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Food and Drug Administration Public Meeting 06-14-2013

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FOOD AND DRUG ADMINISTRATION (FDA)
CENTER FOR DRUG EVALUATION AND RESEARCH (CDER)

MEETING ON HIV PATIENT-FOCUSED
DRUG DEVELOPMENT AND HIV CURE RESEARCH

Friday, June 14, 2013

Food and Drug Administration
White Oak Campus
10903 New Hampshire Avenue
Silver Spring, MD 20993

Reported by: Natalia Thomas
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<p style="text-align: right;">2</p> <p>1 MEETING ROSTER</p> <p>2 FDA STAFF</p> <p>3</p> <p>4 Debra Binkrant, MD Director, Division of Antiviral Products CDER, FDA</p> <p>5</p> <p>6 Edward Cox, MD, MPH Director, Office of Antimicrobial Products CDER, FDA</p> <p>7</p> <p>8 Damon Deming, PhD Virology Reviewer Division of Antiviral Products CDER, FDA</p> <p>9 Sara Eggers, PhD Office of Program and Strategic Analysis (OSP) CDER, FDA</p> <p>10</p> <p>11 Andrea Furia-Helms, MPH Health Programs Coordinator FDA</p> <p>12 Sara Goldkind, MD, MA Senior Bioethicist Office of Good Clinical Practice Office of the Commissioner, FDA</p> <p>13</p> <p>14 Ilan Irony, MD Chief, General Medicine Branch Division of Clinical Evaluation and Pharmacology/Toxicology CDER, FDA</p> <p>15</p> <p>16 Richard Klein Director, Patient Liaison Program Office of Health and Constituent Affairs</p> <p>17</p> <p>18 Office of the Commissioner, FDA</p> <p>19</p> <p>20 Theresa Mullin, PhD Director, Office of Strategic Programs (OSP), CDER, FDA</p>	<p style="text-align: right;">4</p> <p>1 MEETING ROSTER (CONT'D)</p> <p>2 PUBLIC PARTICIPANTS</p> <p>3 David Brakebill Robert Caldwell</p> <p>4 Wanda Commander Catherine Connor</p> <p>5 Lynda Dee Michael Dorosh</p> <p>6 David Evans Kevin Fisher</p> <p>7 Alex Garner Joseph Jefferson</p> <p>8 Andy Kaytes Mabel Martin</p> <p>9 Bob Munk Murray Penner</p> <p>10 Melanie Reese Fred Schaich</p> <p>11 Nathaniel Scruggs Matt Sharp</p> <p>12 Jeff Taylor Dan Tietz</p> <p>13</p> <p>14 PUBLIC PARTICIPANTS IDENTIFIED BY FIRST NAME ONLY</p> <p>15 Robert Tim</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p>
<p style="text-align: right;">3</p> <p>1 MEETING ROSTER (Continued)</p> <p>2 FDA Staff (Continued)</p> <p>3</p> <p>4 Jeffrey Murray, MD, MPH Deputy Director, Division of Antiviral Products CDER, FDA</p> <p>5</p> <p>6 Adam Sherwat, MD Medical Officer, Division of Antiviral Products CDER, FDA</p> <p>7</p> <p>8 Kimberly Struble, PharmD Clinical Team Lead, Division of Antiviral Products CDER, FDA</p> <p>9</p> <p>10 Andrea Tan Operations Research Analyst FDA</p> <p>11</p> <p>12 Celia Witten, MD, PhD Office Director, Office of Cellular, Tissue, and Gene Therapies</p> <p>13</p> <p>14 Janet Woodcock, MD Director CDER, FDA</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p>	<p style="text-align: right;">5</p> <p>1 TABLE OF CONTENTS</p> <p style="text-align: center;">PAGE</p> <p>2</p> <p>3 Welcome 9</p> <p>4 Edward Cox, MPH Director Office of Antimicrobial Products CDER, FDA</p> <p>5</p> <p>6 Overview of FDA's Patient-Focused Drug Development Initiative 16</p> <p>7 Theresa Mullin, PhD Director Office of Strategic Programs (OSP) CDER, FDA</p> <p>8</p> <p>9</p> <p>10 Background on Current HIV Treatment 25</p> <p>11 Kimberly Struble, PharmD Clinical Team Lead Division of Antiviral Products CDER, FDA</p> <p>12</p> <p>13 Overview of Discussion Format 28</p> <p>14 Sara Eggers, PhD Office of Program and Strategic Analysis OSP, CDER, FDA</p> <p>15</p> <p>16 Discussion 1: Patients' Perspectives on Current Approaches to Managing HIV and on Symptoms Experienced Because of HIV or Its Treatments 39</p> <p>17</p> <p>18 Panel #1 Comments on Questions 1 - 3 40</p> <p>19 Large-Group Facilitated Discussion on Questions 1 - 3 54</p> <p>20</p> <p>21 Break 77</p> <p>22</p>

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10	<p>1 welcome, all.</p> <p>2 Today's meeting really is an important</p> <p>3 chance for us to hear from patients and patient</p> <p>4 advocates. And today's meeting is our second in a</p> <p>5 series of meetings conducted as part of the FDA's</p> <p>6 Patient-Focused Drug Development Initiative. So this</p> <p>7 initiative involves obtaining a better understanding</p> <p>8 of patients' perspectives on a particular disease and</p> <p>9 treatments. And Theresa Mullin will speak to this a</p> <p>10 little bit more in just a minute.</p> <p>11 As part of this initiative, this meeting</p> <p>12 provides us a chance to hear directly from patients</p> <p>13 and patient advocates about living with HIV today,</p> <p>14 including the benefits and downsides of currently</p> <p>15 available treatments. And as we work through the day,</p> <p>16 Kim Struble will provide us a brief background</p> <p>17 discussion about the current status of treatment for</p> <p>18 HIV.</p> <p>19 The advances in therapies to manage HIV have</p> <p>20 really been truly remarkable over the last few</p> <p>21 decades, and when I joined the FDA, it's been a little</p> <p>22 bit over a decade ago now, and reflect back upon my</p>	12
11	<p>1 time prior to coming to the FDA, I was an infectious</p> <p>2 disease fellow at NIAID over at NIH, also in my time</p> <p>3 as an ID practitioner, I never really would have</p> <p>4 imagined that the advances that we've seen in the</p> <p>5 development of antiretroviral therapies would have</p> <p>6 happened at the rate that they've happened.</p> <p>7 So today HIV infection is often viewed as a</p> <p>8 manageable chronic infection. However, we also need</p> <p>9 to keep in mind that HIV still is a serious and life-</p> <p>10 threatening condition that can have a significant</p> <p>11 impact on people's lives. And the New York Times had</p> <p>12 an article a couple of weeks ago that described this</p> <p>13 very point, went through a series of discussions of</p> <p>14 patients and what they were experiencing with their</p> <p>15 HIV infection, so I think that really helps to</p> <p>16 illustrate the points of the challenges of living with</p> <p>17 HIV today.</p> <p>18 So we're hear today recognizing that there</p> <p>19 is still more progress to be made and more work to be</p> <p>20 done to further advance the treatment and management</p> <p>21 of HIV. The meeting will also give us a chance this</p> <p>22 afternoon to explore important issues as we look</p>	13
10	<p>1 forward to research and development in the area of</p> <p>2 cure research for HIV. And for the purposes of our</p> <p>3 meeting today, when we are talking about cure</p> <p>4 research, we're using the term to refer to any</p> <p>5 investigation that evaluates a possible therapy</p> <p>6 intended to control or eliminate HIV infection so that</p> <p>7 no further medications are needed to maintain health.</p> <p>8 HIV cure research is in early stages in</p> <p>9 testing in patients, but the products and approaches</p> <p>10 being evaluated may represent important foundational</p> <p>11 work for advances in treating HIV.</p> <p>12 As in many areas of research, clinical</p> <p>13 trials studying HIV cure interventions may not provide</p> <p>14 direct benefit to a participant but may provide</p> <p>15 scientific information that could guide future</p> <p>16 research and drug development. Today's meeting is an</p> <p>17 important opportunity to hear from and gain an</p> <p>18 understanding of patients' perspectives on potential</p> <p>19 benefits and risks of participating in HIV cure</p> <p>20 research. What we learn today will help us as we</p> <p>21 evaluate sponsors' study protocols and informed</p> <p>22 consent procedures for trials exploring HIV cure</p>	12
11	<p>1 research. Ilan Irony, from the FDA Center for</p> <p>2 Biologics Evaluation and Research, and Sara Goldkind</p> <p>3 will give us a presentation this afternoon and provide</p> <p>4 background for the discussion on the questions that</p> <p>5 we'll be discussing as part of the HIV cure research</p> <p>6 discussion this afternoon.</p> <p>7 Today's meeting focuses on having</p> <p>8 conversations with patients and advocates, and Sara</p> <p>9 Eggers will guide us through that and give us a little</p> <p>10 more information on the ground rules as we course</p> <p>11 through the day. And you will also notice that my FDA</p> <p>12 colleagues are sitting to my left here, and they will</p> <p>13 be here listening carefully to the discussions and</p> <p>14 occasionally asking clarifying questions as we go</p> <p>15 through the course of the day. And I thought also at</p> <p>16 this point what we would do is we would ask folks at</p> <p>17 the table to introduce themselves, and I'll start with</p> <p>18 Sara, and then we'll work our way down the table.</p> <p>19 DR. EGGERS: Again, my name is Sara Eggers,</p> <p>20 from the Office of Strategic Programs in the Center of</p> <p>21 Drug Evaluation and Research.</p> <p>22 DR. MULLIN: Good morning. I'm Theresa</p>	13

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14	<p>1 Mullin. I direct the Office of Strategic Programs in 2 the Center for Drugs, and I am leading this Patient- 3 Focused Drug Development effort for CDER. 4 DR. BIRNKRANT: My name is Debbie Birnkrant. 5 I'm Director of the Division of Antiviral Products, 6 and I'm happy to say that I've been with the agency in 7 the same division in different positions however, 8 since 9 1989. 10 DR. WITTEN: Celia Witten. I'm the Office 11 Director of the Office of Cell, Tissue, and Gene 12 Therapy in the Center for Biologics. And our 13 oversight includes products such as gene therapy and 14 cell therapy products. 15 DR. IRONY: Ilan Irony. I am Chief of the 16 General Medicine Branch in the Office where Celia is 17 our Director, Dr. Witten. And we go over the cell 18 gene therapies for a variety of indications including 19 HIV, which is a major component of the work we do. 20 DR. SHERWAT: Hi. I'm Adam Sherwat, from 21 the Division of Antiviral Products, Medical Officer. 22 DR. COX: Great. Thank you. And as Sara</p>	16	<p>1 products that are approved. Critically important to 2 the overall process and development of new medications 3 is the collective work and participation of 4 researchers, drug developers, patient communities, and 5 patients all coming together to advance the field and 6 the study of new agents for HIV care. 7 So with that, I want to thank all for 8 joining us and we look forward to a productive day and 9 discussion and opportunity to listen and to learn from 10 the comments that we hear. And I will now turn it 11 over to Theresa Mullin, who will talk to us a little 12 bit more about the Patient-Focused Drug Development 13 activities. 14 Thank you all. Overview of FDA's Patient- 15 Focused Drug Development Initiative 16 DR. MULLIN: Thank you, Ed. And thank you 17 to the people who just pulled my slides up. 18 So good morning. I'm Theresa Mullin, you 19 know that already, but I am going to talk about this 20 Patient-Focused Drug Development Initiative overall, 21 and this meeting is the second that we're having under 22 this initiative that we're beginning under PDUFA V,</p>
15	<p>1 has mentioned, at the end of the afternoon we'll have 2 an open comment period, and for folks that are 3 interested, at the registration table out by the doors 4 where you came in is a signup sheet, so we do ask that 5 you sign up if you would like to make comments at the 6 end of the day, particularly in areas if there are 7 comments that have not been covered over the course of 8 the day's discussions. 9 We're happy to see so many folks here, and 10 we know that a number of folks are joining us via the 11 web for today's meeting. And we're excited to see the 12 level of interest by patients, patient advocates, 13 researchers, drug developers, government agencies, and 14 other stakeholders that have joined us here today. 15 The disease HIV has served to unite us in a 16 common goal of the continual search for safe and 17 effective therapies to help millions of people that 18 are affected with the disease. And FDA has an 19 important part in drug development, but we also have 20 to recognize, too, that FDA's role is only a part. 21 FDA's key role is to ensure the safety of clinical 22 trials and also the safety and effectiveness of</p>	17	<p>1 and I'll say a little bit more about that, and we plan 2 to continue this effort. We're in sort of a learning 3 mode generally about this process that we're using to 4 get input as well as learning in this case today about 5 the questions that we're asking in particular for 6 patient input related to HIV drug development and cure 7 research. 8 So just to go on a bit here, this Patient- 9 Focused Drug Development Initiative is connected very 10 closely to an effort at FDA and CDER to develop a more 11 formalized framing for benefit-risk assessment for new 12 drugs, and, of course, FDA, in any decision making 13 related to marketing of drugs, weighs the benefits 14 against the risks to determine whether or not the drug 15 can be approved and put on the market. And that 16 benefit-risk assessment framework includes the 17 severity of the condition, the degree of unmet need -- 18 and we just consider those two components, severity of 19 condition and degree of unmet need -- to really 20 constitute the clinical context, and we recognize that 21 patients have a unique and pretty critical perspective 22 on FDA's understanding of that clinical context.</p>

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18	<p>1 Patients are the ones who take the medicines, will get 2 any benefit that can be gotten from it, will also 3 suffer all the risks, so we really need a better 4 understanding. 5 We have some ways to obtain that kind of 6 input today through an advisory committee, but that's 7 usually on a particular drug, and through our patient 8 representative program, and again those are very 9 valuable venues, but they are limited. So we are 10 undertaking this Patient-Focused Drug Development 11 effort to have a chance to talk to patients about 12 questions that the review divisions are sort of 13 grappling with or would really like to get greater 14 input related to them to give them greater insight 15 about how patients feel about the disease that they 16 are living with and the therapies that they may or may 17 not have to help us with both informing drug 18 development efforts and the review of an application 19 that comes in after we have this kind of input to 20 really have that extra insight that we may not have 21 prior to hearing from you. So that's why we focused 22 this meeting on hearing from patients. When we get to</p>	20
19	<p>1 the public input part at the end, others can speak, 2 but before that, everybody else is in listening mode. 3 And so as part of PDUFA V, which was 4 reauthorized last year, we agreed to have at least 20 5 of these kinds of meetings in different disease areas 6 over the next 5 years. Our review division staff are 7 here to hear what you have to tell us, or they're 8 listening in through our webcast, but that's one of 9 the key listening groups. We hope that patients, 10 patient advocates, health care providers, in the 11 disease area, drug developers, are also able to listen 12 to what we hear and what we learn in these meetings. 13 So how did this process start? Well, I 14 would say that we waited until the ink dried on the 15 reauthorization, but we didn't actually wait until the 16 ink dried. We started last summer, and when we 17 expected to get reauthorization, to try to talk to the 18 review divisions and others in the FDA, and also we're 19 listening to patients who have been talking to us 20 throughout the reauthorization process and giving us 21 their input along with the negotiations of PDUFA to 22 sort of look at what kinds of criteria should we use</p>	21
18	<p>1 to pick the diseases because one thing we did hear 2 from patient groups is concern that we are doing so 3 few. 4 I mean, there are so many diseases and 20 5 doesn't sound like a big number when you think about 6 how many diseases there are for which drugs are 7 developed, but we try to develop criteria. I'll tell 8 you in a minute what criteria we used. And we went to 9 the review divisions to ask, what disease areas would 10 you nominate for public comment? We developed a list. 11 We published that list in September of last year. We 12 had a public meeting in October to get input initially 13 and talk about the list and our thinking. We got 14 about 4,500 comments into the docket on this. There 15 were about 90 disease areas identified through that 16 public docket process, and we went back and analyzed 17 what we got from the public docket and from the input 18 in the meeting, talked again to the review divisions 19 to sort of identify what diseases will we try to cover 20 in the next 3 years. 21 And so we didn't want to speak for the whole 22 5 years, we went with the first 3, and it was based on</p>	20
19	<p>1 a combination of questions that are before the review 2 divisions now or that they see coming where they had a 3 sort of more urgent need to hear in certain disease 4 areas. There were other diseases we were covering in 5 other venues. So a variety of factors were taken into 6 consideration, including what we heard in the docket 7 and what patients identified as most critical, and 8 that's how we developed this list, which we published 9 on April 11th, and it's available on the internet. 10 You can see the list that we have for this first 3 11 years, and in 2015, we'll come back again and finish 12 it and say what other diseases we're going to cover in 13 those last 2 years of this PDUFA reauthorization. 14 And so here we have the disease criteria 15 that we had developed. And so we were looking for 16 diseases that were largely chronic and symptomatic and 17 that would affect the functioning or the quality of 18 daily life of the patients, and thus a really critical 19 aspect is hearing firsthand from patients how it feels 20 to live with the disease, diseases for which we really 21 are not capturing those considerations very well in 22 our clinical trials today and the endpoints we have</p>	21

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22	<p>1 today, and diseases where there are currently no good 2 therapies or very few therapies available. We wanted 3 to capture a range of diseases where there was a range 4 of severity and maybe there are subpopulations that 5 experience different severity, perhaps the elderly or 6 pediatric population, and also, as a set, we wanted to 7 cover a wide range of disease areas and affected 8 populations in this set of 20, so that went into our 9 thinking in what disease areas we chose.</p> <p>10 Now, there is a very diverse set there, and 11 so each of these meetings will be designed slightly 12 differently. We have some standard questions that we 13 had patients help us develop. We periodically have 14 convened patient groups who will meet with us to help 15 us think through process considerations related to all 16 these meetings. We got a lot of great input from 17 those sessions that we've had so far, and to make the 18 questions, that are basic questions, as relevant and 19 kind of meaningfully worded as possible going in to 20 talk to patients, but we heard from patients in those 21 meetings that we have to make sure we modify the 22 questions to fit the special considerations of the</p>	24
23	<p>1 disease that they are experiencing and also the 2 questions that reviewers in particular wanted to 3 cover. We've modified the questions today along those 4 lines for this HIV drug development and research.</p> <p>5 We're also, as we go through this, 6 experimenting with different methods because we're 7 really learning how to do this. And one of the things 8 we're trying to balance here is folks that are able to 9 make it here and those who can't. And a lot of 10 patients, for various reasons, whether it's the cost 11 of getting here or just the inconvenience or the lack 12 of mobility they may experience, we want to make sure 13 we have good methods for remote participation.</p> <p>14 And so this is our second meeting. The 15 first one we had was on chronic fatigue syndrome, and 16 that was held in April. And so we're trying some new 17 technologies today. We have a webcast that's 18 interactive today, and so that will be a new thing. 19 And we're going to try using the clicker technology 20 for some questions that are asked later to try to get 21 a sense of patients' responses and how you feel about 22 those questions. And we'll see how that goes.</p>	25
	<p>1 This is a little bit of a work in progress; 2 we're trying to see what's the best way to get the 3 kind of input we're trying to achieve in these 4 meetings. We'll be successful if we get input on how 5 people feel about it, very frank, candid input. We 6 hope and plan to faithfully capture that, capture the 7 words, capture the way that it's described to us, 8 provide that back to review divisions, and we're going 9 to be developing meeting reports that we will also 10 post on our website from what we capture in our 11 meetings.</p> <p>12 And just a little bit more about the format. 13 We'll try to format each of these meetings to really 14 capture the best way to get input, and it's a little 15 bit based on the questions that we have, and perhaps 16 the patient population that we're trying to work with.</p> <p>17 So with that, I will turn it over to our 18 next speaker. And we're really looking forward to 19 hearing your perspective today. It will be very 20 helpful to us going forward in this area.</p> <p>21 Thank you.</p> <p>22 Background on Current HIV Treatment</p>	

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26	<p>1 improvements to existing therapy approaches. There is 2 also continued development of novel therapy 3 approaches, and this is really the focus of today's 4 meeting, because your input and perspectives really 5 help us and hopefully industry and academia to move 6 the drug development process forward. 7 As we all know, antiretroviral therapy has 8 benefits, and today's treatments are highly 9 successful. And the recommended treatment is three or 10 more antiretroviral regimens, and the benefits of this 11 treatment is that people are living near normal 12 lifespans and it's being treated as a chronic disease 13 today. And there have been significant improvements 14 in the last several years for these treatment 15 regimens. And the picture on the left shows a handful 16 of antiretrovirals, it's what patients used to have to 17 take, and, today, the picture on the right shows the 18 simplified dosing regimen. So many patients have 19 available to them one pill that's a complete regimen 20 that they can take once a day. 21 But we all know that antiretroviral therapy 22 comes with many side effects; they can be both short-</p>	28
27	<p>1 term and long-term side effects. The short-term 2 effects can be some GI toxicity such as diarrhea and 3 nausea, it can be headaches, sleep disturbances, skin 4 changes. And there are also the long-term effects, 5 such as body changes, kidney or liver or heart or bone 6 effects. And antiretroviral therapy can affect the 7 quality of life, and these side effects of this 8 therapy can worsen over time. 9 We know that there are downsides to taking 10 therapy because we recognize it takes a lot of energy 11 and commitment to adhere to a lifelong treatment. And 12 we know that people get fatigued, they get fatigued 13 from having to take medications every day. They also 14 get fatigued from having to live with a lifelong and 15 long-term condition. And the natural response is 16 people may not want to take treatment anymore. But we 17 do know from recent studies that show that taking pill 18 holidays or stopping and restarting your medications 19 can result in serious health risks. Therefore, it's 20 important for all of us to find ways to take 21 medications daily because we all know that suboptimal 22 adherence could lead to loss of virologic response and</p>	29
26	<p>1 resistance. So input and perspectives that we hear 2 today will also help foster, hopefully, additional 3 drug development to deal with some of these issues. 4 So we do want your perspectives. And the 5 topic for this morning's discussions are going to 6 center around current HIV treatments and your most 7 significant symptoms. We are definitely interested in 8 your input on, what are you currently doing to help 9 manage your HIV symptoms? How well does your current 10 treatment treat your significant symptoms? What are 11 the most significant downsides to your treatments, and 12 how do they affect your daily life? And what specific 13 things do you look for in an ideal treatment to manage 14 your condition? 15 And with that, I am going to turn it back 16 over to Sara Eggers, who is going to give us an 17 overview of the discussion format, and we are very 18 much looking forward to your input today. 19 Thank you. Overview of Discussion Format 20 DR. EGGERS: Okay. Now the work begins. I 21 want to thank my colleagues for setting the context. 22 And now we're going to look for the patients and</p>	28
27	<p>1 patient representatives to provide the real input. 2 And when I say "patients," when we all say "patients," 3 we're using that as a shorthand to be people living 4 with HIV; and "patient representatives," we're using 5 that as a shorthand to be caretakers, loved ones, 6 advocates who speak on behalf of patients and who can 7 really kind of directly represent the points of view 8 of people living with HIV. 9 So the discussion will be rather different 10 from the types of government-sponsored public meetings 11 that you may have participated in. And as Dr. Mullin 12 described, today's questions and discussion format 13 were developed based on a standard structure for the 14 Patient-Focused Drug Development meetings. 15 This morning, we will focus on the current 16 landscape of HIV and its treatment, and we're going to 17 break this morning's discussion into two parts. We'll 18 first focus on HIV treatments before the break, and 19 we're going to include discussion on what are the good 20 things about today's treatments and what are the 21 downsides. And then after the break we'll focus on 22 the most significant symptoms that HIV patients</p>	29

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30	<p>1 experience because of their HIV infection or because 2 of the treatments that they take to control the 3 infection. 4 So I'm going to spend a few minutes just to 5 go over the discussion format and some important 6 ground rules to ensure an effective and fair dialogue. 7 And at this point, I'm going to ask the 8 folks who are serving on the panel discussion for the 9 morning to work their way up to the front and take a 10 seat. And I'm also going to ask for the clickers to 11 be handed out to anyone who is a patient or patient 12 representative who identifies themselves as such, 13 including up here, please. 14 So we are first going to hear from a panel 15 of patients and patient representatives, and the 16 purpose here is to really set a good foundation for 17 our discussion. There are four panel discussants this 18 morning, I'll introduce them in a bit, and they 19 represent a range of experience with HIV and HIV 20 advocacy. They have each prepared some minutes of 21 comments in response to the questions. And after we 22 hear from them, as long as time permits, we will have</p>	32	<p>1 is an experiment. We will be periodically inviting 2 those of you in person and those of you on the web to 3 respond to specific polling questions. The purpose 4 here is really to aid the discussion to see how many 5 participants share a particular perspective. So the 6 in-person participants will use the clickers, and 7 we'll practice that in a minute, and those 8 participating by the live webcast can add comments 9 through the polling questions that will be up on your 10 screen at the appropriate time. 11 We do have a lot of people participating on 12 the web, and this meeting is your meeting as well. 13 Those participating can add comments through the 14 webcast comment box, and again we would ask for the 15 comments to come primarily from people who identify 16 themselves as patients or patient representatives. 17 This meeting is being transcribed, and we 18 have many people on our team taking detailed notes, so 19 we are listening to what you are saying. 20 There are a few ground rules that we'll 21 ensure that this meeting adds the most value to FDA 22 and to the patients and patient representatives and to</p>
31	<p>1 follow-up questions for the panel, and my FDA 2 colleagues can help ask those questions. 3 After the panel discussion, we will broaden 4 the dialogue to include other patients and 5 representatives in the audience, and I hope that if 6 you identify as a patient or patient representative, 7 you are sitting in the first four rows here on my 8 right. The purpose here is to really build on the 9 experiences shared by the panel and get a sense for 10 what's generally similar and what may be different in 11 your experiences from what you heard. So I'll be 12 asking a number of follow-up questions and inviting 13 participants to raise their hand to speak. And we're 14 going to have FDA staff around with microphones to 15 come to you so you don't have to go to a microphone, 16 and if I can see name tags, especially if you're 17 sitting as close as possible to the front, I can call 18 on you by name. I'll be working to try to give 19 priority to people who haven't spoken, as long as 20 everyone who is comfortable speaking, we hope that you 21 get to speak as much as you want to today. 22 And we are trying something new today. This</p>	33	<p>1 all the others listening here today. 2 We are first and foremost here to learn 3 about the perspective of people who have this 4 condition, who live with HIV, so I'm going to ask all 5 the patients and patient representatives to 6 contribute. 7 We are very happy to see participants here 8 who represent industry, research, and government 9 agencies and a number of other stakeholders, and we 10 believe that this input is as important to you as it 11 is to us. We just ask that you stay in listening mode 12 and do not contribute to the discussion. Again, there 13 is an open public comment period that we would welcome 14 your participation in. 15 So the purpose of the opening panel is 16 really to give the discussion a good foundation, but 17 the opening panelists, their comments have no greater 18 weight than anyone on the web or in the audience. And 19 we will be taking all the comments and listening 20 carefully and incorporating all of those into our 21 final report. 22 So this meeting is a bit different in that</p>

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34	<p>1 we hope to have the discussion flow building off on 2 what people say. So since you don't have to come and 3 stand in line at the microphones, we really hope that 4 when you have a thought and it comes to mind, that you 5 can say it as the discussion is flowing and we'll have 6 a really good flowing discussion today. 7 If we don't get everyone's full thoughts on 8 a topic, we strongly encourage you to elaborate on 9 your comments in the public docket, and our meeting 10 web page has that information on how you can 11 contribute, and we really encourage everyone, even if 12 you're here today, to follow up and to elaborate on 13 what you share today through the public comment so 14 that we can review those comments as well. 15 Our discussion today will focus on the 16 common ground regarding the symptoms, impacts, 17 treatment, and research regarding HIV. We understand 18 there are other important issues to ensuring that 19 people with HIV get the health care treatment and 20 support that they need, and those are very important 21 issues. For our facilitated discussion today, we want 22 to focus on the questions that are being asked, the</p>	36
35	<p>1 topic that FDA needs the most input on today. 2 Our discussion may touch upon specific 3 treatments; however, the discussion of any specific 4 treatment should be done in a way that helps to 5 understand the broader issues, such as what symptoms 6 various treatments address or what general downsides 7 treatments have. Therefore, as part of my job today, 8 I will keep asking questions that keep us on this 9 common ground and keep us from getting too narrowly 10 focused. And, again, there is a docket for which you 11 can elaborate. 12 So the FDA staff is here to listen and there 13 is some time for FDA to sort of comment and provide 14 some remarks at the end of the facilitated discussion. 15 Now, I'm going to give a personal 16 disclaimer. I am not an expert in HIV or its 17 treatment, and I, in particular, have a really hard 18 time pronouncing drug names, so if I can do it, I 19 won't say any today, so I'll stay more general, but 20 that is why we have our FDA colleagues, my colleagues, 21 up here who are the real experts in this, and they are 22 helping me with some detailed follow-up questions, so</p>	37
34	<p>1 I thank them for contributing their time. 2 We do want your feedback on this meeting. 3 Participant feedback is very important. And we have 4 evaluation forms that I believe are at the front 5 table, and if they're not up there now, then they will 6 be during the breaks or at lunch, and we really 7 encourage you to grab one of those evaluation forms, 8 completely voluntary, and submit them to the front 9 desk and provide your feedback. 10 Above all, courtesy and respect is paramount 11 and so critical to a discussion like this. Our goal 12 today is really to enable a fair and open discussion, 13 so please wait to be acknowledged before speaking, 14 speak into the microphone, and if you feel 15 comfortable, we ask that you also just state your 16 first and last name so that our transcriptionist can 17 capture that, and we can put that into our 18 transcription. 19 Of course, avoid negative and derogatory 20 language. I don't have to say that here. And keep 21 all side conversations to a minimum, and if you have 22 to take a phone call, please do so out in the hallway.</p>	36
35	<p>1 If at any point you need to get up, feel 2 free. I said the restrooms are located behind the 3 cafeteria down a pretty long hallway. And we'll be 4 taking a break at some point in the middle of our 5 discussion. 6 That was a lot of talking on my part. I am 7 excited to turn it over, but before we do, we want to 8 practice the clickers and the web polling. So, Chad, 9 if we could have questions 1 through 5. 10 We're going to ask a few demographic 11 questions because we would like to get a sense of who 12 is in the room and who is participating via the 13 webcast, and we'll see how this goes. These are no 14 longer draft, these are in real time, we are moving 15 ahead with these questions. 16 So the first question is an easy one. Do 17 you live within the Washington, D.C. metropolitan area 18 or outside of the Washington, D.C. metropolitan area? 19 And in-person, click the corresponding number on your 20 keypad. Okay. And I think once everyone has done 21 that, then the results will come up. I'm not sure how 22 much time we get.</p>	37

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38	<p>1 (Answering question.) 2 DR. EGGERS: Okay. Great. And this is Chad 3 up here, and he is instrumental into making this work 4 today, so I thank him. Okay. 50 percent. Great. 5 That was easy. So okay. So questions? We all know 6 how to work the clickers? 7 (No audible response.) 8 DR. EGGERS: All right. 9 Let's go on to, what is your age? Younger 10 than 25, 25 to 34, 35 to 44, 45 to 54, 55 to 64, or 65 11 and greater? 12 (Answering question.) 13 DR. EGGERS: Okay, great. It's nice to see 14 that we have our distinguished guests here today. 15 All right. Can we move on to the next 16 question? Are you male, female, transgender, or 17 prefer not to answer? 18 (Answering question.) 19 DR. EGGERS: Okay, good. A pretty balanced 20 split there, with 60 percent male. 21 Okay, moving on to the next question, have 22 you been diagnosed as having HIV infection?</p>	40	<p>1 Because of HIV or Its Treatment Panel #1 Comments on 2 Questions 1 - 3 3 DR. EGGERS: So with that, let's start with 4 the first panel discussion to give a few remarks. And 5 I'm going to introduce them. 6 We have David Brakebill. Did I pronounce 7 that right, David? 8 MR. BRAKEBILL: Close enough. 9 DR. EGGERS: Okay. I'm a little bit better 10 with last names than I am with drug names, but still 11 not perfect. 12 We have Melanie Reese. 13 We have Joseph Jefferson, from the -- oh, 14 Joseph, can you -- I forgot my notes up here. 15 MR. JEFFERSON: I'm Director of Advocacy and 16 Alliance Development with Health HIV, and I'm also a 17 patient. 18 DR. EGGERS: Okay. And we have Catherine 19 Connor, from the Elizabeth Glaser Pediatric AIDS 20 Foundation. 21 So we're going to start with David, and if 22 you could just give a few remarks that answer -- let</p>
39	<p>1 (Answering question.) 2 DR. EGGERS: Okay. Great. So about half of 3 you are here living with, half of the patients and 4 patient representatives in person are living with the 5 condition, and have of you are speaking on behalf of 6 those who do. And I'm going to give my personal 7 thanks to those living with the condition. It can 8 take a lot of courage, and we really do thank you. 9 Can I ask on the web, can we get the sense 10 of how people are living with HIV? 11 MS. FURIA-HELMS: About 92 percent. 12 DR. EGGERS: Okay. Great. So we really -- 13 MS. FURIA-HELMS: Oh, I'm sorry. It's the 14 opposite. I'm looking at the wrong one. Six percent 15 or 7 percent. 16 DR. EGGERS: Six percent. Okay. Okay. So 17 we are listening to you as well, even if your comments 18 aren't summarized today and in their entirety or at 19 all, depending on how the discussion flows, but we are 20 listening to your comments, we will be reviewing them. 21 Okay. Discussion 1: Patients' Perspectives on Current 22 Approaches to Managing HIV and on Symptoms Experienced</p>	41	<p>1 me get to the questions. Again, we're focusing this 2 first part on treatments to manage HIV. So what 3 you're currently doing to help manage your HIV, what 4 you see as the greatest benefits of those treatments, 5 and the most significant downsides to those 6 treatments. 7 MR. BRAKEBILL: Well, besides the usual HIV 8 treatments, because of advanced age and other 9 comorbidities, I also take a daily dose of Lipitor. 10 I'm on lisinopril for high blood pressure, and I do as 11 much as possible with diet and exercise to try to 12 control symptoms as well. 13 Probably the biggest challenge that I think 14 a lot of people have is access to alternative 15 therapies. You know, depending on where you live in 16 the country, sometimes you have access to those and 17 sometimes you don't. So I think that's something 18 that's been proven to work in a lot of instances, but 19 it's not always available to folks. 20 Go into A and B as well? 21 DR. EGGERS: You can keep going. Do you 22 have any --</p>

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42	<p>1 MR. BRAKEBILL: So the specific symptoms 2 that my treatments address, obviously, the high blood 3 pressure, the high triglycerides. One of the things 4 that I recently found out that I'm sort of waiting to 5 see if some of the symptoms I've been experiencing, 6 about 3 years ago my physician changed by regimen. 7 When he changed my regimen, he didn't change my 8 Lipitor, which was contraindicated with Prezista, and 9 so about 3 weeks ago I go to the pharmacy to get my 10 prescription, and I noticed it's a smaller pill. And 11 so even 3 years after being on a contraindicated 12 regimen, it took a pharmacist to say, "Whoa, you 13 shouldn't be taking this." 14 So even though I consider myself pretty 15 savvy about the treatments that are available, that 16 was one that got past me. So I'm kind of sort of 17 waiting to see if some of the muscle aches and those 18 kinds of things that are indicated as side effects of 19 statins will subside as the treatment sort of adjusts 20 itself. 21 As far as how long I've been on treatment, I 22 started in 1999. My first regimen was AZT/3TC before</p>	44
43	<p>1 they were Combivir, and Viracept, which if anybody was 2 around Viracept, not one of the ones we use much 3 anymore at all. And then I switched to Crixivan and 4 Combivir, Norvir -- the first 400/400, and then 5 800/100, those of you who prescribe know what I'm 6 talking about -- and 100, of course, boosted Norvir. 7 Never failed a regimen and simply changed regimens to 8 downplay side effects and to go to safer. 9 The last change I made was about 3 years ago 10 to Truvada, Prezista, and, of course, boosted Norvir 11 again, and probably the best results I've seen in 12 terms of T cell, but even on the early regimen with 13 Viracept and the AZT/3TC, my viral load was suppressed 14 fairly quickly. I was diagnosed with full-blown AIDS 15 -- well, we don't use "full-blown" because AIDS is 16 what it is -- with seven T cells, and within about 6 17 to 8 months was able to get my viral load suppressed. 18 So I think probably because I'm a good patient and I 19 take all my pills most of the time I'm probably one of 20 the poster childs for success stories of ART. 21 DR. EGGERS: That's great. Thank you. 22 Next, we'll move on to Melanie Reese, who</p>	45
42	<p>1 will share her experiences. 2 MS. REESE: Yes. And you asked him to 3 identify who he was? 4 DR. EGGERS: Yes. 5 MS. REESE: Okay. I'm a consumer. I live 6 with HIV, but I'm also a patient advocate, a patient 7 educator, community health planner. I'm a caretaker, 8 a lobbyist. I wear many hats. Okay? And I was 9 diagnosed in 1999, and I began taking antiretrovirals 10 in 2004. I asked to get on it because according to 11 the CDC guidelines at that time, 350 T cells or less, 12 they recommended. But that was before name-based 13 reporting. I didn't want my name to get on the books, 14 just my unique identifier, so I asked to get on 15 medications because I had been on medications all my 16 life, and I've had chronic illnesses since birth, so 17 what's another pill or two or three or whatever to 18 keep living? 19 So I've been on medication for 9 years. I'm 20 on the same regimen; however, starting in 2004, it was 21 three pills, and then it wasn't even 3 years later, it 22 went to two, Truvada and Sustiva, and then now I'm on</p>	44
43	<p>1 the one pill a day, Atripla, but it's the same 2 regimen. And my viral load never got higher than 3 6,500. And so the next visit, I was suppressed and 4 I've been suppressed ever since. 5 Because I have a multitude of other chronic 6 illnesses, my HIV is not something that my doctors are 7 concerned with; it's everything else, and some of the 8 treatments that would be the best for those conditions 9 I can't have because of my antiretrovirals. They 10 don't want that to be compromised in any way. 11 So I have chronic fatigue, fibromyalgia, 12 chronic bronchial asthma, I have seizure syndrome, I 13 have degenerative disk disease of my spine, I have 14 arthritis, osteopenia, which is the precursor to 15 osteoporosis, I have arthritis, bursitis, tendonitis. 16 The list goes on. And I have irritable bowel. It's 17 been going on long enough it's chronic, and they don't 18 know if it's the disease or the syndrome, but because 19 the immune system is primarily in the gut, when you 20 already have gut issues, even if it's a slight chance 21 to have gastro discomfort, it's magnified, so I have 22 to take MiraLAX, Metamucil, Imodium Extra Strength,</p>	45

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46	<p>1 it's a combination plus. 2 I take dicyclomine for my stomach issues and 3 pain. I have GERD. If anybody doesn't know, that's 4 gastroesophageal reflux disease, and so I have to take 5 omeprazole. I take Lipitor, I take QVAR, I take 6 ProAir, I take -- I'm bipolar, so I take Zolofl, and I 7 used to take Depakote for mood, but since I have a 8 concussion, had a seizure, brain surgery and all, they 9 had to take Depakote away and give me Keppra. It's a 10 long name because it's -- I don't know if it's generic 11 or what, but "Keppra" I can pronounce. 12 So I have chronic pain, I cannot take 13 anything for pain other than if it gets too severe, I 14 can take Tylenol, but I have stomach issues where my 15 lining gets very thin, and just so that it won't 16 rupture, I can only take that periodically. So I just 17 have to grin and bear it. 18 DR. EGGERS: Well, we will have a lot of 19 follow-up questions, I think, after the break on how 20 you manage all of that, but thank you so much for 21 sharing that. Did you have anything else you wanted 22 to add, or should we move on to Joseph?</p>	48
47	<p>1 MS. REESE: Go ahead and move on because -- 2 DR. EGGERS: We'll move to Joseph. 3 MR. JEFFERSON: Well, I just have to start 4 by saying when I read the questions that were 5 disseminated, I sort of had to ask myself if I was the 6 appropriate candidate to speak. That's perhaps 7 because my status yields a somewhat boring analysis. 8 I have been positive for 25 years, asymptomatic for 25 9 years, virally suppressed for 25 years. In the early 10 years, there were a number of meds that came and went. 11 I've been on a fairly consistent regimen for the last 12 8 years. I get sick less often than virtually 13 everybody I know. So I'm sort of this outlier 14 perhaps, but I thought, after giving it a little 15 reflection, that folks in this room need to hear from 16 those of us that are actually faring well, and I can't 17 really go any further on a personal level without 18 acknowledging the folks that stood on the steps of 19 this building or nearby buildings 20 years ago 20 fighting to get in and here we are on the inside. 21 DR. EGGERS: Yes. 22 MR. JEFFERSON: So I thank them. I thank</p>	49
	<p>1 all of the folks at FDA that responded. I definitely 2 want to tip my hat to the brilliant research community 3 and to industry for really stepping up, and I likely 4 would not be here were it not for the efforts of those 5 groups. 6 So that's my story. I suppose I wanted to 7 also come and give a voice also to those of us that 8 are now I'm well situated in and many others are about 9 to enter the new sort of emerging demographic of 10 interest, which is, of course, the over 50 population 11 with HIV, and, of course, most everybody in this room 12 knows that in 2 years more than half of all folks 13 living with HIV will be over the age of 50, and I 14 think that presents a whole wide variety of challenges 15 both in the clinical trial setting as well as in 16 adherence issues, which is a big concern of mine that 17 I'll get more into in the facilitated discussion later 18 because I think that there are some things that we 19 need to press forward on as it relates to tailoring, 20 treatment methodologies, and adherence interventions 21 for those of us that are going to be soon likely 22 managing multi-comorbidities that are typically</p>	
	<p>1 associated with folks 10 and 20 years older than we 2 are. 3 So there is a lot of work to do, and I am 4 happy to participate in the discussion. Thank you for 5 having me. 6 DR. EGGERS: Thank you. 7 And then I'll move on to Catherine Connor, 8 who will provide -- we have asked her to sit up here 9 and provide the pediatric point of view to make sure 10 that very important population is represented today. 11 Thank you, Catherine. 12 MS. CONNOR: Thank you. And I have the 13 unenviable position of trying to describe what the 14 pediatric population is now. You know, it used to be 15 very easy to say, especially when you look at the 16 legacy of Elizabeth's Foundation of what the fight 17 looked like, and now you have to remember that 18 pediatric covers a wide range, and when you talk about 19 managing symptoms and the drug regimens when you go 20 from a neonate to the youth and teen years, even into 21 college now, it's really a diverse population, and the 22 needs of that population are really diverse, and then</p>	

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50	<p>1 sometimes you forget that especially with the younger 2 children, you have somebody else who is involved in 3 this, which is the caregiver, and the caregiver 4 actually has a lot, and they have differing opinions 5 than the patient as to how to manage the symptoms and 6 what needs to be done. And so I think that it's 7 important with this group in particular to think about 8 how the drugs are administered, how tough the 9 adherence is for the different age groups in 10 particular.</p> <p>11 When it comes to the impact of the side 12 effects, you actually don't see necessarily more side 13 effects in children than in adults when it comes to 14 using these drugs, but the impact of the side effects 15 on young people and in children can be very dramatic. 16 Before this meeting, we actually worked with AIDS 17 allies to talk to some of the beneficiaries and the 18 families that we work with, and it was interesting, 19 when you talk to both the children and the young 20 people and their parents, some of the ones that came 21 to the top were some of the night terrors and 22 insomnia. You know, if you're a 6-year-old or 7-year-</p>	52	<p>1 organs. We have a number of families that we work 2 with that now, being a 20-year-old who has had HIV 3 since they were either perinatally infected or 4 infected as a youth or a young child, really are 5 getting more and more of the type of things where they 6 have to worry about the impact of a lifetime on ARVs, 7 what it's done to their bodies, and how they continue 8 to live, and again acknowledging sort of the different 9 side effects as these kids grow up.</p> <p>10 When you talk to these families and these 11 young people, they actually switch regimens quite 12 often because puberty affects them differently, and 13 anyone who knows pharmacokinetics, you know, you 14 really do start to have to shift and change a lot and 15 more frequently as a child on HIV medicine or as a 16 young adult on HIV medicine, and so they may have -- 17 actually their bodies are a little bit more worn down 18 and the side effects change as they use these drugs in 19 different age groups.</p> <p>20 And one last -- well, two last points I kind 21 of wanted to make on this topic is when you talk about 22 managing HIV, we work with a practitioner here in D.C.</p>
51	<p>1 old living with HIV having night terrors, the impact 2 of that on you is different than an adult, who knows 3 how to deal with it. The same thing with some of the 4 gastrointestinal issues that come with medicine. As 5 an adult, you kind of know how to deal with it. As a 6 child who is in school or a child who doesn't even 7 really know their status because of disclosure 8 decisions made by the adult, how they handle those 9 side effects can be very different as well.</p> <p>10 Something that also came up in our 11 conversations was an acknowledgement of some of the 12 longer term impacts, and we have folks on the panel 13 who have been addressing their status for a number of 14 years. With children, obviously, one of my colleagues 15 like to say it's not always the immediate side 16 effects, you have to think about the bones, the body, 17 and the brain, because all those things are developing 18 at a time they're taking toxic drugs to deal with a 19 chronic illness, and so you do see the longer term 20 things that are still being studied, the developmental 21 issues that a lot of people growing up with HIV or 22 infected as youth with HIV have, impact on their</p>	53	<p>1 who often remarks on how she has young 2 people in their teens that are already on salvage 3 therapy, and this is because of the very specific 4 population who have gone through first-line, second- 5 line, you know, there just aren't a lot of options for 6 them, and I think that's something that's really 7 important on the research agenda, that these kids do 8 end up on some really harsh drugs at a very young age, 9 and we have to keep that in mind as we start to look 10 for better formulations with the least amount of side 11 effects with the most effectiveness. That needs to be 12 kept in mind.</p> <p>13 Also -- and I thought about holding this off 14 for the adherence conversation, but I think it's also 15 important to mark for this patient population -- is 16 sort of how the use of drugs impacts when they 17 transition to adult care because a lot of times the 18 adult HIV treatment community is a little bit more 19 lockstep, you know, "Oh, you're infected. Here is our 20 first line. Here we go." These are folks who have 21 complicated medical histories, they've been on a 22 number of treatments. They know their side effects.</p>

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54	<p>1 They probably know more about HIV than all of us, 2 having grown up with it, but sometimes when they 3 transition to adult care, that isn't recognized or 4 understood, and so a lot of times that can impact 5 adherence, but it also impacts how these treatments 6 affect them because there isn't this recognition as a 7 young person or a child who has lived with this for a 8 long time when they get to that new part of the health 9 system. 10 DR. EGGERS: Great. Thank you very much, 11 Catherine. 12 Do any of my FDA colleagues have a real 13 question that they want to ask to one of the panel 14 members before we move out to the large discussion? 15 We'll be able to engage you guys as well. Thank you. 16 (No audible response.) Large-Group 17 Facilitated Discussion on Questions 1- 3 18 DR. EGGERS: Okay. Then we're going to move 19 to the facilitated discussion. I'm going to make my 20 way out to the front, as it was called in our first 21 meeting, "talk show style," so we'll see how that 22 goes. And if we can get the next question up.</p>	56	<p>1 would like to get a sense of, how many different types 2 of ART regimens have you taken? Have you never taken 3 any, currently on your first, have taken two to three 4 different regimens, more regimens, or if you're not 5 sure? 6 (Answering question.) 7 DR. EGGERS: Okay. So again lots of wisdom 8 in the room, lots of experience with many different 9 things. Everyone has taken at least two or more 10 regimens. Okay. Great. 11 So we heard a lot of great things from the 12 panel's discussion up in front, and I'm going to 13 follow up on a few of those things and get more 14 feedback, and again I encourage my FDA colleagues to 15 follow up. 16 We heard a lot about the benefits, being 17 able to lead life with a chronic condition and living 18 it for a long time, so I would like to follow up on 19 that a bit more, and I would like to follow up on a 20 few of the issues regarding decision making about how 21 you choose a regimen and how you choose to change a 22 regimen, and then look at some of the downsides of the</p>
55	<p>1 I can't squeeze through. 2 Is this on? Okay. I'm going to do my best 3 to talk into the microphone, but sometimes I get a 4 little lazy at that, so please let me know if you 5 can't hear me. So we'll ask this question before we 6 get into the discussion. So how long ago was your 7 diagnosis, for those living with HIV, in person and on 8 the web? 9 (Answering question.) 10 DR. EGGERS: Okay. So it looks like 11 everyone here is 10 years ago or more, although we do 12 have the pediatric population represented here. Do we 13 have those numbers on the web? 14 MS. FURIA-HELMS: Can you hear me? 15 DR. EGGERS: Yes. 16 MS. FURIA-HELMS: Yes, more than 20 years 17 ago, and it's 100 percent, but only four people have 18 responded. 19 DR. EGGERS: Okay. All right. So we will 20 frame this as having lots of wisdom in the room and on 21 the web. 22 There is another question. Okay. So we</p>	57	<p>1 regimens that we heard about, particularly the 2 complexity of that treatment that Melanie was talking 3 about, and also, David, you alluded to that as well 4 with the contraindications and the effects on the 5 other conditions that you have. 6 So with that, let's start with the benefits 7 of the current medications out there. We heard from 8 the panelists up here, but I would like to see if 9 anyone, any of you in the audience, wants to sort of 10 echo or follow up on what you heard about the benefits 11 that were mentioned up here. 12 Does anyone? Yes. 13 MR. SHARP: Hi, everybody. I'm Matt Sharp. 14 I'm a long-term survivor and obviously have had a lot 15 of benefits with treatments. I wanted to bring up one 16 thing that I have had to experience, and that's 17 immunologic non-response to the therapies. I've been 18 pretty tolerant of almost every medication I've been 19 on except, say, for Fuzeon. That's supposed to be a 20 joke. 21 MR. SHARP: But I never was able to really 22 respond immunologically. So I just wanted to bring</p>

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58	<p>1 that up as an important issue with the state of 2 therapy today. 3 DR. EGGERS: Okay. Would anyone else like 4 to comment on what they see as the real benefits of 5 today's treatments? 6 Yes, David. 7 MR. BRAKEBILL: Well, I think the benefit in 8 terms of particularly people who are newly diagnosed, 9 you can start on a once-a-day single pill regimen. 10 You know, for me, even changing regimens when I was 11 undetectable was a tough decision because, you know, 12 if ain't broke, why fix it? So my doctor even tried 13 to convince me that, "You need to move to these safer 14 regimens," was something I struggled with, but if I 15 change and it doesn't work, then am I using up one of 16 those pools of meds that I have access to? 17 But I think the thing that sort of concerns 18 me at the same time is even though we have simpler 19 therapies, those of you who are familiar with the 20 treatment cascade, we're not really seeing any 21 improvement in viral suppression. So there is 22 something about how we're approaching taking medicine</p>	60	<p>1 that, "You're going to have to do this the rest of 2 your life," and I think that's why you do -- again, I 3 know this is more an adherence issue, but it's a 4 different discussion with that population, and I think 5 that's why you see such erratic adherence issues with 6 that population, because that question in its own 7 right is sort of heart-stopping for that population in 8 a way I don't think it is necessarily for newly 9 infected adult patients. 10 MS. REESE: I have a comment. 11 DR. EGGERS: Yes. Go ahead, Melanie. 12 MS. REESE: I appreciate your comment for 13 the pediatric, but that applies across the age 14 spectrum because people don't want to take anything if 15 they're feeling okay, and they'll take it and then 16 somebody will tell you, "Oh, you're UD, undetectable." 17 "Why do I have to take this now?" It's hard to wrap 18 people -- I started off my life with medications, so I 19 know you take it regardless so you don't die. But 20 most of the population, that does not compute. 21 DR. EGGERS: Thank you, Melanie and 22 Catherine, from the pediatric perspective. Can we get</p>
59	<p>1 with suppression of the virus. You know, I don't know 2 whether it's because we're asking people to start 3 treatment before they're ready, where there is not the 4 correct amount of counseling and advice around that, 5 but that sort of disturbs me, that even though we have 6 simpler regimens, we're not really seeing an increase 7 in the number of people who have suppressed viral 8 loads. 9 DR. EGGERS: Would any of my colleagues like 10 to ask a follow-up question to that? 11 Yes, Catherine. 12 MS. CONNOR: This is just a comment, but I 13 just wanted to comment on actually the phrasing of the 14 question again for my population. "The rest of your 15 life" is a very deep thing for young people, and again 16 I'm 37, the rest of my life feels like next weekend, 17 but for them it is a very daunting idea, and 18 especially when you have an asymptomatic young person 19 who is looking at having these pills, and, again, as 20 we have moved to one-a-day pills, this has lessened a 21 little bit, but it is very, very daunting to tell an 22 8-year- old or a 12-year-old or even a 15-year-old</p>	61	<p>1 a little bit more into what you hear, the reasons that 2 they give, for not wanting to be on those medications? 3 Do they, for example, say, "Well, I'll go back on them 4 when I need to," or do they have other reasons? And 5 feel free, anyone can answer that. 6 MS. REESE: There are lots of reasons. 7 Some, if they are trying to get in a relationship or 8 are in a relationship and have not yet disclosed, they 9 don't want anybody seeing them taking their 10 medications, so they'll avoid taking medications if 11 their companion, friend, are around. Some, it's even 12 their family. If their family knew that they were 13 infected with HIV, they would be rejected, wouldn't be 14 allowed to eat at the big table or with regular 15 utensils, everything has to be plastic, to be thrown 16 away. So it runs the gamut, the reasons why people 17 don't want to take it. 18 DR. EGGERS: Catherine? 19 MS. CONNOR: And sort of, as I mentioned in 20 my opening comments talking about a wide range of 21 people here, we see a lot of folks who just again 22 growing up with HIV population, it's a little bit of</p>

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62	<p>1 exhaustion. I don't think it's unique to them, but 2 they've been on this medication for years, they've 3 probably been on their third, some of them would just 4 sort of rather not -- you know, we have a couple of 5 families, I mean, the Elizabeth Glaser Pediatric AIDS 6 Foundation has been around for 25 years, and some of 7 these families we've worked with a long time, you do 8 see patients who just sort of throw in the towel, 9 they're just a little exhausted from, again, the side 10 effects of it, the memory lapses, inability to have 11 people understand what they're going through, they 12 would just rather not take treatment. You know, with 13 other folks again, more the youth infected, again it 14 is the cavaliness of, "I don't have any symptoms, 15 I'm taking this medication. I don't feel like I have 16 to." And, you know, part of this is attributable to 17 just being young people. I mean, you know, you can 18 only ask so much maturity from a certain age 19 demographic, but I do think you see that. 20 And I do have one, again, a lot of the work 21 that we do also is with the provider community, and I 22 do think that where people get their care and</p>	64	<p>1 would not have a significant impact on my daily life? 2 Overall it does or would have a significant impact on 3 my daily life, but I feel that I am able or would be 4 able to take my medicines as prescribed by my doctor. 5 Overall it does or would have a significant impact on 6 my daily life, and I am worried that I might not be 7 able to take my medications every day as prescribed by 8 my doctor. Or if you are not sure which of those 9 statements reflects your perspective. 10 (Answering question.) 11 DR. EGGERS: I've give you a few more 12 seconds. Okay, we can put those up. So really a wide 13 range. So, yes, it's a big burden for a lot of folks 14 in the room. On the web? 15 MS. FURIA-HELMS: About 80 percent said it 16 does or would have a significant impact. The total N 17 is 5. 18 DR. EGGERS: Okay. But that they would be 19 able to or they would not be able to? So the middle 20 choice? 21 MS. FURIA-HELMS: The second choice: it 22 does/would have a significant impact.</p>
63	<p>1 information dramatically impacts whether you answer 2 this question one way or another. And, again, in a 3 lot of the pediatric care settings, you have some 4 really dedicated professionals who are very good at 5 explaining to parents and children why they need to 6 take this and supporting them even in decisions to 7 switch medications and discussing side effects. Other 8 parts of the provider community are not as good at 9 that. And so I think it really does matter, not just 10 the medication itself but how the medication is 11 explained and the support they get while taking 12 medication. 13 DR. EGGERS: Great. Thank you. 14 Before I take one more, let's actually ask 15 this question that's up here on the screen, so if you 16 have your clickers, please feel free to answer, and on 17 the web. For those that are living with HIV, which of 18 the following statements best reflects your overall 19 perspective on having to take multiple HIV medications 20 every day for the rest of your life? Maybe you take 21 multiple or maybe you just take one, but thinking 22 about having to take multiple, overall it does not or</p>	65	<p>1 DR. EGGERS: Okay. So it sounds like it 2 does or would have a significant on life, though it, 3 for many of you, would be manageable. Does anyone 4 want to follow up on that? And I think Randy had 5 someone? And could you state your name, please? 6 MR. SCRUGGS: Good morning. My name is 7 Nathaniel Scruggs. I was listening and I thinking 8 about my own journey getting to this seat where I'm at 9 today, and I was listening to the panel. I think in 10 dealing with AIDS/HIV -- and I heard you all mention 11 that this is the second of this type of event or 12 coming together -- but when I first found out, I 13 didn't want nobody to know, I just didn't. I didn't 14 want nobody to know, and that was because of my 15 ignorance. That was because of my ignorance and it 16 was because the way society viewed and the information 17 that was presented about people living with HIV and 18 AIDS. I was fortunate to be ignorant enough to go 19 seek out help through alternative groups and was 20 blessed to get a provider who could tolerate my 21 ignorance and disrespectful behavior based off of the 22 fear of what was projected to me through the</p>

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66	<p>1 community.</p> <p>2 So I didn't know, and I was listening, you</p> <p>3 know, how I think one of the key things that is</p> <p>4 misgiving in the treatment of HIV and AIDS is that you</p> <p>5 can't lump everybody in the same basket, and which I</p> <p>6 know the government has what it's supposed to do and</p> <p>7 policies set, but they just talked about it. You</p> <p>8 can't take a child that was born with AIDS or HIV</p> <p>9 through their mother and subject them to what you</p> <p>10 expect a hardcore drug addict, sexual promiscuous,</p> <p>11 heterosexual male to deal with in taking medicine.</p> <p>12 So I think what's happening here is vital to</p> <p>13 what's the next step going on in the treatment of HIV</p> <p>14 and AIDS because this is what needs to take place.</p> <p>15 You need to have everybody sitting in a room and</p> <p>16 discussing their perspective or their point of view</p> <p>17 around how they feel and what do they think the best</p> <p>18 outcome would be for that particular group of people.</p> <p>19 And I was looking at the regimens. I've</p> <p>20 been on about four regimens, but what they didn't tell</p> <p>21 me until later on that I found out through my own,</p> <p>22 each regimen that I've been on affected me in some</p>	68	<p>1 with the question is, it says, "Take my medications</p> <p>2 every day as prescribed by my doctor for the rest of</p> <p>3 your life." I find that just, you know, impossible</p> <p>4 for most people. You're going to miss a dose here and</p> <p>5 there. I do know people that are amazingly adherent</p> <p>6 every single day at the same time, a few, but I just</p> <p>7 wanted to point out that, remember, we need really to</p> <p>8 focus on long-acting formulations so that this is sort</p> <p>9 of the next hurdle, I believe, that we need to get</p> <p>10 over so that we can complete sort of the</p> <p>11 antiretroviral picture and make it 100 percent.</p> <p>12 DR. EGGERS: Okay. Well, Matt, I hope that</p> <p>13 you bring up the long-acting formulas when we ask our</p> <p>14 last question before lunch, which will be: What are</p> <p>15 you looking for in an ideal treatment? So we'll come</p> <p>16 back to that.</p> <p>17 Does anyone else want to follow up on what</p> <p>18 they've heard?</p> <p>19 Yes, Wanda.</p> <p>20 MS. COMMANDER: I have been infected for</p> <p>21 over 26 years now, and I'm symptomatic. I've had a</p> <p>22 lot of OIs, opportune infections. And I want to say</p>
67	<p>1 type of way and it's irreversible affectedness of this</p> <p>2 medication: cholesterol, high blood pressure, kidney</p> <p>3 problems. So it's vital to what we have to do.</p> <p>4 And I was listening to Melanie, and Melanie</p> <p>5 was talking about the lesser of the two evils, that's</p> <p>6 what that really was, the lesser of the two evils. Do</p> <p>7 I bite the bullet to continue tolerating these other</p> <p>8 conditions so that I can manage my HIV? You know, I</p> <p>9 was in that situation at one time, I was taking</p> <p>10 medicine that was affecting my kidneys and my liver,</p> <p>11 but through medicine, pharmaceutical companies, they</p> <p>12 became more patient conscious, they're still making</p> <p>13 the money, but they became more patient conscious to</p> <p>14 realize that what they're doing to help us people</p> <p>15 that's living with HIV, they're hurting us in the same</p> <p>16 way. So we've got to do something with these</p> <p>17 formularies.</p> <p>18 DR. EGGERS: Thank you very much, Nathaniel.</p> <p>19 I think we had Matt?</p> <p>20 MR. SHARP: So I just wanted -- there is no</p> <p>21 question that the medications have become more</p> <p>22 tolerable and easier to take, but the problem I have</p>	69	<p>1 that the medicines today are really doing some</p> <p>2 spectacular work in my life because even though I'm</p> <p>3 undetectable, I still have a very low CD4 count, and</p> <p>4 the medicines are keeping me going.</p> <p>5 DR. EGGERS: Thank you very much, Wanda.</p> <p>6 Does anyone else want to follow up on that?</p> <p>7 Yes, Joe.</p> <p>8 MR. JEFFERSON: Well, again, I think it's</p> <p>9 important to acknowledge that these questions are</p> <p>10 phrased in sort of an isolationist manner. It's to</p> <p>11 assume that HIV is your one and only or your sort of</p> <p>12 top-line condition that you're working with your</p> <p>13 provider hopefully to manage. And, again, for those</p> <p>14 in the room and others who are battling multiple</p> <p>15 conditions, I think it's hard to really bring a</p> <p>16 sophisticated analysis to these questions without</p> <p>17 considering the co-occurring challenges, if you will,</p> <p>18 of managing multiple conditions, and so I think as we</p> <p>19 get into the discussions before lunch about the future</p> <p>20 of pharmacology, there is a rich discussion to have</p> <p>21 around that.</p> <p>22 DR. EGGERS: Yes, Ed.</p>

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70	<p>1 DR. COX: Can I just follow up on that? I 2 guess I'm wondering, and we heard in some of the 3 comments earlier, the issue of drug interactions that 4 seems to be an ever-present challenge both with 5 antiretrovirals and other meds. I'm curious if the 6 panelists might be able to comment more about drug 7 interactions. It sounds like I think it was David's 8 comments where something sort of popped up a little 9 bit and he didn't recognize the potential for 10 interaction initially. And given the complexity in 11 interactions, are pharmacists pointing them out to 12 you? Are physicians pointing them out to you? Are 13 patients? How are those things surfacing in the real 14 world? And any comments that you might have on that 15 would be appreciated.</p> <p>16 MR. BRAKEBILL: Well, I think in my case, 17 you know, I mean, most doctors that are practicing HIV 18 or infectious disease or anything are seeing more 19 patients than they can handle, so part of it is 20 capacity in the system. The other piece of that is 21 that this is a relatively new pharmacist. I've been 22 using the same pharmacy for 11 years. The doctor</p>	72
71	<p>1 probably, when he changed regimens, forgot that -- 2 didn't look that I was on Lipitor, I mean, he's an HIV 3 specialist, he's certified, the whole thing, just it 4 never happened, and like I said, 2 weeks ago this 5 relatively new pharmacist working at the pharmacy 6 flagged it, and I'm immediately going, "What? What? 7 What? What? What?"</p> <p>8 And so I was as surprised by it as the 9 system, but I think that's just a systematic thing. I 10 mean, maybe with e-prescribing and some of these 11 things that are coming up, that are coming online, 12 those things will be flagged automatically, that when 13 you're filling a prescription, and it just so happened 14 that this pharmacist called the doctor and the doctor 15 said, "Let's reduce the dose." You know, when I go 16 back to see my follow-up visit in August, I'll say, 17 "Okay, let's talk about this and see what we can work 18 around."</p> <p>19 But I think that happens, you know, in this 20 case it -- I think for a number of reasons. As I 21 mentioned, I think HIV docs, clinicians, people that 22 are working just it's -- you know, and medical care in</p>	73
70	<p>1 general is, "Get them in, get them out," unless you're 2 in, you know, some specialized clinic in some big city 3 that treats the whole person. That's the other thing. 4 You know, you have for HIV patients you're sending 5 them here for this, there for that, you know. If you 6 have the luxury of being in a metropolitan area where 7 you have holistic treatment available to people where 8 four or five different people are looking at your 9 medical records, probably the chances of that are 10 slimmer, but I think in particularly small rural areas 11 where access to care in general is an issue, that 12 you're lucky to see a doctor, that those things are 13 sort of not looked at as closely. That's my opinion.</p> <p>14 DR. EGGERS: So I think both Melanie and 15 Joe, and we'll see if anyone else wants to comment and 16 then we'll go take a break after that.</p> <p>17 So how about Joe first?</p> <p>18 MR. JEFFERSON: I just want to amplify a 19 couple of things David referred to. So at Health HIV, 20 we do a lot of workforce development work with 21 providers and health departments across the country, 22 and we also do an HIV primary care survey every year,</p>	73

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74	<p>1 seasoned provider to get some guidance. So I think 2 there is a lot of rich opportunity in the whole 3 workforce arena as well. 4 DR. EGGERS: Thanks, Joe. 5 Melanie? 6 MS. REESE: To piggyback on what he said 7 about primary care providers not understanding the 8 complexity of managing multiple conditions, I guess my 9 neurosurgeon just fired me because he said I have too 10 many things going on, he throws his hands up because 11 every time he tries to prescribe something to ease 12 something that's going on in my head or my seizures, 13 it doesn't work with what I'm already taking for all 14 my other stuff. So he said, "Go to your primary care 15 and see what they can do to manage it." 16 MS. REESE: So at one time when I was in the 17 hospital with my brain surgery, I was overmedicated 18 because they didn't realize that what they were giving 19 me for my seizures and relieving brain pressure and 20 all that stuff was counterproductive to my HIV meds 21 and they were putting me in a critical situation, and 22 I didn't know that was happening to me, and when I</p>	76	<p>1 going to take those drugs once approved are almost to 2 a person have other challenges or are on other 3 medications, and yet there is little post- 4 approval/post-marketing follow-up that's really 5 compelled by the FDA from manufacturers to sort of go 6 back and study and report in some really active way 7 what's happening with people who are taking their meds 8 in real life who have got other conditions, because, 9 of course, in the original clinical trials on the way 10 to approval, those folks weren't participants. So I 11 think it would be really useful if that happened, and 12 I think you could hear more than from folks who are in 13 -- you know, if only in a trial that's sort of looked 14 at, just their real life experience in reporting would 15 be really useful. 16 DR. EGGERS: I see the follow-ups. If 17 they're short, we'll take them now, otherwise, we can 18 have a broadness discussion and have it after. 19 MR. BRAKEBILL: And I think to what Dan just 20 said, you add women, you can add transgender folks. 21 There are a whole lot of people that are being missed 22 in the research end that really need to be -- I mean,</p>
75	<p>1 went back to refill what I got from the hospital, the 2 pharmacist said, "How long have you been taking all 3 this stuff together?" and I said, "Oh, 6 weeks," and 4 he goes, "We have to call all these doctors and figure 5 out something." So that's a scary thing. 6 And with ACA coming and people with an 7 insurance card who are used to just going to emergency 8 departments when they're on they think their death 9 bed, they're not going to know what to do, they're not 10 going to know what questions to ask, and doctors don't 11 know how to speak to people who have more than one 12 thing going on with them. 13 DR. EGGERS: Okay. Someone out here? 14 MR. TIETZ: Hi. I'm Dan Tietz, from Kryon 15 in New York. I just want to add a little bit to what 16 Joe said and then some to what Dr. Cox asked. As you 17 know, for pivotal drug trials, pretty much they top 18 out in terms of age at 58, 60. 19 DR. EGGERS: Yes. 20 MR. TIETZ: And most folks in ARV drug 21 trials are otherwise, generally speaking, healthy, 22 say, for their HIV disease, yet the people who are</p>	77	<p>1 why are women less adherent? I mean, we found that 2 again and again in some of these big prep studies that 3 women just for whatever reason don't seem -- you know, 4 it's the mother thing or whatever, just aren't 5 adherent to drugs as well as men are. So I think 6 there is a lot on the research end that needs to be 7 looked at in terms of if we're going to talk about 8 more effective drugs, we need to talk about targeting 9 populations in those studies as well. 10 DR. EGGERS: Okay. Then I'm going to 11 propose that we ask, when we come back, we'll revisit 12 this topic thinking about not just what an ideal 13 treatment would be but maybe what an ideal treatment 14 study will be, which I think will be a great prelude 15 for the afternoon discussion when we think about HIV 16 cure research. 17 So I want to thank you all. We'll come back 18 after a 15-minute break, so at 11:15, and we'll resume 19 the discussion just like we're having. Okay? 20 (Whereupon, a brief recess was taken.) Panel 21 #1 Comments on Question 4 - 5 Large-Group Facilitated 22 Discussion on Questions 4 - 5</p>

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78	<p>1 DR. EGGERS: Okay, if we can again work our 2 way up, we'll get started. And you can feel free to 3 if you, of course, need to leave or head out of the 4 room at any time, this is, as you can see, a very open 5 discussion and very free flowing. 6 So we want to continue on what we talked 7 about before the break, there were some very good 8 points, and my FDA colleagues have given me some 9 really good follow-up questions to probe a bit more 10 into particularly managing the complex decisions that 11 you have to make when managing your multiple 12 conditions, including HIV. And so we'll probe into 13 that in a little bit. 14 But, first, we did have a series of 15 questions that we wanted to get from our panel 16 discussions to set a foundation for moving into a 17 discussion as well in this before lunch period that 18 really talks about any conditions or any symptoms that 19 are the most significant or conditions that you 20 believe are associated with HIV infection that really 21 have the most significant impact on your life. And we 22 heard earlier the range of things, you know, the range</p>	80
79	<p>1 of conditions, but maybe just now focusing on, what's 2 life like trying to manage all these conditions, and 3 how does that impact life? 4 So I think I'm going to put the panel 5 members back on the spot, and if you have any comments 6 that you want to present to start the discussion, we, 7 of course, will revisit them. Then we'll do that. 8 Should we start again with David, or would you -- 9 okay. Why don't we start and we'll talk about the 10 pediatric point of view with Catherine, and then we'll 11 move our way this way. 12 MS. CONNOR: Thanks. You know, looking at 13 the questions again, I feel like I'm making an excuse, 14 but it's sort of difficult because of the wide range 15 of the age population I'm talking about, but a lot of 16 it has to do again with managing or the significance 17 of the symptoms, you know, age, disease state really 18 matter? 19 I think, you know, across the board when we 20 talk to our families and our kids and, again, remember 21 the population we're talking about, I think nausea 22 really is a factor. And, again, I keep putting this</p>	81

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82	<p>1 to kind of get used to it and to take them regularly. 2 But, again, so it's sort of interesting that you have 3 to kind of think about the easy administration when 4 you work with the younger population. 5 DR. EGGERS: Can I ask a follow-up question? 6 You mentioned earlier about the night terrors. And 7 can you expand upon that a little bit and maybe what 8 degree that's felt, that's experienced, in the 9 population that you're familiar with and how it 10 affects? 11 MS. CONNOR: I hesitate to only because the 12 stories are very personal and they're also told by 13 people who could tell it better than I can. But, no, 14 I think it is something that happens frequently. And 15 one of our ambassadors, it started when he was young 16 and they continue to this day, and he's almost 30 now. 17 But there are the sort of -- and they just wake up -- 18 I mean, I can't describe a night terror any better 19 than anybody else, but, no, it shakes them, and it's 20 hard for them to understand it's part of their 21 condition and part of the medicine they're taking. 22 It's a bad dream, and it's a very bad dream, and if</p>	84	<p>1 components of a cocktail and not the third. But night 2 terrors. 3 And my worst thing is even after -- I'm 4 postmenopausal, and so I had the hot flashes and night 5 sweats, but several of my conditions have those, so 6 it's compounded, so at any moment I can feel like I'm 7 going to just burst into flames and disintegrate, and 8 then not long after be so cold to the bone that there 9 isn't enough heat or blankets or clothes that I can 10 put on to be warm, and there is no rhyme or reason to 11 that. And so that's the worst thing for me. And then, 12 you know, add my seizure syndrome and brain surgery 13 and all that, I can't drive, so that's one element of 14 mobility. And then I have balance issues because with 15 the trauma to my head, I have ringing in the ears, 16 whooshing and pulsating and whatnot, and I have 17 vertigo. 18 MS. REESE: So those things are the worst 19 things for me. 20 DR. EGGERS: Okay. Joe, would you like to 21 follow up? 22 MR. JEFFERSON: As I said at the outset, I'm</p>
83	<p>1 you had that regularly, there are some of our patients 2 that we've worked with who it could be a deciding 3 factor on going off of medication because it is so 4 traumatic for that age group. But as far as the 5 specificity, I probably can't speak to that very well. 6 DR. EGGERS: Okay. Well, that was very 7 helpful. Thanks. 8 MS. REESE: Can I say something about that? 9 DR. EGGERS: Sure. 10 MS. REESE: Night terrors and bad dreams, 11 Sustiva, anything with Sustiva in it, it goes across 12 the age spectrum because people refuse -- it's 4-D, 5- 13 D, you know the impact of 3-D, the vividness and the 14 strangeness of how things -- you're -- Atripla has 15 Sustiva in it, and they said, well, after a while it 16 would diminish. It doesn't. I have them. But I've 17 also been programmed from birth to take medicines 18 regardless because you want to live and experience 19 life. So that wouldn't be an excuse for me, but I 20 know a lot of people who had to stop that or stopped 21 it and didn't tell their provider, especially when it 22 was a separate pill. They would take two of their</p>	85	<p>1 so boring, I don't have a lot of these problems, and 2 so I don't take it for granted, and I recognize the 3 challenges. 4 UNIDENTIFIED MALE SPEAKER: That's great. 5 MR. JEFFERSON: Yeah. And so certainly I'm 6 aware of the science, I know what's coming, and I'm 7 concerned about that. I suppose my public health 8 orientation keeps pointing me to sort of the 9 structural problems. I mean, we can sort of get at 10 what's good about medicine applied optimally, but I 11 think we have to think cross-departmentally in the 12 bureaucracy about, what are FDA's specific 13 responsibilities to address this whole adherence 14 question? There are many other bureaus within HHS 15 that have a foothold in this certainly, and we in the 16 advocacy world as well, as well as those of us who 17 want to sort of empower a more robust consumer 18 accountability sort of philosophy, so there are a lot 19 of moving parts here, but I think we have to sort of 20 ask ourselves, what is it that's holding folks back 21 even if the medication on their shelf is good and can 22 work?</p>

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86	<p>1 You know, we just finished a survey of 2 consumers, an HIV survey, and we found that though 3 it's a bit skewed because we find that most of the 4 respondents are fairly seasoned consumers who are 5 relatively good at self-care, but even among that 6 population, 95 percent of them say they're on 7 treatment, and only 60 percent of them self-report as 8 being adherent, and this is a very good sort of 9 population in terms of self-care. So if it's 40 10 percent, almost half, of them are not adherent, you 11 know, that speaks volumes about the larger population 12 of folks that are -- and this is just HIV, we're not 13 even talking about all the other meds. So I just 14 think that the whole system has to work more 15 collaboratively to really come up with some 16 interventions to get people to pick up the bottles and 17 take the pills. 18 DR. EGGERS: Thanks, Joe. 19 David, would you like to provide any 20 comments? 21 MR. BRAKEBILL: Yeah, I think in terms of 22 the side effects that probably most impact my daily</p>	88	<p>1 night sweats. You know, the primary driver -- and I 2 think this goes back to a lot of the research that's 3 come out in the past years -- is the whole situation 4 of inflammation and, how do we control that constant 5 revving of the immune system that seems to put people 6 at risk? We know inflammation is the number one cause 7 of heart disease, which we see presenting more and 8 more in older folks with HIV at earlier ages. 9 So probably -- and the other sort of fatigue 10 thing is only being able to sleep 4 or 5 hours at 11 night and then having to take a 2- or 3-hour nap in 12 the afternoon, so that my clock is sort of constantly 13 in flux. 14 So those are the kinds of things that sort 15 of keep folks who -- you know, I'm sort of one of 16 those people who has been on disability for a long 17 time because at the time that -- that was what 18 happened. You know, people were diagnosed with AIDS, 19 you went on disability, so there is sort of that 20 dynamic plays out in the HIV community as well about 21 those disability people and, "Why do I still have to 22 work?" sort of mentality.</p>
87	<p>1 living, probably number one on the list would be 2 peripheral neuropathy. You know, when you're trimming 3 your toenails and realize that you've cut your toe 4 because you can't feel where the clippers are going, 5 and there aren't really, in my experience, a lot of 6 really good treatments on the market for that that are 7 labeled for use in people with HIV, let's put it that 8 way, and so I think the FDA probably could look at 9 some of the treatments that are available for, say, 10 people with diabetes that are approved for diabetes 11 treatment for neuropathy but aren't necessarily 12 approved for HIV. I know that in my experience there 13 are doctors prescribing Lyrica for that condition, and 14 it is working in some patients. 15 Probably secondarily to that, fatigue. Some 16 days I get up and I can conquer the world and do 500 17 reps of 500 sets of exercises at the gym, and some 18 days I just want to lay on the couch, and I never know 19 when that's going to be. And, again, is it HIV? Is 20 it the meds? I think the jury is still out on that. 21 Probably third, I think not a real common 22 occurrence anymore, but I still get the occasional</p>	89	<p>1 So I often think that I would like to be 2 productive again, but then when I have one of those 3 days where I can't make it quite through the day, I 4 go, "How can I hold an 8-hour job?" 5 And I think the other dynamic that has to be 6 continued to look at in research and in terms of 7 medications, too, is we know that depending on your 8 nadir in terms of your T cell count and/or your viral 9 load, you know, how high your viral load once was or 10 how low your T cells went, that outcomes are different 11 for people. So success in viral suppression and 12 things like that are a lot dependent on where you 13 started treatment. So that also needs to be 14 considered in terms of, can we find more effective 15 treatments for people who have an AIDS diagnosis 16 versus people who simply are HIV-positive? Because we 17 tend to have better outcomes with people who have 18 never experienced an AIDS diagnosis, and I think that 19 while there has been some study, I think there 20 probably are some, at least on the genetic side, maybe 21 as to why more people are more predisposed to 22 developing AIDS and the more long-term progressives.</p>

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90	<p>1 So I think those are sort of the things that</p> <p>2 were probably in terms of -- are you ready to move</p> <p>3 forward with the next question in terms of the</p> <p>4 complete cure?</p> <p>5 DR. EGGERS: Well, let's wait on that ideal</p> <p>6 question, and first let me see if my colleagues want</p> <p>7 to follow up on any of the symptoms that they've</p> <p>8 heard.</p> <p>9 Yes, Ilan.</p> <p>10 DR. IRONY: Yeah. I wanted to follow up on</p> <p>11 something that David just touched upon, but Matt and</p> <p>12 Wanda also alluded to, which is the immunologic non-</p> <p>13 responders, people that have virologic suppression or</p> <p>14 undetectable viral load but have no rebound of CD4</p> <p>15 counts. And since the topic here is about symptoms or</p> <p>16 concerns related to a particular lab finding, I wanted</p> <p>17 to know what kind of impact this has either as type of</p> <p>18 symptoms, of not having an immunological rebound, or</p> <p>19 concerns about this.</p> <p>20 DR. EGGERS: Okay. So the impact of the</p> <p>21 viral load? Is that essentially what the --</p> <p>22 DR. IRONY: The immunologic non-response.</p>	92
91	<p>1 DR. EGGERS: The immunological non-response.</p> <p>2 Can you tell? In other words, can you tell or does</p> <p>3 that have any impact on your life as you experience</p> <p>4 it?</p> <p>5 David, do you want to go -- oh.</p> <p>6 MR. BRAKEBILL: I think anybody that --</p> <p>7 DR. EGGERS: Let's give Wanda a chance</p> <p>8 because she hasn't had too much, so if we could bring</p> <p>9 a mic up to her, and then we'll come to David.</p> <p>10 Oop, I don't think it's on yet.</p> <p>11 UNIDENTIFIED MALE SPEAKER: Here you go.</p> <p>12 Try this one.</p> <p>13 MS. COMMANDER: Okay. I wanted to say</p> <p>14 something about the CD4 count, about it being so low.</p> <p>15 Physically, I feel as though I have to pace myself all</p> <p>16 the time now. I'm vulnerable because with a low CD4</p> <p>17 count and me not being able to take certain</p> <p>18 medications for preventative measures, I had hep C</p> <p>19 real bad, so a lot of things went on with me that</p> <p>20 cause me to take it one day at a time now. It allows</p> <p>21 me to be grateful for whatever rest I get now. I'm</p> <p>22 thankful for the medicines that I do take because</p>	93

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94	<p>1 have been studies that indicate that.</p> <p>2 But I think really this goes back to the</p> <p>3 whole epidemic and it's a lot of stuff that's outside</p> <p>4 of the purview of just the FDA, but in terms of, you</p> <p>5 know, we continue to see 50,000 new infections a year,</p> <p>6 we continue to see younger people infected, we</p> <p>7 continue to see all these things that, you know, it's</p> <p>8 just frustrating as a person living with the disease.</p> <p>9 You know, vaccine studies, you know, takes us 30, 60,</p> <p>10 90 years sometimes to develop a vaccine. You know,</p> <p>11 it's just frustrating that science doesn't move as</p> <p>12 quickly as we want it to, and I'm sure that happens to</p> <p>13 you guys all the time.</p> <p>14 But I think a lot of it in terms of how</p> <p>15 people get over -- you know, it's really about the</p> <p>16 individual and how they deal with their diagnosis. A</p> <p>17 lot of it is psychosocial support. You know, in a lot</p> <p>18 of the comments today I continue to hear, although I</p> <p>19 haven't heard the word "stigma" around taking</p> <p>20 medications, around disclosure, around everything. So</p> <p>21 I think that still -- I don't know -- I mean, we've</p> <p>22 been talking about stigma for 32, 30 years now into</p>	96
95	<p>1 the epidemic, and we're still talking about it. So I</p> <p>2 think that's a lot of the frustration for people</p> <p>3 living with HIV, is, you know, it's been 30 years, you</p> <p>4 know, but we've been studying cancer for hundreds of</p> <p>5 years probably now, those kinds of things.</p> <p>6 So I think that certainly there are</p> <p>7 advantages to people, depending on where you're</p> <p>8 diagnosed in the disease progression, and I think it's</p> <p>9 been proven that outcomes are better for people who</p> <p>10 have never fallen below 200 T cells, for example, or</p> <p>11 haven't had viral loads above a million. And I don't</p> <p>12 know what the answer is to stop all of that or improve</p> <p>13 all that except that, you know, trying to get people</p> <p>14 and engage them in care. Hopefully in states --</p> <p>15 unfortunately, mine is not one of them -- that have</p> <p>16 chosen to expand their Medicaid programs and we'll see</p> <p>17 more people have access to care and get into care and</p> <p>18 probably try to solve some of this.</p> <p>19 DR. EGGERS: Thank you, David.</p> <p>20 So Debra asked me a question at the break,</p> <p>21 and I'm going to ask it as a follow-up question here,</p> <p>22 and it ties to what Wanda said, it's tied to what</p>	97

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98	<p>1 know I had them, because I wasn't going to the doctor, 2 but I'm able to manage my HIV very well. 3 And I was listening, I don't know how many 4 people that I know, and I don't do it, some days I do 5 miss my medicine, that's just me, but as far as it 6 being manageable, yes, my HIV is manageable, to the 7 place that when I go see my primary and we discuss 8 some of my other conditions, my HIV is not at the 9 forefront of our conversation. When I go see my 10 infectious disease doctor, my HIV is not the primary 11 conversation. So I take that that it's manageable. 12 My T cells are superb from when they were 13 single digits in 1996. I'm like over 1,000 now, but I 14 understand why, because all my T cells are not valid. 15 My viral load is not fully undetectable. It's low, 16 but HIV is not physically affecting me as much as it 17 does some days mentally being concerned about, will I 18 continue to keep insurance? If I happen to lose my 19 job, will I be able to manage my lifestyle? Will any 20 of the opportunistic infections reoccur if I don't 21 take my medicine? 22 So it's other things that play into, and you</p>	100
99	<p>1 can't look at HIV from just a physical standpoint. 2 Melanie just spoke to that. You've got to address HIV 3 in the realm of a person's mental capacity, what the 4 emotional and spiritual support they have, and how 5 physical they are. I heard David talk about how he 6 can go to the gym. I don't trick myself. I ain't 7 going to the gym. I do a lot of walking. That's my 8 exercise. And I commend people that can go to the gym 9 and do all that, but I had to learn how to fit my life 10 where it best suit me for the information I have at 11 that time. 12 Melanie just talked about how, you know, the 13 stigma -- David just talked about how the stigma is 14 still happening, it is, but why is it happening? Why 15 aren't people listening to the facts? If you're 16 having unprotected sex, you use protection and you 17 won't have it. I tell people all the time, guys, 18 women, if you're going to have unprotected sex, the 19 quickest way to let somebody put on a condom is tell 20 them, "I like you, I want to have sex with you, but I 21 don't want no babies." 22 DR. EGGERS: That's a good point.</p>	101
100	<p>1 MR. SCRUGGS: Yeah, but my -- different 2 people it's manageable with. 3 Different people, they do manage their HIV, 4 and it comes not just from a physical point. And it 5 has to be looked at in threefold. 6 DR. EGGERS: Thank you, Nathaniel. 7 We have another comment. Matt Sharp? 8 MR. SHARP: Just what about chronic 9 inflammation? That's been brought up already. You 10 know, this may be considered a chronic manageable 11 disease, but what I worry about and what many people 12 are worried about as we grow older is the inflammation 13 that has not been controlled by antiretroviral 14 medications. Certainly, we know that it's controlled 15 to a point, but there is still that low level 16 inflammation and consideration of what may happen in 17 terms of heart disease, bones. 18 And then the second thing I wanted to bring 19 up is like cumulative effect of medications, that 20 toxicities cumulatively, what is the long-term effect? 21 We haven't really talked a lot about that today. And 22 I don't think we know, and we won't know until we get</p>	102
101	<p>1 further into the epidemic, but what's the cumulative 2 effect on organs? is one of the big things that is 3 being focused on today. 4 DR. EGGERS: Okay. Go ahead, Joe. 5 MR. JEFFERSON: I just wanted to also point 6 at two things. I think it's important to distinguish 7 are we distinguishing between a manageable disease and 8 a clinical -- under a clinical sort of rigor in terms 9 of lifestyle and sort of other comorbidities? Because 10 I think if one has their HIV in check and yet the HIV 11 is the precursor to all of these other conditions, is 12 HIV actually a manageable condition? I don't know. 13 I'm also concerned about the impact that the 14 whole messaging of a manageable chronic disease sort 15 of portends for the prevention efforts that we're all 16 engaged in because we, I think, know that for those 17 who are infected, they might hear that and think that, 18 again, "I'll deal with it when it's a problem, I don't 19 have to take meds until that time," or for those who 20 are not infected, of course, it diminishes a sense of 21 urgency around practicing safe sex. I think from a 22 research standpoint also it may sort of turn the dial</p>	103

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102	<p>1 down on the sort of volume of urgency because now we 2 can move to another disease state that maybe isn't 3 manageable because we've now got HIV in -- we can 4 check that box and move on. So I'm concerned about us 5 locating too much emphasis on this notion of 6 manageable disease. 7 DR. EGGERS: Thank you very much. 8 I want to make sure that we get to the 9 ideal, not cure, the ideal treatment question, and I'm 10 going to broaden, like I said before the break. 11 Actually, can we go back to the presentation slides 12 and not the question slide anymore? Yeah, thank you. 13 Because we'll close before we let my FDA colleagues 14 speak, really getting your final thoughts on what 15 major improvements could be made for future treatments 16 to help manage your condition, and we'll include in 17 that if you want to comment on the research studies to 18 help foster to those treatments. 19 Theresa, do you want to follow up? 20 21 DR. MULLIN: Yes. Maybe before we go on, I 22 would like to just follow up with something that David</p>	104	<p>1 have been there for years, but if you live in 2 Marathon, 50 miles up the road or up the Keys, your 3 doctor comes and sees you once a month. If you live 4 in Sebring, which is smack-dab in the middle of the 5 state, there is a nice health department that offers 6 lots of HIV care, but specialty care? You know, 7 unless they find something therapeutic in gator 8 hunting, there is probably not much to be offered 9 there. 10 So I think that as the model moves, I think 11 there is going to be less and less available in terms 12 of even in the larger metropolitan areas. I know 13 they're already feeling the pinch of reduction in Ryan 14 White funding, but it's just not something that's 15 available, widely available. Personally, I believe in 16 it, I think it helps a lot. We actually have written 17 a small grant for massage therapy. You get a 18 prescription from the doctor, we have a volunteer 19 massage therapist that comes in and gives you a 30- 20 minute massage once a month or whatever. So there are 21 ways to work it, but it's just not something that's 22 available, widely available, to people, and it's just</p>
103	<p>1 said in the beginning. And you were mentioning that a 2 big challenge was access to alternative therapies, and 3 I wonder if you could say more about what you had in 4 mind with alternative therapies. 5 MR. BRAKEBILL: Well, let me qualify this by 6 saying that in many cases, particularly if you live in 7 a larger metropolitan area, I'm speaking particularly 8 of the coasts on either side, because of the large 9 amount of money that tends to flow to the bigger 10 cities in the epidemic, there is much more money 11 available for those sort of auxiliary things like 12 massage therapy and acupuncture and acupressure and 13 seeing an herbalist and those non-traditional medicine 14 sorts of things. If you're living in the rural South, 15 you're lucky if you don't have to drive 200 miles to 16 see a doctor to have your HIV treated. 17 So the health disparities that continue to - 18 - I live in Florida, I live in Key West, it was the 19 epicenter of the epidemic. Fortunately, it's the kind 20 of community that sort of rallied around and we own 21 and operate 98 units of housing for people living with 22 HIV, we have three great HIV specialists there that</p>	105	<p>1 not accessible. And again, this goes to our whole 2 system of care and how it works and whether you live 3 in a big city or whether you live in rural America, if 4 you live in the Northeast or you live in the South. 5 So until we sort of fix a lot of things that are 6 broken about how health care is administered and 7 delivered in this country, I think we will continue to 8 see health disparities, you know, across disease 9 states depending on where you live. You know, it's 10 economics, it's everything. 11 DR. EGGERS: Thanks, David. 12 Yes, Ilan has a question? 13 DR. IRONY: I just want to follow up with 14 what David was saying, that the same kind of health 15 disparities we see in medical care we also see in 16 clinical trials. We always want, in particular, for 17 Phase III trials when it gets to the end of the 18 preapproval development of a product to have 19 participation of as many people as possible to reflect 20 the real world use of that particular product, but 21 sometimes access is a problem, access to clinical 22 trial sites. If you live in rural Florida, for</p>

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106	<p>1 example, it's difficult, so it's not going to reflect 2 older people or female because of different schedule 3 obligations to have participation in clinical trials 4 that sometimes are demanding in terms of travel or 5 cost, et cetera. So we see that reflected in what the 6 studies show even though we try to extrapolate as much 7 as possible to the real use population. 8 DR. EGGERS: Thank you. Well, that's a 9 great segue. Let me ask if anyone wants to follow up 10 on what they said this morning about clinical trials 11 and other improvements that you have. 12 Yeah. 13 MR. TIETZ: Yeah, I think one of the other 14 things that comes up increasingly, and not necessarily 15 with folks who are older with HIV, although I think 16 mostly, and it's the folks who are highly treatment 17 experience, and the real challenge I think is the 18 narrowing of the antiretroviral drug pipeline. There 19 are in the last few years been a few drugs that have 20 been pulled from development by the companies that 21 were developing them I think mostly because they 22 thought that they were too much of a look-alike or me-</p>	108	
107	<p>1 too drug and they wouldn't capture enough market share 2 or they wouldn't make enough money on it, and so end 3 of development. 4 But, you know, there is probably, you know, 5 what, 10 percent? It's hard to know exactly, no one 6 tracks the folks who are resistant to four, five, and 7 six classes of drugs that are currently available, and 8 for them, the absence of many drugs in the pipeline is 9 frankly scary, they're running out of options. 10 They're never nondetectable anymore. Clinicians 11 across the country who have been at this practice for 12 a long time, have these highly experienced folks, and 13 it's that each of them are sort of waiting for that 14 day when their viral load spikes and there is nothing 15 more to be done, and so I think that's a real worry. 16 And I realize that the FDA isn't exactly in 17 the position of developing drugs, they're in the 18 position of approving drugs developed by others, but I 19 think in some instances you may need to look at ways 20 of taking some of those drugs that pharma has declined 21 to finish development on and finish it. 22 DR. EGGERS: Any other comments?</p>	<p>1 MR. BRAKEBILL: And to see the progress that 2 we made in HCV. I mean, virtually now HCV is curable 3 with drugs that have been developed just within the 4 past few years. So I think that there is stuff out 5 there, and I think part of the incentive for the 6 pharmaceutical industry is to follow whatever disease 7 they see the most money in. 8 DR. EGGERS: Melanie, did you have something 9 to add? Oh, put your mic on. 10 MS. REESE: You know, osteoporosis and some 11 other diseases, they have like either a once-a-month 12 or twice-a-year dosing to control. Why can't we get 13 to that with HIV since it's a disease that can easily 14 be transmitted if you are careless? 15 And another thing I wanted to say is we do a 16 lot of work with prevention and we're really going to 17 have to pay attention to the cascade to develop new 18 prevention techniques, but there are people who don't 19 realize that just because that person has HIV and this 20 person has HIV, oh, wow, throw all the stuff away. 21 They can get a different strain of HIV. Prevention 22 among positives, did it go out the window? I don't</p>	109

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110	<p>1 hear about that, but I think to the extent that we can 2 start to narrow the quantity of pills folks take that 3 are dealing with multiple conditions and reduce the 4 frequency, I think we start to address the adherence 5 question. 6 DR. EGGERS: Catherine, would you like to 7 give any final words from the pediatric perspective? 8 MS. CONNOR: I really sort of made the 9 comment before. I mean, administration is always 10 something that we really worry about because our 11 populations are younger ones, you know, you have to 12 use the liquid syrups, or sprinkles are a big thing, 13 in the developing world. 14 But also I would just be remiss if I didn't 15 mention sort of the research lag time for pediatric 16 drugs. A lot of the reasons it happens is very 17 justifiable, but there is still a very long lag time 18 between when adult ARVs are available for the younger 19 populations, particularly the neonatal populations, 20 which, again, may not be as much an issue in the 21 United States but globally is a big issue. So I 22 always sort of encourage folks in FDA to sort of</p>	112	<p>1 their comments on this most recent topic that we've 2 been discussing. We do recognize that the pipeline 3 for HIV drugs is not as great as it used to be, and 4 that's why we're happy to have not only our 5 participants here today to state the obvious, but also 6 industry here so they can hear that there is still a 7 need to develop drugs for HIV, new drugs, and drugs 8 for salvage populations as well. So we appreciate all 9 of your comments. Thank you. 10 DR. EGGERS: Thank you. 11 And with that, that is a great way, I think, 12 to end the morning discussion. We're going to save 13 some time for the FDA to give comments and questions. 14 Did you want to say something? 15 DR. BIRNKRANT: Now? 16 DR. EGGERS: Let me just say one thing, 17 because there are a few things that we didn't get to 18 cover today, and so you have homework. Those of you 19 in person and those of you listening to the webcast, 20 we didn't get to talk about as much the decisions 21 about how you change medications and why you change 22 medications and how you choose to go to a combination</p>
111	<p>1 remember that there is this lag time for our 2 population with the banded age group studies. 3 DR. EGGERS: Great. Any final comments? 4 Matt? 5 MR. SHARP: Hello. So we're going to talk 6 about this, this afternoon, obviously, but even before 7 we get to talking about a cure, there is a step before 8 that called a functional cure, which is using the host 9 response to treat HIV basically without medication. 10 So I think we'll talk about that this afternoon, I'm 11 sure. 12 But then the other thing I wanted to bring 13 up is, you know, I am passionate about the salvage 14 population because I was a salvage patient for so many 15 years, and I know that that population has certainly 16 decreased because of the effect of great 17 antiretroviral drugs, but there are still people out 18 there who fall into that category that we need to 19 remember. 20 DR. EGGERS: All right. 21 Yes, Deb. 22 DR. BIRNKRANT: I want to thank everyone for</p>	113	<p>1 therapy and why you choose to go to a one pill once a 2 day, or if you decided not to, why that, too? And so 3 I really encourage you to go to the docket and follow 4 up with what you've said here and address that topic 5 and address more the symptoms that you experience and 6 the other conditions that you attribute to your HIV 7 infection and explain more about those. So you heard 8 David and Melanie, for example, talk about -- oh, help 9 me out with the -- 10 MS. REESE: Peripheral neuropathy? 11 DR. EGGERS: Yes -- and the night terrors 12 and the night sweats and the fatigue, follow up on 13 those and provide your experiences to that. 14 Discussion with FDA Panel 15 With that, I will turn it over for a few minutes. We 16 are going to lunch in about 10 minutes, but I want to 17 see if any of my FDA colleagues want to follow up on 18 anything else that they've heard and if -- well, we'll 19 see how long we go with that, if you want to follow 20 up. Maybe we might have time for a question from the 21 patients. 22 Go ahead, Deb.</p>

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114	<p>1 DR. BIRNKRANT: Thank you. I wanted to 2 follow up on something David had said earlier about 3 fear of switching regimens if you're controlled with 4 your viral load. I was wondering what other panel 5 members thought and if David could elaborate a little 6 more on that topic. So, in other words, if you're 7 well-controlled on a regimen that may be a little more 8 complex, how willing are you to switch just because a 9 regimen may be somewhat easier? So do you still have 10 concerns about switching even though perhaps it may be 11 a little easier to adhere going from a few pills a day 12 to one pill a day? Is that something that would be 13 attractive to you and would make your lives more 14 manageable?</p> <p>15 MR. JEFFERSON: I'll jump in. I've given 16 that some thought. I take three pills at night. I 17 think there are four or five compounds in those 18 treatments, and, of course, it would be great to take 19 a pill, but this regimen is working, it has been 20 working for 7, 8 years. No, I wouldn't make the 21 switch to a single dosage, a single pill dosage, if it 22 meant changing the regimen. I would prefer instead</p>	116	<p>1 sort of convinced me was my blood sugar was starting 2 elevate, so we did a fasting glucose and the doctor 3 says, you know, really this is better.</p> <p>4 But I think, you know, the whole point is to 5 get your virus suppressed, get it undetectable, so as 6 a person living with it, you've met that goal, and so 7 fear of change I think for everybody regardless 8 whether it's a disease state or just fear of change in 9 general, people, by their nature, are sort of 10 resistant to that.</p> <p>11 Would I go to a once-a-day pill? I don't 12 know. You know, 80 percent of our regimens have 13 Truvada in them now, which makes me nervous about 14 using Truvada for prep, that's just a personal thing. 15 It concerns me a little bit. But I have to say that 16 for me, I'm a creature of habit, so taking three or 17 four pills at a time, you know, my partner looks at me 18 and says, "How can you take all those pills at once?" 19 and he says, "I can barely get one down at a time." I 20 said, you know, when you're taking 12, you know, you 21 learn. And so for me, at some point in time maybe. 22 For me right now where I am, it's sort of like the</p>
115	<p>1 for there to be -- and this gets back to drug 2 development -- some means by which whatever 3 combination one happens to be taking that's working 4 for them -- this is a little pipe dream, pipe dream 5 for the pipeline -- is how about a more tailored sort 6 of capacity to put together the meds I am taking into 7 one pill at some point in the future?</p> <p>8 MS. REESE: Well, for me, since I have so 9 many other conditions, opportunity to change would 10 have to go through all the other medications I take to 11 see if those would be impacted versus -- I'm only 12 taking one pill for HIV, which is a cocktail, but I 13 take 20 others for everything else I have, so, you 14 know, it's really like for me I would not change 15 unless it was a once-a- year.</p> <p>16 MR. BRAKEBILL: Well, I think for me, I 17 mean, the most recent change in my regimen was 18 Prezista going from 600 milligrams, two 600s to one 19 800 milligram, so it's one less pill, but for me, you 20 know, the whole thing about even switching from 21 Crixivan and Combivir, Crixivan, which is notorious 22 for buffalo humps and kidney problems, what finally</p>	117	<p>1 question about, would taking all these pills the rest 2 of your life -- you know, I don't know whether I'm 3 going to be 85 or 90 years old sitting in assisted 4 living having somebody force-feed me and giving me my 5 HIV meds. You know, at that point in time, I might 6 say forget it.</p> <p>7 MR. BRAKEBILL: But for me, it's not 8 something for right now I would do. I think it's 9 easier for physicians to prescribe now, particularly 10 newly infected, you know, it's only one pill once a 11 day. On the other hand, we still have the ads in the 12 magazines that show the guys climbing mountains, 13 which, you know, some of us who have been around a 14 while sort of push back on that when that happened, 15 that, oh, you can cure all of this by taking one pill.</p> <p>16 So the message is still that -- you know, 17 this goes back to the chronic disease, you don't get 18 diabetes from having unprotected sex with someone, you 19 don't get fibromyalgia, you don't get lupus from 20 having unprotected sex with someone, you do HIV. So I 21 think the fact that it's still communicable makes it a 22 little different than other chronic diseases for me.</p>

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118	<p>1 DR. EGGERS: Any of my other colleagues? 2 (No audible response.) 3 DR. EGGERS: We would probably have time if 4 there was one question or two questions for you to 5 answer on this topic. Is there any? 6 DR. CALDWELL: Hi. Thank you. My name is 7 Dr. Robert Caldwell, and about 15 years ago I was 8 involved in an HIV vaccine study. Well, it was a 9 collaboration between the NIH, Vanderbilt, and Chiron 10 Pharmaceuticals. And, sure enough, I got the 11 experimental. So when I get tested for HIV, like I 12 did last week, the ELISA comes back positive, the 13 Western blot and the PCR come back negative, and 14 that's been 15 years ago. 15 So my question is, if you look at breast 16 cancer and HER2 as antibody-based therapy and Provenge 17 as a prostate cancer-based therapy, why aren't there 18 currently any second-line drugs for HIV therapy? Is 19 there a higher standard or a higher bar set for 20 therapeutic HIV vaccines as a current treatment 21 option? 22 DR. WITTEN: I'm not sure exactly how to</p>	120	<p>1 we can give. 2 DR. EGGERS: Okay. So we have one question 3 here? 4 ROBERT: My first name is Robert. And I 5 have a question about hepatitis C and co-infection 6 with HIV, and I'm wondering why the FDA, and I think 7 it's about politics, why the FDA rushed when Anthony 8 Fauci was being pressured by AIDS activists to approve 9 drugs for HIV, and yet they're sorting of dragging 10 their feet, it seems to me, on hepatitis C infection. 11 There is a new drug coming available sometime in the 12 winter of 2013 that, you know, it's amazing, and I 13 don't remember the name of it, but there is not the 14 political pressure on the FDA, and you all don't seem 15 to be responding the way you did when Anthony Fauci 16 was being pressured by AIDS activists. So I'm 17 wondering if you could address that as well because I 18 do have cirrhosis of my liver, and I would like to get 19 it treated before it turns into liver cancer on the 20 hepatitis C. 21 DR. BIRNKRANT: Thank you for your comment. 22 We know that that patient population, the population</p>
119	<p>1 answer that. Your question is, why aren't there 2 therapeutic HIV vaccines? Is that the question? 3 DR. CALDWELL: Yes, ma'am. Why aren't there 4 more vaccines or perhaps pro-vaccine options in the 5 pipeline? Therapeutic vaccines, not preventative; I'm 6 speaking specifically to therapeutic. 7 DR. WITTEN: Okay, specifically to 8 therapeutic. I just think it's a very complex area, 9 and even the Provenge, which you are citing, was the 10 one vaccine that's been approved for a cancer 11 indication following several decades of efforts of 12 development in that cancer immunotherapy area. So I 13 think it's really just a matter of it being a 14 complicated effort. We certainly meet with sponsors 15 or researchers who are interested in developing 16 products, and we would like to see this area move 17 along, but I think it's just a matter of the science 18 and the technical issues involved. 19 Did you have a more specific question? 20 (No audible response.) 21 DR. WITTEN: I know that's not a very 22 satisfying answer, but that's probably the best answer</p>	121	<p>1 who are co-infected, is a very seriously ill 2 population. We also understand how difficult 3 sometimes it is to do trials in that population 4 because we first have to learn in the beginning 5 whether or not a drug is active, and then to allow a 6 population who is taking other medications, we have to 7 do drug-drug interaction studies, so that takes a bit 8 of time compared to a mono infected or a population 9 who only has HCV. 10 I will say that the urge and the enthusiasm 11 that the division had back in the '90s with the 12 protease inhibitors is there today as well for the new 13 hepatitis C treatments. One example of that is we 14 recently modified the endpoint in clinical trials to 15 shorten it by approximately 3 months to enable us to 16 get the therapies to patients even sooner, so we're 17 quite excited about that. 18 In addition, I will share with you, unlike 19 the HIV pipeline, the HCV pipeline is quite full, and 20 we have dedicated teams working on a multitude of 21 products, not only alone, that is, single products but 22 multiple products together in fixed dose combinations</p>

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122	<p>1 to be able again to take perhaps one pill once a day. 2 So I think you can be assured that we have 3 drugs in the pipeline and we have a team of scientists 4 and experts ready to do the review work that we've 5 done all along and will show you in the next few years 6 that there will be more drugs on the market for 7 hepatitis C. 8 Thank you very much for your question and 9 comment. 10 DR. EGGERS: Okay. Well, so one more, and 11 then it's time for lunch. 12 MR. TIETZ: I would just second that on the 13 HCV. In fact, you can see some drug companies have 14 moved almost their entire virology divisions to work 15 on HCV from HIV, but it raises the thing I mentioned 16 earlier, which is that it's all about the money, they 17 want to be first out the gate with some product, and 18 so it's narrowed the -- I mean, we're pleased with 19 what the FDA is doing and what industry is doing with 20 regard to HCV, but there has been some tradeoff there 21 as well. 22 I will also just note that I don't know if</p>	124	<p>1 and just summarize those as part of our afternoon 2 opening remarks. 3 With that, we will come back at 1:30 and we 4 will get started with our afternoon discussion then. 5 Thanks a lot. 6 (Whereupon, a lunch recess was taken.) 7 DR. EGGERS: Well, welcome back to the 8 afternoon session of the Public Meeting on HIV 9 Patient- Focused Drug Development and HIV Cure 10 Research. We had a great morning discussion, and we 11 look forward to a great afternoon discussion. For 12 those of you who are just joining us, my name is Sara 13 Eggers, and I am from CDER's Office of Strategic 14 Programs, and I will be facilitating much of the 15 discussion today. 16 Before we get to the discussion, we will 17 have a few welcome remarks, and then we'll set the 18 context for our discussion and some of my FDA 19 colleagues will present some background information. 20 And then we'll get into the discussion. I'll go over 21 a bit about the discussion format after that before we 22 do.</p>
123	<p>1 this can be fixed in the current regulatory scheme, it 2 may actually require action from Congress, but there 3 actually are a few drugs that are in development that 4 are long-acting. So, for example, Timed (ph) has a 5 monoclonal antibody that is in trials, injectable, 6 maybe every 2 weeks, maybe every month, that's still 7 being worked on, but they have a challenge in terms of 8 financing for finishing their clinical trials, and so 9 in the scheme that we have, that's their problem, not 10 your problem, and yet, you know, this goes on and on 11 and people wait and wait. 12 DR. EGGERS: Okay. So I think we are going 13 to stop to break for lunch. I do want to thank 14 sincerely the panelists who have been up here and have 15 shared their stories, and, as sincerely, thank those 16 of you in the audience. 17 On the web, I am going to suggest that if 18 you want to get some comments, if you have any 19 comments that you would like to put in through the 20 webcast in the next 15 minutes or so when we open up 21 in the afternoon discussion, we can see if there are 22 some things that we haven't heard yet in the morning</p>	125	<p>1 And with that, I would like to turn it over 2 to Dr. Janet Woodcock, who is the Center Director, for 3 a few comments. 4 Thank you, Dr. Woodcock. Afternoon Opening 5 Comments 6 DR. WOODCOCK: Thank you, Sara. And good 7 afternoon, everyone. It's great to see the folks who 8 have turned out for this meeting, and I hear there are 9 a lot of people on the web. That's fantastic. I 10 especially want to thank the HIV patients and patient 11 advocates for sharing your experiences and your 12 perspectives on this disease and on the therapies. 13 Today's meeting is part of an initiative 14 that we are running that is called Patient-Focused 15 Drug Development. We are quite excited about this. 16 Theresa Mullin gave an overview this morning, but I 17 would like to reiterate some of her points especially 18 since some of the folks were not actually able to be 19 here this morning. 20 As Theresa mentioned, Patient-Focused Drug 21 Development was an important aspect of the package for 22 the fifth authorization of the Prescription Drug User</p>

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126	<p>1 Fee Act, or PDUFA V, and it's an enhancement of our 2 current mechanism for getting patient input on 3 important issues regarding their diseases, which have 4 tended to generally focus on specific drug products, 5 and we want to focus more broadly on the disease 6 entity. 7 Patient-Focused Drug Development, therefore, 8 is a broader, more systematic method of obtaining 9 patients' perspectives on the severity of the 10 condition and its impact on daily life as well as 11 their perspective on the range of available treatment 12 options and the impacts for good and for ill of those 13 various treatment options. And we recognize that even 14 within a disease -- and in some diseases this is more 15 true than others -- there is a range of severity that 16 people are experiencing often from being relatively 17 well and functioning to suffering severe effects from 18 the disease or from the treatment in fact, and we want 19 to hear about that, we want to hear about the burden 20 of disease and the burden of therapy. 21 It's valuable for our drug review because it 22 helps provide the clinical context in which we</p>	128	<p>1 experience that. 2 But more broadly, we would like to have 3 outcome measures that we devise for benefit as well 4 that are really relevant to patients and patients feel 5 are the right outcome measures for that disease and 6 the burden of disease that they experience. 7 So this is an ambitious undertaking, I 8 think, and part of our commitment under PDUFA that we 9 made to Congress, we will convene at least 20 public 10 meetings over the next 5 years with each being focused 11 on a different and specific disease area. And today 12 is our second meeting within this initiative. 13 Our first meeting was on April 25th, and it 14 focused on chronic fatigue syndrome and myalgic 15 encephalomyelitis. It was, from our point of view, 16 very valuable, and that's a disease that really 17 doesn't have any approved treatments at all and has a 18 very profound effect on the most severely afflicted 19 people. We received a lot of positive feedback from 20 participants in the patient community who attended 21 that meeting, they felt it was very helpful, and in 22 that disease we're really seeking to attract drug</p>
127	<p>1 evaluate new treatments because we don't do that in a 2 vacuum. We say they're safe and effective but really 3 mean the benefits of a new treatment outweigh the 4 risks, and therefore you have to understand the 5 disease, its risks, and the effect of the current 6 treatments and really do that I think partly from the 7 patients' point of view as well as from the medical 8 point of view. 9 Patient input can help drug development's 10 efforts more broadly also by highlighting where new 11 types of outcome measures are needed to help make sure 12 that new therapies treat the symptoms that most matter 13 to patients or they avoid side effects that are most 14 important to patients. And often we don't put all of 15 these outcome measures in the trials, so we may not 16 know about certain important impacts on patients. For 17 example, for many diseases, we have never learned 18 anything about impact on sexual function of some of 19 the treatments for various diseases, and some 20 therapies have very profound impact on sexual 21 function, and if you don't ask about that and record 22 it, then you never learn, and people simply have to</p>	129	<p>1 development and understand what outcome measures would 2 be most appropriate in that disorder. 3 This morning's discussion here focused on 4 the most significant symptoms associated with HIV 5 infection or its treatment and what impact it has on 6 daily life. We also heard your perspective on the 7 currently available therapies to treat HIV. This 8 afternoon's discussion is a bit different, and I think 9 each meeting we have will have different flavor. It 10 will focus on some important issues with respect to 11 cure research studies. 12 In the past, HIV cure did not seem possible, 13 but today researchers are looking at new ways to 14 either clear HIV from the body or control the virus 15 without the need for antiretroviral therapies. One of 16 my colleagues is going to provide more background on 17 what we mean by "cure research," but understanding the 18 patient's perspective on the potential benefits and 19 risks of participating in HIV cure research studies 20 will help FDA evaluate drug sponsors' protocols for 21 clinical trials and their informed consent procedures. 22 So this is very exciting I think for HIV and</p>

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130	<p>1 shows that in this disorder we're in a more advanced 2 state of treatment, say, than we are with, say, 3 chronic fatigue syndrome, where we really don't even 4 understand the etiology and we have no available 5 treatments.</p> <p>6 So thank you again for your valuable time 7 and input on HIV symptoms, currently available 8 therapies, and I wish you luck this afternoon. I hope 9 we have a very good discussion on both the ethics and 10 the feasibility and desirability of HIV cure research.</p> <p>11 Thank you very much.</p> <p>12 Summary of Morning Discussion</p> <p>13 MR. KLEIN: Thank you, Janet. And good 14 afternoon, everyone. My name is Richard Klein. I am 15 the Director of the Patient Liaison Program at FDA in 16 the Office of Health and Constituent Affairs, formerly 17 known as Office of Special Health Issues. And I just 18 wanted to do a brief overview of the main thoughts, at 19 least that I heard this morning, and try to summarize 20 what we heard.</p> <p>21 To me, one of the main issues that came up 22 and kept coming up was comorbidities, people dealing</p>	132	<p>1 and better adherence? And people were a little 2 reluctant to do that if they were successful; it's 3 kind of if it's not broke, don't fix it.</p> <p>4 Unanticipated consequences, I think people 5 were talking about hesitancy of changing drug regimens 6 also because of the fear of switching regimens and 7 then using up something that would have been a future 8 option for you to use, and so people didn't really 9 feel comfortable with the idea of burning through 10 different classes of drugs. So changing regimens is a 11 difficult decision that people were dealing with, and 12 that question about using up scarce options for 13 future.</p> <p>14 Whether HIV is a manageable condition was a 15 question that came up and that differed from person to 16 person depending on whether or not you thought that 17 the problems that you were having related to your 18 therapy and to your HIV were part of the question. So 19 if you could manage HIV but still had all these 20 adverse events from the drugs, was that a manageable 21 disease?</p> <p>22 I think we were pretty well reminded that</p>
131	<p>1 not only with HIV but with HIV's concomitant problems 2 and other diseases. So it had a lot of ramifications 3 that kept coming up through the morning, managing 4 hepatitis, managing hypertension, managing new drugs 5 and drug interactions. And drug interactions was I 6 think the second most common thought that kept arising 7 for me this morning, people dealing with multiple 8 drugs for multiple conditions and how to work those 9 drugs together and deal with the drug-drug 10 interactions and finding the right drug combinations.</p> <p>11 I think e-prescribing was raised as one 12 potential way to address those kind of problems.</p> <p>13 Could people have electronic records that would help 14 guide and prevent the use of drugs that shouldn't be 15 used together that are contraindicated or that had 16 drug-drug interactions?</p> <p>17 Adherence and ease of dosing was another 18 issue that came up this morning, and that led to 19 another question about challenges of changing meds. 20 Were people comfortable with simply changing meds when 21 you had a workable, successful therapy? Would people 22 be able to switch to something else for ease of use</p>	133	<p>1 stigma is still a problem, that people are worried 2 about diagnosis, talking about their HIV diagnosis, 3 talking about even being on therapy, and that stigma 4 remains a problem.</p> <p>5 And, finally, reminded about the fact of 6 transmissibility of HIV and whether or not being a 7 chronic but manageable disease could affect whether or 8 not people were going to be -- whether or not 9 prevention could be impacted by the ease or the 10 alleged ease of treating the disease and the question 11 about whether or not that could possibly undermine 12 prevention efforts.</p> <p>13 And I think those were the top issues that 14 had occurred to me this morning. I don't know if 15 other people had other points, but, if not, then we 16 want to shift gears for the afternoon and talk about 17 the future, about cure research and where that is, 18 where it's going. And for background on cure 19 research, I want to introduce the Chief of the General 20 Medicine Branch, Division of Clinical Evaluation and 21 Pharmacology/Toxicology at the Center for Biologics, 22 and his name is Ilan Irony. And with that, I'll turn</p>

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134	<p>1 it over. Background on HIV Cure Research 2 DR. IRONY: Hi. Good afternoon. Again, my 3 name is Ilan Irony. Thank you very much for the 4 introduction. And I am from CBER, the Center for 5 Biologics Evaluation and Research. And so this is an 6 outline of my brief introduction to the subject of HIV 7 cure research and this is the background. And so I'm 8 basically going to describe the FDA organization and 9 our particular place in the FDA organization, our 10 center and our office, talk about the strategies for 11 research that aim towards a cure of HIV infection. I 12 will talk a little bit about gene therapies as they 13 pertain to HIV cure research, which is part of what we 14 do in our office and our center, and then wrap up with 15 combination strategies, and the ideas and the 16 controversies in combination strategies in also HIV 17 cure research. 18 So first a word about the general FDA 19 organization. We are all under the Office of the 20 Commissioner of the FDA, and the list here contains a 21 list of the centers, each center is particularly 22 responsible for an area of human health or animal</p>	136
135	<p>1 health, but I wanted to emphasize the last three 2 centers here that pertain also to HIV, human health 3 related to HIV. So the Center for Devices and 4 Radiological Health, Center for Drug Evaluation and 5 Research, which you heard from representatives this 6 morning and from Dr. Woodcock. And in red here, the 7 last, the Center for Biologics Evaluation and 8 Research, where Dr. Witten and I here on the panel 9 work. 10 And within the CBER organization, there are 11 multiple offices that support the operations of the 12 center, but I also want to emphasize three offices 13 that pertain particular to HIV treatment and HIV 14 research, one of them being the Office of Blood 15 Research and Review, which regulates the blood supply 16 of the nation and tests for HIV, in vitro tests for 17 HIV; Office of Vaccines Research and Review, which 18 regulates the development of preventive vaccines for 19 HIV to prevent transmission of HIV. As we heard in 20 the morning, there was some discussion about the unmet 21 need in terms of having a vaccine, successful vaccine, 22 for HIV prevention. And finally in red here, in the</p>	137

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138	<p>1 of cure is either elimination or control of HIV 2 infection without further medical intervention to 3 maintain health.</p> <p>4 So what are the research strategies that we 5 have seen in development? One approach is in the 6 first bullet, is the shock and kill. Shock we define 7 as activation of the virus from reservoir from this 8 where it's latent, where the virus is sleeping, to be 9 awakened, to be manifested, and then followed by kill. 10 So clear the viruses from the body using both boosters 11 of the immune system plus an antiretroviral regimen 12 that's effective to clear the virus.</p> <p>13 Another approach would be the induction of 14 resistance to HIV infection, and that, in theory, can 15 be accomplished by transplantation of immune cells, 16 CD4 cells or precursors of CD4 cells, from donors that 17 are resistant to HIV, known to be resistant to HIV, or 18 through gene therapies that modify some cells to make 19 them resistant to HIV and then transfuse them to a 20 patient with HIV.</p> <p>21 And a third possible approach is some 22 experimental drugs or vaccines, therapeutic vaccines,</p>	140	<p>1 patient in that particular research study? 2 And there is a challenge also in defining 3 what is sterilizing cure, that means no detectable 4 virus, because, as you know, the assays for what's 5 detectable virus and what's the limit of 6 quantification of that has changed in whether we 7 consider a fragment of the virus a detectable virus or 8 not. Those are debatable issues in terms of 9 sterilizing cure.</p> <p>10 Equally, there is some debate about 11 functional cure. So functional cure we define as no 12 evidence of disease and no ability to transmit HIV 13 infection, but it's very hard to validate those 14 measures, so the endpoints, as we refer to in clinical 15 trials, for each type of cure to make this a valid 16 endpoint for research and for clinical trials.</p> <p>17 So let me talk a little bit about gene 18 therapies as they pertain again to HIV cure research. 19 So first there are some challenges with manufacturing. 20 The production is usually relatively slow compared to 21 manufacturing of a small drug and identification of 22 the gene subtype and the general manufacturing issues</p>
139	<p>1 vaccines aimed to treat rather than prevent, to 2 stimulate the patient's immune system to recognize and 3 eliminate HIV.</p> <p>4 So that's the realities that there are lots 5 of challenges in cure research. One of them is for 6 FDA, we need to look at each development step about 7 the protection of subjects in human research. So 8 safety is paramount for that. And making sure that 9 there is a good balance of risk and benefits. So the 10 risks for the patient versus the benefits for patients 11 and benefits for society in general for that research 12 to be accomplished and to yield some results.</p> <p>13 In the balance of recent benefits of 14 research interventions, they change over the course of 15 each product development, so as a product moves along 16 the development from Phase I first in human study all 17 the way to Phase III, there is a change in the notion 18 of how much we accrue in terms of knowledge about the 19 product and what the risk-benefit balance is. And as 20 we learn more about parallel development of other 21 therapies or new approved therapies, for example, how 22 does that impact the risk-benefit for that particular</p>	141	<p>1 are more challenging than for a small drug. The use 2 of retroviruses or lentiviruses, gene carriers, those 3 are the buses that carry the gene of interest that you 4 want to insert in humans, they allow for prolonged 5 gene activity. So it's not like you can turn off the 6 effect by stopping a pill, for example, it's another 7 challenge.</p> <p>8 Usually, the product activity, if present, 9 is from a gene-modified cell that needs to survive and 10 function in the patient, and the goal here is to raise 11 resistance to HIV infection, but for that cell to 12 survive, that gene-modified cell to survive, you need 13 to some Busophren (ph) or chemotherapy or some other 14 drugs that are risky to try to make room for these 15 cells and improve the odds that more and more of those 16 cells survive and function and provide resistance to 17 infection.</p> <p>18 And then there is also the issue of the long 19 presence or long duration of activity, perhaps a 20 lifetime, for those retrovirus or lentivirus gene 21 vectors that carry the gene of interest to the human 22 being. So there is an inability to withdraw or</p>

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142	<p>1 discontinue the product when adverse events occur. 2 And they have also concerns about late onset risks 3 such as cancer, malignancy. 4 And I'm going to talk also about the 5 combination of strategies. People in academia and 6 industry recognize that it's likely that if there is a 7 chance of success for curing HIV, it will come from a 8 combination of multiple different approaches. And to 9 attack the different mechanisms of HIV persistence, 10 for example, the low level replication or the 11 reservoirs of HIV, it recognize that combinations with 12 these different approaches may be needed. But there 13 are some scientific issues that are associated with 14 this approach of combination therapies particularly 15 when we include investigational therapies in the 16 combination. So if it's two approved products and we 17 are combining them, it's a little less challenging 18 because we know a lot about those products, but when 19 it's one product is new or new in humans and 20 investigation, it creates some challenges in looking 21 at the combination therapy. One of them is how much 22 information we need about the safety and the</p>	144	<p>1 And, finally, what else do you want FDA to know about 2 HIV cure research? 3 So this is my contact information. I just 4 want to emphasize that in the last point here is that 5 Learn webinar series from our office, Office of 6 Cellular, Tissue and Gene Therapies, which is 7 available in the FDA external website and provides a 8 little bit of our thinking about general product 9 development and issues in pediatric research or some 10 of the challenges we face in clinical trials with our 11 products. And this is also some of the websites of 12 public access to the Center for Biologics and 13 Evaluation Research. 14 Thank you very much. 15 DR. IRONY: With that, Dr. Goldkind. 16 Informed Consent Issues in HIV Cure Research 17 DR. GOLDKIND: Good afternoon. So I am Dr. 18 Sara Goldkind. I am the senior bioethicist here at 19 the FDA, and I would like to talk to you today about 20 issues related to informed consent and provide some 21 background for our future discussions because we would 22 really like to get your input on a number of different</p>
143	<p>1 effectiveness of each of components alone in the 2 course of this development. And the recognition that 3 if combination therapy is needed, each component alone 4 may not work to cure HIV, so patients may be at risk 5 of this drug, but they are unlikely to benefit from 6 research from each component alone, so that raises 7 some informed consent issues, and Dr. Goldkind is 8 going to be talking more about this. 9 And so for Topic 2 for the afternoon, those 10 are the basic questions, and we are going to hear them 11 again and discuss them individually during the course 12 of the afternoon, so I am not going to go over them in 13 detail now, but basically what we want is to know what 14 you perceive as being the benefits of participating in 15 research or the factors you want to consider when you 16 decide to participate in research for HIV cure or not 17 and what kind of risks you would accept or not accept 18 to take into your decision to participate in HIV cure 19 research studies. Or if you are required to stop your 20 antiretroviral therapy which makes you stable and 21 relatively healthy and manage your chronic condition, 22 how would that affect your decision to participate?</p>	145	<p>1 issues that are impactful on being able to accomplish 2 an informed consent process in a way that's most 3 useful to patients who would be enrolled in clinical 4 trials, which I'll call "participants" in this 5 presentation. 6 And before I get started on my presentation, 7 just by a show of hands, I would like to see how many 8 of you have been enrolled in a clinical trial before, 9 a clinical trial of any sort, and have gone through an 10 informed consent process. 11 (Show of hands.) 12 DR. GOLDKIND: Well, that will be great. I 13 am really very, very interested in hearing the input 14 from those of you who have experienced an informed 15 consent and those of you who are naive to one of those 16 processes. 17 So just by way, I am going to very briefly 18 summarize the informed consent process for you today 19 and then I am going to discuss out of the 15 or so 20 elements of informed consent that are required under 21 FDA regulations, I am going to discuss three of them 22 in specific, and then I want to talk about a</p>

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146	<p>1 particular issue called therapeutic misconception, 2 which I'll define for you during my talk, and then 3 finally outline a number of the questions that we 4 would like to have your input on during our discussion 5 session.</p> <p>6 So first of all, what is an informed consent 7 process? Ideally, what it should be is an ongoing 8 educational process between the investigator or 9 another qualified individual that the investigator 10 appoints, and the potential or the current participant 11 in the trial. And a summary of the process and what 12 it should really accomplish is that there would be 13 adequate disclosure of information to allow for an 14 informed decision about participation in the research. 15 There should be adequate comprehension of the 16 information that's presented and adequate opportunity 17 to consider whether or not to participate, it 18 shouldn't be done in such a hurried manner that you 19 really don't feel like you had ample time to consider 20 the clinical trial and its ramifications, to talk to 21 trusted family or friends, and then, finally, a 22 voluntary agreement to participate.</p>	148	<p>1 ethically be accomplished, and we have actually 2 incorporated those recommendations into FDA's 3 regulations. And I am going to present to you three 4 of them today for our discussion, the three that we 5 feel are the most challenging in relation to HIV cure 6 research, but certainly our discussion can go beyond 7 these if you feel that you want to raise other issues.</p> <p>8 And the first one is the description of any 9 reasonably foreseeable risks or discomforts to the 10 participant; a description of any benefits to the 11 participant, either direct benefit or to others who 12 may reasonably be expected to benefit from the 13 research; and then a disclosure of appropriate 14 alternative procedures or courses of treatment, if 15 any, that might be advantageous to the participant. 16 So, in other words, if you're not in the clinical 17 trial, what would you be getting as a form of 18 treatment or what would be happening with you?</p> <p>19 So I want to drill down. In the next few 20 slides, what I want to do is take each of those three 21 elements that I just pointed out and look at them a 22 little bit more in detail. And the first, the</p>
147	<p>1 But the informed consent process doesn't end 2 there, it's more than just signing the informed 3 consent document. It should really be a continued 4 disclosure of information as the clinical trial 5 progresses. There may be new information that arises 6 during the course of the trial that you, as a 7 participant, will want to know about, perhaps new 8 risks, or you may have some particular questions that 9 are pertinent to you and you would want to go back and 10 have continued discussion with the investigator.</p> <p>11 So as I mentioned earlier, FDA has quite a 12 lot of requirements for the informed consent process. 13 I like to say that these are not just simply 14 regulatory requirements, but they are requirements 15 that were developed by the National Commission, which 16 was a presidentially appointed what I would call 17 almost an ethics think tank, if you will, that was 18 appointed after there were a series of egregious 19 clinical trials that were exposed, and in the early 20 1970s, the National Commission came up with a set of 21 recommendations for the federal agencies about what 22 informed consent should look like, how it should</p>	149	<p>1 description of reasonably foreseeable risks or 2 discomforts FDA advises should describe the risks or 3 discomforts of tests, interventions, and procedures 4 required by the protocol, especially those that carry 5 significant risk of morbidity or mortality; the 6 possible risks or discomforts due to changes to a 7 participant's medical care -- that is, what's going to 8 happen differently in the clinical trial than would 9 have happened if you were receiving your care in the 10 clinical setting? -- what are the risks of the drug 11 itself? and what are the common and serious risks of 12 the drug and what might be done to lessen these risks 13 or discomforts?</p> <p>14 And so, of course, we don't feel that the 15 informed consent should in any way understate the 16 likelihood, severity, or duration of these reasonably 17 foreseeable risks and discomforts. And it may 18 actually need to include information on foreseeable 19 risks to others, such as to a fetus or to someone 20 because of an infectious -- possibility of infection 21 to others or radiation exposure to others. 22 And then the description of benefits we feel</p>

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150	<p>1 should be clear, balanced, and not overly optimistic 2 or overstated. We don't want to encourage people to 3 be part of clinical trials by promoting the clinical 4 trial, we want it to be a very balanced approach to 5 the description of risk in the informed consent 6 document. 7 And, again, it should describe the benefits 8 not only to the participants in the research, but to 9 others, if there are any. And if there aren't any 10 benefits that are direct, that should be stated 11 clearly as well. 12 And here I want to pause and describe what 13 the therapeutic misconception is. This was a term 14 that was adopted, proposed, in the early 1980s, and it 15 was proposed by Dr. Paul Appelbaum and others, Dr. 16 Appelbaum is eminent psychiatrist, and what he noticed 17 is that people were confusing the intent of clinical 18 research, and they were thinking that clinical 19 research was really being designed to provide medical 20 care. 21 And in some circumstances, that certainly 22 can be true, but there are very notable differences</p>	152	<p>1 alternatives are to their entering research, if any, 2 that might be advantageous to them. It should 3 include, if any, current medically recognized standard 4 of care, approved therapies, or other forms of 5 therapy, for example, surgical care or supportive 6 care, and it should describe if participation in one 7 clinical trial prohibits participation in another 8 clinical trial, in other words, being enrolled dually 9 in two clinical trials simultaneously. 10 So today, in particular, we would really 11 like to have your perspectives on -- and this is all 12 within the context of HIV cure research -- how should 13 the informed consent clearly communicate to you the 14 purpose of the research, the potential benefits, 15 particularly if there are no direct health benefits 16 for the participants, and the potential risks, 17 particularly if there is very limited understanding 18 about those potential risks? As Dr. Irony said, as 19 the product moves down the trajectory of development, 20 our understanding about its risks as well as its 21 benefits may change, and so when you're in the very 22 early phase where you've only introduced the product</p>
151	<p>1 between clinical research and clinical care, and that 2 is that clinical research is ultimately designed to 3 answer a series of specific scientific questions or to 4 meet a series of specific goals or objectives, and the 5 care that a person will obtain in that clinical 6 research protocol is dictated by the protocol itself; 7 whereas the medical care that a person receives in the 8 clinical setting delivered by his or her own physician 9 is tailored to what would be the best medical care for 10 a given patient. 11 And so we tend to use the term "therapeutic 12 misconception" when people believe that they are 13 coming into a clinical trial to get the best medical 14 care they can for themselves rather than they may get 15 the best medical care they could get as part of that 16 clinical trial, but the overall objective of that 17 activity is to increase scientific knowledge and the 18 objectives of the trial. 19 So, finally, the last element of informed 20 consent that I wanted to describe for you today in 21 more detail is the description of alternatives. 22 Participants should be made aware of what the</p>	153	<p>1 in animals, we don't know always what the risks are 2 for human beings, so we want to understand how that 3 can be best communicated to potential subjects, 4 potential participants. And then, finally, is there 5 any other information that you think we would find 6 helpful? 7 I have included my contact information and 8 the contact information of my office. We receive 9 queries to this particular website, if you have any. 10 And I have also included a public access to our web 11 page, which I think you would find very interesting 12 because it has lots of information that's helpful to 13 clinical research participants as well as 14 investigators and sponsors. 15 Thank you. 16 DR. EGGERS: Thank you, Dr. Goldkind. 17 We're about ready to get started on our 18 discussion, but I'm going to do two things first. The 19 first is there were some comments on the web this 20 morning that pertain to the morning, and so I just 21 want to make sure that those get summarized a bit. 22 But while we're doing that, I'm also going to ask my</p>

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154	<p>1 colleagues at the table to reintroduce themselves 2 because there are some new faces up here and we also 3 have some new faces out there, so it would be helpful 4 if we could just go down the line. 5 You already introduced yourself, so maybe -- 6 DR. DEMING: Damon Deming. I'm a virologist 7 with the Division of Antiviral Products. 8 DR. MURRAY: Jeff Murray, Deputy for 9 Antiviral Products. 10 DR. STRUBLE: Kim Struble, Medical Team 11 Leader, Antiviral Products. 12 DR. BIRNKRANT: Debbie Birnkrant, Division 13 Director, Antiviral Products. 14 DR. WITTEN: Celia Witten, Office Director 15 of the Office of Cell, Tissue and Gene Therapies at 16 the Center for Biologics at FDA. 17 DR. IRONY: Ilan Irony. I'm the Branch 18 Chief of the General Medicine Branch in the Office of 19 Cellular, Tissue, and Gene Therapies at CBER. 20 DR. SHERWAT: Adam Sherwat, Medical Officer, 21 Antiviral Products. 22 DR. COX: Ed Cox, Director of the Office of</p>	156	<p>1 they're prohibitively expensive and out of reach for 2 most, and that this issue is still huge in terms of 3 stigma, self-esteem, depression, and isolation. So I 4 think that's something new that we didn't touch on 5 yet. 6 And then just two other comments about 7 developing long-acting injectable treatments and 8 monthly visits that would be required. So this person 9 was interested, maybe we can work this into the 10 discussion or if patients have comments on this, they 11 could submit it to the docket, but this person was 12 wondering how best they could support patients for 13 monthly injections and if patients would be willing to 14 receive monthly injections versus daily pills and the 15 impact on their lives. 16 And then, finally, we had a general comment 17 about the context of this meeting and its relevance, 18 and this commenter said that it's important to 19 understand the importance of these issues in a global 20 context and not just the U.S. And this person 21 provided more details about the conclusions about 22 today's meeting will have wide influence</p>
155	<p>1 Antimicrobial Products within CDER, FDA. 2 DR. EGGERS: And while Andrea is summarizing 3 these, if I can ask the panel members for this 4 afternoon to come up. And we are getting one more 5 chair for you because I guess I don't count very well. 6 It looked like there were more chairs up there than 7 there were. 8 MS. TAN: Hi. So I'll just briefly 9 summarize the webcast comments we received from this 10 morning. We have a few folks who commented about the 11 side effects from HIV and taking HIV meds. So someone 12 commented that taking HIV meds when dealing with 13 nausea from chemotherapy is incredible horrible. 14 We have someone else who said that their 15 dreams for HIV treatment would be no food restrictions 16 and long-term dosing. And the most debilitating side 17 effect for that patient would be intractable 18 neuropathy. 19 We also have someone who mentioned that the 20 biggest issue is lipodystrophy in the form of facial 21 wasting, and he provided some more details about that, 22 about the treatments using facial fillers and that</p>	157	<p>1 internationally, that this is a start, but it's 2 important to also reach out to others. 3 DR. EGGERS: Thank you, Andrea. Overview of 4 Discussion Format 5 DR. EGGERS: Well, I'm not going to spend 6 too much time going over the discussion format, but 7 again we have some new folks in the room, so I do want 8 to make a few points about our discussion. Our 9 discussion format will be very similar to this 10 morning. We will first hear from a panel of patients 11 and patient representatives. And, again, when we say 12 "patients," we are talking about people living with 13 HIV; and when we say "representatives," we mean 14 caretakers, loved ones, and advocates who speak on 15 behalf of patients and who can provide comments that 16 fit the patient's perspective. Again, we're really 17 focusing on getting the patient's perspective on the 18 issues that we're discussing today. 19 So we're first going to hear from the 20 patients and patient representatives. I'll introduce 21 them in a minute. And again the purpose is just to 22 set a good foundation for our discussion to give us</p>

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158	<p>1 something that we can react to and discuss further. 2 And then we will be moving out into the audience and 3 opening it up like we did this morning, which is much 4 more of a free discussion. 5 So we're going to try our experiment again. 6 Periodically we will invite in-person and web 7 participants to respond to some specific questions. 8 Again, this is just a discussion aid, it just helps us 9 understand the perspectives in the room and see how 10 many participants share a particular perspective 11 without needing a raise of hands or anything in the 12 room. 13 In person, we use the response clickers, and 14 if you haven't gotten a response clicker and you are 15 identified as a patient or patient representative, 16 could you please raise your hand? 17 (Show of hands.) 18 DR. EGGERS: All right, so Andrea will take 19 care of that. 20 And the web participants can respond through 21 the poll through the webcast, and we got feedback that 22 we went really quickly through those, so we will try</p>	160	<p>1 agencies, et cetera. And as I said this morning, we 2 hope that you find this as useful as my colleagues up 3 here, but for today, you are in a listening mode and 4 asking not to contribute to the discussion. There is 5 an open public comment, and we will take until the 6 next break, if you want to make a comment in the open 7 public comment, please see the registration desk. 8 Our discussion today will focus on 9 understanding the common ground on important issues, 10 and we fully recognize that there are a number of 11 important issues regarding HIV care and the support of 12 patients, people who live with HIV. We will be trying 13 to stay to the questions that we are trying to discuss 14 today, the participation in cure research and the 15 informed consent and how to clearly communicate about 16 that. Again, there is a public comment if there is 17 something else that you want to comment on. 18 And if you haven't gotten a feedback form, 19 we encourage you to grab an evaluation form and 20 provide your feedback. This is completely voluntary, 21 but we appreciate the feedback we get on how to make 22 these meetings in the future as effective for</p>
159	<p>1 to give you some more time. And regarding the 2 webcast, if you're just joining us on the webcast for 3 this afternoon, we have about 180 to 200 people on the 4 webcast -- no, we have more than 100 people on the 5 webcast, I can't give an exact number -- and you are 6 very important to this meeting as well, and we are 7 talking to you and we are listening to you. Even if 8 we can't summarize all your comments in real time, we 9 are taking them. Use the comment box and share your 10 experiences as well. 11 And for all of you, for those in the room, 12 on the web, and others, we encourage you to provide 13 your comments to the docket that is available on our 14 meeting web page. You can add on to what was talked 15 about today, you can react to what you heard. We will 16 be taking all of these comments and reviewing them, 17 and they will ultimately get into our final product, 18 which is a report on what we heard today. 19 So a few ground rules. We really, again, 20 want to hear from patients and patient 21 representatives. There are a number of other 22 stakeholders here from industry, other government</p>	161	<p>1 everyone, for us, for the patient communities, and for 2 other stakeholders. 3 So thank you. 4 Okay, so with that, we're going to test the 5 clickers again and we're going to ask the same 6 demographic type questions that we asked this morning 7 because we do have new folks here, and I guess 8 practicing the clickers never hurts. 9 So if we could have the clicker questions 10 come up. While we do that, can we have the front 11 panel members introduce themselves? I'll let you 12 introduce yourselves. 13 MR. SHARP: Good afternoon, everybody. I am 14 Matt Sharp. I am San Francisco. I'm a long-term HIV 15 treatment activist. I have worked with several AIDS 16 service organizations. I've been on many, many 17 advisory boards for pharmaceutical companies and also 18 for research institutions. I am currently doing 19 independent consulting work. And I am no longer in 20 San Francisco, I'm in Alameda. I had to say that. 21 MR. PENNER: Good afternoon. My name is 22 Murray Penner. I am the Deputy Executive Director of</p>

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162	<p>1 the National Alliance of State and Territorial AIDS 2 Directors, or NASTAD. We are a membership 3 organization that represents state health departments 4 and their staff in HIV/AIDS programming as well as 5 viral hepatitis programs all the way from prevention 6 through access to care and treatment primarily through 7 the AIDS drug assistance programs.</p> <p>8 I'm a person living with HIV and AIDS since 9 1986, and I have been in this field since '96, but 10 it's only recently that I've become much more involved 11 in sort of the advocacy community. Up until that 12 point, I was doing a lot of on-the-ground work at a 13 local health department.</p> <p>14 MR. TAYLOR: My name is Jeff Taylor, and I 15 have been living with HIV for over 30 years. I first 16 got involved in the first AZT trials back in the '80s 17 and have been involved in clinical research ever 18 since. I was on the AIDS Clinical Trials Group, 19 Community Constituency Group, and currently I work 20 with a group called the AIDS Treatment Activists 21 Coalition, serve on the newly formed CARE 22 Collaboratory Community Advisory Board, and I'm on the</p>	164	<p>1 think it's important to note that we've been doing 2 this for a long time, but it's great that we can 3 actually get to the point where we can use the "C" 4 word.</p> <p>5 MS. DEE: The "C" word. Okay.</p> <p>6 Hi, I'm Linda Dee, and I'm from AIDS Action 7 Baltimore. Let me see, I'm all these little hats. I 8 think that I've probably worked with most of the 9 groups that everybody has talked about, AIDS Treatment 10 Activists Coalition, the Community Constituency Group 11 of the ACTG, the CARE Collaboratory. I've worked with 12 the FDA on a number of things, including their 13 advisory panels, industry, advisory boards, you know, 14 Hopkins Advisory Board for a very long time. You 15 know, just invested.</p> <p>16 My organization was formed in 1986, '87 it 17 was actually incorporated, and my husband died as a 18 result of AIDS in 1987, and so many friends that 19 probably as many people as are in this audience. So 20 I'm sick of this, and I want this to go away, and I 21 know that the only way that it will happen is if we 22 find a cure for this. And I have worked with all of</p>
163	<p>1 Antiretroviral Guidelines Panel. And I live in Palm 2 Springs, California.</p> <p>3 MR. EVANS: Hi. My name is David Evans. 4 I'm a patient representative here from Project Inform 5 in San Francisco. And where I come at this is that 6 back in 1989 some eventful things happened. First I 7 came out, then I got a boyfriend, and he told me a 8 week later that he was positive. Shortly thereafter, 9 two of my closest friends died, and then by cousin 10 came out as both gay and positive and had 30 T cells 11 and pneumocystis pneumonia. And as a result of that, 12 I joined ACT UP, which was a direct action group that 13 still fortunately exists in some places, and shortly 14 thereafter joined Project Inform's treatment hotline 15 where we answered thousands of calls from all over the 16 country for people who were desperate for information 17 about treatment.</p> <p>18 And one thing I just want to say about that 19 activist background and doing this so long is in one 20 way or another we've been talking about a cure for a 21 long time, but we didn't use the "C" word, we called 22 it pathogenesis, we called it other things, and I just</p>	165	<p>1 these people for many years, a lot of the people that 2 are in the audience for many years, and it's very 3 heartening that we're getting to even think about the 4 "cure" word, let alone say it and working in that 5 regard, and I really would like to applaud the agency 6 for getting to these questions and these points from 7 not only a patient perspective but in a timely way so 8 that we can really have more of a chance to prepare 9 for this than we did the first time around. So we're 10 not knocking the doors now, we're working on this 11 together.</p> <p>12 DR. EGGERS: Okay. Thank you very much.</p> <p>13 So let's ask those demographic questions 14 that we asked this morning. The first one is an easy 15 one. Do you live within the Washington, D.C. 16 metropolitan area or outside of the Washington, D.C. 17 metro area? If you can figure out the clickers, it's 18 1 or 2.</p> <p>19 (Answering question.)</p> <p>20 DR. EGGERS: Okay. Can we have the -- all 21 right. We are 50-50 this morning, so it's nice to see 22 so many people travel from outside, and we really</p>

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166	<p>1 thank you because this is quite an effort to do so. 2 So our appreciation always for those living in town, 3 too, but our special thanks to those who have traveled 4 here. 5 Okay, let's go on to the next one. What is 6 your age? Younger than 25, 25 to 34, 35 to 44, 45 to 7 54, 55 to 64, or 65 and better. 8 (Answering question.) 9 DR. EGGERS: Okay. Again we have a 10 distinguished crowd here today, so it's great to see 11 all this wisdom in the room. 12 Okay. Can we go on to the next one? Are 13 you male, female, transgender, or prefer not to 14 answer? 15 (Answering question.) 16 DR. EGGERS: Okay. Just like this morning, 17 we have about the same split. Okay. Was it 50-50 18 this morning? 19 UNIDENTIFIED MALE SPEAKER: 60-40. 20 DR. EGGERS: Okay. Thank you for correcting 21 me. You guys keep me honest. 22 Okay. Have you been diagnosed as having HIV</p>	168	<p>1 For persons living with HIV, how many 2 different types of antiretroviral treatment, ART, 3 regimens have you taken? And please include your 4 current ART regimen if you're on one in your count. 5 You've never taken any ART regimens, you're currently 6 on your first, you've taken two to three different 7 regimens, more than three different regimens, or if 8 you're not sure. 9 (Answering question.) 10 DR. EGGERS: Okay. Lots of experience, too, 11 with different treatments and different regimens. 12 Okay. Good. Thank you. 13 This really helps us set sort of the 14 understanding of who is in the room and what kind of 15 perspectives we're getting today, so I thank you for 16 answering those questions. We're going to have more 17 questions throughout the afternoon, but enough of my 18 talking. I'm going to ask the panel members to go 19 down, and I might start with David. I understand that 20 you have some data, some to share, so we'll start with 21 David, and then we'll work and go throughout. 22 Now, agendas are what they are, we're a</p>
167	<p>1 infection? 2 (Answering question.) 3 DR. EGGERS: Okay. Great. So two-thirds of 4 patient and patient representatives here today who 5 have answered the question. 6 Can I ask Andrea, are the numbers available 7 for the web? 8 MS. FURIA-HELMS: Yes. About 70 percent 9 answered no out of 20 responses. 10 DR. EGGERS: Okay. Well, I would have to do 11 math for that, but we've got representation on the web 12 as well. So, again, we encourage those on the web to 13 keep your comments coming in. 14 Do we have one more? Yes. For persons 15 living with HIV, how long ago was your diagnosis? 16 Less than 2 years ago, 2 years ago to 10 years ago, 10 17 to 20 years ago, more than 20, I don't know, or prefer 18 not to answer. 19 (Answering question.) 20 DR. EGGERS: Okay. Again a lot of wisdom in 21 the room. Okay. And then I think there is one more 22 demographic. Let's see. Yes.</p>	169	<p>1 little bit behind the agenda, so if you could stick to 2 your comments to 2 to 3 minutes, and then we'll go and 3 you'll have plenty of time after that. 4 So, David, thank you. 5 MR. EVANS: Sure. So one of the reasons 6 that I wanted to be here today is that a really 7 fantastic activist named Nelson Vergel and I conducted 8 a survey of people living with HIV about a year ago 9 about cure research, and one of the things that I want 10 to say about the survey is that we did so based on the 11 belief that people really would want to show up for 12 these trials even though they might not get any 13 benefit out of them. And we fielded the survey 14 between December of 2011 and early 2012. Within 6 15 weeks, we got 2,100 people to answer the survey, which 16 for an online survey that we did for free and begged 17 and borrowed and stole any kind of advertising that we 18 could get, that's a pretty high response. The design 19 of the survey was such that we made people have to 20 answer every single question, so we got 100 percent 21 completion on the survey response. 22 You know, I don't have time to describe all</p>

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170	<p>1 the demographics. I can say that despite really 2 extensive outreach on our part to groups that are 3 serving women, people of color, and people who are 4 more recently diagnosed, our demographic looks a lot 5 like the people who are here today, and that it tended 6 to be a little bit more male, white, older, and having 7 lived with HIV for a very long time.</p> <p>8 We also asked people before they answered 9 the questions to read a primer that I would call it 10 medium length. It wasn't short, but it wasn't really 11 long, and it described a lot of the risks of the kind 12 of cure research that we are engaged in right now or 13 soon will be. We couldn't be sure that people 14 actually read it, though, before they answered the 15 questions, so we can't say for certain how much they 16 really understood the risks when they answered 17 questions that we did.</p> <p>18 But when we asked people to state how 19 motivated they were to participate in a study that 20 would benefit others but might carry risks for 21 themselves, 88 percent reported being at least 22 somewhat motivated, and 24 percent reported being very</p>	172	<p>1 about before is that when we looked at people who were 2 very motivated to participate to benefit others, they 3 were also very, very motivated to benefit themselves 4 in a study, and so I think that if we're depending on 5 people's altruism, we also have to be very careful not 6 to in any way play on any misperceptions they may have 7 that they are going to benefit from a study when they 8 actually won't, so we'll talk more about that.</p> <p>9 DR. EGGERS: Thank you, David.</p> <p>10 Discussion 2: Patients' Perspectives on HIV Cure 11 Research Panel #2 Comments on Question 1 - 4</p> <p>12 DR. EGGERS: And then we'll start here with 13 Matt and address the rest. And I didn't remind us, 14 because the panel will come back later after a break 15 later this afternoon, so right now we're just focusing 16 on the participation in cure research, what you 17 believe are the benefits, what would motivate you to 18 participate or not in an HIV cure research study, what 19 risks you would find acceptable and why, and in 20 particular if you are asked to stop any HIV 21 medications that you are currently taking, how that 22 would affect your decision to participate.</p>
171	<p>1 motivated to participate. Granted, there is a 2 tremendous risk for what they call social desirability 3 bias -- of course, everybody wants to help somebody 4 else -- and so that could be affecting the results a 5 bit, but we still felt that was a pretty profound 6 response.</p> <p>7 We also asked the question in a different 8 way, and received a very similar response. We asked 9 people what their willingness to participate in a 10 study would be if it definitely would not benefit them 11 but it might advance cure research in general, so a 12 little bit more diffuse, not will it help people, but 13 it will advance the scientific field, and there we 14 still had 81 percent reported being at least somewhat 15 motivated, and 16 percent reported being very willing 16 to motivate to participate.</p> <p>17 But I think that there are other benefits to 18 participation in a study beyond altruism, and there 19 are things that I think we have to really be careful 20 and keep in mind, and we'll be talking about some of 21 those things. But one little piece of data that we 22 did when we did a deeper dive that I haven't talked</p>	173	<p>1 So, Matt.</p> <p>2 MR. SHARP: So I have some prepared 3 statements if you don't mind. So I've been a 4 participant in dozens of clinical trials over the 5 years. I was actually first in every first-in-class 6 trial of almost every antiretroviral drug class except 7 for nucleoside analogs, and I survived, obviously, but 8 unfortunately developed resistance due to sequential 9 monotherapy.</p> <p>10 I was always most interested in host 11 targeted approaches to HIV, but, as you all know, you 12 all know what ended up taking precedence. So I needed 13 other options to buy more time, as my immune system 14 was not up to snuff, and I am in that older HIV 15 population at risk for inflammatory-related 16 comorbidities that we talked about this morning.</p> <p>17 I participated in invasive trials such as 18 Dick Hong's thymus transplantation trial. I was in 19 the first injectable Fuzeon TORO trials. I was in the 20 first placebo-controlled human growth hormone trial. 21 I was in the placebo arm at first of that trial. And 22 most recently, I entered a Sangamo zinc finger</p>

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174	<p>1 nuclease gene therapy trial.</p> <p>2 So mostly I really had no choice to be in</p> <p>3 all of the studies, and despite my highly resistant</p> <p>4 virus, I've been undetectable for over 5 years now,</p> <p>5 and my T cells have doubled, remaining that way 2</p> <p>6 years after the zinc finger trial. So I believe I'm</p> <p>7 really here as a result of being in clinical trials</p> <p>8 and aggressive approach to fighting HIV from the very</p> <p>9 beginning.</p> <p>10 But the motivation for entering these cure-</p> <p>11 related trials is different today than what it was in</p> <p>12 the early days of the epidemic, as you all know.</p> <p>13 People needed treatment to buy time to live and</p> <p>14 survive. We have to do better today. There is much</p> <p>15 room for improvement in the care and treatment of</p> <p>16 people with HIV. This is something that we may have</p> <p>17 already discovered through Sangamo's first gene</p> <p>18 therapy trials where a functional cure may not be</p> <p>19 likely but additional immune recovery certainly has</p> <p>20 been shown in a few patients in the first cohort.</p> <p>21 So there are a lot of people out there like</p> <p>22 myself who want to take these risks and where there is</p>	176	
175	<p>1 no benefit because we want to live to see a cure, we</p> <p>2 want a cure ourselves, or we want at least a</p> <p>3 functional cure. And then, as David said, many people</p> <p>4 enroll for altruistic reasons.</p> <p>5 And at least I know in the gay community,</p> <p>6 it's known that people want to give back in the form</p> <p>7 of clinical research to help their own. When I go out</p> <p>8 and talk about a cure in the community, I always ask</p> <p>9 how many people would want to be involved in a cure-</p> <p>10 related trial and almost every hand goes up in the</p> <p>11 room. But there are risks. And I'm a very different</p> <p>12 patient; I've been willing to risk a lot to be in</p> <p>13 these clinical trials. In the thymus transplantation</p> <p>14 study, I risked an invasive surgery in transplant</p> <p>15 rejection drugs. In the gene therapy trial, I</p> <p>16 obviously took a lot of risks with the manipulation of</p> <p>17 my own CD4 cells. Everyone is individual, though, and</p> <p>18 the risks they take might be more or less than others.</p> <p>19 Everyone needs to weigh their own informed decisions</p> <p>20 against the risk and benefit obviously. And as the</p> <p>21 treatment guidelines state, everyone is individual.</p> <p>22 I feel that since there is going to be much</p>	<p>1 variety in cure-related research, setting a standard</p> <p>2 of what is too risky or, on the other hand, not in</p> <p>3 depth enough to get a clinical outcome won't really</p> <p>4 move the field forward. It's for this reason that the</p> <p>5 scientific and community collaboration is critical so</p> <p>6 that each risk and benefit is weighed carefully as we</p> <p>7 go in a step-by-step manner and everyone learns and</p> <p>8 eventually we're all going to win.</p> <p>9 And I guess I'll stop there.</p> <p>10 DR. EGGERS: Thank you very much.</p> <p>11 MR. PENNER: So much like Matt, I've been</p> <p>12 infected since 1986, and in the very early days of the</p> <p>13 epidemic, as you all know, there were few treatment</p> <p>14 options, and so I was fortunate enough myself as well</p> <p>15 to participate in several clinical trials. And at the</p> <p>16 time, I was really looking at it from a very personal</p> <p>17 and a very selfish motivation because I wanted access</p> <p>18 to what I knew was very promising in terms of options</p> <p>19 for therapy. Obviously, we are in a very different</p> <p>20 place now, and then I think that even at the time I</p> <p>21 felt like there were probably a lot of risks that I</p> <p>22 didn't know the answers to, but I was willing to take</p>	177

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178	<p>1 go through a 5-hour process with 9,000 different pages 2 of something I didn't necessarily understand. 3 From risks that I would find unacceptable, I 4 think I'm very used to sort of the nausea, the 5 fatigue, and the diarrhea. Of course, some of that 6 could be that I'm getting older, so you never which is 7 caused by what, but nonetheless, some of the more 8 immediate risks are symptoms that you might experience 9 or ones that I would be concerned about to try to 10 minimize, whereas some of the longer term risks, I 11 probably wouldn't be quite as concerned about, even 12 though I know there could be a risk for cancer or 13 others kinds of longer term events, blood clots, 14 seizures, et cetera. I think I would be less worried 15 about that than I would be about the day-to-day kind 16 of interactions that medications have on me. 17 And then, lastly, I think being asked to 18 give up my treatment regimen that I've worked very 19 hard to get something that works, number one, and, 20 two, doesn't interrupt my daily flow is a real barrier 21 in terms of participating in cure research. For 22 myself, I'm not sure I would do it, giving that up and</p>	180	<p>1 got to that place and how it shaped my perceptions. 2 One of the early ACTG-PCP prophylaxis trials 3 was comparing Bactrim, Mepron, and aerosolized 4 pentamidine to see which was most effective at 5 preventing PCP. And I started on Bactrim, got the 6 horrible rash, the same thing with Mepron, so I was 7 finally put on aerosolized pentamidine, and as the 8 study progressed, it was becoming more and more 9 evident that that was not the optimal arm to be on. 10 And my private physician came to me and said, "You 11 know, you're on all these different antibiotics for 12 all these things, I could desensitize you back to 13 Bactrim, I've done it with other patients, I'm sure I 14 could do it with you, you take fewer pills, and it 15 would be better at preventing your PCP as well." 16 And so I was presented with a real dilemma. 17 I went to the study nurses and I said, "My doctor has 18 told me this," and they said, "You know, you're right, 19 this is an option for you, and we're not going to tell 20 you what to do, all we can tell you is that on our 21 site nobody has broken through with aerosolized 22 pentamidine, they've done fine, you've got 6 more</p>
179	<p>1 having the risk of further complications as a result 2 of not staying on medications. I've taught myself 3 over many, many years how to stay adherent, and to 4 change that whole regimen up might be difficult for me 5 to make that leap. 6 I'll stop there. 7 DR. EGGERS: Thank you, Murray. 8 MR. TAYLOR: Well, like Matt and Murray, I 9 started early on basically for the same reasons, to 10 get access to drugs to stay alive. And I think it's 11 very different now, but back in those days, I mean, 12 most of the trials were placebo-controlled -- you got 13 the drug, you didn't -- and then they waited to see 14 who lived or died, which is a kind of grim way of 15 measuring efficacy, and fortunately we moved beyond 16 that, but I think as we move into this arena, we're 17 going to be back in those situations where there is no 18 benefit in the control arm, or even in the treatment 19 arm for that matter. 20 And I would like to share an anecdote about 21 a couple of trials I was in where I didn't receive 22 benefit and actually had some harm and kind of how I</p>	181	<p>1 months on the study, and the decision is yours." So 2 being the altruistic individual that I was, I said, 3 what the heck, what's another 6 months after 2-plus 4 years of being in this trial? 5 Well, sure enough, with 2 T cells, I 6 developed PCP, both my lungs collapsed, and then I 7 nearly died. But I pulled through and it was a 8 valuable lesson learned. And would I do it again? 9 Maybe not. I think I might have placed my own health 10 as a priority because I still have lasting lung damage 11 as a result of that. 12 More recently, I was in a vaccine trial that 13 had a structured treatment interruption, and I did the 14 interruption. It was unfortunate enough to be during 15 flu season and I got the flu the same week I stopped 16 my meds. So I think I really skewed their study 17 results. And when I had to go back on the regimen, I 18 restarted my original regimen, and for some reason it 19 didn't work. We couldn't find any evidence of 20 resistance fortunately, but they had to throw more 21 pills on top to make me undetectable again. So I 22 think again it's a personal example of where something</p>

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182	<p>1 where it didn't work, and I didn't get a benefit, and 2 I would probably not be eligible to do a structured 3 treatment interruption again. 4 But even given that, I mean, in other 5 circumstances, I think it's well worth it. I'm very 6 committed to research. And we're asked these 7 questions, and there are no answers, it's just a lot 8 of situations where it's highly individualized, each 9 person has to look at their own situation, sit down 10 with their personal physician as well as the study 11 doctors and staff, and figure out what's going to work 12 for them, what their options are if it doesn't work, 13 you know, examine all the scenarios one-by-one, and 14 decide what's best for them. 15 That's all I'm going to say. 16 DR. EGGERS: Thank you very much. 17 And, Lynda? 18 MS. DEE: So, you know, I'm struck by 19 something that on the CARE CAB, the doc, the PI of the 20 study came to us and gave us a letter from somebody 21 from the North Carolina area who was a heterosexual 22 who I think he may have said that he had all these</p>	184	<p>1 CARE Collaboratory, I have helped them get study 2 participants for their leukapheresis cell trial, and I 3 was wondering because everybody that I thought of -- 4 because you have to sit there for 3 hours -- was on 5 disability and could really use that \$50 that they 6 got, you know. So those are the kind of people that I 7 got in touch with and a lot of them signed up. And I 8 talked to a number of the other docs there, and they 9 have found exactly what David's study has found, that 10 there are a lot of people that are really interested 11 in being in trials just for altruistic reasons, and 12 most of those people are not on disability, you know, 13 at least in that little Hopkins group. So I guess 14 people have different reasons for participating. 15 And what would be an acceptable risk? I 16 just finished a clinical trial in HCV, and you get 17 these pages and pages of stuff that say, well, this 18 could happen, that could happen, and I really often 19 wonder again if people really understand what some of 20 this stuff means, they either want to do it or they 21 don't, or that they pay attention to what's even 22 included in the informed consent. But with HIV cure</p>
183	<p>1 religious issues, and I think felt very guilty that he 2 was HIV-positive and that he might have infected his 3 wife, and all of that sort of thing. So he was 4 begging to be put on one of these clinical trials 5 because of his situation. Now, here was a person that 6 had no idea that these trials couldn't help him 7 really, that he would really have no benefit. 8 So I guess the point that I'm trying to make 9 is that we really need to be sure that people know 10 what they're getting into. I mean, not everybody has 11 been through what the panelists have, you know, 12 through years of the epidemic, so people hear "cure." 13 You know, in the United States we're like, you know, 14 little blurbs of cure, so, "Okay, well, where can I 15 get some of that?" 16 So we really have to be careful, and I think 17 it's the community's role as much as the agency's role 18 to make sure that people know what they're getting 19 into, and we'll talk about that more in the informed 20 consent stuff. 21 And what would motivate you to participate? 22 You know, being involved with the Hopkins CAB and the</p>	185	<p>1 trials, it's going to be so important that people 2 understand that this could really affect where you are 3 now. So it's I think important to look at people in 4 different groups. 5 Now, you know, a year ago I would have said, 6 well, maybe if I was newly diagnosed, I might be a 7 better candidate for this, there might not be as big a 8 chance for me to get off my treatment or I wouldn't 9 have a regimen like Murray described that has taken 10 him years to get right, but now then you have this new 11 data that says, well, you know, if you can get treated 12 early enough and stay on for just enough amount of 13 time, that you might be essentially able to go off 14 treatment. So maybe that patient population is not 15 the right patient population to start. I'm trying to 16 think about this as how I would think about it. 17 So maybe the patients in the middle are the 18 best ones. I don't know. But somehow all of this 19 information has to be communicated to people to be 20 sure that they understand what the risk really is. 21 You could get cancer. Well, what does that mean? 22 When? How much? I mean, you see people that smoke,</p>

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186	<p>1 still smoke, well, "Oh, I won't get cancer." You 2 know, you've heard people say that, I'm sure. 3 So if we could somehow do a better job of 4 actually defining what risks we're talking about and 5 if it's risk of a disease, if we could get a little 6 bit more clear instead of this -- and I'm sure we'll 7 talk about this more when we get to informed consents, 8 but a lot of those documents are really not anymore, I 9 think, not to protect patients, but they're to protect 10 the IRBs and the institutions. So I think we need to 11 really, really drill down on what they should say, and 12 I think we'll talk about that later, as I said. 13 About stopping medications, I mean, that's 14 really a tough one. I mean, it's really hard to have 15 somebody that has really been sick for so long and 16 say, okay, you're all right now, but the way to prove 17 this drug is for you to stop taking your medications 18 to see, or procedure, that it's really worked. So, I 19 mean, I think that it's going to be so important to be 20 sure that people know what it is they're getting 21 themselves into. 22 DR. EGGERS: Thank you, Lynda.</p>	188	<p>1 down the road kinds of things I'm willing to take some 2 risks on more so than I am my quality of life now. 3 MR. EVANS: I can add to that a little bit 4 just based on the survey that we did. First of all, 5 it was interesting that people who had been positive 6 the least long who had the highest CD4 count were the 7 least likely to take part in these kinds of studies. 8 The other thing we found that I thought was 9 interesting, though, that runs a little counter to 10 what Murray said, was that people felt very positive 11 about their current antiretroviral therapy, and almost 12 everybody was on it. Ninety-two percent said they 13 felt positive or very positive, so very few people 14 didn't like their therapy. And 75 percent reported 15 only having mild or moderate side effects. And when 16 we tried to analyze it and see how people felt about 17 therapy affected their choice to participate in a 18 clinical trial, what we found is that it didn't, 19 whether they felt great about their therapy or didn't 20 like it, it didn't seem to matter. Granted, the 21 people who didn't like it, there was a smaller number 22 of people.</p>
187	<p>1 Do any of my colleagues want to have a sort 2 of clarifying question? 3 Kim? Yeah. 4 DR. STRUBLE: I have a follow-up question 5 for Murray. I guess I was kind of struck by your 6 comment because I thought the other way, that you 7 thought that unacceptable risk, the long-term toxicity 8 like having cancer, wasn't immediate for you, it was 9 more the day- to-day types of toxicities, and the 10 known toxicities versus the theoretical toxicities. 11 And I was wondering if others shared that same 12 perspective or could elaborate more on what they found 13 was the immediate versus long term, hypothetical 14 versus known, unacceptable risk for cure research. 15 MR. PENNER: Well, I just want to make sure 16 that I'm clear. It's not that I wouldn't care about 17 that. I think that's far less in my mind than would 18 be what I have to deal with every day. You know, I 19 feel like we've all sort of experienced, "Oh, you 20 could die." I mean, I was told when I was diagnosed 21 that I had 6 months to live, and here it is nearly 30 22 years later fortunately, but I think it's sort of the</p>	189	<p>1 What was I going to say? Yeah, that's it. 2 DR. EGGERS: Anyone else from FDA? 3 Okay. I'm sorry, Matt. 4 MR. SHARP: Yeah, just quick another 5 anecdote. In San Francisco, Quest Laboratories is 6 performing some of the gene therapy trials that you 7 may be aware of, and they performed my cohort, and in 8 the protocol they came back and asked us if we would 9 like -- after the initial infusion of the product, 10 asked us if we wanted to stop therapy, and there were 11 eight participants in that cohort, and only person 12 said that they would, so that's just that example. 13 And then there is a second study, a follow- 14 up study, that Sangamo is doing that they are actually 15 looking at a treatment interruption, and surprisingly, 16 Jay, Dr. Jay, is finding enough people to enter and 17 enroll in that study. 18 DR. EGGERS: Celia? 19 DR. WITTEN: Yeah, we had some comments 20 about stopping a treatment, about the treatment 21 interruption, and a comment to stop to see if the 22 treatment really worked, but in a lot of cases, the</p>

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190	<p>1 treatment interruption would really be more to stop to 2 measure something, to see how well it's worked and not 3 really with the expectation that it's worked. So I'm 4 wondering if that would change any of your comments. 5 And other question I have is about risk and 6 the comments made, "Well, we would like to know better 7 what the risk is." But at least for our products what 8 we have is just a level of uncertainty regarding what 9 the risks really are because truly the animal models 10 are not good enough to even delineate them, and the 11 kinds of things that Dr. Irony talked about, like the 12 risk of cancer, what vectors to integrate, those are 13 risks, but those kinds of things can come up without 14 really being understood from the animal models. 15 So I'm just wondering how the additional 16 layer of uncertainty as it relates to risk would 17 factor into your answer to Number 3. So it's a 18 question about your answer to Number 4 and Number 3. 19 MR. TAYLOR: Well, I think to piggyback on 20 the discussion, I'm unlike Murray in that I would be 21 willing to tough out some short-term discomfort and 22 inconvenience if I thought it was going to benefit</p>	192	<p>1 me where I had a lot of diarrhea, where I had a lot of 2 nausea, and I had a lot of vomiting, and those were 3 terrible days, and that's why I think I'm motivated to 4 say it the way I say it, that those things for me are 5 really something that I don't want to repeat again, 6 whereas the longer term ones, yes, important, are less 7 in my mind as those initial symptoms might be. 8 MS. DEE: You know, I may have said that 9 badly about to see if it works per se, to see if what 10 you're measuring is really happening the way you would 11 like for it to be coming out, but, you know, I guess 12 what I was trying to get at is that maybe there are 13 some populations for which that's less of a risk than 14 others. 15 And, you know, for some of this stuff, we 16 don't know what the risk is going to be, and if you 17 asked five people the same question, you might get 18 five different answers about that. So when I was 19 looking at these questions, I went around in circles a 20 number of times, and I thought, well, we're going to 21 be a lot of help, you'll have more questions than 22 answers by the time we get done.</p>
191	<p>1 science, but if I thought I might get cancer later, 2 that might give me more pause. So I think people are 3 very different and you can't generalize in this, that 4 it's going to be very different across the board, and 5 you really can't make assumptions, but I think if you 6 ask enough people, you're going to find people to step 7 forward for whatever reasons as long as you ascertain 8 that they're genuine and they really understand the 9 risks. 10 MR. PENNER: Yeah, I think Lynda mentioned 11 earlier that it is very individualized, and I would 12 certainly concur with that. And I think that your 13 question about potentially stopping for a period of 14 time to determine the effectiveness and then have the 15 particular options again, that might change my mind. 16 I think some of the comments that I have made have 17 been very broad and not specific to a situation. So I 18 think that's certainly an important part of this as 19 well as the situation in which you're asked to do 20 things. 21 You know, for me, I went through a period of 22 time when I was determining regimens that worked for</p>	193	<p>1 But I think if you think about it really, if 2 you think about the way we have developed drugs 3 before, you know, try and look at the populations 4 where you can do the least harm, try and make sure 5 that people know what it is you're talking about, try 6 to define the risks as best you can, be sure that you 7 delineate or that the person understands that there is 8 no benefit here for you, you know, that sort of thing, 9 are the concrete things that I could think of that 10 were good take-home messages. 11 DR. EGGERS: I'm going to interrupt this 12 because I want to make sure that we allow the folks in 13 the audience to also participate and contribute and 14 build on what we're hearing. And before we do that, 15 just to set the context, we have a couple of questions 16 for your clickers and for the folks on the web. This 17 just lets us understand the experience with clinical 18 research. 19 So have you ever participated in any type of 20 clinical study related to HIV? Yes, no, or I'm not 21 sure. 22 (Answering question.)</p>

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194	<p>1 DR. EGGERS: Okay. So the majority of you 2 have participated in some form of clinical research 3 related to HIV. 4 Do we have the experiences on the web? 5 MS. FURIA-HELMS: About 66 percent have not, 6 33 percent have. 7 DR. EGGERS: Okay. Okay. And then another 8 question is, have you ever participated in any type of 9 clinical studies specifically related to HIV cure 10 research? Yes, no, or you're not sure. 11 (Answering question.) 12 DR. EGGERS: Okay. So more experience with 13 the clinical research just in general related to HIV 14 and less with cure research, which is not surprising, 15 but it does help us understand where the perspectives 16 are in the room. 17 Did we get the numbers for the web? 18 MS. FURIA-HELMS: Yep. The majority have 19 not, 93 percent. 20 DR. EGGERS: Okay. Great. Thank you. 21 Large-Group Facilitated Discussion on Question 1 - 4 22 DR. EGGERS: So I know that my colleagues</p>	196	<p>1 talk about how people will feel inclined to 2 participate in this study, how they're impacted by all 3 these other elements of their life -- class, race, 4 sexuality, gender, et cetera -- have an impact on 5 that, and it's not just whether or not they're going 6 to be feeling altruistic or not, it's all these other 7 elements. 8 So that's it. 9 DR. EGGERS: Great. Thank you. 10 Does anyone else have any first reactions 11 that were surprising? 12 Yes, Melanie. 13 MS. REESE: Not surprising, based on the 14 fact that a lot of these are long-term survivors in 15 the beginning -- being infected in the beginning of 16 the epidemic, and their desire to continue to live, to 17 grab onto hope, that it would transform from just 18 staying alive to eventually being able to help 19 somebody get a cure and not have to live long term 20 with having to take meds, I wasn't surprised about 21 that. 22 But, for instance, in my particular case</p>
195	<p>1 have more questions to ask, but what I want to ask 2 first is if anyone here in the audience found anything 3 said by the panel members really surprising, like it 4 doesn't necessarily relate with your experience or you 5 would have thought something different or just 6 surprising in general. Oh, and if you could state 7 your name before you speak. 8 MR. GARNER: Hi. My name is Alex Garner. 9 And I guess I was more surprised by what wasn't said 10 in the sense that as we had those demographic 11 questions earlier before the discussion, I was struck 12 by who wasn't represented and who isn't here and who 13 historically isn't represented in studies. And as we 14 talk about the sort of vast experience that all of us 15 in this room have, it's troubling to think of the 16 future of the epidemic which looks like it's black and 17 brown young gay men, and they're not here. 18 So part of me wants to encourage all of us 19 to sort of remember that because it's critical to the 20 work that we're doing especially when communities of 21 color have such a troubling history with federal 22 agencies and studies and stuff like that. And when we</p>	197	<p>1 with all my other conditions, I would not be willing 2 to risk getting off the medication that I have been on 3 because I don't know if pulling the plug on that would 4 cause something horrendous to happen to all my other 5 conditions. So that's my perspective, although 6 altruistically, idealistically I would be happy to be 7 in a trial. But being a woman, there haven't been 8 that many. 9 However, I was able to be in one because I 10 was on Depakote, and somewhere in Australia Depakote 11 was shown to deplete the reservoir of the virus, you 12 know, when you were suppressed, and so I was able to 13 be in that one, but most of the other ones I was not. 14 DR. EGGERS: Okay. So let's -- oh, go 15 ahead. Was there another hand up? 16 (No audible response.) 17 DR. EGGERS: Let's just make sure that we 18 have fully discussed the idea of the benefit. And we 19 heard the altruism. 20 Can I ask, David, did people have open-ended 21 responses, the 80 percent who would participate, did 22 they --</p>

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198	<p>1 MR. EVANS: No. It was on a Likert scale, 2 so it was "Very willing," "Willing." 3 DR. EGGERS: So does anyone want to follow 4 up and build upon what we heard about any of the 5 benefits or the perceived benefits of participating in 6 a trial, understanding that there is perception of 7 benefits and then there is actual, you know, real 8 benefits, so if we could focus on what you believe are 9 the benefits of the trial. If anyone wants to comment 10 on that? 11 And the panel you can expand upon -- Matt. 12 MR. SHARP: So something I brought up this 13 morning was getting to the cure, there are going to be 14 a lot of steps along the way that we discover, and one 15 of those might be improvement in immunology and 16 immunologic response. So that's one thing that could 17 be a benefit. 18 DR. EGGERS: Any question from FDA to follow 19 up on that? 20 (No audible response.) 21 DR. EGGERS: No? Okay. 22 Any other benefits?</p>	200	<p>1 let me just put it this way. When I talked to one of 2 the doctors at Hopkins, I also asked about biopsies, 3 and does that dissuade people when he talks to them 4 about what's actually required in a trial? And he was 5 saying, well, no, you know, that they're required to 6 do anal biopsies in some of the prep trials, and 7 people don't seem to mind, but that they really need 8 to be compensated for what they're going through, and 9 there is nothing wrong with that. I mean, I think 10 that people are putting themselves on the line and 11 some people need the money, some people don't, but it 12 ought to at least be offered to people if we're sure 13 they know what they're getting into and we're not 14 using them in any sort of illegal way. But I think 15 that's a real important thing in the beginning of 16 this. 17 DR. EGGERS: Anyone in the audience? 18 Yes, go ahead. And if you could state your 19 name, please. 20 MR. FISHER: My name is Kevin Fisher. One 21 of the questions about benefit or one of the things 22 where sort of altruism overlaps with benefit, is that</p>
199	<p>1 MR. EVANS: There are a couple things that 2 people might perceive as a benefit that we sometimes 3 don't like to think about, and one of the things that 4 I can tell you is that when I was a broke student 5 living on part-time money, I participated in research 6 because it paid money. And another experience I've 7 had as a clinical trial participant was going in even 8 though I knew I didn't want the therapy, but it would 9 give me access to diagnostic procedures that weren't 10 standard medical care that I had read would be 11 beneficial to me. So just things that people think 12 about. 13 MS. DEE: You know, and a lot of the people 14 that we have referred to Hopkins, a lot of them are 15 African American MSM and a lot of them are on 16 disability, and a lot of them were interested in the 17 money that they got because they needed it. Now, I 18 think we have to be really careful about the 19 inducement there and whether we're getting people into 20 things that are harmful or that they don't know what 21 really the score is about. 22 But I think that we really should -- well,</p>	201	<p>1 there was a study that was very similar to the study 2 that David referred to that was done in Holland with 3 HVM where they asked HIV-positive individuals what 4 they thought about a cure and why they might be 5 interested in a cure, and interesting, one of the 6 things, as David said, a lot of people weren't 7 necessarily concerned about their medications or 8 toxicities necessarily, but one of the biggest 9 concerns was about the future, like what will things 10 happen in 20 years and basically how will my life end 11 and how will this disease affect me in ways that I 12 don't quite understand? And one of the benefits of 13 going to cure research was actually maybe to get a 14 step towards that way. 15 So this would be a case where you might join 16 a trial even though it wouldn't necessarily benefit 17 you, but you would actually in some sense push forward 18 the general knowledge -- this actually kind of goes to 19 Matt's point -- push forward the general knowledge so 20 that maybe one day actually people will have an answer 21 to that and they can maybe diminish some of that 22 anxiety.</p>

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202	<p>1 DR. EGGERS: Are you talking of helping your 2 future self or something different than that? 3 MR. FISHER: Yes, a little bit. I mean, 4 there is a general altruistic, but helping your future 5 self in some sense, and so that's where altruism and 6 personal benefit kind of overlap in a way. 7 DR. EGGERS: Okay. 8 MS. DEE: You know, I think some people 9 think, too, and they did in the old days of the 10 epidemic, that, "Well, I'm going to get my foot in the 11 door because if I get in here, maybe I'll be 12 considered for the next one and the next one, and I'll 13 be in line for something that really will be 14 beneficial two steps down the line." Now, a lot of 15 times, it disqualifies you from being in the next step 16 and people should be informed of that, you know, but I 17 do think people think that way. 18 DR. EGGERS: Okay. 19 MR. PENNER: Yeah, I was going to reiterate 20 that a little bit. That's sort of the motivation that 21 I had early on, Lynda, was really like I'm going to 22 get in, it's going to lead to the next place, it's</p>	204	<p>1 listened to the panelists about risks and your 2 thinking about those risks and how you might consider 3 those for a cure research study. 4 Nathaniel? 5 MR. SCRUGGS: Good evening. I was listening 6 and looking at the panel, and I thank you all for 7 doing what you all are doing so I could be here, but I 8 was listening to Murray, and I had almost forgot the 9 days of diarrhea and throwing up and headaches. And 10 I'm somewhat appreciative of your honesty. You know 11 what I mean? Because what happens today, medicine, 12 scientists, come together and they say we're coming up 13 with these clinical trials and we want this certain 14 cohort of persons in the trial, and, Lydia (sic), you 15 spoke to it. A lot of them don't even read all that 16 information that's in there, and they don't even look 17 at the long-term effects that might happen down the 18 road. I know I was one that didn't, and I got in the 19 trial for what David spoke about, for the money, at 20 first, and then it dawned on me that I could get free 21 health exams every 6 months, not for my HIV but for my 22 high blood pressure, whatever else might be going on.</p>
203	<p>1 going to lead to the next place. Of course, there 2 weren't any options at the time, so it was like 3 looking for that option that may be out there that 4 ended up being there. But one of the things that I did 5 find out, obviously, is that my T cells increased, my 6 viral load decreased as a result of being in this, and 7 so I was seeing personal benefits. 8 So the continuous feedback about consent 9 about what's happening as a result of your 10 participation in the study at least for me would keep 11 me very motivated thinking that there were other 12 options that would help me improve my own life moving 13 forward. 14 DR. EGGERS: Do my panel members have any 15 follow up questions on the idea of motivation for 16 participating or benefit? 17 (No audible response.) 18 DR. EGGERS: If not, let's continue the 19 discussion on the risks and the uncertainty about 20 those risks. And we heard a lot mentioned up at the 21 panel, and what I would like to ask is in the audience 22 if you had any thoughts that came to mind as you</p>	205	<p>1 And I was thinking, would I sacrifice the 2 quality of my life today to get in a clinical trial 3 for the future of somebody else? No, I wouldn't, and 4 the reason I say, no, I wouldn't, because the way the 5 quality of my life is right now, can't no clinical 6 trial help me to maintain not a high level of my 7 quality of life but just a minimal level without me 8 going back into throwing up, the aches, the pain, the 9 sleepless nights, and that's just the physical 10 aspects. I ain't talking about mentally thinking I'm 11 on the island by myself. 12 So, no, no. Clinical trials have to give me 13 more of a guarantee that I can still have some 14 remnants of a mental and spiritual quality of life. 15 Physically, I'll be able to deal with that if my mind 16 and spirit is in tact. So a lot of times -- and I'm 17 looking at you all and I want to say when you have 18 people in your life that support you, your life is 19 more healthier and enriched. When I was single, my 20 life wasn't enriched because I felt like every time I 21 threw up, it was going to the worst, not fully 22 understanding what was happening.</p>

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206	<p>1 But what clinical trials are not looking at 2 -- and Murray kept speaking to it, and it's so true -- 3 once you get over a hurdle of physical discomfort and 4 you realize that you are over that hurdle, you are not 5 willing to subject yourself to that hurdle anymore for 6 any particular reason without you getting a guarantee. 7 You want a guarantee. And if anybody is involved, and 8 they have enough courage and integrity to self-impose, 9 they will say that. I don't care how much money is 10 involved, Lydia (sic), but your quality of life is 11 more than money. 12 DR. EGGERS: Thank you very much, Nathaniel. 13 We have a follow-up question, or comment I 14 mean? 15 MR. SCHAICH: Not to that, but just to the 16 risk versus the benefit? 17 DR. EGGERS: Sure. Yes. 18 MR. SCHAICH: My name is Fred Schaich. I'm 19 with IFARA and ATAC. I am concerned. I don't 20 discount in any way David and Nelson's attempt to 21 really get a good chunk of information from the 22 community, and they did. The one thing that I do care</p>	208	<p>1 we worked so hard to change the risks associated with 2 getting credit. You know, you get very simple 3 language, you understand what your risks are if you 4 get a credit card, and we worked really hard to do 5 that. I would suggest we do the same thing around 6 clinical trials so that people fully understand what 7 the risks are in very clear language. We're also sort 8 of assuming that they're at a particular level of 9 health literacy, which isn't always the case. 10 So I think those sorts of things help people 11 understand what the risks are better, and they're more 12 likely to trust the institution who is going to 13 potentially put them at risks and therefore more 14 likely to want to participate and engage in that way. 15 DR. EGGERS: Can I build on one thing that 16 you just said, which is trust in the institution? And 17 we haven't talked about that at all today. Would 18 anyone like to comment on that point? Does that 19 matter? 20 MR. PENNER: I'll take a stab at that as 21 I've been thinking after a couple of people have 22 talked. One is that I think at least some of us up</p>
207	<p>1 about is that when you take an arbitrary idea and you 2 put it out there, it is that, but I think when you're 3 talking about the reality of a trial, you have to 4 really understand -- that's what we're really going to 5 be talking about next, I guess, the consideration of, 6 what is actually in that trial? What are the risks? 7 What are the perceived risks? What are the discussed 8 or potential risks that person could really evaluate 9 fairly and honestly in themselves? And then the fact 10 that you have a family or a job that may be interfered 11 with in this protocol, those are all those 12 considerations that may make a difference. 13 Altruism is a wonderful thing, and I tell 14 you, most people have it, but it comes to a point 15 where you have to take the reality in perspective, and 16 that's the only thing I would like to throw out there. 17 DR. EGGERS: Thank you. 18 Anyone else want to comment on risk? 19 Yes. 20 MR. GARNER: Hi. This is Alex Garner again. 21 As I'm thinking about the sort of risks and benefits 22 associated with being in a trial, I am reminded of how</p>	209	<p>1 here have the benefit of a really informed treatment 2 network and brilliant friends and really good doctors 3 and a working relationship with the FDA and other 4 agencies, et cetera, to the point where I think we 5 probably do have a lot of trust, and I think that 6 makes a big difference. 7 Many underserved populations, people living 8 with HIV and AIDS, and it's been referenced here, 9 don't have access to that, and I think it would be a 10 lot more difficult to really have an honest dialogue 11 with those individuals and have them involved in this, 12 and we need those people involved in this type of 13 research, and so that's one of the schisms I think 14 that's out there that needs to be addressed to develop 15 some trust such that individuals do feel as though 16 there is a good support system as well as really clear 17 informed risks, benefits, et cetera, rather than just 18 what's on a piece of paper that you sign. 19 DR. EGGERS: Great. Thanks. 20 Anyone else want to build on that? 21 Yes. 22 UNIDENTIFIED MALE SPEAKER: I want to</p>

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210	<p>1 basically say what Murray said in terms of like 2 involvement in the process from the beginning, not 3 just in the process after you have developed your 4 informed consent, until you have your conversation. 5 Like, I mean, I love all my comrades here from years, 6 but here we don't represent the demographics of the 7 epidemic, the experiences of all people with AIDS, so 8 in the process, that would be a good way to start 9 building that trust for the future, and more in cure 10 research that is going to be even more complicated. 11 DR. EGGERS: I think when we come back after 12 the break I think we should spend quite a bit of time 13 following up on how to engage the folks that aren't 14 like those here in the room, so we can follow up on 15 that. 16 I want to ask my colleagues, though, before 17 we -- there are two more polling questions, so we're 18 going to get to those before the break, but before we 19 do, are there any follow-up questions that you want to 20 ask? 21 Sara, yes. 22 DR. GOLDKIND: I have a follow-up question,</p>	212	<p>1 So I would like to understand better what 2 you think would be an ideal informed consent process 3 in a sense. 4 And the second thing that I've been hearing 5 is that people don't read these very long, complicated 6 informed consent documents, and so how can we 7 communicate the information that's really salient in 8 the informed consent documents to participants in a 9 way that they will understand the information? 10 DR. EGGERS: I have a feeling we won't -- 11 we're going to be taking a break in a few minutes, and 12 that's a huge discussion, so if we don't get to it 13 now, we'll revisit that. 14 But maybe one thing that I think could be 15 asked that's more directly related to the questions 16 that will lead into after the break is that role of 17 the personal physician, your own personal physician. 18 I'm curious on how they shape your thinking and your 19 motivation to participate in a trial, and I think that 20 would feed into -- we can revisit the question about 21 informed consent then after the break. 22 We heard a couple of folks up here. Would</p>
211	<p>1 but it might be something that we may have to revisit 2 after the break. I've been hearing a lot of repeated 3 comments, it's become a theme. There are two themes 4 that I wanted to flush out a little bit more. One is 5 that it's an individual decision whether someone 6 participates in research or not, and it's a very 7 different decision from one person to the next how 8 risks and benefits are weighed. 9 And so my question that I would have is, how 10 do we help participants make that individual decision? 11 Is the onus on the investigator or the person who is 12 doing the informed consent or on the participant or on 13 their discussion together? So, in other words, we 14 could communicate information to the potential 15 participant, and is it then that person's job to take 16 that informed consent document to his or her health 17 care provider or family members or community and 18 figure out the risks and benefits? Or should there be 19 a second meeting after the original consent discussion 20 with the investigator again for there to be additional 21 discussion about the contents of the informed consent 22 document?</p>	213	<p>1 anyone else like to comment on that? 2 Melanie? 3 MS. REESE: Yes. My name is Melanie Reese. 4 I get my treatment at Johns Hopkins University, and 5 they are a teaching research medical facility, and 6 they push, push, push you getting into clinical 7 trials. I don't know if they get a kickback if they 8 get so many of their patients in or not, but they 9 don't really -- they leave that informed consent to 10 the investigator, and whether or not you get through 11 the -- what's that called when you get screened? You 12 go for the screening and then see if you could go to 13 the next step, to the next step. But they push it. 14 DR. EGGERS: Anyone else have a different 15 experience? 16 Yes? 17 UNIDENTIFIED MALE SPEAKER: The regular 18 physician of the patient? 19 DR. EGGERS: Your regular physician. 20 UNIDENTIFIED MALE SPEAKER: Well, I mean, I 21 have the same experience that everybody in terms of 22 like having access to good doctors. But now you made</p>

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214	<p>1 me think about the changing environment, like with 2 expansion of Medicaid, the Affordable Care Act, Ryan 3 White changing also in terms of how they provide the 4 services, that when I think about the rest of the 5 population that depend on that, and that probably they 6 will go with primary care physicians that will have 7 just 15, 10 minutes to see these people, where would 8 we have that conversation? How we support the 9 physician to bring up that conversation? I just bring 10 that up. 11 DR. EGGERS: Great points. Okay. 12 I want to make sure we get to a couple 13 polling questions, and then we'll have a 15-minute 14 break because that's what my agenda is telling me. 15 So we've had a very rich conversation, and 16 these are just two summary points, questions, to get 17 at the perspectives in the room. 18 So if we could have the next question. 19 Okay. Now, this is completely voluntary, and we're not 20 going to hold you to these answers, but after hearing 21 this discussion today, would you consider 22 participating in an HIV cure research study if it was</p>	216	<p>1 going to get hurt," "You're not going to get hurt," 2 it's not all that clear, I think. 3 DR. EGGERS: You make a very good point. 4 Perhaps for this would be the more intensive kind of 5 trials. 6 Okay. So a lot of folks would still 7 consider participating in a study, although there are 8 some folks who would not consider. Okay. 9 Andrea, do we happen to have on the web? 10 MS. FURIA-HELMS: 50-50. 11 DR. EGGERS: Okay. Okay. Good. So lots of 12 good discussion. There is one other question that we 13 want to put up, a similar question to the last one. 14 Would you consider participating in an HIV 15 cure research study if it meant that you had to 16 temporarily stop taking your current HIV medications? 17 Yes, you would consider participating in a study; no, 18 you would not consider participating in a study; or 19 you're not sure. 20 (Answering question.) 21 DR. EGGERS: And I understand that these two 22 questions are really tied together, you know, it's</p>
215	<p>1 unlikely that you would gain any direct health benefit 2 from participating? Yes, you would consider; no, you 3 would not consider participating in a study; or you're 4 not sure. 5 (Answering question.) 6 MS. DEE: While people are answering that, 7 can I say something about this question? 8 DR. EGGERS: Sure. 9 MS. DEE: You know, we've kind of lumped 10 together trials here today, cure trials about whether 11 you're going to get any benefit or whether it's going 12 to really harm you and that you're going to have to 13 stop your regimen, or you might put yourself in 14 danger. I mean, there are a lot of trials in the 15 beginning that aren't going to really be like that, 16 they all don't require that you stop your medications, 17 so there are some where you have to sit there for a 18 couple hours and let somebody take some blood, you 19 know, come back and that sort of thing. So, you know, 20 and it's going to be a very stepwise sort of thing. 21 Now, there are other trials that do require more or 22 will require more, but it's not all, you know, "You're</p>	217	<p>1 very related to the last question. Okay. Okay. 2 Maybe it's not so related to the last 3 question. This might be surprising to some of my 4 colleagues. Thank you for your input. And on the 5 web, so for those of you on the web, we had over half 6 who said, no, you would not consider participating in 7 a study, and about 20 percent of you in this, again, 8 very small, small N, but are not sure about that. 9 On the web? 10 MS. FURIA-HELMS: 40 percent yes, 40 percent 11 "I'm not sure," and 20 percent no. 12 DR. EGGERS: Okay. There are a lot of 13 unanswered questions then. 14 Yes, go ahead. 15 UNIDENTIFIED MALE SPEAKER: Just a real 16 comment on the risks before we go to break. I think 17 it's really important that the FDA pay attention to 18 exclusion criteria and what I call "eggs in the 19 basket." So with a lot of the earlier trials, you 20 know, there were all these things like you can't have 21 taken this class of drug or you can't have done this 22 or you can't have done that, so what I think there is</p>

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218	<p>1 going to be a lot of concern on is, "If I do the HDAC 2 inhibitor, will I be excluded from the PD-1?" and, "If 3 I do disulfiram trial, will I be excluded from this?" 4 In other words, there needs to be a really 5 good reason if you're going to exclude under those 6 types of things, if you know what I'm saying. And I 7 understand that early, small pilot proof-of-concept 8 studies need to be really clean, you don't want to 9 muddy it with anything, but I think in the more 10 advanced trials, you really have to justify very well 11 any reason you're excluding people. 12 DR. EGGERS: Okay. Good. Okay. So why 13 don't we take a break. We can revisit these topics 14 again. We will focus first on the informed consent 15 issues, but that's related to what we've been talking 16 about all afternoon. So we'll take 15 minutes, and 17 that means 3:45. Am I correct on that? We'll be back 18 at 3:45. Thanks. 19 (Whereupon, a brief recess was taken.) 20 DR. EGGERS: As we take our seats, I will 21 say that I spent such a fascinating conversation 22 before the break, and we look forward to carry that on</p>	220	<p>1 really about, how should informed consent clearly 2 communicate the purpose of a study, especially when 3 it's not directly -- you know, it's in the early 4 stages perhaps? How the informed consent should 5 clearly communicate the potential benefits, and we 6 talked about what we perceive those benefits to be, 7 and how should it communicate the potential risks? 8 And that includes the uncertainty about the risks, so 9 in the cases where it's really unclear, it's 10 uncertain, what those risks are. And other information 11 that you would find helpful when deciding whether to 12 enter an HIV cure research study. 13 And for those of you who have participated 14 in a study, perhaps what we could do is focus on 15 things, information, that you haven't yet seen in your 16 experiences, what kind of new information would you 17 get if you're already familiar with those consent 18 procedures? 19 And I think we also want to ask a question - 20 - and so maybe the panelists, if you have some 21 thoughts as we go through, as we make our opening 22 remarks -- about how we reach people and make sure</p>
219	<p>1 now for the remainder of our discussion. What I do 2 want to say is on the web, it's been very clear we 3 have a group of perspectives here in person that are 4 shared, and those might not be shared by folks who are 5 on the web, so I will encourage the folks on the web, 6 if you have a brief comment about something that 7 you've heard today or something that you think you 8 experience or your perspective is much different than 9 what you've heard expressed here by the folks in the 10 room, then I encourage you to submit those comments 11 and we will do our best to review those, and even if 12 we don't review them, we will have them and we will 13 read that and it will be included as part of the 14 public record as well. Okay? 15 Panel #2 Comments on Questions 5 - 6 16 DR. EGGERS: So now we're going to turn to - 17 - we have alluded to this and we've touched upon it 18 some, but we want to now talk about informed consent, 19 and I have a feeling that the questions and the 20 discussion is going to be broader than just the 21 questions that are up on the screen. 22 So the questions that we do have up are</p>	221	<p>1 that the communications are reaching the range of 2 folks who may be considering participating in a 3 research trial, even if those perspectives may not be 4 fully reflected here today. So you can comment on 5 that. 6 And then I think Dr. Goldkind will probably 7 also have some other follow-up questions to ask. She 8 has been instrumental in helping us shape this portion 9 of the day. 10 So with that, I'm done talking. We'll have 11 the same format. We're probably, of course, a little 12 bit behind schedule, but that's okay, we're going to 13 have a full discussion, and we'll get you out of here 14 on time. So I think maybe we'll start down the row 15 and we'll start with Matt to address these questions, 16 and we'll open it up for the full discussion. 17 MR. SHARP: Thank you. So I guess I want to 18 start out by saying that we've been talking about 19 informed consent and the informed consent process for 20 so long and we've been trying to explain it and trying 21 to make it easier involvement with the people that we 22 train and teach and talk to, and so I don't think</p>

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222	<p>1 that's -- none of that's changed, it's the same 2 issues. What's changed is the science and the 3 technology, so those are differences there that we 4 need to remember. This is not a new thing, we've been 5 doing this a long time. 6 And one of the main things that I think is 7 so important in informed consent is the word "process" 8 and is the word "counseling." Why can't we make this 9 a counseling effort that really goes in depth with 10 these protocols? And I know there are issues with 11 time and who is going to do it, but all of those 12 things could be worked out later. 13 But I love the idea of especially with the 14 new technology that exists out there. I know there 15 are new startup companies using tablet technology for 16 informed consents, other ways of implementing informed 17 consent rather than just a paper document that often 18 the words are too big and nobody wants to read. I 19 mean, I honestly, after you get a fifth revision of a 20 protocol, often I don't even read it. So there is a 21 lot of new technology. More time needs to be taken. 22 And I was going to say, oh, testing, testing</p>	224	<p>1 the purpose is. And then also talking about the 2 potential benefits as well as the potential risks. 3 You know, I think as much as possible to 4 quantify things in terms of this is very likely or 5 it's unknown completely, we have no idea, or there is 6 a slight likelihood, or in rare instances, if it can 7 be as descriptive as possible about what is known 8 based on previous trials or previous studies that have 9 been done, I think the better. 10 But I guess the last thing related to it is 11 that we can't underestimate the power of working in 12 the community through this process. And you asked the 13 question at the very end, how do we get this outward? 14 And I think we're not the representative folks, we're 15 not the ones that need to be a part of any kind of 16 these studies. I mean, we may need to be as well, but 17 we really need to be thinking much broader, and that's 18 a challenge, and I don't think any of us have the 19 answer to how we outreach into the community because 20 if we did, we wouldn't have 20 percent of our HIV 21 infected population in this country that don't even 22 know their status. So there are some real challenges</p>
223	<p>1 the individual after an informed consent is performed, 2 and just a simple test to see if they really 3 understood what they were reading. 4 Those are my ideas. 5 DR. EGGERS: Thanks, Matt. 6 MR. PENNER: So I have been thinking a lot 7 about this, and I even have mentioned some of this, so 8 I won't go into a lot of detail here, but I think 9 informed consent is a very -- it's a large process, 10 and it's more than just a form that you sign, and I 11 think we really need to be thinking that that's really 12 sort of the last thing that probably happens, that 13 there should be a lot of other discussion. I think 14 Matt's suggestion about a counselor or even if it's 15 your provider, you know, I can't imagine any of our 16 providers sitting down with us and going over an 17 informed consent about all the risks and benefits 18 about a potential trial for 30 minutes or 45 minutes. 19 What provider is going to have the time to do that and 20 take the time to do that? But the more resources that 21 can be provided as part of that informed consent 22 process, I think would help clearly communicate what</p>	225	<p>1 with that, but it's a critical piece that we need to 2 be focusing on as well. 3 DR. EGGERS: Thank you, Murray. 4 MR. TAYLOR: Yeah, I think Murray hit it on 5 the head when he talked about outreach to community 6 because we're fooling ourselves if we think that any 7 document or any process, no matter how involved, is 8 going to fully provide informed consent for something 9 this complicated. The reason you can provide informed 10 consent for the standard, you know, what's the next 3- 11 in-1 combo pill is because people understand the 12 process, the science, they know what they're getting 13 into because they're familiar with it. This is 14 completely uncharted territory for the patients and 15 often for the researchers. 16 So I think we need to step back and look at 17 the much bigger picture and realize we need to start 18 educating the entire community. I think all 19 stakeholders, regulatory, the Delaney Collaboratories, 20 pharma, need to collaborate with community leaders to 21 go out and educate the community about the research as 22 it's happening so we're bringing people up to speed in</p>

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226	<p>1 real time because this is going to be a lengthy 2 process of years if we're really going to let people 3 know what's going on and what they're getting into. 4 And so I think this could include the 5 development of robust community advisory boards and 6 the Delaney Collaboratories and the communities where 7 the first studies will be taking place, public forums 8 by those CABs, the Collaboratories, to educate their 9 communities, well written, and the emphasis on well 10 written and not sensationalized or hyped stories in 11 the press about what's happening and what it means, 12 webinars, and especially -- and I think Alex referred 13 to this earlier -- targeting the education of the 14 underserved communities, such as the African American 15 community and women, in conjunction with groups like 16 the Black AIDS Institute, that have done really good 17 work in educating the communities and bringing up 18 community leaders to ensure that study participation 19 is open and understood by those communities to avoid 20 the usual skewed demographics that we've been talking 21 about today. 22 So this will take time and resources, but I</p>	228	<p>1 consent process, we can actually test the process 2 before we test the people who are consented. You can 3 have a provider go out to a local community-based 4 organization, you can pay participants 20 bucks, 25 5 bucks to show up, you can have them do their spiel, 6 you can do a sample consent form, and then you can 7 test the participants to see how understandable it is 8 before you ever field the process. And, you know, 9 businesses do this kind of stuff all the time, so I 10 think we can learn from them. 11 I think also video technology has gotten so 12 much cheaper, and I think that sometimes people really 13 learn better from watching a video, particularly when 14 we're describing complex processes that are very 15 difficult to imagine if you don't understand the 16 underlying biology. 17 I think something else that's important to 18 do that's a little bit different than I see sometimes 19 in the consent forms that I'm asked to review is that 20 when you're describing the potential benefit of some 21 of these very early studies and you're talking about 22 the research goal -- so, for instance, I'll give a</p>
227	<p>1 think we need to start now so we can ensure that the 2 community is well educated and able to provide the 3 consent so that when we do sit down with them, with a 4 possibly long piece of paper and a counselor and a 5 follow-up test, that they're going to have the 6 background to actually comprehend it and provide that 7 informed consent. 8 DR. EGGERS: Thank you, Jeff. 9 MR. EVANS: Yeah, I agree with everything 10 that's been said so far, but first I think it's 11 important to keep in mind that investigators have a 12 rather perverse incentive when it comes to informed 13 consent. You know, they are driven by cost and by 14 resources and by time, and I know for a fact that 15 there have been complaints in at least one of the 16 research networks by the investigators for having to 17 do testing of informed consents because it takes so 18 much time and it takes so much personnel, and that's a 19 short simple that they do. So I think, you know -- so 20 that's important to keep in mind. 21 That said, I think that there are some 22 things that we can do. I think in devising the</p>	229	<p>1 very specific example, when you're talking about HDAC 2 inhibitors, and they might describe that an HDAC 3 inhibitor we hope will wake up latent virus, therefore 4 perhaps making it more susceptible to the body for 5 destruction. 6 Now, that's the research goal that's 7 described, but I think what often doesn't end up 8 happening is the little bit further information that 9 perhaps we think people are too dumb to understand, 10 and that's to explain the fact that we don't even know 11 how much you have to wake up the virus. So there is 12 the sort of additional information that I hope we 13 don't oversimplify because I think that's really 14 important for people to know. 15 That's it. 16 DR. EGGERS: Thank you, David. 17 Lynda? 18 MS. DEE: So everybody has been great and 19 said a lot of good things. You know, informed consent 20 is like a legal term of art, and I think it has left 21 the patients behind, you know. I think that when you 22 look at an informed consent form, it's this long, and</p>

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230	<p>1 it has nothing to do with protecting the patients 2 anymore. I mean, I really believe that. I think it's 3 about making sure that people don't get sued and that 4 the IRBs are protected and that the institution is 5 also protected, and the patients have gotten lost in 6 this, I think. I think investigators are too busy. 7 When is the last time -- I don't know of an 8 investigator except some individual docs, but from an 9 institution that sits down and talks to the patient 10 and goes through the form. I mean, you're lucky if 11 their phone number is on it, you know. That page is 12 usually empty, you know. Anyway. 13 But, I mean, I really think it behooves us 14 to get people educated and to learn about what things 15 are happening and what things mean, and I think that, 16 you know, how can you clearly communicate -- let's 17 see, the purpose of the study. 18 Oh, there's one, benefit. How can you -- 19 I'm sorry -- communicate potential benefit? Well, it 20 should be the other way around. How can you be sure 21 to communicate that there is no benefit there and that 22 people get that? And we can educate everybody in the</p>	232	<p>1 people that know what this stuff means and there are 2 people that don't. So we have to be able to try and 3 get things as much individualized as possible, and I 4 think a good way to start that is to have a good study 5 nurse that's going to take time with people to really 6 know that they get it. 7 I mean, you know, I think the video 8 technology that David talked about is really helpful. 9 I think it's really helpful, too, to videotape the 10 nurse to make sure she's asking the right questions of 11 people. You know, I don't know how that would be for 12 privacy concerns if people want to be on tape, you 13 know, but, I mean, I think that really nobody is 14 better to get this stuff done than the great research 15 nurses that are out there that are used to taking time 16 with patients that are ones that make sure that you 17 come in and that you stay enrolled and that you're 18 doing what you're supposed to. I mean, they're like - 19 - you know, women run the world, right? Most of them 20 are women. A lot of them are men, but, I mean, I 21 think that -- that's a joke, I'm just joking here with 22 that.</p>
231	<p>1 world, but then there will be somebody that comes in 2 that hasn't been to one of our things -- do you know 3 what I mean? -- that isn't aware of any of this stuff. 4 So you've got an investigator who really wants to get 5 the study enrolled and get those bodies in there so he 6 can get his study finished, and you've got some that 7 have even more wrong motives than that, I guess. 8 So what is it that we do? It's funny, I 9 just finished a trial at Hopkins, and I was interested 10 to hear what my friend in the audience said about what 11 her experience was. Now, I don't know, just because 12 it was me, and they all know me there, that the nurse 13 sat down with me until she got on my nerves, you know 14 what I mean? 15 "Okay, this, this, this." But that's what 16 you need to do with people, you need to sit there with 17 them individually. Some people will need to take it 18 home and discuss it with their family. Other people 19 were like me, like, "Okay, I understand this. Where 20 do I sign?" 21 But, you know, just like there are people 22 that will do things and won't do things, there are</p>	233	<p>1 But, you know, I mean, I think somebody has 2 got to take time with people individually to make sure 3 that they get it, you know. 4 DR. EGGERS: Thank you very much. 5 Large- Group Facilitated Discussion on Questions 5-6 6 DR. EGGERS: I want to pick up before I ask 7 my colleagues to see if they have any questions, and I 8 think instead of doing that, I think we'll open it up 9 for the whole discussion so that everyone can do that. 10 But I was struck, David, you presented a really 11 concrete thing about -- was it the length -- did 12 someone mention the length of time that the study was 13 going to be going? David, you presented something. 14 It lost me. A concrete piece of information that you 15 would want to see communicated in the informed 16 consent. And I was wondering if you could each go 17 through and talk about something concrete, description 18 of something or -- oh, it was how much is needed to 19 activate the -- okay, there I got it. I got it. 20 So if you could go through as I make my way 21 to the front, and give an example of something that 22 you would really concretely like to see included and</p>

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234	<p>1 be clearly communicated in an informed consent. And 2 I'll go to the front. 3 MR. SHARP: Well, you know adults learn in 4 different ways, so you can go back to the adult 5 learning model, you know, use of new technology, 6 different technologies, drawings. I mean, it may 7 sound silly, but some people can get a better idea of 8 a concept through a drawing or a picture than through 9 words. 10 DR. EGGERS: But is there a specific concept 11 that you think should be communicated in the informed 12 consent about cure research or about what we've been 13 talking, about the science or about the risk or how to 14 communicate the uncertainty, et cetera? 15 MS. DEE: You know, I really think -- and I 16 was trying to read it when I was speaking before, but 17 I really want to reiterate that you should say that 18 there is no benefit here, you know, no immediate 19 benefit, period, because people just don't think -- 20 don't know that. 21 DR. EGGERS: And what words would you use? 22 MS. DEE: "There is no immediate benefit to</p>	236	<p>1 do you think about the whole title of this research, 2 cure research? Should it be called something else, 3 like Reservoir Elimination or something else? What do 4 you think about that? 5 DR. EGGERS: And we'll let anyone address 6 this as well. So we'll start with David. 7 MR. BRAKEBILL: I just think the word 8 "cure," it opens up a whole thing. I mean, take 9 Facebook or any social media network over the last 10 couple of weeks, anybody that follows any of the 11 listservs or anything, all these stories break and 12 people are talking about stopping taking their meds, 13 and it's like this is crazy. 14 So I agree with you, Debra, that perhaps we 15 need to look at some other nomenclature in terms of -- 16 because I think, although those of us who work in the 17 field and live with the disease certainly hope for a 18 cure, we know that realistically it's probably 19 sometime away, and I get discouraged every time 20 somebody uses the "C" word, as David used earlier, 21 that it gives people false hope, and it's sort of like 22 NSA secrets being let out or something, you know?</p>
235	<p>1 you as a result of participating in this study." 2 DR. EGGERS: Okay. 3 MR. SHARP: But there might be an unknown 4 benefit -- 5 MS. DEE: Right. 6 MR. SHARP: -- so you need to clarify that, 7 you know, if that's going to be the case. 8 MS. DEE: "There is no known immediate -- 9 DR. EGGERS: Oops. Can you turn on your 10 mic? Yeah. 11 MS. DEE: "There is no known," put the word 12 "known" in there. But, I mean, this is amorphous, 13 "Well, this may not --," you know. I mean, people 14 want to get cured, people want to do better, you know. 15 I mean, I think that there is altruism and there is 16 altruism, they want to do what's good for the group 17 and themselves. So I think it's really got to be 18 straightforward from Jump Street that, guess what, you 19 ain't getting cured if you get in this protocol. 20 DR. EGGERS: Any other concrete things? 21 Oh, Deb, do you want to follow up on that? 22 DR. BIRNKRANT: I was wondering also, what</p>	237	<p>1 DR. EGGERS: Any follow-up? 2 Yes. In the front. 3 TIN: Just one point I wanted to make, and I 4 was talking with David and Lynda about this earlier -- 5 DR. EGGERS: Oh, can you state your name? 6 TIM: -- which is in the concept of cure, a 7 lot of us, myself included, who actually participated 8 in the pathogenesis study around 12 years ago, I think 9 some of that data has actually contributed very much 10 to where we are today. So that concept of cure 11 research is something much, much larger than I think 12 what we're talking about here. There doesn't 13 necessarily need to be this treatment endpoint. So I 14 think this is something that we've really been 15 involved in for many, many years. 16 MR. SHARP: Can I just add that even the NIH 17 has trouble with describing this, and there was a 18 group of people that tried to assess how much funding 19 was being put into the NIH for cure research. Well, 20 the coding system for cure is specific to the word 21 "cure," but there could be a lot of other things like 22 pathogenesis, vaccine trials, and so forth, so it's</p>

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238	<p>1 been even hard for the scientists to come up with a 2 good word. 3 DR. EGGERS: Murray? 4 MR. PENNER: I do agree that if I hear the 5 word "cure," and I'm in the community and potential 6 for me to go into a trial that is cure related, 7 whether I'm told there is a benefit, you know, or not, 8 and an informed consent process, I'm going to be 9 hoping that there is a cure at the end of that for me, 10 that that could result in that. So I think that is an 11 important consideration and/or the way that's 12 described. 13 DR. EGGERS: And, David, I'm also going to 14 ask you to reflect on the survey that you did and 15 maybe provide some of that perspective as well. 16 MR. EVANS: Sure. So the first thing I want 17 to say is that for me I think it's a really hopeful 18 sign of where we are socially in the epidemic, that 19 the "C" word can even be used, but when I'm talking 20 about research and what I think is appropriate for 21 research, I don't think it should be used at all. And 22 if there is a term -- I don't think any term is</p>	240	<p>1 shouldn't underestimate the amount of optimism that 2 talking about the cure has provided the community, 3 both the research community and then the people living 4 with HIV. It's really too late to turn back the clock 5 on that, I think that's unrealistic. 6 And I'm not really concerned about the 7 individual trials because none of these trials are 8 going to be called, "This is a cure trial," it's going 9 to be, you know, eradication or latency or waking up 10 the immune system, and it's not going to be described 11 in those terms. So I don't really think there is a 12 danger in that, and I think as long as the individual 13 sites, when they're advertising these trials, are 14 being ethical and not advertising it as cure research 15 but saying we're doing a trial about the immune system 16 or something like that, it's going to be fine, so I 17 don't think we need to tie ourselves in knots about 18 this. 19 DR. EGGERS: Okay. Go ahead. 20 MR. DOROSH: I was just going to say I don't 21 like the "cure" word at all. 22 DR. EGGERS: Can you state your name?</p>
239	<p>1 perfect because with some of the gene therapies, we 2 may not reach eradication of the reservoir, but they 3 may still very well control the virus, but maybe 4 reservoir depletion would be -- because that is one of 5 the goals regardless of what we're doing, so I think 6 that's a term that I think is safe to use, it's a 7 little obscure, but it's safer to use, I think. 8 And in terms of the studies, you know, our 9 partner Nelson and I are hoping to get funding to do a 10 second study, and we want to do it this time not on 11 the cheap, and this time with some social scientists 12 and some ethicists, trials experts, because we want to 13 understand better how much the word motivates people 14 and demotivates people and maybe misrepresents what's 15 going on, and we also want to really better understand 16 in a very specific way how they understand and 17 perceive risk in a meaningful way, not just in an 18 abstract way. So I don't have a lot of data on 19 terminology yet from the study we did so far. 20 DR. EGGERS: Let's go with Jeff and then 21 we'll go here. 22 MR. TAYLOR: Yeah, I mean, I think we</p>	241	<p>1 MR. DOROSH: Michael Dorosh, Treatment 2 Education Network, Denver. 3 So I don't like the "cure" thing. And just 4 a real quick little anecdote. When the ACTG reformed 5 into the TSGs, and they always have the short names 6 for everything, like in the old days, you know, TRAD 7 (ph) and OpMan and OPART (ph) and all that. So they 8 were coming up with a name for us, and the actual name 9 of that, Cure TSG, it's not a Cure TSG, it's HIV 10 reservoirs and viral eradication. So I suggested, why 11 don't we call it RAVE, like this is the latest rave, 12 Reservoirs and Viral Eradication? Joe Eron liked it. 13 John Miller said, "Oh, that implies circuit parties 14 and drugs, we can't call ourselves that." So now 15 we're called the Cure TSG, and I think that's crazy. 16 MS. DEE: The cat's out of the bag with that 17 cure business; I think there is no going back as far 18 as trying to get the word out to the community. And 19 like everything, it's a double-edged sword, it has 20 good things and bad things. I mean, as I think Jeff 21 says, if you do it like the Collaboratories, you know, 22 therapy, gene therapy, eradication therapy, none of</p>

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242	<p>1 those -- you know, they all mean a lot of different 2 things, too, but you can take the sensationalism out 3 of it by using those kind of things, but I think 4 people are interested in cure. 5 6 DR. EGGERS: Yes. Oh, and then we'll come 7 back to the yellow shirt. 8 MR. BRAKEBILL: But I also think that if you 9 went back and asked those poll questions and used, 10 "Would you participate in a whatever study instead of 11 a cure study?" that the responses might be different. 12 DR. EGGERS: Yes. Good point. 13 MS. MARTIN: Hello. My name is Mabel 14 Martin, and I'm thinking something more along the 15 lines of HIV virus advance target research so to not 16 as like proclaim that there is going to be some kind 17 of a cure but to kind of make it seem more like it's 18 more advanced research than what's available now. 19 And also to piggyback on the informed 20 consent, I think in creating an informed consent, it's 21 important to allow the individual to understand that 22 although they may not benefit directly from this</p>	244	<p>1 given to that process and maybe it needs to be a 2 multimodality process, but I'm wondering if you have 3 more to say, and within as you think about what that 4 process would look like, if there are any other 5 specifics. We've already heard Lynda say that we 6 should really be very cut and dry, very clear, that it 7 should say you will not get benefit from this trial if 8 there are no projected benefits, but if there are 9 other examples that you have for us about how to 10 explain the risks or benefits, we would like to hear 11 those, too. 12 MS. DEE: You know, I wonder, Murray, and I 13 think maybe Jeff, talked about this earlier, you know, 14 I think human beings, you worry about what's happening 15 to you now and what you're going through now and if 16 you're suffering side effects now and maybe that will 17 go away and you don't want that to happen again. You 18 know, that's more of a reality than, okay, well, maybe 19 you'll get cancer. Well, maybe I won't, you know. I 20 mean, that's more far away and we'll worry about that 21 later. 22 So I think if there is a way to -- and I</p>
243	<p>1 research or participating in the research, that they 2 will get satisfaction in knowing that them 3 participating in the research will potentially help 4 others. 5 DR. EGGERS: Okay. So Sara asked a question 6 earlier that I'm going to revisit about who should be 7 doing -- do you want to restate your question about 8 should it be with the investigator and the person who 9 should be -- well, you state it better than I did. 10 DR. GOLDKIND: So what I'm trying to drill 11 down and understand better is, what would be an ideal 12 consent process so that we could really feel 13 comfortable that we've allowed the potential 14 participant to analyze the risks and the benefits and 15 alternatives for himself or herself, and they've had 16 the opportunity to ask the questions that they need to 17 ask to understand that calculus for themselves, and 18 that the investigator or whoever is doing the consent 19 process would have a sense that the participant 20 understands what's being asked? 21 So you started to touch on it a little bit 22 by saying you think that there needs to be more time</p>	245	<p>1 know a lot of informed consents that I've seen list 2 what the risks of these other things are, but, I mean, 3 you know, if you could put into -- I mean, if you 4 could put in there definite information about what the 5 percentages of, how many people does this happen to 6 and how many years from now? It may be that if I have 7 a life- threatening disease, that I ain't going to 8 worry about what's going to happen 20 years from now. 9 You know? So if you could be more definite about not 10 only the risk, but what the real risk of that 11 happening to you is. Does that make sense? 12 DR. EGGERS: Can I follow up and say, how 13 would you characterize uncertainty if you couldn't 14 give those -- if you couldn't give as clear-cut 15 numbers that you're looking for, that you, as the 16 person deciding to participate, if those numbers don't 17 exist, how would you communicate the uncertainty about 18 that? 19 MS. DEE: I mean, you just have to say that. 20 We've been doing Phase I trials for -- how many years 21 have you guys been in existence? But there have been 22 Phase I trials that do this all the time. So I really</p>

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246	<p>1 think it's important to say we're uncertain about --</p> <p>2 you know, I like really short sentence, boom, boom,</p> <p>3 boom, boom, and I think that's easier for people to</p> <p>4 read than some long rolling sort of paragraph.</p> <p>5 DR. EGGERS: Celia.</p> <p>6 DR. WITTEN: And to add to that uncertainty</p> <p>7 about what the risks are and how to quantify them, we</p> <p>8 are interested in communicating for some of our</p> <p>9 treatments that the treatments have perhaps an</p> <p>10 indefinite residence in the body. In other words,</p> <p>11 unlike the therapies that have been so far under</p> <p>12 investigation or development, some of the ones in our</p> <p>13 office may last, so the risks may be lifetime risks,</p> <p>14 and that is a bit different, you know, it makes it a</p> <p>15 little less, well, it's something in the future,</p> <p>16 because sometimes I think people think, "Well, I'll</p> <p>17 withdraw the drug, and then after a certain period of</p> <p>18 time, that risk is not there," which I think is often</p> <p>19 true, if you didn't have the risk in the short term,</p> <p>20 you may not get it in the longer term.</p> <p>21 DR. EGGERS: So there is a --</p> <p>22 MR. PENNER: I think to the extent that that</p>	248	<p>1 DR. EGGERS: Oh, David. I'm sorry.</p> <p>2 MR. EVANS: No, I just wanted to give a</p> <p>3 process suggestion, and that's that -- I mean, you,</p> <p>4 I'm sure, you know this better than I would know it,</p> <p>5 of course, be it you're a decision-making scientist,</p> <p>6 but I think that how we pose the opportunity for a</p> <p>7 decision to people is so critically important, and I</p> <p>8 think if you simply say, "Do you have any more</p> <p>9 questions?" you get one answer. I think even if you</p> <p>10 say, "Do you have any more questions? Would you like</p> <p>11 some time to think about it?" you get another answer.</p> <p>12 And I think if you say, "I would suggest that you take</p> <p>13 some time to think about this, and we can talk about</p> <p>14 it again later if you have any more questions," gets</p> <p>15 you yet another answer.</p> <p>16 And so I know that the FDA can't mandate a</p> <p>17 process, but I think those kinds of processes could be</p> <p>18 really helpful to suggest to investigators.</p> <p>19 DR. EGGERS: Okay. We'll go to Tim. Oh,</p> <p>20 I'm sorry. And then Tim.</p> <p>21 MR. MUNK: Hi. I'm Bob Munk, from the AIDS</p> <p>22 InfoNet. And I have long been concerned about the</p>
247	<p>1 is potentially happening if you go off of a treatment</p> <p>2 and it's going to remain in your body as best you</p> <p>3 know, that has to be said so clearly up front even</p> <p>4 though you may not know what the risks of that</p> <p>5 happening are, that's got to be really -- those are</p> <p>6 the kinds of things that have to be explicitly stated,</p> <p>7 and then you can get into kind of the mumbo-jumbo</p> <p>8 that's necessary in order to achieve true informed</p> <p>9 consent, but it's almost like there is a fact sheet</p> <p>10 with bullets that are really short and to the point</p> <p>11 that sort of lay out what the document itself is</p> <p>12 trying to tell you.</p> <p>13 You know, when you go to sign all the papers</p> <p>14 at your mortgage company when you're buying a house,</p> <p>15 you're signing all kinds of crap that you don't know</p> <p>16 what it is; right? So if there was a cheat sheet that</p> <p>17 said, "Okay, Form 1 is going to tell you about this,"</p> <p>18 and just in very simple language, those kinds of</p> <p>19 things I think would be really helpful.</p> <p>20 DR. EGGERS: Lynda, and then someone in the</p> <p>21 audience.</p> <p>22 MS. DEE: I think it was David.</p>	249	<p>1 patient consent process because there is no</p> <p>2 disinterested party or no third party involved. I've</p> <p>3 been to some investigator meetings that are like the</p> <p>4 most cheerleader kind of things that you could</p> <p>5 imagine, you know, "Yea, you've enrolled 34 at your</p> <p>6 site." Of course, your goal is 50. And there is a</p> <p>7 lot of pressure on these research nurses to produce.</p> <p>8 I don't know how it would be feasible, but I like the</p> <p>9 idea of, "Would you like some time to think about it?"</p> <p>10 We won't sign you up today. Come back whenever." But</p> <p>11 I'm very concerned about that.</p> <p>12 DR. EGGERS: Okay. And then Tim, and then</p> <p>13 we'll go back.</p> <p>14 TIM: I just wanted to go back to a point</p> <p>15 that David raised earlier in this session, which is I</p> <p>16 think he talked about really the concept of taking</p> <p>17 advantage of different technologies for informed</p> <p>18 consent, one such being video. We don't do that,</p> <p>19 because there is a very famous literacy study that</p> <p>20 came out about 10 years ago that basically said that</p> <p>21 10 percent of what is read is remembered versus around</p> <p>22 to 30 to 40 percent of what is watched and heard is</p>

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250	<p>1 remembered. And we're not really just talking about 2 providing an educated permission to participate in the 3 study, we're also talking about getting people to 4 remember why they participated, remember what the 5 risks are, remember what the potential benefits are, 6 and importantly, to remember what their rights are. 7 So I think that we really have a very wide array of 8 different technologies that we can take care of that 9 were really not talked about here. 10 DR. EGGERS: Okay. So then -- 11 MR. KAYTES: Andy Kaytes. I think health 12 literacy plays a really, really big role in this 13 because if informed consents are supposed to be 14 written at the 8th grade level, is that 8th grade at 15 an Ivy League prep school? 8th grade at an inner city 16 school? 8th grade at a school on the border in El 17 Paso, Texas? 18 And to Tim's point, I think that videos are 19 something that can transcend all of those grade 20 qualities, if not levels, and certainly you can't have 21 a video of every aspect of informed consent, but if 22 you can show a video of procedures and maybe have</p>	252	<p>1 able to study, you know, how do they get reached? It 2 seems like we need to kind of start earlier in the 3 communities as a whole, in schools, and start to 4 educate people not just about HIV research, but 5 research in general, and then have a mechanism that 6 would allow those of us that are advocates to be able 7 to reach them in a much more fruitful way. 8 DR. EGGERS: We'll go down the row. 9 MR. DOROSH: I'm going to tag again on what 10 Tim was talking about in terms of a video. I don't 11 know about where you all live, but where I live, when 12 you get called for jury duty, you have to sit and 13 watch this video, and it's very simple, it's very 14 basic, it's aimed at anybody, and it tells you about 15 the whole trial process and the defendant and all the 16 rest of it, and you just sit there and you watch that 17 and then you kind of know a little bit more. 18 19 And I don't know if you guys could do this, 20 but I'm just wondering if the FDA could create, you 21 know, a really good slick, quick, maybe 5 minutes or 22 less, video just on cure research in general that's a</p>
251	<p>1 interviews of people that have gone through those 2 procedures that have had good results, bad results, 3 that can be very helpful. 4 The other thing is one of the hurdles that I 5 perceive is the community members or research 6 participants you would be looking for aren't 7 necessarily the ones that have gotten the most 8 education regarding research. So those of us that 9 have volunteered our time to learn, to understand, to 10 be able to speak to our peers in lay terms, we're in 11 some ways cut out of that informed consent process due 12 to HIPAA and other things, we can't go out and 13 actively recruit for trials, we can't sit in the lobby 14 of a research site and talk to people before they go 15 in and meet with a study nurse. 16 I'm not saying we shouldn't have privacy and 17 confidentiality, but if the people that we're looking 18 to get into research trials are those that are not 19 necessarily in the know, they're newly infected, 20 they're in acute infection, they're going through 21 crazy thoughts in their head about their diagnosis, 22 yet they're the ones that we would really like to be</p>	253	<p>1 requirement of anybody who is considering entering a 2 clinical trial before they even get to the informed 3 consent process, something like that. I don't know if 4 that's possible. I don't know if IRBs would freak out 5 on that. That's one thing to consider. When you look 6 at the word "informed consent," "consent" is easy, 7 that's yes or no, you consent to let the guy in your 8 lane when you're driving. "Informed" is information, 9 it's informing, and really need that more and more and 10 more in this whole arena. 11 At our pre-CROI community cure workshop this 12 year we identified that educating and informing the 13 community, our HIV community, about this whole field 14 is crucial, and it's an unmet need right now, and 15 we're currently trying to come up with ways to do 16 that. There are national publications, videos, a 17 number of other things, but I think it's really, 18 really important and -- I just lost my train of 19 thought. It needs to happen -- the informed consent 20 process shouldn't start with the informed consent, I 21 think it needs to start with that information 22 dissemination.</p>

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254	<p>1 Oh, what I was going to say was a bunch of</p> <p>2 us put out all kinds of fires after those press</p> <p>3 releases, the daily telegraph, all that crap that was</p> <p>4 going on. I was getting e-mails. It was crazy what</p> <p>5 was going on. I mean, we all knew good Kate was</p> <p>6 pregnant before she was pregnant in this day and age.</p> <p>7 DR. EGGERS: I hear a recurring theme about</p> <p>8 needing to start earlier than actual informed consent,</p> <p>9 and my colleagues can echo on this. I think it needs</p> <p>10 to be reiterated that drug development is -- the FDA</p> <p>11 has a part in that, and so I hope that there are other</p> <p>12 folks hearing what you're saying.</p> <p>13 Discussion with FDA Panel</p> <p>14 DR. EGGERS: Does anyone want to comment on</p> <p>15 the theme of sort of general education about research?</p> <p>16 Not to put any of you on the spot.</p> <p>17 DR. SHERWAT: Actually, it's not that, but</p> <p>18 I'm wondering, do you think there is any utility in,</p> <p>19 say, a post-test process where you go through the</p> <p>20 informed consent process and then you have a very</p> <p>21 brief focused test that you take that covers the most</p> <p>22 salient points, covering the biggest risks that have</p>	256	<p>1 test, number one. Call it a survey or whatever. That</p> <p>2 freaks people out. But also don't disqualify people,</p> <p>3 but you have them have another opportunity to learn</p> <p>4 the information so that you might be able to use them</p> <p>5 in the study.</p> <p>6 MS. DEE: You know, if this was a</p> <p>7 requirement, I bet the docs would find a way to get</p> <p>8 somebody in there to actually explain what they were</p> <p>9 supposed to be knowing. Right?</p> <p>10 DR. EGGERS: Oh, we have someone. Okay.</p> <p>11 MR. SCHAICH: Yeah. Three things. One is</p> <p>12 that certainly it would be far from me to say anything</p> <p>13 bad about video, I love it, but I think it's important</p> <p>14 to get the -- the nice thing about a video is you can</p> <p>15 custom make it for the culturally and ethnically</p> <p>16 specific and languages, et cetera, so it makes it</p> <p>17 really a buy-in for the people that it needs to</p> <p>18 address and work with.</p> <p>19 The other one is I think it's really</p> <p>20 important to consider families who that person feels</p> <p>21 is important in their decision making process, and</p> <p>22 make sure that happens because I've heard I don't know</p>
255	<p>1 to do with whatever this type of research is, and</p> <p>2 unless the person is able to pass that, say, on one or</p> <p>3 two attempts, you just feel like they're not getting</p> <p>4 these points and they're not going to be someone that</p> <p>5 really should be in that type of a trial?</p> <p>6 DR. EGGERS: This is a great question. In</p> <p>7 fact, we have a polling question on it. It's our</p> <p>8 final polling question.</p> <p>9 DR. SHERWAT: Never mind.</p> <p>10 DR. EGGERS: No, let's ask it now, this is</p> <p>11 great. We just need to get it set up, but it's</p> <p>12 directly to this point. Okay.</p> <p>13 Do you think it would be appropriate for HIV</p> <p>14 cure research study participants to take a post-test</p> <p>15 at the end of the informed consent process whether</p> <p>16 they understood important aspects of the study, its</p> <p>17 purpose, the potential benefits, and the potential</p> <p>18 risks? Did I get that right?</p> <p>19 (Answering question.)</p> <p>20 DR. EGGERS: Okay. Yeah, Matt.</p> <p>21 MR. SHARP: So I want to just say with a</p> <p>22 caveat, I mean, I don't think you should call it a</p>	257	<p>1 how many meetings like this where people said they</p> <p>2 were pulled from the trial by their husband who were</p> <p>3 outraged that they were in this trial in the first</p> <p>4 place. So I think it's important to have that</p> <p>5 discussion as a part of the process before they get</p> <p>6 into the informed consent.</p> <p>7 MR. EVANS: I just wanted to note really</p> <p>8 quickly that I think there are a couple of ways you</p> <p>9 can do that kind of an assessment, and I would call it</p> <p>10 an assessment and not a test, and I think that one of</p> <p>11 the ways you can do that is verbally, and you can ask</p> <p>12 people to explain in their own understanding what they</p> <p>13 know, what they think they heard about X, Y, or Z. So</p> <p>14 I think that's important.</p> <p>15 DR. GOLDKIND: Also I just want to point out</p> <p>16 -- and maybe Richard Klein wants to speak to this a</p> <p>17 little bit more -- but FDA does have resources about</p> <p>18 clinical trial research and what it means to be in a</p> <p>19 clinical trial. So, I mean, it's a starting point,</p> <p>20 but I take your point, that maybe us or other groups</p> <p>21 can do something more specific to these issues, but we</p> <p>22 do have some sort of education system in place</p>

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258	<p>1 already.</p> <p>2 DR. EGGERS: Thanks for clarifying.</p> <p>3 We'll go to David?</p> <p>4 MR. BRAKEBILL: I'm just curious. You know,</p> <p>5 one of the models that's really worked well on the</p> <p>6 care side is the use of pure navigators and the</p> <p>7 possibility of using somebody to do the informed</p> <p>8 consent who has been through a trial before. I think</p> <p>9 you sort of alluded to it when you said using people</p> <p>10 that have been in the video, "I did this," and so and</p> <p>11 so forth, but I think that that may be one way, a</p> <p>12 better way, to engage people to get into trials but</p> <p>13 also keeping them in, that you also have some sort of</p> <p>14 peer support system that once they're in a trial, to</p> <p>15 keep them engaged in the trial. It's been very</p> <p>16 successful in the Ryan White CARE system for keeping</p> <p>17 people in CARE and engaged in CARE, and I think it's</p> <p>18 the same sort of principle with research.</p> <p>19 DR. EGGERS: Murray?</p> <p>20 MR. PENNER: I recently became or heard a</p> <p>21 presentation of a doctor in Denver that had done some</p> <p>22 tremendous work related to linkages to CARE and</p>	260
259	<p>1 keeping patients in CARE, and I think this could be</p> <p>2 applicable. They did on the initial arrival of the</p> <p>3 patient to the clinic had a kiosk where they were</p> <p>4 asked a series of questions related to substance use</p> <p>5 and homelessness and the kinds of things that a doctor</p> <p>6 might not either be comfortable talking with the</p> <p>7 patient about or have time to or whatever, but it was</p> <p>8 an anonymous kind of way of getting some input from</p> <p>9 that patient early in the process of an entire visit,</p> <p>10 and they showed some incredible outcomes as a result</p> <p>11 of that. So I'm wondering if there could be some</p> <p>12 things like that that could be built into an informed</p> <p>13 consent process either on a tablet where you answered</p> <p>14 some questions and then came back later and the</p> <p>15 conclusion was another set of questions, and that</p> <p>16 could be a pre- and post-test to really kind of see</p> <p>17 where you're going, but it's not called that, and you</p> <p>18 think you're interacting with the whole process that</p> <p>19 way.</p> <p>20 DR. EGGERS: Could you include that in the</p> <p>21 docket? If you write to the docket, include that in</p> <p>22 there.</p>	261
260	<p>1 MR. PENNER: Sure.</p> <p>2 DR. EGGERS: Okay. I'm going to do a time</p> <p>3 check. We are at 4:35, which is, according to the</p> <p>4 agenda, the end of the large-group facilitated</p> <p>5 discussion, but we don't have any public comment</p> <p>6 signed up. Am I correct in that?</p> <p>7 (No audible response.)</p> <p>8 DR. EGGERS: Okay. So we are shaving some</p> <p>9 time off. So I think that given that it's a Friday</p> <p>10 afternoon in June, and I'm thinking it's gorgeous</p> <p>11 outside, I think we can cut the meeting a little bit</p> <p>12 short and still make sure that we have gotten done</p> <p>13 with all the questions and all the points that we want</p> <p>14 to make. So my suggestion is that we can try to close</p> <p>15 out and see if FDA has any further questions. And</p> <p>16 then if you have any remarks that you want to make,</p> <p>17 we'll do that. And then we'll ask Theresa Mullin to</p> <p>18 come up. And between this and Theresa, we'll have if</p> <p>19 there are any web comments, we'll summarize those.</p> <p>20 So if you're on the web, this is your sort</p> <p>21 of final chance. We can't promise that we'll review</p> <p>22 all of them, but if you have something that's really</p>	261
261	<p>1 different than what you've heard said here today, you</p> <p>2 can include that.</p> <p>3 MS. DEE: Sara, before we leave this --</p> <p>4 DR. EGGERS: Yeah.</p> <p>5 MS. DEE: You know, I don't know, I feel</p> <p>6 like we really haven't done justice to this informed</p> <p>7 consent thing. I mean, I think it's broken the way it</p> <p>8 is now, and I think we've been around the rosie, but I</p> <p>9 wonder if there is anything else we could do to work</p> <p>10 with Sara directly to convene something to talk about</p> <p>11 this, just this one aspect, a little bit more to make</p> <p>12 some recommendations or something. I don't know. I'm</p> <p>13 not sure what you are allowed to do and what's within</p> <p>14 your purview as far as the informed consent processes,</p> <p>15 but I think of all the things that we've talked about</p> <p>16 today, this might be the most important, and I think</p> <p>17 we've probably given you the least concrete</p> <p>18 information.</p> <p>19 MR. KLEIN: Hi. If I could make a quick</p> <p>20 comment. What we could do is put together a webinar</p> <p>21 through my office and continue a conversation that way</p> <p>22 if that works for you. So I can work with Lynda.</p>	261

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262	<p>1 DR. GOLDKIND: That would be great. And the 2 other thing I was going to say is that FDA is 3 developing a guidance on informed consent, and when it 4 is published, it's going to be published in draft, and 5 we would welcome comments to our public docket that 6 can be as detailed as you would like, and they will 7 all be carefully considered.</p> <p>8 But before we close, I don't want to stand 9 in between us and a beautiful day, but I did want to 10 see if anyone had any more specific comments about how 11 we could sort of chip away at this idea of the 12 therapeutic misconception, whether there are any 13 suggestions about how people can understand that 14 they're enrolling in research that's not going to be 15 designed to treat them specifically but that the care 16 they get is going to be protocol driven.</p> <p>17 MS. DEE: "There are no known benefits to 18 you participating in this trial."</p> <p>19 MR. SHARP: Just really quickly, I think one 20 thing that we can do with these studies is to be 21 abundantly clear that the therapies that are being 22 prescribed or a treatment interruption that is being</p>	264	<p>1 there any concrete perspective that you have on how to 2 inform about having to stop the medications and the 3 risks that could be associated with it? I don't think 4 we've talked about that at all yet on how to 5 communicate that.</p> <p>6 MR. PENNER: I think it's sort of what David 7 just said, that, you know, this is not consistent 8 with, you know, U.S. Public Health Service 9 recommendations, you know. There could be risks that 10 we don't know what these are. And it has to just be 11 as clear and as simple as what Lynda and David were 12 talking about.</p> <p>13 UNIDENTIFIED MALE SPEAKER: "Kids, don't try 14 this at home."</p> <p>15 MR. PENNER: Yeah.</p> <p>16 MR. EVANS: Well, and I think also it 17 depends on the population that you're studying. I 18 think if it's people who have CD4 counts in the 750 19 range and they happen to already be on therapy, that's 20 one kind of consent in process. If someone had a CD4 21 nadir of 50 and they currently have a CD4 count of 22 350, so it's technically above the range of the SMART</p>
263	<p>1 conducted is not consistent with the federal 2 guidelines on treatment for people living with HIV, 3 and I think that should be in every consent form, only 4 because it's true. And recommended medical practice 5 is one thing, and research is another, and I think 6 making that very clear in a consent process is 7 important. It might dissuade some people from 8 participating, but you know what? That's great 9 because if they understand that and they don't want to 10 participate, it's good that we knew that, you know.</p> <p>11 DR. EGGERS: Murray? Murray, do you have --</p> <p>12 MR. PENNER: I'm thinking to some of the 13 vaccine trials and some of the vaccine research that's 14 going on, I know that there are portions of studies 15 that don't really result in any benefit, and I'm just 16 wondering if there are messages that can be borrowed 17 from that process because I know they've done a lot of 18 work on making sure that the messages are clear about 19 we're not developing a -- "You're not getting 20 vaccinated and this is not going to protect you from 21 getting HIV."</p> <p>22 DR. EGGERS: What about informing -- is</p>	265	<p>1 study, they need to really understand that SMART study 2 and what the results of it were.</p> <p>3 DR. EGGERS: Okay. We had Robert and then 4 someone. Okay.</p> <p>5 ROBERT: I want to thank all of you from the 6 FDA that are here for all your hard work. I'm 7 wondering if you could just comment generally about 8 the sequester and what effects it's going to have on 9 your funding and what your plans are, the constriction 10 that might come for your research.</p> <p>11 DR. BIRNKRANT: Don't quote me.</p> <p>12 DR. BIRNKRANT: I mean, the impact we've 13 felt to date has been basically that our travel has 14 been limited, but we've still been allowed to hire new 15 reviewers and we are fortunate that we are able to 16 hire, not large numbers, but what we feel at this 17 point are enough to get our jobs accomplished. And as 18 far as we know, there won't be any furloughs of FDA 19 employees.</p> <p>20 And I will be honest with you, it has had an 21 impact on morale overall in general, but I think we're 22 all grateful that we're able to come to work, we have</p>

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266	<p>1 a job, and we have a meaningful job. So I guess in 2 the end it hasn't really directly affected us as it 3 has perhaps some other agencies. But we're still 4 continuing to do the work that we are asked to do by 5 the public. 6 MS. DEE: Deb, and that travel can be a big 7 thing, though. I mean, you don't get to go to 8 research meetings, where they just presented, where 9 you can interact with researchers and industry. 10 DR. BIRNKRANT: Well, that's true. Right. 11 MS. DEE: I mean, that's a really important 12 thing. 13 DR. BIRNKRANT: You're right. 14 MS. DEE: It's not like you're going to 15 Paris; right? 16 DR. BIRNKRANT: No. We haven't been to 17 Paris in a long time. 18 But we do participate in webinars and we go 19 to local AIDS and hepatitis meetings, and we give our 20 talks on the phone to large groups. Kim just did one 21 on long-acting therapies, and others have done similar 22 presentations via phone. You're right, though; it's</p>	268	<p>1 to whatever in terms of the interruption in any 2 informed consent. For example, if somebody is taking 3 efavirenz, you know, there is a whole protocol for how 4 you interrupt that therapy, you just don't stop it 5 like all at once, and that needs to be conveyed, and 6 again some people really get it and some people really 7 don't, so that can be a very tough thing. 8 And then general education again. I know a 9 young guy in his twenties just infected a couple of 10 years ago, he acquired a resistant virus, and so they 11 had to like adjust his regimen or whatever, so now 12 he's on a specific regimen, he knows that, and he 13 wants to do like the Sangamo zinc finger trial, 14 heterologous still to 32, and he's like, "Oh, I can't 15 interrupt because I have this resistant virus." Well, 16 really, couldn't he interrupt if it works? You know? 17 I mean, we don't know. We know and we don't know, you 18 know, but that's part of this whole information thing 19 that really has to happen before the informed consent 20 and definitely be a part of that for that individual. 21 DR. EGGERS: Anything else from up here? 22 Adam?</p>
267	<p>1 not the same as being at the meeting, networking, et 2 cetera. 3 DR. COX: And there may also be some new 4 activities and some additional planned activities that 5 either may be difficult to get to, may take more time 6 to get to, or that we simply just have to wait before 7 we tackle them, based on the current prioritization of 8 activities. And that really just is in essence common 9 sense with regards to when you're facing a situation 10 where there are limitations on the resources or 11 resources that you thought might be there aren't 12 present. 13 ROBERT: I was just wondering if 14 (inaudible). 15 DR. COX: So that's probably getting beyond 16 the scope of what we can cover here today. 17 DR. EGGERS: I'll do the ground rule check 18 that we are kind of focusing on the questions that 19 we're being asked, but a fair question. 20 I'll go here. 21 MR. DOROSH: I'm tagging on I think what 22 Dave was saying, that it really needs to be specific</p>	269	<p>1 DR. SHERWAT: Just a couple of questions 2 that I had jotted down. 3 DR. EGGERS: Great. 4 DR. SHERWAT: From your perspective, is 5 there -- oh, I'm sorry, can you hear? 6 (No audible response.) 7 DR. SHERWAT: Is there a threshold that you 8 feel the FDA shouldn't allow a study to go forward 9 based on the safety risks that may be inherent in the 10 trial, or should it always be up to the patient via 11 the informed consent process to make that 12 determination? And if you do believe that there is a 13 safety threshold, where do you think that exists? 14 Where would you draw the line if you were on this side 15 of the table if you think that that's a role? 16 MR. EVANS: I mean, personally, I get 17 uncomfortable with treatment interruptions with 18 anything below 500 as a CD4 count just personally. I 19 would prefer that we don't allow people with high 20 Framingham Risk Scores to enter these studies. I just 21 think, why do that to people? 22 And I think also that, you know, we probably</p>

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270	<p>1 are going to have to talk about treatment 2 interruptions that are longer than 16 weeks at some 3 point, and I think we need to start thinking about 4 that just because there may be therapies where the 5 stopping rule is that your CD4 count falls below 500 6 or your viral load climbs back up above 50, and if 7 someone hasn't met that stopping rule, should they be 8 allowed to continue on their treatment interruption, 9 and what might that tell us scientifically? So I 10 think those are the things that I think about when it 11 comes to treatment interruptions. 12 DR. SHERWAT: Besides the population that 13 you would be choosing as far as choosing the safest 14 population, are there any particular risks inherent to 15 the drugs that might be used or that the genetic 16 manipulation that you think would be something that we 17 shouldn't allow to go forward? Do you think that 18 should also be up to the patient to make that 19 decision? 20 MS. DEE: It depends on if it's been four 21 people and three of them died. I mean, you know, it's 22 kind of you have to be a little bit more -- give us a</p>	272	<p>1 is a theoretical risk of cancer, but you were only 2 giving them a single dose, it was a small dose, and 3 you didn't see risks of cancer in the -- you know, 4 additional cancers in the cancer studies, so I think 5 that was a reasonable go decision to make. 6 So I think it's hard to say it in the 7 theoretical because it really depends on the therapy 8 that you're looking at. I think it's important that, 9 though -- but I think there are two other important 10 things about studies. One is that I think it's not 11 always just about the safety of the drug, it's about 12 the trial design, and I think we have a real 13 obligation if we're going to ask people to donate 14 their bodies and lives to these things to make sure 15 that the trial is designed, as best as it can, to get 16 the answer that you're going for. And I think a 17 perfect example of that -- and we were talking about 18 it earlier today in a different meaning -- are the 19 assays that you use to determine latency. 20 You know, the Siliciano study came out and 21 said that there was absolutely no correlation between 22 six different assays. And so what do you do about</p>
271	<p>1 little bit more information about -- do you see what 2 I'm saying? 3 DR. SHERWAT: Yeah. I mean, a lot of times 4 the problem is that the medications that are being 5 used, of course, they weren't approved for that 6 population, so it's hard to gauge some of the risks, 7 even the risks that are known for the drugs let alone 8 the theoretical risks. So that's always the 9 difficulty. I was just curious from the patient's 10 perspective, where you do kind of draw the line where 11 you think this much risk is too much risk for us to 12 even -- if you were on our side of the table, for us 13 to even let it go forward as a study? 14 MS. DEE: I see. 15 MR. EVANS: I mean, I think you can always 16 do more animal studies. I think that's always good to 17 do because where it will give us information -- I know 18 it won't always give us that information, and I know 19 you can't always do that with gene therapies, but I 20 think that's really important. I think, you know, 21 like the vorinostat study is I think a perfect example 22 where you had a drug that was Ames-positive, so there</p>	273	<p>1 that? Well, maybe you require that they have to do 2 three, you know, three different ones, to prove that 3 you've done something to the reservoir, I don't know, 4 but I think that there are things you can do cleverly 5 to manage and mitigate risk. 6 MS. DEE: I think David gave you a perfect 7 example about vorinostat, and now we're in a position 8 to, well, how many doses can we do now and to look at, 9 23, 25, and to do that safely. But, you know, I mean, 10 the way things are, we don't know a lot of the 11 answers, so doing it in a stepwise fashion like you've 12 been doing I think is all you can do. 13 DR. EGGERS: Can I interrupt with a real 14 process question? Can we collect the clickers so that 15 we can let Chad go home? 16 And I think we should give Chad a round of 17 applause for helping us with this. 18 Okay. Now we can continue. 19 MR. SHARP: So in regard to this question, I 20 don't want to sound naive in saying this, but just in 21 working on the DARE CAB with UCSF and some of the 22 researchers in Australia, I know they are being</p>

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274	<p>1 extremely careful about moving forward in the trials 2 that they're doing, and you don't want to completely 3 rely on that obviously, but it's moving very slowly in 4 terms of some of these riskier procedures and drugs 5 being used so far, and that may be because of you 6 guys. 7 But it's true, I think they're really being 8 -- and actually some of the biotechs are, too; others 9 aren't. 10 DR. EGGERS: Anything else? 11 Okay, yes, go ahead, Jeff. 12 MR. TAYLOR: Well, you know, and I think 13 most of these processes have already been in place for 14 a long time to ensure patient safety, and I think we 15 need to rest assured that they are in place, and as 16 everybody said, evaluate each therapy as it comes up, 17 but on the other hand, I hate to see us become overly 18 paternalistic to patients and not let them make 19 decisions because these are their lives and they're 20 allowed to make that decision. So there needs to be a 21 balance. 22 DR. EGGERS: Okay, with that, I think we'll</p>
276	<p>1 And then a few other comments about the 2 informed consent process. One comment echoes what we 3 heard about education, especially those on the front 4 line, i.e., the research coordination staff because of 5 the lack of time on the part of principal 6 investigators. And also echoing the comments about 7 videos with pre- and post-testing. And also a 8 suggestion about study participants taking part in 9 half-day or full-day training at a local ASO or health 10 department. 11 Finally, we have a few comments. Someone 12 commented it might be interesting to the community 13 that there is a Generic Drug Regulatory Science 14 Initiatives Public Meeting that the FDA is holding on 15 June 21st about the public discussion of agency 16 generic drug research priorities and an overview of 17 current efforts. 18 And then, finally, we have someone else who 19 commented that maybe an HIV 101 document would be 20 helpful, a long legal 20-pager, and then a short 2- 21 pager that is really for the patient. Those are just 22 a few of our comments.</p>
275	<p>1 call the facilitated discussion closed, and my job is 2 almost done, and the panel members' jobs are almost 3 done. As Theresa is making her way up to the front, 4 I'm going to ask Andrea just to see if there are any 5 web remarks. 6 MS. TAN: There were actually quite a few 7 comments on the webcast, and I apologize, I won't be 8 able to summarize all of them, so just bear with me as 9 I sift through them. 10 We have some comments based on our earlier 11 discussion about clinical trials and the case of a 12 trial that shows therapeutic benefit in an immunologic 13 non-responder with a doubling of T cells. And the 14 comment asked: How can the FDA help provide a clear 15 pathway for further development of the therapy? 16 We also have a comment about incentivizing 17 patients to take part in cure research in clinical 18 trials. I think that's a new thought, that it might 19 be a standard and often necessary practice, but would 20 patients be willing to take more of a risk if they 21 received an incentive or medical care during a cure 22 trial?</p>
277	<p>1 DR. EGGERS: Great. All right. And with 2 that, I will thank the panel members, and I will thank 3 the folks in the audience and the folks on the web. I 4 think this has been some great input. I have learned 5 a lot today. I think Theresa is going to probably 6 echo my comments. And with that, I will turn it over 7 to Theresa, Theresa Mullin, to give the closing 8 remarks, and then we'll be done. 9 Closing Remarks 10 DR. MULLIN: Okay. Well, I guess I really 11 am the last thing between you and a beautiful weekend, 12 so let me try to finish up. And I want to thank you 13 so much also for coming here to this meeting and 14 giving us the benefit of your very thoughtful 15 perspectives, a lot of great ideas. 16 I'm not even a transcriptionist, and I took 17 21 pages of notes. So I'm going to spare you most of 18 my notes, but on the other hand, I want to sort of say 19 a little bit of what I took away from what we heard 20 today. 21 And so on the patient perspectives on 22 current approaches, just hearing about the critical</p>

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278	<p>1 importance of paying attention to comorbidities and of 2 including people in trials who really are like the 3 real population that has HIV and also considering the 4 drug- drug interactions for those drugs that you have 5 to take to treat the comorbidities, the adherence to 6 your regimen and changes in the regimen and the 7 concerns about changing the regimen, trying to find 8 ways to ease administration and concerns that no more 9 drugs in the same class might be getting developed, 10 and so there may be fewer options going forward for 11 new therapies in those classes, the same in any class. 12 And the special challenges we heard earlier 13 for many of the pediatric populations because there 14 are various age segments and times when people become 15 HIV- positive, the prospect of having the rest of your 16 life on therapy and the earlier age at which you 17 experience the side effects from those therapies, and 18 things just like night terrors, which are also harder 19 for young children probably or children to have to 20 contend with. 21 And then in terms of perspectives on cure 22 research, I mean, one thing I clearly heard is that</p>	280	<p>1 achieve that. 2 And that there might be specific benefits 3 that different folks mentioned. Money may be 4 something that some will want to include in their 5 calculus of whether or not they want to participate, 6 high quality care, access to high quality care that 7 they might not otherwise have, and, of course, 8 clinical benefits if there are any. 9 And that you made the point I think 10 repeatedly that this is a very individual decision and 11 that the individual's perspective has to be reflected. 12 And another observation that came after that I think 13 was that there are critical subpopulations that are 14 not here today, that the young and maybe minority 15 populations are not here, women populations are not 16 here, and that their perspectives are going to be 17 critical to take into account. 18 So all of that about what people need to 19 understand to see whether or not they even are willing 20 to participate in this kind of cure research led us 21 very I think nicely to the informed consent process 22 discussion. And the point was made, at least that I</p>
279	<p>1 you're not making a participation decision from the 2 same perspective that patients made it when the 3 epidemic began, you're at a very different place, and 4 available therapies that work, they work pretty well. 5 You're looking at potential loss of what you have from 6 that therapy, so you're at a very different place in 7 terms of prospect and looking at the risks. And that 8 just has to be understood, and it was also confirmed 9 by the clicker input, that about half said they would 10 not be interested in participating in this kind of 11 research. 12 And we have to be much clearer about what 13 the benefits are. In fact, the point was made by many 14 of you that we have to be very clear, or the sponsor, 15 the clinical investigator, needs to be very clear 16 about what the specific risks and benefits the patient 17 would be exposed to, and you need to really understand 18 exactly what is entailed in the trial protocol. What 19 are you going to experience? What specific benefits, 20 if any? And the more clear and quantitative and 21 simple we can be and that can be in being presented, 22 simple but not simplistic, the better, to help really</p>	281	<p>1 heard, that paper forms today, they're often long, 2 they're not clear, they're not particularly quantified 3 or helpful, that people don't necessarily even go 4 through a careful reading let alone understanding of 5 them. 6 And the process today may be a little bit 7 motivated toward enrollment and the parties involved 8 are disinterested, and that makes things more 9 challenging for a good process. And it's not clear 10 that people understand already, what does cure 11 research mean? That might not even be a good name for 12 it. We spent a while talking about maybe that name is 13 misleading and how to talk about the benefits, and 14 there may not be any to being in these trials. 15 You talked about the potential value of 16 video and visual presentation and how that might be 17 better understood. At least I think you're saying 18 providing background on what this sort of research is 19 about, maybe general information about this kind of 20 research or trials to give people some understanding 21 going into the informed consent process. And there 22 was wide support here for some sort of assessment, 100</p>

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