same doctor for 17 years. I'm not letting nobody else touch me. She calls the doctors—Abode is one of the doctors that work with Dr. Wiznia—and she calls, she has his cell phone number. When I feel sick I'm going to call him directly. So this is a relationship that teenagers perinatally effected or high risk kids, it doesn't matter. They, they come into, they get diagnosed. They are in a place where they know that this is going to be life changing. And they find somebody that actually gets them. And the only reason that they are going to this place is because they have been diagnosed with something that they can not get rid of. And then you're telling them that you need to transition. We need to look into that a little bit more, okay.

I'm going to keep it short. Thank you everybody for listening. If you have questions I'm here. And that's it. And thank you for having me here.

[Applause]

DR. HETLAND: I'm going to give you all a ten minute break. Run out, run back fast. We need to be out of here by a certain period of time. People have planes to catch. But we still want to have time, leave enough time to talk. So we'll move the table up. We'll ask our afternoon speakers to come up again and we will have a similar discourse. Thank you.

[END TAPE MZ000023]

[START TAPE MZ000024]

[Background noise and off mic]

DR. HETLAND: Thank you. Now it's working. All right, almost everybody's in their seats.

[Laughter]

DR. HETLAND: Again, I want to thank our speakers for laying it out on the line. We are doing our best to respond and to listen. For those of you who weren't here this morning, I need to make a couple of housekeeping announcements. If you need help with parking see Reese [phonetic]. She's got the special permits. Also those of you—I know some of you are going to be leaving. Please fill out the evaluation forms and give the to Reese. We do look at them. We want this to be a continuing experience that gets better each time we do it. I wonder the third thing? I've already forgotten what I was supposed to remember. Mr. Eigen, I'm going to let you start. And you need a mic.

FEMALE VOICE: Need a mic.

MR. EIGEN: Okay. This question makes my head hurt, I have to tell you. I'm not sure if I'm even going to be able to articulate it very clearly. But the major purpose of this meeting is to help us figure out how to weather and how to rise the specific listings. So I was particularly interested in Dr. Wiznia's recommendation for the listing for HIV with bacterial infections where we divide up where we limit the listing to kids under the age of 13 and your recommendation that we remove that, that age limit. I was recalling that when we first wrote the listing back in 1993 the reason we did it was that the prognosis for the smaller kids was worse so that even a kid who had—these are pretty bad infections—but this listing allows a child to qualify with one of these bad infections in a year, twice. In other words, one year one infection and then the next year another infection. If those two events occur the kid qualifies under the listing. And at the time, and even when we revisited it recently, we thought that, that this was a marker of some more serious disease, but that when the kids reached adolescence they were more like the adults. And so this is a very long question, you know. But I looked at the adult version of, of, of the listing, which requires multiple or recurrent bacterial infections, required hospitalization or intravenous antibiotic treatment three or more times in 12 month period. And that got me thinking about the issue of the transition

such that if we remove the 13 year, 13 year age cut off, you would have some kids who say at age 16 qualified under this listing by having had two infections in two years. And then at age 18—you see where I'm going? I probably don't need to keep talking about it.

I guess my bottom line question is what's right? You know is, is it right to have the two infections in two years for any child at any age? Is it right to have the three infections for people age 18? Should we be switching them? You see what I'm saying?

[Laughter]

FEMALE VOICE: I think you should switch it to two for the adults and have it at any age. I mean I think, you know, when, in today's world where you have available therapies, you know, any of these patients that breakthrough and have these severe infections are on the far end of the spectrum and they're not the, you know, blind share in the middle of the normal distribution. So I think that my personal opinion would be that that could be made more lenient. Take the age criteria away and make it apply to both kids and adolescence and adults with just the two instead of requiring three.

MALE VOICE: Now that's exactly what I would say. And the other part I would add to it is that there's a disconnect between looking at a number, like a CD4 number, and actually what does your immune system do when it's exposed to a foreign protein. So you can look at—and I think adults are being to learn from the pediatric experience. If you look at our population we were involved in a clinical trial. It's called PACTG377, where we took children, we gave them HAART. We looked at their tetanus antibodies before. We put them on an aggressive therapy and we found out 2/3 did not have protective antibodies even though the aver CD4 was 24%, which is a good number, and they've gotten all their vaccines. And then when we treated them and then we revaccinated them they made antibodies higher, but they didn't persist.

So it says challenging immune system. It looks pretty good from a CD4 count perspective, but when you really challenge it with a bacterial protein it doesn't really respond well. So you can have a decent CD4 count and recurrent bateremaia, recurrent serious bacterial infections. And that's, I think, a disability. So I would actually - - two infections that

would seem to be reasonable. I think that's—creating a harmony is really where you want to go and not - - .

MALE VOICE: Dr. Nadler, do you have any comments?

FEMALE VOICE: Either way.

DR. NADLER: So I think that's one of the scientific disconnects that we live with for lack of any other way to approach the question, and that is that we look at a CD4 number but it doesn't tell us about function. We don't have a good functional test. And some of these antibody production and persistence studies that were really done in the pediatric section probably apply to adults as well. And so, you know, we say oh well the number is normal. But many of these patients still get sick. And they get sick with illnesses with opportunistic infections that would normally define and immunodeficiency. So the number, to me, becomes secondary in that setting.

Now in the implications for clinician, that's a situation where you see a normal CD4 number, but maybe it's more critical to make sure the virus is adequately suppressed, as low as you can go. And there are anomalous situations. For instance, someone who's co-infected with HTLV1 Human T-Lymphotropic Virus, another virus entirely. But co-infection is not extremely rare. For some reason that's still not explained that secondary infection causes an abnormally elevated CD4 count. And so all bets are off 'cause you can't manage those patients on the basis of the CD4 count. They may have a profound defect and yet have a number that's more normal than mine.

So I would support two infections and I would pretty much support it across the age range. Because it's telling us something about function.

MALE VOICE: Okay.

FEMALE VOICE: Here you go.

MALE VOICE: Please identify yourself.

MS. CHRISTINE LUBINSKI: Christine Lubinski the Medicine Association. I wanted to shift gears a little bit and talk about follow up on some of the transition discussion. And obviously—and, and we've certainly heard this from our pediatric members around the country as a majority of these kids are aging into adolescence and adulthood. There are all

kind of care issues. But, but sort of speaking to some of the recommendations regarding transition and having to reapply for Social Security disability. I think it's—well I would be remiss if I didn't sort of—one of the elephants in the room always in this discussion is that when we're talking about certifying somebody or recertifying or denying somebody's Social Security disability, in most parts of the country we're not just talking about cash benefits. We're talking about precisely the healthcare that's allowed them to improve to begin with. So the stakes are very high from an HIV context and go well beyond economics.

But, but in this, in this particular issue of people over 18, I think it's important to note that the New York State Medicaid program is pretty much unparalleled in the country in that in most places in the country not only are these adolescents at 18 having to reapply and potentially looking too healthy to re-qualify, but they're loosing their Medicaid. And so what gets lost in that transition could be kids lives. And so I realize that the focus of this meeting is on the listings. But to the extent to which you and your colleagues can bring back to the appropriate people the real issues that exist in this transition period and the implications for those adolescents. I mean I've had pediatric ID doctors in a panic called me because, you know, 19 and 20 year olds loosing their Medicaid in the state of Illinois, which is not to trivialize the loss of cash benefits. But that, at least, is not going to happen in New York. But it's going to happen in virtually every other state in the country with the exception of New York, DC, and Massachusetts. I just wanted to highlight that. Thanks.

MALE VOICE: Mr. Sklar, would you care to…?

MR. SKLAR: Actually thanks for raising the issue. I think it is important recognize that this is indeed a meeting being held in New York to form a national standard. So we can't forget that the New York Medicaid program may be far more generous than many others. And the consequences of loosing benefits at the age 18 and the related health insurance piece that goes with it is pretty profound in many cases. So - - the healthcare issue, for us, is a tricky one. Again, some of the things we've been talking about offline are guidance through - - , not only emphasizing things we heard about today that they should be attentive to, but the potential consequences of not paying attention to them. This is not typical to think beyond the benefit stream and this really is

a life or death, make or break decision. And if you don't get it right and you don't spend the extra time and you make a mistake it's pretty tough to get that back. And by the time it can even get rectified the consequences of that can be very severe. So I think that's a great point. I think it's something that, again, this is a national standard. The listings are for everybody. And not everybody has the great safety net, or at least a safety net, like they do in this state.

MALE VOICE: Mr. Eigen, more comments? You always have more comments.

[Laughter]

DR. HANDLESMAN: Hi, Ed Handlesman from DAIDS again. I actually have a question for actually the people from Social Security. Dr. Wiznia made a very specific proposal, I think. It sounded as though renewing at 18 is extremely difficult. There are a lot of kids at 18 who are not ready to take on those tasks of the world, which include renewing their benefits. I'm not sure that you guys have any purview [phonetic] to change that age or to change the year period of time in which they have to do it. Could that be extended to three years? So I'm asking do you have an purview in, in that regard? Is that a possibility?

MALE VOICE: The answer is no. But I'll let—

[Laughter]

MALE VOICE: --unfortunately it's statute.

MALE VOICE: - - The basic, Monte, Dr. Hetland, gave the basic answer. What we do have purview over is the rules for how we determine how a person qualifies. And when we, particularly when we consider the listings, but also in all of our roles for determining disability, we're very cognoscente of the need to have a smooth transition across this boundary because it bothers us too. It bothers us that a person could be found eligible at age 17 ½ for example and for some reason would not be found eligible at age 18, 6 months later. That shouldn't happen. And we're constantly trying to figure out ways to make it so that that doesn't happen. And this is one of the things that we can do. We can make sure that the listings smoothly go across so that at least for those rules. So we do care about that.

MALE VOICE: Then in terms of—it's not a reapplication—the actual term is called re-adjudication.

MALE VOICE: Redetermination.

MALE VOICE: Redetermination, okay, to change the time of 18 years would go to Congress and have them change the law. Otherwise I think we're stuck with it.

MALE VOICE: - - could you change the time period that they have to do it?

MALE VOICE: Would you speak into the microphone, please?

MALE VOICE: Sorry. I, I, I'm not surprised by that that that would require a change in the law. As I understood it you, someone said that they had one year to do this. Is that one year extendable at all?

MALE VOICE: No - - . Oh well.

DR. WIZNIA: So just coming back—excuse me—just coming back to the suggestion, it was actually a smooth transition and I understand the age. So what I was also proposing was a grouping of soft mental health findings that would allow us to do this given the prevalence and the severity and the tasks that are there that need to be attended to in a finite period of time. So I guess the suggestion would be to address this, use what authority you have, but to—maybe even, maybe - - want to make a comment. But that may be a certain criteria between 18 and 25 that may be eligible for the soft findings because we are going to protect, we are going to provide a safety net because it's too vulnerable.

Because I can tell you one of the, one of the rules of thumb with adolescents—and even though somebody may be 19 they may be functionally 15—is that you don't betray their trust, their trust that we're going to take care of them. And you don't throw them away. Because once you do that it's hard to bring them back. And they'll talk about that, how school, dah-dah-dah-dah. It's actually easier to talk about that than to talk about their illness 'cause that's something that I can yell about. And taking my medication is something that I really don't have a great answer for you. So I'm going to yell about SSI and how they turned us down. But—I think this is an important age group. So it's somewhere between 18 and some number maybe have—if you can't make it applicable to all

of HIV then make it applicable for this vulnerable population.

FEMALE VOICE: I think all of us sort of eluded to it when we were speaking. And when I went to get a cup of coffee I heard somebody mention it. But, you know, I think, you know, globally in our society here in the US, 18 has always been this magic number. But that magic number, in reality, is no longer 18. It's more like 21, 22, 23. And I think we also, Barry said, it may be our fault for the way we coddled these patients that we never thought were going to learn to survive. But they, they don't have the skills to survive in today's world. And I think Andy can tell you as well that, you know, if they're going to get them, usually by 22, 23 they're, they're a different person. So maybe we just delayed their maturity by five years. Some of it may be just our society, but some of it may be the way we managed them as young kids.

MALE VOICE: Yeah, the population we're talking about is the congenitally infected?

MALE VOICE: Yeah.

MALE VOICE: Okay.

FEMALE VOICE: If you want to know the truth, all adolescents take till 23 to mature these days.

[Laughter].

[Crosstalk]

MALE VOICE: I understand.

MALE VOICE: Yes.

L.J. FISHER: Yes, I'm L.J. Fisher from the Empire Justice Center. My suggestion would be in order to transition someone from age 18 to an adult listening is perhaps insert something in the adult listing like we have in the 1205 listing for mental retardation that shows an onset date before age 18 and transition it that way. That's just one way we can look at that.

MALE VOICE: Good suggestion. - - .

MALE VOICE: I wanted to ask, does iris [phonetic] happen in kids? And how does it go?

FEMALE VOICE: Yes. Most of what we see is iris in kids happens in the developing world. A lot of those kids are also infected with tuberculosis. I have only seen what I thought was iris once and that was a patient with CMV retinitis. And it was an older adolescent. You know some of that may be that, you know, particularly the young babies that are perinatally infected when we put them on therapy they're sick as hell anyways. So you may not be able to distinguish it.

FEMALE VOICE: Andy have you seen it?

DR. WIZNIA: Yeah. We've seen it in the older adolescents. So, not common because many of them are partially treated, you know half of our population is undetectable, so that's good. So therefore you're not going to see it. You're seeing it acutely in the developing world because - - are now being rolled out - - first. The other thing we do see—and it goes back to that bacterial infection question—is sort of—and it's not well written. I'm not sure if anyone's written about it. but I'll tell you, we see it clinically, which is that patients are not taking their medicines and then they come in and they say we're going to and within the first two to three, four or five weeks you see some bad bacterial infection happening out of nowhere. And what I think is going on—and I haven't studied it so I can't give you data—is that the immune system is redundant. So if this part doesn't work - - is activated and - - are activated. The helper cells aren't really functional. There's something else kicking in. And that kick in is because there's a lot of virus. So the virus is kicking the immune system off because you really have good therapy. And then whatever that background noise is is gone. And part of that background noise is protecting you from these other bacterial infections which you may get exposed to. So there's a, sort of a, I think a - - where your immune system sort of punks out because we're turning the virus off, which is good. But it leaves you vulnerable, which is not iris, which is immune reconstitution. What iris is, the immune system is healing and you have the low lever viral infections or other infections in your body and now your immune system is attacking them, okay, and activated.

So this is sort of like the opposite part. It's not well—have you seen that?

FEMALE VOICE: No, but we see it in cancer patients all the time.

DR. WIZNIA: Okay, so.

FEMALE VOICE: So, - - .

DR. WIZNIA: So yeah, we definitely see that.

MALE VOICE: Are you seeing in adults, Dr. Nadler, here in the United States or is it still throwing people overseas, iris?

DR. NADLER: I think most—we see iris more commonly in the less developed world as therapy has been rolled out to about three million people over the last three to five years, most of it in the last three years. We do occasionally see it here in the developed world as well. My European colleagues in particular report that, which is interesting because if anything the average CD4 count at which they start therapy in Europe is about ten cells higher than in the US. But it's not a significant difference, but they're slightly, slightly less sick on a population average.

MALE VOICE: Another question: hepatitis B or hepatitis C plus HIV in the pediatric population.

FEMALE VOICE: It occurs. Most of the hepatitis C that we see is congenital hepatitis C that was likely transmitted along with their HIV. I would say that it's about 1-2%. In the adolescent population that are infected as adolescents we look sever years ago at hepatitis C and there was around 2% zero prevalence. We looked again a couple of years ago and it was up somewhere between 5-10%. So that seems to be increasing, at least in the population that's infected by high risk behaviors. Hepatitis B is probably very uncommon. We do have, in our clinic population, which is about 250 now, about 3. 2 infected by high risk behaviors and one that has a newborn disease.

MALE VOICE: And what's the clinical course?

FEMALE VOICE: Right now the ones that we've seen are, you know, we have not treated any of the hepatitis C's. I take that back. We did attempt one treatment and they felt so rotten they refused further treatment. The other one we're really just watching right now. Hepatitis B, of course we gear our therapy to make sure that we have adequate anti retro vials to cover the to cover the disease. And at this point in time, you know, clearly down the lines there's some problems that can occur with liver failure and cancers. But I don't

think that we followed them long enough to see that long enough, at least in my population.

MALE VOICE: Our experience is pretty similar except that we've had some of our perinatally effected population that didn't have hepatitis C become infected with hepatitis C through high risk activity, you know, adolescent activity. So we've treated two of our perinatally infected kids who then developed hepatitis C. And they've done well. But once again, it's small numbers. But I think that you have to assume that anything that you can acquire sexually, we're going to begin to see in our, in our population.

MALE VOICE: Okay.

MALE VOICE: We really don't know. We don't know.

FEMALE VOICE: Just—

MALE VOICE: [Interposing] Dr. Adler, will you comment?

FEMALE VOICE: --sort of going back on my cancer history, we also have very large cohort study we're following now with kids who got hepatitis C through transfusion and, you know, the rate of seeing events. It really takes years and years and years to show up. So I just think we haven't seen it yet.

MALE VOICE: So I would say that we're, people are living long enough for us to see the effects of hepatitis C, which causes chronic infection at a much higher rate than hepatitis B. And hepatitis B and the association with malignancy may take longer to unfold. When I was still in Florida we did an epidemiologic [phonetic] survey. And we showed that the rate of liver death in those chronically infected with hepatitis B was about 45 fold higher than in the general hepatitis B infected population. And that was substantially worse than even the rate of liver death associated with hepatitis C. Not much we can do about it except transplants. And, you know, we at NIH are running a transplant study in HIV infected population because there's inadequate data to support whether we should or shouldn't do it. So stay tuned for another year or so. Hopefully, we'll get you some more data.

MALE VOICE: I'm trying to remember my immunology. One becomes a chronic hepatitis C infection when the virus persists for six months, still identified after six months.

MALE VOICE: Okay, all right.

DR. WIZNIA: The other thing that I didn't mention in my slides is we're beginning to see kidney failure that no one mentioned today so I - - . We have a few of our population on dialysis at the moment, the population less than 18. So I'm assuming that that's covered under SSA, under another thing, which is why - - .

MALE VOICE: When somebody's on dialysis that's an automatic allowance. I'm curious did creat [phonetic] needs of children one qualifies with creat needs of one or higher. And I'm just curious what was the time difference and how long did it take for them to, you know, did the creat, overnight, go up into renal failure or was it over a couple years?

MALE VOICE: I don't want to misspeak so I'm not going to comment. I actually would like to look at the data. I'll pull it up for you and I'll give you that information.

MALE VOICE: Okay. So - - .

MALE VOICE: It's actually a little more liberal. In adults you have to have a creat need of four or higher, whereas in kids it's a creat need of three or higher.

FEMALE VOICE: So our renal problems have been mostly protnuria [phonetic] which is a symptomatic or—we haven't really seen that in ours yet.

MALE VOICE: Dr. Handlesman?

DR. HANDELSMAN: Yes. And again, going back to the line listing, you know, in my sense it looks like the line listings do a pretty good job of, of evaluating the opportunistic infections that would qualify someone, the AIDS defining conditions, etc. I think where it becomes a little bit more difficult is when the impact of treatment, and not just the adverse effects of treatment, but coming to the, the, the hospital once a month for your regular visit, once a month for your renal, once a week for your support group visit. If there's a way—and I know it looks like you can take those into account, but that goes through the whole process of going back and forth between the adjudicator and the provider and possibly missing information. Is there a way that, that, that you, the panel would recommend, and that you guys could enact, that would take into account when, either going for care or adhering to medication would prevent someone from

being able to hold down a job or go to school and not have to go through the back and forths to do it on a case-by-case.

FEMALE VOICE: I want to echo what Ed said. And I think also interestingly enough, Andy and I talked about this beforehand and not just kind of tossed out ideas of, almost checklist of some of these soft conditions. And you're required to have three of five or something like that where you could, you know, actually quantitate these soft symptoms into some sort of grid where you would look not only at the symptom, but at the severity and grading them to come up with some formula for, for using these so that they could be applied in a standardized fashion.

MALE VOICE: As Ed was talking I was making - - .

[Laughter]

MALE VOICE: Sorry.

MALE VOICE: Yes?

MS. CATHY BOWMAN: I'm Cathy Bowman from South Brooklyn Legal Services. And I actually wanted to go back to the adult listings and to the hepatitis C issue. And there is no separate section in the HIV listing for hepatitis. It's only mentioned in the repeated manifestations section. And I was just wondering if Dr. Nadler might have some ideas of what a listing would look like for disability for someone who's co-infected as apposed to just the general hepatitis list that's in the regulations.

DR. NADLER: I think that an issue with co-infection, it's not so much that it's necessarily a different disease process, but it tends to be more accelerated. And so if time is a function—and I'm not sure of this—chronic hepatitis listings, then that may need to be specifically explored in the co-infected population. It's unclear at this point if the severity's increased. And we, again, we don't have good measures of function. And that's a problem for us in prescribing some of our drugs as well. So we have some numbers. We can do a biopsy, which, of course, has it's own risks and sampling error. And that can, perhaps, address an issue of severity or extent of disease if you will. But we, we need more, we need more science in the background.

MALE VOICE: I guess I should just clarify, having just recently worked on our digestive listings, there is no listing

anywhere for hepatitis A, B, C, or D. it is based on, the disability decision is based on the residual liver function so that what are the coags? What'd the albumen? What is the evidence that the liver is unable to function? So it actually doesn't make a different whether it's rich Hep A, Hep B, Hep C, got you there. It's how is the liver functioning. That's what the digestive listing is based on, okay. I think I need to clarify that. So it's not just a diagnosis. Hepatitis you will not find in the listings anywhere. It's what is the liver function?

MALE VOICE: Is, is there any allowance for evidence of some dysfunction and concern with treating with - - and being depressed?

MALE VOICE: There are instructions that judicators are supposed to take into consideration effects of medications and adverse effects that go along with that. I believe if you're a responder you stay on - - or Ferron [phonetic] and for 48 weeks, which gets you almost to the magic 52 weeks, 12 months. That is our legal standard. So it's, it's there in the instructions in a more global sense. I don't think it's there specifically.

MALE VOICE: All right so you have to have that depression for 52 weeks or… I don't understand that.

MALE VOICE: I don't think I answered that quite well. You want to try?

[Laughter]

MALE VOICE: By law, in order to qualify, you not only have to meet the standard of severity of disability, whether you're an adult or a child, your disability has to persist for at least 12 continuous months or be expected to result in death. So the way we operationalize that is there are some people who are disabled, who meet our definition of disability continuously for 12 months, but that's not a practical way of defining disability for all conditions 'cause there are lots of conditions that have good days and bad days. And we recognize that. So you don't have to be depressed 24 hours a day, 7 days a week for 52 weeks in order to qualify. It can be on and off recognizing the exacerbations and remission if overall, over the course of a year, clearly you're unable to function that we define.

MALE VOICE: I guess the flip side of that is there is the HIV listing that if you have diarrhea persisting for one month. The come back question that I, I feel is tell us how that makes somebody disabled for 12 months. Because it's lasted one month. How do you know it's going to last the 12 months, which is the legal standard? Dr. Aberg said this morning, "I don't have a crystal ball." Want to comment?

FEMALE VOICE: I think that accentuates my frustration with the listings as they are now. Because, you know, you have diseases that, you know, are like diarrhea for a month. Okay, so if you have it 32 days you met that criteria. We know you have all this other stuff going on in the background, but that's resolved and you're doing okay. Or you maybe have PCP. I mean I had one kid who was diagnosed as an infant who has PCP. And he's, you know, about 12 years old now and he's fine. You know he qualifies for disability and there's no way to—or they don't get it. They're a pretty middle class, wealthy family. And really he's fine. But he, he would have qualified because the PCP that he had was treated and now he's fine. But yet the patients who have multiple of these soft signs that we've come to call that are additive that really impair their daily functioning, they're much harder to say hey, you meet this one criteria, you're okay, you pass. And that's, I think what's frustrating to me and, and, and probably why we're here. 'Cause it must be frustrating to a lot of other people as well.

MALE VOICE: It's very frustrating.

MS. BEBE ANDERSON: And I think others will correct me if I'm wrong, but a lot of the focus—

MALE VOICE: [Interposing] - - .

MS. ANDERSON: I'm sorry. Bebe Anderson, Lambda legal. The person has HIV for at least 12 months and then you're trying to evaluate the severity of the HIV to determine if they're disabled by their HIV. So there are markers that you look at. And just like you would and say that someone had to have pneumonia for 12 consecutive months in order to have their HIV considered sufficient severe that they're disabled, similarly with other indicators whether it's diarrhea or anything else. It's not that they have to have all of those symptoms for a full 12 months. It's an indicator, again as I say, of the HIV that they have then had for at least 12

months. And they're certainly expected to have for a lot longer than 12 months.

MALE VOICE: Well I guess if we ask the right questions it would be this individual has diarrhea for one month. And by that it implies X, Y, Z, etc, none of which we ever write in notes. I was a clinician; I didn't write things like that. Help us to ask the right questions.

DR. HETLAND: Hand waving? Okay, I'm going to wind this up. I want to thank our panel very much.

[Applause]

DR. HETLAND: for those of you who are advocates in the field, I want to also point out that we are having a cardiovascular body system outreach in two weeks in Baltimore. I believe the dates are September 24 and 25. You would be invited as well. Please don't forget to turn in the evaluations. Thank you.

[Applause]

[Background noise and talking]

[END TAPE MZ000024]