PRESIDENTIAL ADVISORY COUNCIL ON HIV/AIDS

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TWENTY-SEVENTH MEETING

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MONDAY,

JUNE 20, 2005

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The Presidential Advisory Council meeting was held in Room 800, Hubert Humphrey Building, 200 Independence Avenue, S.W., Washington, D.C., Louis Sullivan, M.D., and Anita Smith, Co-Chairpersons, presiding.

PRESENT:

LOUIS SULLIVAN, M.D., Co-Chairperson

ANITA SMITH, Co-Chairperson

ROSA M. BIAGGI, M.P.H., M.P.A.

JACQUELINE S. CLEMENTS

MILDRED FREEMAN

JOHN F. GALBRAITH

EDWARD C. GREEN, Ph.D.

CHERYL-ANNE HALL

PRESENT (Continued):

KAREN IVANTIC-DOUCETTE, M.S.N., FNP, ACRN

RASHIDA JOLLEY

FRANKLYN N. JUDSON, M.D.

ABNER MASON

SANDRA McDONALD

JOE McILHANEY, M.D.

HENRY McKINNELL, JR., Ph.D.

JOSE MONTERO, M.D., F.A.C.P.

BENY PRIMM, M.D.

DAVID REZNIK, D.D.S.

REVEREND EDWIN SANDERS

LISA MAI SHOEMAKER

M. MONICA SWEENEY, M.D., M.P.H.

RAM YOGEV, M.D.

PACHA STAFF PRESENT:

JOSEPH GROGAN, ESQ.

DANA CEASAR

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1 P R O C E E D I N G S

2 (8:42 a.m.)

3 CO-CHAIRPERSON SULLIVAN: Good morning.

4 PARTICIPANTS: Good morning.

5 CO-CHAIRPERSON SULLIVAN: Let me thank all
6 of you for coming and we very much appreciate your
7 input. We have quit a full agenda for today and
8 tomorrow, but I'm sure it will be a very productive
9 day.

10 As we begin, let me first of all thank
11 Dana Ceasar and Delta Saint-Vil for their work in
12 arranging the logistics for today's meeting and
13 tomorrow, and Wanda Chestnutt from NIH also has been
14 helpful. So we want to thank her as well.

15 We also have a very productive council.
16 Members who have published books recently that we'd
17 like to recognize and thank and congratulate:

18 Ted Green. Where's Ted? I saw him. Yes,
19 right. Ted, congratulations on your book, Rethinking
20 AIDS Prevention. That has gotten a lot of attention.

21 And also Hank McKinnell has published a
22 book, A Call to Action, about our health care system

1 and health care reform. So, Hank, thank you very much
2 for that. And that also includes a chapter on
3 HIV/AIDS, which all of you, if you haven't read it, I
4 certainly invite you to do so.
5 Then Monica Sweeney has published the book
6 Condom Sense.
7 So those are three publications from our
8 members. I think we should all congratulate them for
9 their productivity.
10 (Applause.)
11 CO-CHAIRPERSON SULLIVAN: Now, let me be
12 sure. Is there anyone else that we may have
13 overlooked since this is a very prolific group?
14 Well, thank you very much.
15 Our public comment is scheduled for 9:35
16 on tomorrow, and Carol Thompson and Joe O'Neill will
17 speak after the public comment. And members of the
18 public who wish to speak can register to speak on
19 tomorrow.
20 And Joe Grogan, our Executive Director,
21 also has a couple of comments pertaining to Carol
22 Thompson and Joe O'Neill's visit.

1 So Joe.

2 MR. GROGAN: I know there was a lot of
3 people who were looking forward to Carol and Joe's
4 presentation, and they will be here tomorrow. The
5 original expectation was that they were going to be
6 able to unveil the administration's Ryan White
7 proposal, but that looks like it's not going to be
8 possible.

9 They will be here. There are a couple of
10 elements that came out in the final approval of the
11 Ryan White proposal that need to be more thoroughly
12 vetted, and it's not going to be possible with the
13 number of people traveling on the Medicare
14 Modernization Act rollout.

15 So I apologize that they're not going to
16 be able to unveil the Ryan White proposal, but they
17 are going to be here, and they will touch briefly
18 about some of the larger principals around Ryan White,
19 and then engage in a round table discussion with the
20 members and solicit some of your views on prevention
21 and the nest steps beyond Ryan White reauthorization
22 and what we need to do in the federal government to

1 advance our HIV prevention and treatment efforts.
2 CO-CHAIRPERSON SULLIVAN: Let me also
3 mention that lunch for members of the council is
4 available, but must be eaten here in the room. So we
5 certainly would invite you to participate in that.
6 Adjournment is scheduled for five o'clock,
7 and depending upon how efficient we are in getting
8 through our agenda, we'll see if we are successful
9 with that or whether we might finish even earlier.
10 Also, unfortunately I have a conflict. I
11 will not be here tomorrow, but you'll be in the hands
12 of our very able Co-Chair, Anita Smith, who will be
13 chairing the session tomorrow.
14 And then finally, a bus is scheduled to
15 leave at 5:30 for the hotel at the end of the day.
16 Are there any other questions or comments
17 from members of the Council before we proceed?
18 If not, then we will proceed with the
19 agenda, and our first discussion will be from the
20 Treatment and Care Committee that our chair of that
21 committee, Dave Reznik, will guide us through that.
22 So David.

1 DR. REZNIK: Thank you, Dr. Sullivan, and
2 good morning, everyone.
3 We have quite an incredible set of
4 speakers that are going to be joining us today
5 covering some very important topics. I don't normally
6 read parts of people's biographical sketch, but when I
7 was reviewing them yesterday they were so impressive I
8 think that the people in the audience who might not
9 have access and everyone should actually know we have
10 two speakers.
11 Our first speaker -- I want to be sure I
12 get this right -- is James Goedert. Did I get that
13 properly? Names are not my specialty -- who received
14 his B.A. in psychology from Yale University, his M.D.
15 from Loyola University. He completed a residency in
16 internal medicine and fellowship in medical oncology
17 at Georgetown University Hospital.
18 In 1980, he joined the National Cancer
19 Institute, NIH, as a research fellow in epidemiology.
20 Timing seems to be very important for many of our
21 careers and why we're at where we are today.
22 He recognized an unusual case of Kaposi's

1 sarcoma in a young homosexual man in early 1981 and
2 contributed to the original report of the disease now
3 known as AIDS KS.
4 From 1981 through 1999, he led prospective
5 cohort studies of homosexual men, persons with
6 hemophilia and pregnant women and their offspring.
7 His study identified the major modes of HIV
8 transmission, initial epidemiological evidence that
9 HIV-1 causes AIDS, AIDS specific AIDS hazard rates
10 used by others to estimate HIV-1 infection incidence
11 and prevalence throughout the U.S., and the predictive
12 value of CD4 lymphocyte counts, HIV viral load, and
13 other markers for AIDS; the role of variations in
14 human genes on HIV-1 susceptibility and progress and
15 the effect of HIV/AIDS on infection of human papilloma
16 viruses, which is the bane of oral health people and
17 dermatologists in HIV right now and certainly a cause
18 for cervical cancer and Hepatitis B and C; and
19 numerous awards, over 288 publications, truly a
20 remarkable individual that we have with us.
21 We also have Dr. Yarchoan -- how did I do?
22 I'm two for two starting off in the morning -- who is

1 Chief of the HIV and AIDS malignancy branch in the
2 Center for Cancer Research, National Cancer Institute.
3 Along with two fellow doctors in the staff
4 of Burroughs Wellcome Company, he co-developed AZT as
5 the first effective AIDS drug and played a lead role
6 in the first clinical trial of this drug. Also with
7 the fellow doctors, he co-invented DDI and DDC as the
8 next two effective AIDS drugs, as he led the first
9 clinical trials of these agents. I think that is
10 absolutely remarkable.
11 He was Section Chief of the Medicine
12 Branch of the National Cancer Institute from 1991 to
13 '96, and was named Chief of the newly formed HIV/AIDS
14 Malignancy Branch in '96.
15 Since that time he has focused most of his
16 research on AIDS related malignancies. Again, over
17 200 scientific articles and chapters and is co-
18 inventer on ten issued U.S. patents. He has been
19 awarded the Assistant Secretary for Health Award and
20 several metals as a commissioned officer in the United
21 States Public Health Service, including the
22 Outstanding Service Medal in 2002.

1 I hope one day before I retire that a
2 quarter of my bio sounds as good as these two short
3 bios. It's really truly remarkable.
4 We're going to start our presentations
5 with cancer and HIV in the population with Dr. Goedert
6 today. So we please welcome you.
7 DR. GOEDERT: Good morning, Mr. Chairman,
8 ladies and gentlemen. Thank you for that very nice
9 introduction.
10 I'm going to be a little back in the
11 corner here. If people can hear me I'll just speak up
12 because it's going to be hard for me to see a little
13 bit from there.
14 REPORTER: Doctor, we need to report you
15 for a transcript. You do need that microphone.
16 DR. GOEDERT: I'm not going to be able to
17 see the screen from here.
18 Okay. So I appreciate the opportunity to
19 discuss the magnitude of and changes in the problem in
20 malignancy among people living with HIV/AIDS.
21 Even as persons with HIV/AIDS are living
22 longer and better, from the oncology perspective the

1 problems are continuing and increasing in complexity.
2 My colleague Dr. Yarchoan and I will discuss briefly
3 these issues and summarize some of the points and
4 leave some opportunity for discussion.
5 If I can have the next slide, please.
6 Thank you.
7 Focusing initially on the U.S., I will
8 touch on Kaposi's sarcoma, KS, the sentinel AIDS
9 associated malignant disease; point out that the
10 epidemic has changed with an increasing and aging
11 population; describe our MET registry for surveillance
12 of cancer among persons with HIV/AIDS; summarize the
13 knowns and unknowns regarding cancer in highly
14 antiretroviral treatment era; and finally, offer my
15 impressions of the future implications.
16 Next.
17 Twenty-four years ago, in 1981, my
18 colleagues and I reported the outbreak of KS among
19 homosexual men in New York City, San Francisco, and
20 Los Angeles.
21 Next.
22 Particularly among white men in San

1 Francisco, shown in pink, the incidence rate of KS
2 increased like a rocket in the population based cancer
3 registries know as SEER.
4 Next.
5 This continued through the discovery of
6 HIV by Dr. Yarchoan, et al.
7 Next.
8 It peaked in the dual therapy era.
9 Next.
10 And then plummeted a bit before the HAART
11 era.
12 In the early 1889s, we recognized -- I'm
13 sorry. The AIDS epidemic shown in triangles followed
14 a similar pattern. Of note, there continued to be
15 twice as many AIDS cases, about 40,000, as deaths,
16 about 20,000, resulting in the steadily increasing
17 prevalence of people living with AIDS.
18 There are now a million living with HIV in
19 the U.S., half of whom meet the CDC surveillance
20 definition of AIDS.
21 Next.
22 In the early 1990s, the recognized the

1 need for population based surveillance of cancer among
2 people with AIDS. To better characterize cancer risk
3 in the affected population and to uncover clues to
4 cancer etiology, more broadly we launched the
5 computerized linkage project we call the AIDS-Cancer
6 Match Registry.
7 Next.
8 For this project we developed and shared
9 with the world new methods for computerized matching
10 individual AIDS records to individual cancer records.
11 We also developed new methods to assess cancer risk
12 during the years before AIDS was diagnosed and during
13 the progressive immune deficiency typical of the
14 individual's AIDS relative time scale.
15 Next.
16 The risk of SK and non-Hodgkin's lymphoma,
17 NHL, is increased hundreds to thousands-fold compared
18 to the general population, although AIDS defining
19 cervix cancer risk is increased only about fivefold,
20 perhaps due entirely to sexually acquired papilloma
21 virus infection.
22 Anal cancer is related also to papilloma

1 virus infection. Several other cancers have been
2 elevated among people with AIDS. The relative
3 importance of immunosuppression, life style and other
4 factors are under investigation.
5 Next.
6 Currently we have linked the records of
7 465,000 persons with AIDS to the population based
8 cancer registries of six metropolitan areas and seven
9 entire states. We're available; we match but have
10 not yet analyzed the records of persons with HIV
11 infection.
12 This is the AIDS population in these
13 areas. The majority, male; 39 percent white and
14 black; 21 percent Hispanic; 43 percent men who have
15 sex with men; 27 percent injection drug users; and 11
16 percent heterosexual. Thirty-nine percent of the AIDS
17 cases occurred after 1995.
18 Next.
19 Typical of AIDS, most of the cases are age
20 30 to 49.
21 Next.
22 However, on a log scale, the same data can

1 show that we can assess cancer risk among more than
2 5,000 children and more than 2,000 elderly persons
3 with AIDS.
4 Next.
5 We need to characterize the changes
6 occurring in the HAART era. How is the spectrum
7 changing? How large are the persistent excess of KS
8 and lymphoma? What new malignancies are emerging and
9 why? Are there extraordinary risks in certain
10 subpopulations, especially among long-term survivors?
11 What is the impact of HAART on survival
12 for persons who have had both cancer and AIDS?
13 Next.
14 Analyzing the data to these questions is
15 challenging, in part, because each person with AIDS
16 travels through both calendar time and through his or
17 her own individual time scale. Changes in cancer risk
18 must consider both the calendar and individual time
19 scales.
20 Next.
21 We have previously noted that women with
22 AIDS had a reduced risk of breast cancer. This slide

1 shows the individual time scale from four years before
2 to five years after AIDS onset at time zero. Relative
3 risk of one is that for the general population.
4 Essentially all of these points are below one, and
5 risk decreases nonsignificantly from early to late in
6 each woman's HIV course.
7 Next slide.
8 By calendar time a different picture is
9 seen. The points are still below one, but there is a
10 highly significant increase such that the risk appears
11 to be reaching that of the general population. We are
12 working to explain this increase.
13 Next.
14 Four broad points about cancer in the
15 HAART era. KS and non-Hodgkin's lymphoma risk have
16 fallen, but lymphoma has fallen less than KS.
17 Moreover, even now the risk of KS and NHL
18 is still markedly higher for people with AIDS than for
19 the general population. Several studies have noted an
20 increasing risk of Hodgkin's disease of Hodgkin's
21 lymphoma. There are persistent, substantial excesses
22 of cancer that have known causes. Lung cancer with

1 smoking, liver cancer with hepatitis infection, and
2 cervix and anal cancers with papilloma virus
3 infection.
4 We are still at the beginning of the HAART
5 era. Thus, follow-up is short and the impact on
6 cancer is anything but certain.
7 One certainty is that cancer is an
8 increasing cause of death for persons with AIDS. The
9 hospitals in France noted that cancer accounted for
10 ten percent of deaths among AIDS patients before 1996
11 compared to 28 percent during year 2000. NHL was
12 particularly lethal with lung and liver cancers and
13 Hodgkin's lymphoma contributing substantially.
14 Next.
15 If sufficient funds are available, we
16 intend to rematch the population based registries
17 every three to four years to monitor and further study
18 cancer among person with HIV/AIDS.
19 I have not yet mentioned the developing
20 world, but there is a raging epidemic of AIDS
21 associated cancer in sub-Saharan Africa. KS has
22 become the most common of all malignancies in Uganda

1 and South Africa.
2 To get a better handle on AIDS associated
3 cancer in Africa, we modified the efforts that we
4 developed for the United States and recently completed
5 an AIDS cancer match in Kampala, Uganda.
6 Next.
7 Aging of the population in the HAART era
8 inevitably will result in increases of cancer,
9 including common types, such as colon, lung, breast,
10 prostate, et cetera. Superimposed on aging, the
11 immune perturbation that persists in people on HAART
12 sets up the possibility for a vicious interaction.
13 This creates opportunity to understand how cancer
14 relates to other immune perturbations, particularly as
15 occurs in the elderly general population.
16 Areas for emphasis for the HIV/AIDS
17 population that are likely to apply as well to the
18 general population include attention to diagnosis and
19 treatment, vigorous cancer prevention to reduce
20 smoking, to vaccinate for Hepatitis B, and potentially
21 papilloma virus, and to screen for cervical cancer,
22 basic research of carcinogenesis and novel approaches

1 to cancer treatment.
2 The immediate keys to prevention of AIDS
3 associated cancer are to prevent transmission of HIV
4 and to diagnose and effectively treat those who are
5 infected. Although much of the future is cloudy, this
6 much is certain. The number of people with HIV/AIDS
7 and cancer will continue to increase and to present
8 complex challenges.
9 I'll be happy to entertain questions or we
10 can go directly to Dr. Yarchoan's talk.
11 DR. REZNIK: Why don't we go directly to
12 Dr. Yarchoan's talk and save questions at the end?
13 Next we'll have Dr. Yarchoan, and then
14 we'll take some general questions from members after
15 both presentations.
16 DR. YARCHOAN: Thank you.
17 I'll be giving a presentation about
18 malignancies in the HIV era from the perspective of
19 treatment and pathogenesis.
20 Again, following up on Jim's talk, we've
21 traditionally viewed AIDS malignancies as the classic
22 AIDS defining malignancies of Kaposi's sarcoma,

1 lymphoma, and cervical cancer. But there's another
2 spectrum of malignancies that are important in this
3 population. One of those that are increased in
4 patients with subtle immune dysfunction, diseases such
5 as Hodgkin's lymphoma, seminoma, and such.
6 There are also certain cancers, as Dr.
7 Goedert alluded to in his talk, that are associated
8 with exposure factors that are increased in people
9 with HIV/AIDS. Again, this would include cancers such
10 as lung cancer and anal carcinoma.
11 And then finally, there are the panoply of
12 other carcinomas that can occur in people with HIV
13 that, one, pose problems in treatment because of the
14 unique nature of the populations and, two, as we study
15 the population of HIV infected people may be infected
16 by the epidemiology.
17 Next slide, please.
18 So, again, from a clinician, and this is
19 more of a ground's eye view, what sort of patients are
20 presenting now with AIDS malignancies in the era of
21 HAART. One are patients who are not being treated for
22 HIV. Often these are people who are not aware of

1 their HIV status, present with a tumor, and at that
2 time discover that they're HIV infected.
3 There are some patients who are poorly
4 controlled on HIV drugs because of resistance, because
5 of toxicity or because of compliance.
6 There are patients who are otherwise well
7 controlled on HAART, and in particular these patients
8 can present with those tumors that occur at higher CD4
9 counts, such as Burkitt lymphoma, cervical cancer, or
10 Hodgkin's disease.
11 Next slide, please.
12 And one of the themes that has emerged as
13 we've studied AIDS associated malignancies over the
14 years is that most of these cancers are associated
15 with other oncogenic viruses. Shown here is a list of
16 some of the important cancers that are associated with
17 HIV infection. Those in the orange color are those
18 that are in the group of AIDS defining malignancies.
19 Those in white are those that are increased, but not
20 necessarily AIDS defining.
21 And as you can see, they're associated
22 with a number of viruses, and the discovery in 1994 by

1 Yvonne Chang and Patrick Moore of KSHV, Kaposi's
2 sarcoma associated herpes virus, which was a new
3 herpes virus found to be the cause of Kaposi's
4 sarcoma, really nailed this point home.
5 And as you can see, Epstein-Barr virus,
6 Kaposi's sarcoma associated herpes virus, and human
7 papilloma virus are the most important viruses right
8 now in these AIDS associated malignancies.
9 Next slide, please.
10 So these virtual associated malignancies
11 offer certain opportunities and certain challenges.
12 One is that prevention and treatment of these can be
13 affected by any retroviral therapy, and this is
14 especially true for those viruses that occur with low
15 CD4 cells. And some cases of Kaposi's sarcoma, in
16 fact, can respond to effective treatment with highly
17 active anti-retroviral therapy.
18 There's also the possibility of prevention
19 of these cancers in the future with an effective
20 vaccine against the oncogenic virus. For example,
21 researchers in the NCI and those in the private sector
22 are now developing vaccines for human papilloma virus,

1 and these have the potential of dramatically affecting
2 the incidence of cervical and anal carcinoma in the
3 future.
4 There's also the possibility of vaccines
5 against EBV or Kaposi's sarcoma associated herpes
6 virus, and there are also the potential for viral
7 targets for therapy that are unique targets that are
8 different than those in the human cells. One can
9 potentially find ways of using antiviral drugs, for
10 example or immunologic approaches against antigens
11 that are unique to the viruses.
12 And also I should mention that this
13 research will potentially benefit non-AIDS patients
14 with similar viral induced tumors.
15 Next slide, please.
16 As an example, let me just talk for a
17 second about primary effusion lymphoma as seen here.
18 This was really recognized as a distinct form of
19 lymphoma in 1994 when KSHV was discovered. It forms
20 pleural effusions or effusions in other cavities.
21 It's a B cell lymphoma, and it's an AIDS associated
22 tumor. It's found in people who are KSHV positive.

1 The tumor cells are infected with KSHV, and about 80
2 percent of them are also infected with EBV.
3 It's often very poorly responsive to
4 standard cytotoxic chemotherapy that we use for other
5 lymphomas, and the median survival is measured in
6 months right now.
7 And interestingly enough, this tumor is
8 associated with activation of some of the lytic genes
9 of KSHV that can then be targets for therapy for
10 antiviral drugs, and there are a number of groups that
11 are studying this at this point.
12 Next slide.
13 There's also as I mentioned before tumors
14 that develop in the context of sole immune dysfunction
15 or inflammation, and these include, for example,
16 Hodgkin's lymphoma or Burkitt's lymphoma. And as Dr.
17 Goedert mentioned, the incidence of these tumors is
18 likely to increase as HIV infected patients live
19 longer. There's evidence of Hodgkin's lymphoma is
20 also increasing. There's also the possibility of
21 increased incidences of other cancers, and insights
22 from this population and therapy that we develop for

1 it again has the potential of benefitting people who
2 don't have HIV infection.
3 Next slide.
4 So, again, this population of patients
5 with HIV and cancer pose certain unique challenges in
6 terms of developing therapies. One is that these
7 patients have two life threatening diseases, each of
8 which require at this point complex therapies.
9 There are relatively few physicians in the
10 United States who have expertise in both AIDS and
11 cancer, and this is a problem both with the therapy of
12 patients who present with these and also for
13 conducting clinical research in these conditions.
14 The optimal cancer treatment in these
15 tumors may differ from those in non-AIDS patients.
16 For example, these AIDS patients tend to be very
17 fragile. They have compromised immune systems, and
18 they're often more sensitive to various therapies.
19 For example, they often get a lot of mucosal toxicity
20 if giving radiation therapy in the mouse, and there's
21 also cumulative drug toxicities as we combine the
22 complex therapies for HIV with those for cancers, and

1 the possibility for a lot of drug interactions that
2 can affect these drugs in ways that are not totally
3 anticipated.
4 Next slide.
5 There are also substantial challenges in
6 entering these patients in clinical trials. One is
7 that patients are often in minority groups or have
8 poor access to health care, and the other thing is
9 that patients with HIV infection who may present with
10 other common tumors are at present usually excluded
11 from clinical trials with these tumors, again, because
12 of their HIV status makes them a unique population
13 that may respond differently to therapy.
14 And, again, research in this population
15 may provide insights into the optimal therapy of
16 cancer in other fragile patients, for example, the
17 elderly or others with immune dysfunction.
18 Next slide.
19 In spite of this, some progress is being
20 made. For example, in terms of Kaposi's sarcoma, the
21 treatment is markedly improved now. Doxil, which is a
22 liposomal form of an anti-cancer drug has been

1 approved, and scientists in our group are starting the
2 combination of Doxil and a cytokinem IL-12 in people
3 with KS. This shows one patient on one of the trials.
4 This has a dramatic improvement in spite of no real
5 change in its underlying HIV status.
6 Next slide.
7 And, again, in terms of AIDS lymphoma, a
8 regimen of dose adjusted EPOCH, which is a combination
9 of five anti-cancer drugs has been tested. It has
10 been found to overall have about a 79 percent response
11 rate, and these results with a very long survival, and
12 these results suggest that AIDS KS patients can in
13 certain situations be curative and have a very long
14 survival.
15 And the AIDS Malignancy Consortium, which
16 is a group of extramural scientists around the country
17 who studied AIDS, lymphomas, and other tumors are
18 studying this approach in a large, randomized trial at
19 this point.
20 Next slide.
21 So, again, just to summarize, these
22 malignancies offer certain opportunities and

1 challenges. As I said, the viral induces tumors offer
2 opportunities for prevention and therapy. On the
3 other hand, there's an increase in certain tumors as
4 we've seen now as patients live longer and patients
5 are now the most frequent cause of death in AIDS
6 patients. There's a change in distribution as we're
7 seeing of tumors, and this will require research on
8 prevention and therapy, and the optimal treatment for
9 these patients is often different than the general
10 population.
11 So I think at this point I'll end and open
12 the subject for questions, and, Jim, why don't you
13 come up also?
14 DR. REZNIK: We have time for a few
15 questions. So Dr. McKinnell.
16 DR. McKINNELL: Well, thank you for a very
17 interesting presentation and some thought provoking
18 data.
19 And I guess my question is really based on
20 the fact that those of us seeking additional public
21 funding for early treatment I think have a very
22 fundamental problem, which is to most of the public

1 HIV/AIDS is one word. They just don't get the benefit
2 of early treatment of those with HIV, but they do get
3 cancer treatment.
4 So my question is: is your data robust
5 enough to support a statement along the following
6 lines: for every 10,000 HIV positive individuals
7 treated appropriately, you prevent X thousand cases of
8 cancer?
9 DR. GOEDERT: Yes, definitely. Coming up
10 with the actual number would take a little work, but
11 for sure, I mean, the markedly lower incidence rates
12 of Kaposi's sarcoma and non-Hodgkin's lymphoma alone
13 would justify the statement that you're trying to make
14 and coming up with the number would take a little
15 work.
16 DR. McKINNELL: Yeah, I would encourage
17 you to do that work and publish it and then those of
18 us advocating for funding for early treatment would
19 have a pretty powerful argument, I would think.
20 DR. YARCHOAN: If I can add one point,
21 it's that in terms of the epidemic, we don't --
22 because HAART has only been around for a little under

1 a decade now, we can't project beyond ten years. We
2 can certainly say that it delays certain tumors. We
3 just don't know what it's going to be beyond ten or 20
4 years. So those could be tweaked in terms of delaying
5 the onset of tumors, and it would be important.
6 DR. GOEDERT: If I can add one more thing,
7 I guess there's one difference between cancer therapy
8 and HIV/AIDS therapy is that the ladder for HIV as far
9 as we know how is for life, whereas cancer therapy we
10 usually think of as trying to induce remission after,
11 you know, a period of some months to years.
12 DR. REZNIK: Okay. The next question is
13 for Reverend Sanders.
14 REV. SANDERS: No your slide that
15 addresses associated malignancies caused by viruses,
16 you draw the relationship between HPV and cervical
17 cancer. Is there any evidence of the degree to which
18 clinicians, caregivers are addressing the relationship
19 directly and regularly with patients?
20 There's a lot of discussion now as to
21 whether or not some of the same strategies that we
22 have used to deal with issues of prevention around HIV

1 might not be well applied in this regard, but my sense
2 is that it's not routine. It's not necessarily the
3 case that clinicians are making that connection and
4 making it a part of strategies for treatment with
5 people that they're seeing.
6 DR. YARCHOAN: You're accurate in that.
7 The issue with papilloma virus is that it's much more
8 common in the population. There are multiple types of
9 papilloma virus, and there is a sense that cervical
10 cancer is in part related to the degree of exposure.
11 Right now we also have PAP smears as a way
12 of preventing cervical cancer, and that has been the
13 main target for prevention of this, but certainly some
14 of the strategies that would be used against HIV would
15 be effective with cervical cancer. We just have
16 better options in cervical cancer that are easy to
17 apply.
18 And there is also a vaccine that is now in
19 very large scale clinical testing against the main
20 malignant subtypes of cervical cancer that is likely
21 to be very effective around the world.
22 DR. REZNIK: The next question is from Dr.

1 Judson.

2 DR. JUDSON: I just want to follow up on
3 Dr. McKinnell's question on early treatment and not
4 leave the committee here with the impression that the
5 is a simple diagnosis of early disease and that, as we
6 discuss that and recommendations for earlier
7 treatment, you get into all the complexities of CD4
8 viral load, months, years of duration and clinical
9 symptoms so that if we're referring to treating people
10 very, very early in infection, I think that's
11 controversial as it relates to the tradeoffs between
12 cost, treatment, toxicities and improved survival.

13 Did you want to comment on that?

14 DR. GOEDERT: As Bob mentioned, many
15 people these days are not diagnosed at all with HIV
16 infection until they present with a life threatening
17 disease, either a malignancy or an opportunistic
18 infection. I think that's the distinction, is getting
19 them before they get to that point.

20 I think the discussion you're raising is
21 whether to try and treat people very early in the
22 immune deficiency process. If you're lucky enough,

1 effective enough to make the diagnosis at that stage,
2 I agree. I think there's discussion as to when to
3 initiate therapy.
4 But I think everyone would agree that you
5 want to initiate therapy at some point before the
6 onset of clinical disease, malignant or otherwise.
7 DR. JUDSON: The second question is: is
8 there any evidence that any of the current treatments
9 actually promote cancer as an adverse outcome?
10 DR. GOEDERT: No, but it needs to be
11 monitored particularly because you're talking about
12 lifelong therapy for very long periods of time.
13 CO-CHAIRPERSON SULLIVAN: Why don't we
14 give Dr. McKinnell a chance for rebuttal?
15 And I do want to say please limit our
16 questions because we're already behind schedule, and
17 Dr. Sweeney, I will get to you afterwards, but, Dr.
18 Sweeney, this is going to be the last question. I
19 apologize. We are running late today.
20 DR. McKINNELL: Well, it's not so much a
21 rebuttal as a suggestion for further research, which
22 is what scientists do.

1 I think for the HIV to AIDS part of your
2 question, Mike Sagg's data is pretty compelling, that
3 you treat before 250 on CD4. To me that question has
4 been answered.
5 I think the question that need to be
6 answered is where would you treat to present the X
7 thousand cases of cancer I'm trying to prevent. I
8 don't think that work has been done, and it may be a
9 worthwhile avenue for you to follow
10 CO-CHAIRPERSON SULLIVAN: And Dr. Sweeney. And
11 this will be our last question on this section.
12 DR. SWEENEY: So I'm only going to ask,
13 one, because of time, and thank you for recognizing
14 me, one is whether or not there has been any work on
15 preventive screening in HIV patients, males in
16 particular, using the same kind of testing as the
17 papinickuli, for example, or doing screenings, for
18 example, for rectal cancer in men who has sex with men
19 to detect it early.
20 Because eventually that will recognize
21 some savings in treatment if we can start to get them
22 early, and I don't think people are putting the

1 connection to cancer and HIV and AIDS early enough so
2 that by the time many people are diagnosed, it's far
3 along the line. So just screening.
4 DR. YARCHOAN: That's actually a very
5 important point, and members of the AIDS Malignancy
6 Consortium have been looking at the techniques which
7 require special training and trying to do studies to
8 look at the effectiveness of this in prevention of
9 disease early. So this is an important point that's
10 being studied right now.
11 DR. REZNIK: And as the prevention and
12 treatment and care committee will be working together,
13 one of our keys is getting people tested early because
14 at the graded health system infectious disease
15 program, we're seeing a lot of young African American
16 males presenting with relatively advanced Kaposi's
17 sarcoma and plasmobastic lymphoma, having a couple of
18 those cases. So we really do need to get treatment
19 started.
20 I thank both of you for your time and we
21 greatly appreciate it.
22 (Applause.)

1 DR. REZNIK: As we all know, yesterday was
2 Father's Day, and I think there's a very, very proud
3 father in the room today, Dr. Beny Primm, because we
4 have the honor of listening to his daughter, a very
5 accomplished provider in her own right.
6 Dr. Primm is an M.D.-Ph.D. and the
7 Director of Minority and National Affairs for the
8 American Psychiatric Association. She's also an
9 Associate Professor of Psychiatry at Johns Hopkins
10 School of Medicine.
11 Dr. Primm is a graduate of Harvard
12 Radcliffe College and Howard University College of
13 Medicine. She completed her residency in psychiatry,
14 fellowship in social and community psychiatry, and
15 Master's of Public Health degree at Johns Hopkins.
16 She is a nationally recognized expert on
17 cultural issues in psychiatry and co-occurring
18 psychiatric illness and substance abuse and has
19 written and lectured widely on these topics.
20 It's with great honor that I get to
21 introduce the daughter and accomplished Dr. Primm's
22 daughter, Dr. Annelle Primm.

1 (Applause.)

2 DR. ANNELLE PRIM: Thank you, Dr. Reznik,
3 and good morning, everyone.

4 It is, indeed, my pleasure to be here to
5 speak with you today. Dr. Sullivan, thank you,
6 distinguished member of the council, and to Daddy, Dr.
7 Beny Primm, I want to thank you for your tremendous
8 leadership in the area of HIV/AIDS and substance abuse
9 and to thank you for your advocacy in bringing mental
10 health to the table in this forum.

11 I would also like to thank Diane Pennessi
12 and Carol Svoboda of the American Psychiatric
13 Association Office of HIV/AIDS Psychiatry, who
14 provides considerable information on training,
15 resources, technical assistance and policy guidance at
16 the APA, and I hope that you'll take some time to look
17 at your packet of materials which gives an example of
18 the sorts of resource that the APA offers in this
19 area.

20 It is my pleasure to talk about this very
21 important topic of mental health and HIV disease.

22 Next slide, please.

1 I will be covering the following points of
2 what is mental health and mental illness. Some of the
3 links that exist between mental health and HIV/AIDS,
4 the relationship between substance abuse, which is a
5 mental disorder, by the way, and HIV/AIDS, and also to
6 put this in the context of health and mental health
7 disparities as they exist in underserved ethnic and
8 racial groups and the vicious cycle which includes
9 HIV/AIDS, and to leave you with a vision of the
10 future.
11 Next slide, please.
12 What is mental health anyway? We throw
13 around this term rather loosely, and it really
14 describes the successful performance of mental
15 function throughout the life cycle, resulting in
16 productive activity, fulfilling relationships, and the
17 ability to adapt to change and to cope with stress.
18 I think we often talk our mental health
19 for granted, but indeed, it is the foundation for
20 thinking and intellectual functioning, for
21 communication skills, for learning, emotional growth,
22 resilience, and also self-esteem.

1 Next slide, please.
2 Mental illness, which is not really the
3 polar opposite of mental health really describes
4 health conditions that are characterized by changes in
5 thinking, intellectual functioning, and mood, and in
6 behavior or some combination or some permutation of
7 these three.
8 The most important point is that mental
9 illness is associated with distress and/or impaired
10 functioning.
11 Next slide, please.
12 I'd like to call your attention to the
13 Surgeon General's report on mental health. Former
14 Surgeon General Dr. David Satcher really shed some
15 light on mental health, and despite a 20 percent
16 prevalence, at least at that time and some recent
17 reports indicate even higher prevalence at any given
18 point in time, about 30 percent of mental illnesses,
19 they are significantly under treated in this country,
20 and we continue to struggle against the stigma that is
21 associated with having a mental illness and seeking
22 care for it, and this stigma is a major barrier to

1 people receiving mental health care.
2 Associated with this stigma is the
3 discrimination that continues to exist in insurance
4 coverage and reimbursement for the treatment of mental
5 health problems. Even people who are very well
6 insured have to pay a copay. It's handled differently
7 than other sorts of medical problems, and this, too,
8 is a significant barrier.
9 We in this country are experiencing
10 significant under treatment of mental health problems
11 in a number of special populations. They vary by age,
12 ethnicity and race. Certainly children and youth are
13 significant underserved. This is a huge problem.
14 Our older adult population is underserved,
15 and the four major ethnic and racial groups, African
16 Americans, Native Americans, Asian Americans, and
17 Pacific Islanders and Hispanics are significantly
18 underserved. And this really portends a very
19 important role for primary care physicians and other
20 health providers in addressing the mental health needs
21 because of that stigma, if people get any mental
22 health care at all it's most likely to occur in the

1 primary care setting.

2 Well, let's link this with HIV/AIDS now.

3 Next slide, please.

4 Certainly we know that the epidemic is not
5 over, and it continues to exact a huge toll not only
6 on our country with the 1.1 million Americans who were
7 affected as of December 2003, but also globally.
8 Forty million people are infected with HIV and
9 including five million individuals who were newly
10 diagnosed in 2003.

11 Certainly you all are very familiar with
12 these statistics, but they certainly don't reflect
13 some of the human suffering that's associated and
14 often comes out in the form of mental health problems.
15 And perhaps we need to be more cognizant of the ways
16 in which the mental health problems associated with
17 HIV/AIDS exact their toll, and certainly we must labor
18 hard to do something about this.

19 Next slide, please.

20 HIV and mental health issues, certainly
21 HIV can cause significant emotional distress and
22 crisis. And we also know that HIV directly affects

1 the brain, and this can lead to a number of organic
2 mental health disorders, neurocognitive impairment,
3 and what this means is that if we miss a diagnosis of
4 mental illness, it can lead to irreversible
5 impairment, and it also lets us know that if we can
6 intervene, we can help to improve our HIV/AIDS
7 treatment outcomes.
8 Next slide, please.
9 Certainly complex drug regimens can result
10 in mental health problems. Some of the medications
11 that we use in the treatment of HIV are attendant with
12 side effects that may be manifest in psychiatric
13 symptoms.
14 Certainly substance abuse, which is often
15 concomitant with HIV, certainly is a risk factor and
16 even coexistent with it can mask some of the
17 underlying psychiatric symptoms and problems that can
18 surface in the context of HIV infection.
19 And most importantly, for people whose
20 mental health is compromised this can certainly
21 interfere with their adherence to treatment, and we
22 know how critically important it is for people with

1 HIV infection to adhere to their treatment plan in
2 order to maximize their outcomes.
3 Next slide, please.
4 If we look at HIV and mental health as co-
5 occurring disorders, we know that all populations are
6 at risk. However, members of underserved racial and
7 ethnic groups are disproportionately affected, and if
8 we do not treat these problems, they can result in
9 serious disabling consequences and, again, can have an
10 impact on treatment adherence, and this is really a
11 toll that our society cannot afford. It has a
12 tremendous impact on overall health, productivity, and
13 quality of life.
14 Next slide, please.
15 So what about some of the specifics of how
16 mental health has an impact on HIV and vice versa?
17 Certainly the psychological impact is key. We know
18 that HIV infected people experience a great deal of
19 psychological distress and psychiatric disorders, and
20 just receiving the diagnosis of HIV is very stressful.
21 We often see these individuals experiencing a great
22 deal of bereavement as a result of numerous losses, a

1 break-up of relationships, financial worries and work
2 problems, very deep unhappiness associated with the
3 emotional distress that comes along with having this
4 diagnosis.
5 And certainly some of the societal
6 reactions to people who have HIV/AIDS can lead them to
7 feel rejected and discriminated against, which only
8 compounds their psychological distress and causing
9 them to be more depressed, more demoralized, and this
10 can contribute to a rapid progression of disease.
11 We know that there are links between
12 mental health and immune function which certainly can
13 have an impact on HIV/AIDS, and all of this can make
14 it very difficult for individuals to lead a normal
15 life.
16 And here's another dimension. What about
17 those children who will lose their parents to
18 HIV/AIDS? This is certainly traumatic, and the
19 concern is that after the loss of their parents, these
20 children may not be integrated into new families, and
21 certainly in and of itself this is quite traumatic,
22 losing one's parents, but not having support after

1 that can yield devastating consequences to the mental
2 health of these children in terms of their
3 development, and certainly as they become adults.
4 Next slide, please.
5 HIV has a direct impact on the brain, and
6 it can almost be thought of as an assault. It can
7 create central nervous system impairment and a wide
8 range of neuropsychiatric disorders. And,
9 unfortunately, the current antiretroviral treatments
10 that are available show rather poor penetration into
11 the brain, and so it makes certain neuropsychiatric
12 disorders more likely and difficult to treat.
13 And certainly for those individuals who
14 have had a mental illness prior to contracting HIV
15 infection, as well as those who have a significant
16 substance abuse, we need to be very mindful of
17 assessing their cognitive status and neuropsychiatric
18 status which may be compromised by the mental illness
19 and by the substance abuse.
20 So this can be a double or triple whammy
21 in many cases.
22 Next slide, please.

1 The spectrum of HIV related disorders can
2 range from neurocognitive impairments, psychiatric
3 syndromes and somatic syndromes, and I'd like to talk
4 about each of these.
5 In terms of the neurocognitive impairment,
6 there are three dimension of this. In its most severe
7 form really these are referred to as AIDS dementia
8 complex, or ADC.
9 Some of the aspects of the impairment
10 include impairment to cognitive function. For
11 example, people having difficulty with their memory;
12 in terms of behavior, having difficulty with agitation
13 or psychosis, another word for losing touch with
14 reality.
15 Motor functioning can also be compromised
16 and can be borne out in gait disturbance or even
17 incontinence, and certainly we need to take into
18 account that while these neurocognitive deteriorations
19 can progress gradually, we can see some early signs
20 and symptoms, including short term memory loss as
21 manifested by forgetting appointments, misplacing
22 things, forgetting to take medications, which we know

1 is quite concerning, loss of fine coordination, not
2 being able to perform handwriting as usual, difficulty
3 putting objects together; cognitive slowing, not being
4 able to follow a conversation, taking longer to speak
5 or to understand, being slow in interviews; and
6 certainly mood changes, having low motivation and
7 apathy, depression and hyperactivity; and certainly
8 being unresponsive, being agitated, having
9 hallucinations, paranoia, and even having loss of
10 bowel and bladder control, as well as inability to
11 walk.

12 All of these things are controlled by the
13 brain and the impact of HIV infection can have this
14 sort of direct impact.

15 Next slide, please.

16 Other aspects of neurocognitive impairment
17 include two conditions, HIV associated dementia or
18 HAD, and minor cognitive motor disorder, MCMD. These
19 are complications in which there may be direct or
20 indirect impact of HIV on brain tissue, and certainly
21 even at autopsy we see that at 90 percent of AIDS
22 patients have some evidence of central nervous system

1 disease, and 80 percent of those who are hospitalized
2 show some type of organic mental disorder, such as
3 these during their hospitalization.
4 This, by the way, is really a spectrum
5 with the minor cognitive motor disorder being on the
6 lower end of the spectrum in terms of severity, with
7 HIV associated dementia being at the severe end. And
8 certainly these are important to take into account.
9 Many people assume that when these sorts
10 of symptoms, mood swings, depression, et cetera,
11 occur, it is assumed that this may be some sort of
12 only psychological sign and symptom which has no
13 relationship to the HIV, but we know that, indeed,
14 this is a result of the direct effect of the virus on
15 the brain.
16 And what might be some of the
17 manifestations? Imagine an individual, an attorney 35
18 years old who had prided himself on being able to
19 speak very well, be quick on his feet, and suddenly
20 speaking slower, having difficulty following the
21 thread of a conversation, staring off into space, very
22 uncharacteristic for an individual, and this would be

1 an example of the ways in which HIV infection can have
2 an impact on the brain.
3 Next slide, please.
4 Among the most common disorders, mood
5 disorders such as anxiety and depression, commonly
6 seen in co-occurring with HIV infection, certainly
7 substance abuse, personality disorders, individuals
8 who have certain characteristics, perhaps a lot of
9 apathy or negative thinking maybe only more pronounced
10 in the context of HIV/AIDS, and certainly these
11 conditions tend to be seen more in the later stages of
12 HIV infection -- excuse me -- psychotic symptoms, for
13 example, though not very prevalent, can be quite
14 disabling, but at the same time treatable.
15 And certainly, substance abuse frequently
16 coexists with psychiatric disorders, which makes it
17 very difficult to diagnose and treat. Certainly,
18 suicide risk is a huge issue among people with HIV
19 infection and all the more reason why we need to
20 recognize and treat the conditions early so that we
21 can prevent suicide.
22 Next slide.

1 There are numerous somatic syndromes or
2 syndromes which affect the body that are associated
3 with HIV/AIDS and certainly with mental health
4 problems. Pain, in particular, is common in HIV
5 infection really throughout the course of the disease,
6 and we know that pain disorders can be associated with
7 numerous psychological symptoms. In about 30 to 80
8 percent of patients with HIV experience pain, and we
9 know that there are significant disparities among
10 certain ethnic and racial groups, and the extent to
11 which they receive treatment for there and really, in
12 general, individuals with HIV infection may easily be
13 overlooked as needing treatment for pain.
14 Endocrine problems, such as low
15 testosterone on estrogen levels, can produce wasting,
16 fatigue, mood disturbances, difficulty with cognitive
17 functioning and irritability, and regarding the
18 wasting that's associated with these endocrine
19 problems, this adds to the stigmata of the HIV
20 infection which can add to lower self-esteem and that
21 feeling of outside stigma that the infection brings.
22 And in terms of medication side effects,

1 this, too, is a challenge. There's several HIV
2 medications that have mild to severe side effects,
3 which may resemble some of the psychiatric complaints
4 that I've talked about earlier, but it's important to
5 recognize these so that medications can be changed and
6 there can be some alternatives used to address these
7 concerns.
8 Next slide, please.
9 In terms of substance use, very important
10 to recognize that about 34 percent of individuals
11 experience injection drug use, and that direct
12 transmission of HIV may occur through the substance
13 use pathway. With sharing of needles, indirect
14 transmission certainly can occur, through sexual
15 contact with HIV positive injection drug users, and
16 even noninjected drugs, when they are used. For
17 example, alcohol or cocaine, this too increases risk
18 for HIV because of the effect on judgment. People who
19 are intoxicated do not exercise the same level of
20 judgment that they would normally exercise, and this
21 affects their decision making and may involve
22 increased sexual risk taking.

1 This is important for us to consider when
2 we think about teenagers and young adults who may be
3 abusing substances, and this is a direct pathway to
4 HIV infection risk.
5 Next slide, please.
6 When we think about substance abuse,
7 certainly there are a number of symptoms that may be
8 confused with aspects of HIV infection, some of the
9 malaise, fatigue, weight loss, fever, et cetera, that
10 can accompany substance abuse withdrawal. That can be
11 confusing.
12 Some of the medical complications of
13 chronic substance use may also have an extra impact on
14 HIV infection. For example, pneumonia, sepsis,
15 endocarditis, tuberculosis and Hepatitis C are all
16 very common among individuals with substance abuse,
17 and certainly people with HIV infection are
18 particularly vulnerable to these, and neurological
19 symptoms that accompany substance abuse problems of
20 particularly alcohol, severe alcoholism, chronic
21 alcoholism can lead to dementia, and this can be
22 superimposed on some of the neurocognitive problems

1 that I discussed earlier associated with HIV/AIDS.
2 Next slide, please.
3 Substance abuse can, again interfere with
4 rational decision making, and it can interfere with
5 treatment adherence, too, which for those who have
6 both substance abuse and a serious mental illness,
7 this, too, can be a double whammy interfering with the
8 maximization of outcome in the treatment of HIV
9 infection.
10 Next slide, please.
11 And certainly HIV/AIDS sufferers often
12 turn to alcohol or drugs to manage their disease.
13 This only make the problem worse, and again, we need
14 to be cognizant of teenagers who often experiment with
15 drugs and alcohol which can be a significant pathway.
16 Next slide, please.
17 What about populations at risk? Well, the
18 point is really everyone is at risk, but particularly
19 individuals who are in the 13 to 24 year old age
20 group, men who have sex with men, IV drug users,
21 prison inmates, and even seniors. We're seeing more
22 HIV infection among older adults, and certainly among

1 underserved ethnic and racial groups.

2 Next slide, please.

3 Dr. David Satcher and his report as
4 Surgeon General on some of the culture, race, and
5 ethnicity aspects of disparities in mental health, he
6 pointed out that while mental illness affects all,
7 there are striking disparities in mental health care
8 for the four major ethnic and racial groups, and this
9 is manifested in less utilization of mental health
10 services, poorer quality of care, and under
11 representation in mental health research. And all of
12 these taken together impose a significant disability
13 burden on members of these populations.

14 Next slide, please.

15 And there are many factor which affect the
16 utilization of mental health services among these
17 populations, namely, African Americans, Native
18 Americans, Asian Americans and Pacific Islanders, and
19 Hispanics. Certainly racism is something that
20 regardless of socioeconomic status has an impact on
21 all of these populations. Discrimination in so many
22 realms, employment, housing, education, et cetera,

1 often tied to economic impoverishment, certainly
2 mistrust of the health care system that's associated
3 with some of the health disparities that these groups
4 experience, as well as fear.
5 And certainly, we must take into account
6 some of the cultural and social influences in terms of
7 illness behavior, in terms of explanatory models of
8 illness, in terms of idioms of distress. These are
9 all ways that may mediate the presentation of mental
10 illness among different groups.
11 And, of course, we always need to consider
12 biological, psychological, and some of the social and
13 environmental factors in which these mental illness or
14 mental disorders arise.
15 Next slide, please.
16 And in terms of the high need populations,
17 certainly ethnic and racial minority groups experience
18 more than their fair share of these conditions:
19 homelessness, being in the correctional system, and as
20 some of you may know, that the majority of individuals
21 in the correctional system at this time are people of
22 color, with African Americans constituting over 50

1 percent of those in the correctional system.
2 And, by the way, the correctional system
3 is currently the place where the most people with
4 mental illnesses are now housed. It used to be the
5 state psychiatric hospital system, but that's where
6 people with mental health problems and substance abuse
7 are located.
8 Certainly alcohol and drug abuse refugees
9 and those immigrants from other countries are among
10 the high need populations. People of color are over
11 represented among victims of trauma who are quite
12 vulnerable from a mental health standpoint. Certainly
13 homicide, particularly in the African American
14 community, among young African American males,
15 extremely high, but you also have to think about not
16 only the direct victims of homicide, but also the
17 survivors and the witnesses of the violence that
18 occurs in these communities make people vulnerable to
19 mental health problems. And certainly, children in
20 the foster care system, quite high, and many of these
21 young people have unmet mental health needs.
22 Next slide, please.

1 The Institute of Medicine report, "Unequal
2 Treatment," released in 2002, focused on the fact that
3 racial and ethnic disparities exist regardless of
4 socioeconomic status, and this is borne out in the
5 higher morbidity and mortality from some of the
6 leading causes of death, including HIV/AIDS, and a
7 poorer quality of care that has been found across the
8 board in a number of different disease states, with
9 the result being worse outcomes among these
10 populations.
11 And I call this the "death gap."
12 Next slide, please.
13 And the death gap, just some examples to
14 highlight African Americans with excess deaths to
15 heart disease, stroke, cancer, et cetera, and
16 HIV/AIDS, and among Hispanics, also HIV/AIDS among
17 some of the leading causes of death for which they die
18 sooner and more of, and important to put this death
19 gap in the context of mental health because often
20 these diseases co-occur with mental health problems,
21 and because of that it makes it very difficult to
22 recognize and to treat these conditions optimally and

1 to forestall poor outcomes and the ultimate poor
2 outcome being death.
3 Next slide, please.
4 Important to understand some of the
5 barriers and mediators to equitable health and mental
6 health care for racial and ethnic groups. There are
7 many barriers which span from the personal and family
8 barriers to the structural ones. How available mental
9 health services are, for instance, or some of the
10 financial ones in terms of insurance coverage and
11 reimbursement levels which may be barriers to getting
12 health and mental health care; certainly the types of
13 services that are used, whether it's primary care and
14 specialty care, which we know that ethnic and racial
15 minorities tend not to get, and they are more likely
16 to get emergency services, which is not a good place
17 to treat one's HIV nor one's mental health problems.
18 Very little preventive services received by these
19 populations.
20 And let's look at the mediators. How
21 could we intervene here where certainly the quality of
22 providers in terms of their ability to understand the

1 cultural context of individuals, to be able to
2 communicate across cultures, to be knowledgeable about
3 the conditions for which some of these populations are
4 vulnerable, and also to undo some of the bias and
5 stereotyping which may be unintentional, but
6 nevertheless has a significant impact on the quality
7 of care that people receive.
8 And ultimately what we want to reach is
9 improved outcomes, avoiding mortality and maximizing
10 well-being and functioning and good, effective
11 partnerships between patients and providers.
12 Next slide, please.
13 Ultimately what we want to prevent is this
14 vicious cycle, and I propose to you that by
15 identifying and treating mental illness early, it's
16 really a way for us to prevent HIV infection. Imagine
17 if we could identify mental illness early. We might
18 prevent people from self-medicating, which we so often
19 see, people with unmet mental health needs reaching
20 for alcohol and drugs to self-medicate, and
21 unfortunately this is a particular problem in under
22 served ethnic and racial communities which may be low

1 income, and we certainly see in these communities
2 great availability of alcohol, with liquor stores on
3 every other corner, open often 24 hours a day seven
4 days a week. Talk about access.
5 And, again, with open air drug markets,
6 this makes it very accessible to get alcohol and
7 drugs, which as I mentioned before reduces one's
8 ability to exercise the kind of judgment to protect
9 oneself and to keep oneself out of harm's way of
10 exposure to sexually transmitted infections like
11 HIV/AIDS, hepatitis and so forth.
12 And this vicious cycle can go in any of
13 these directions. Think about how the substance abuse
14 can lead to violence and certain incarceration.
15 Certainly among minorities we know that there's very
16 aggressive policing in their communities, and God
17 forbid if such an individual residing here has an
18 untreated mental illness and a substance abuse
19 problem. Rather than getting the mental health needs
20 met, they end up in the correctional system, which
21 unfortunately is not the best place to receive care
22 for these conditions.

1 And certainly as we go around the cycle,
2 the cycle continues of poverty and homelessness and
3 broken families and so forth. So we really need to
4 think about mental illness as a way of interrupting
5 this vicious cycle.
6 Next slide, please.
7 Just to give you some examples, if we
8 think about major depression, an illness that is
9 characterized by change in mood, a change in a sense
10 of well-being, and change in self-esteem, as well as
11 often associated with thoughts of suicide and death,
12 these are the diagnostic criteria for major
13 depression, and someone would need to experience five
14 or more of these in a two-week period in order to
15 reach the diagnosis.
16 Next slide, please.
17 And we know that depression is an equal
18 opportunity illness, and if you look at the ethnic
19 distribution shown here, there is a slightly
20 significantly higher rate among the white population
21 in the lifetime prevalence category, but for the most
22 part these rates of depression are quite similar.

1 Next slide, please.
2 But what is different is the difference
3 between the prevalence of depression -- and these are
4 actually depressive symptoms in this case, not
5 depressive illness or major depression -- and if we
6 compare the prevalence of depression to the actual
7 diagnosis of it, we see a huge gap which is more
8 pronounced among African Americans and Hispanics than
9 their Caucasian counterparts.
10 But I might add that as you can see, we're
11 not doing well across the board in diagnosing the
12 depression that's out there in the community, but this
13 just underscores the level of disparities that we see
14 not only in major depression, but even in some of the
15 subsyndromal types of depression, which can also exact
16 a toll on someone's mental health.
17 The next slide, please.
18 Certainly one of the challenges is being
19 able to recognize depression and other mental
20 illnesses as they arise in different cultural clothes,
21 if you will. Among Latinos the complaint, presenting
22 complaint for depression might be nerves and

1 headaches. Among Asians, weakness or imbalance.
2 Among American Indians, being heartbroken. And among
3 African Americans, the experience of anger or evil may
4 be the presenting complaint. And even though all of
5 these groups may also experience somatic complaints in
6 the context of depression, which also can make it very
7 difficult for the unsuspecting clinician to identify
8 it.
9 So here is an example of how individuals
10 of various groups may go under the radar screen in
11 terms of their mental health, and if they have HIV
12 infection, we risk not being able to maximize the
13 benefits of treatment because of the impact of
14 depression on treatment adherence, et cetera.
15 Next slide, please.
16 Certainly in certain age groups, for
17 instance, adolescents, this may sort of color the way
18 in which an individual presents and may lead to
19 depression not being recognized, the sense of
20 hopelessness, declining academic performance, acting
21 out, loss of interest in activities, and substance
22 abuse, again, often a clue that a young person is

1 having a mood disorder.
2 And in our seniors, where it is also quite
3 difficult to recognize and treat depression, physical
4 complaints, anxiety, loss of ability to feel pleasure,
5 lack of interest in personal care.
6 Next slide.
7 And, again, mentioning the fact that
8 depression occurs with a number of other diseases,
9 HIV/AIDS, heart disease and stroke, and even cancer,
10 which we heard about a moment ago, making all of these
11 conditions quite difficult to treat.
12 Next slide, please.
13 In terms of mental illness and substance
14 abuse, we know that there's a very high risk of
15 substance use disorders in people with anxiety
16 disorders, mood disorders, and schizophrenia, and it
17 can go in either direction, that people with substance
18 abuse have high risk of mental illness, and people
19 with mental illness have high risk of having co-
20 occurring substance abuse.
21 And all of this increases risk for a whole
22 plethora of negative outcomes.

1 Next slide.

2 Now, we also know that there's a drug
3 treatment gap, that 3.9 million people in our country
4 need drug treatment for whom no services are
5 available. So these populations are very much at
6 play. Race is a main factor in admission to treatment
7 outside of the criminal justice system, meaning that
8 populations of color are very vulnerable in this
9 regard.

10 And we know that admissions are linked to
11 insurance status, which means that 62 percent of those
12 who are receiving care are white, 24 percent African
13 American, and less than 13 percent Latino.

14 Next slide, please.

15 I've spoken about this before, about the
16 risks of incarceration in populations where mental
17 illness and substance abuse have not been recognized.
18 Certainly these conditions predispose to
19 incarceration for the minor offenses, and certainly
20 the high arrest rates that we see in association with
21 the War on Drugs also fuels this.

22 But the problem is that once people end u

1 in the correctional system, they find themselves in a
2 hotbed of HIV/AIDS transmission, only fueling the
3 epidemic more, and when people are released, you know
4 what happens in the community.
5 Next slide.
6 We know that these trends are increasing
7 and that more and more it is people of color who will
8 be populating the correctional institutions.
9 Next slide.
10 Certainly our government has taken some
11 leadership in these areas. SAMHSA has expressed a
12 vision of life in the community for everyone and the
13 need to build resilience and facility recovery.
14 They've developed programs and issues to focus on that
15 include co-occurring substance abuse and mental
16 illness programs, looking at substance abuse treatment
17 and homelessness, targeting some of these high need
18 populations, those with HIV/AIDS and hepatitis, and
19 the criminal justice system, and always crosscutting
20 with these is the need to pay attention to cultural
21 issues and the need to eliminate disparities.
22 Next slide, please.

1 And certainly the President's new Freedom
2 Commission on Mental Health in 2003 talked about
3 achieving the promise, transforming mental health care
4 in America, and improving access to quality care
5 that's culturally competent, and certainly imploring
6 states to address ethnic and racial disparities and
7 increase diversity in the mental health work force
8 which really relates to Dr. Sullivan's leadership and
9 his report on missing persons, and this is quite an
10 issue for us in the mental health sectors as well.
11 Next slide, please.
12 To summarize, mental illness is a risk
13 factor for and consequence of HIV/AIDS. Certainly co-
14 occurring mental illness and substance abuse is a
15 common pathway to HIV/AIDS exposure, and addressing
16 these issues is one way to reduce HIV/AIDS risk.
17 Certainly integrated treatment of co-
18 occurring disorders can improve HIV/AIDS adherence and
19 outcome, and we certainly need to take into account
20 the ways in which ethnic and racial disparities in
21 HIV/AIDS. We know that communities of color are
22 particularly hard hit with HIV/AIDS, and that means

1 that we must identify and treat mental health needs
2 and substance abuse whenever we can because without
3 that, it's a lethal combination.
4 Next slide.
5 I'd like to leave you with a vision for
6 the future, that we must improve public awareness of
7 mental health problems in people with HIV/AIDS,
8 awareness of effective treatment that exists for these
9 conditions, and promote prevention, early detection
10 and access to integrated care, in particular, where
11 people in one location can get HIV care, substance
12 abuse care, and mental health care, sort of the idea
13 of a one-stop shop, which improves adherence and
14 receipt of treatment, certainly increased funding for
15 treatment and research.
16 And next slide, please.
17 We must insure the supply of mental health
18 services and providers. We must increase the work
19 force and educate them about these co-occurring
20 disorders, HIV/AIDS, substance abuse, and mental
21 illness.
22 Certainly, parity in the way that we

1 provide services, community based approaches and
2 culturally competent clinicians so that we can be
3 better able to tailor treatment to age, gender, race,
4 ethnicity, and culture.
5 Next slide, please.
6 I want to thank you so much for your
7 attention and just provide you with some hope that in
8 working together that we can tackle these very
9 significant problems in our society. I hope that the
10 American Psychiatric Association, my Office of
11 Minority and National Affairs, as well as the Office
12 of HIV/AIDS Psychiatry can be helpful to this council
13 and individually to each of you with your
14 constituencies.
15 Thank you very much.
16 (Applause.)
17 DR. REZNIK: Thank you, Dr. Primm. That
18 was an exceptional presentation, and each of us is
19 charged with writing a paper this year, and we will be
20 calling upon you.
21 I actually told Joe Grogan. I said we
22 should just get the transcript and that could be our

1 mental health section of the treatment and care part
2 of the program. It was very well done.
3 We have a few minutes for questions. We
4 are running late, but let me get a pen and who? Okay.
5 Dr. Yogev.
6 DR. YOGEV: Thank you very much for your
7 talk.
8 I would like to urge you to separate the
9 pediatric adolescent into those who have got the
10 infection through pregnancy, who already had the brain
11 affected to such a way that they are already
12 handicapped by the cognitive, to start with, and then
13 they're coming into adolescence in a different set-up,
14 already being in a minority, single mother, poor, and
15 cognitively handicapped.
16 DR. ANNELLE PRIM: Yes.
17 DR. YOGEV: And discrimination is part of
18 it, but disclosure is a majority, that they don't know
19 about the disease suddenly to discover. And it's a
20 different population that needs help, and as you
21 mentioned, the pediatric is really way behind on
22 psychiatric approach, and I don't see the government

1 putting them in a special category to work versus the
2 adolescent who just received the infection, which have
3 a different perspective.
4 So I would appreciate if your office will
5 really put stress because we find major difficulties
6 in getting psychiatric, psychological/psychiatric help
7 to this type of population that are small in number,
8 but each one of them is very important.
9 DR. ANNELLE PRIM: Yes, thank you for
10 pointing that out.
11 I had not focused on that population, but
12 I think your point is well taken. They're extremely
13 vulnerable and need mental health services probably
14 right from the start. So thank you for that.
15 DR. REZNIK: Our next question is from
16 Jackie Clements.
17 MS. CLEMENTS: Thank you.
18 As you did say and we all know that HIV
19 does affect the brain and sometimes the onset of
20 mental illness can be very, very subtle, and if you'll
21 allow me the experience of my husband, you know, from
22 beginning to forget keys, where he put them, to what

1 you think, "Oh, that's age," to the point of
2 forgetting numbers, which was probably his quick, you
3 know, best thing. He was like a phone book and then
4 all of a sudden to the point of forgetting how to get
5 home.
6 So how often and when? Because we do
7 think, you know, as we age, oh, it's okay to forget
8 those things. It's natural to forget some things, but
9 how often and when do you begin to assess a person's
10 mental illness possibly so that it doesn't get to the
11 point of dementia and forgetting your way home before
12 you realize that they're becoming affected mentally by
13 this disease with dementia?
14 DR. ANNELLE PRIM: HIV infection can
15 affect the brain directly from the very sort of
16 inception of infection, if you will, and I think what
17 it really suggests is that psychiatrists need to be an
18 important part of the treatment for anyone with
19 HIV/AIDS so that they are evaluated and you establish
20 very early on in the illness a baseline against which
21 you can compare people over time what they look like
22 in cross-section so that you'll know, you know, what

1 is occurring and be able to pick up on, you know,
2 symptoms and signs like what you just described.
3 So I think that really just makes a case
4 for the involvement of psychiatric evaluation very
5 early on, you know, once the infection is detected.
6 Very difficult to know that if there's no baseline and
7 it's just sort of coming out of the blue, but a very,
8 very important point.
9 I think my first case of AIDS that I ever
10 saw, I had just finished my residency and a family
11 member brought in a young woman who just suddenly
12 seemed just out of it and sort of looking off into
13 space. And you know, over time we figured out what
14 was going on. It was in the early '80s when this
15 occurred, and no one had seen her behave that way
16 before. It was very uncharacteristic.
17 So you're very right. These are quite
18 subtle. So we need to have a high index of suspicion
19 for someone who has the infection to be able to
20 identify those as dementia.
21 DR. REZNIK: Dr. Primm -- a committee
22 chair choice here -- we heard from the oncologists

1 early today how they're tracking incidents of cancers.
2 People are living longer and longer on antiretroviral
3 therapy. Is there a similar tracking that's going on
4 on mental health status for people who have been on
5 therapy for several years?
6 DR. ANNELLE PRIM: Diane, if you're in the
7 audience, maybe you know this better than I, if there
8 is some sort of registry or tracking process that's
9 going on.
10 MS. PENNESSI: No.
11 DR. ANNELLE PRIM: Okay. I guess
12 someplace for us to get to, something for us to work
13 on, but thank you for raising that.
14 DR. REZNIK: Dr. Green?
15 DR. GREEN: Yes. Thanks for a very
16 interesting presentation, Dr. Primm.
17 DR. ANNELLE PRIM: Thank you.
18 DR. GREEN: I was looking at your slide,
19 the vicious cycle, substance abuse, mental illness,
20 violence, incarceration, and so forth, and that's not
21 even adding the possibility of being HIV infected and
22 having neurocognitive disorder.

1 Your plea is for early detection and
2 treatment of mental illness, and this certainly sounds
3 reasonable, but you know, what realistically would the
4 options be for treatment? Who would do the treatment
5 and how much treatment is needed?
6 Just thinking about substance abuse,
7 arguably self-help groups like Alcoholics Anonymous
8 have done as much or more than professional treatment
9 of just that one problem here in the vicious cycle.
10 If we're talking especially about somebody poor, from
11 a minority group with these multiple problems, you
12 know, realistically what would the treatment or the
13 care options be?
14 DR. ANNELLE PRIM: Well, certainly there
15 are community mental health services that are
16 available. I do have to agree with you that it's
17 difficult to get people to treatment because of the
18 stigma that exists, and I've been fortunate to be
19 involved in some community based activities, to
20 actually organize community leaders, church members,
21 et cetera, to conduct health fares where individuals
22 receive depression screening and other sorts of mental

1 health screening, and then are equipped with the
2 resources to provide individuals about where to get
3 help.
4 Of course, these are supervised. These
5 health fares are supervised and backed up by mental
6 health professionals, such as psychiatrists, nurses
7 and social workers, but this has been a very effective
8 way of penetrating some of the barrier and some of the
9 stigma that people may associate with coming to an
10 institution to get help.
11 Other ways are to locate mental health
12 services in the same place where people get other
13 sorts of services, like social services, for instance.
14 There has been a very successful program like that in
15 the State of Illinois where mental health services
16 have been locate and screening has been located where
17 people come to receive their welfare to work sorts of
18 resources.
19 There are other examples. I have had a
20 very wonderful experience being the first psychiatrist
21 to ever set foot in the Johns Hopkins substance abuse
22 treatment program, where I worked alongside the

1 primary care physician treating the individuals there
2 who were receiving substance abuse care, treating them
3 for mental illness and often working in concert with
4 the HIV/AIDS physicians, as well.

5 And so, again, that one-stop shop approach
6 where you don't always have to wait on someone coming
7 to the mental health provider, which is unlikely,
8 particularly in these populations, given the stigma,
9 you really need to be strategic about where those
10 mental health services are offered so as to increase
11 the likelihood that people will receive them and
12 benefit from them.

13 Another approach is to educate primary
14 care physicians and others how to identify and treat
15 mental illness. We know that particularly in the
16 minority community if individuals are going to get
17 care at all, it's most likely to come from a primary
18 care physicians.

19 So equipping and empowering primary care
20 physicians to be able to better treat those conditions
21 using effective screening and quick screening, for
22 instance, for depression tools like the PHQ-9, for

1 instance, this is another mechanism for quickly
2 identifying depression and being able to treat it and
3 track it over time. There are a lot of things that
4 we're employing, and some of my work in developing
5 educational video tapes on depression, one called
6 "Black and Blue, Depression in the African American
7 Community," the other "Gray and Blue, Depression in
8 Older Adults," which is a multi-cultural video, shows
9 individuals of these ethnic and age groups who have
10 experienced depression themselves, talk about it, and
11 it really helps for individuals who might have
12 depression to relate to that person and to see that it
13 is good to get help, professional help, or to get
14 treatment.
15 So those are just some of the examples to
16 try and reverse that trend that you speak of.
17 DR. REZNIK: Dr. Primm, would you be able
18 to stay through our lunch break today?
19 DR. ANNELLE PRIM: Yes.
20 DR. REZNIK: Because there are other
21 questions, and I've turned down Dr. McIlhaney twice
22 now, and it's not appropriate because in the military

1 -- I'm sorry -- but the last question is going to go
2 to Dr. Sullivan, but you will be at the top of our
3 list after our next mental health update from SAMHSA.
4 CO-CHAIRPERSON SULLIVAN: Well, thank you
5 very much, Mr. Chairman, for this special privilege
6 you've granted me.
7 (Laughter.)
8 DR. REZNIK: I think it's on target.
9 CO-CHAIRPERSON SULLIVAN: The question I
10 have, I was struck by your statement. I want to be
11 sure that I heard it correctly, and that is there are
12 more HIV/AIDS individuals in corrections institutions
13 than in the health system.
14 DR. ANNELLE PRIM: No. I mean there were
15 more people with mental health problems in the
16 correctional system. That's the place, the
17 correctional system is the place where the most, the
18 largest number of people with mental illness are now
19 housed.
20 It used to be the state psychiatric
21 system, but I think my point was that in being in the
22 correctional system, those individuals who are

1 vulnerable because of their mental health needs and
2 their substance abuse issues are vulnerable yet again,
3 being in a setting that is currently a hotbed of
4 HIV/AIDS. I did say that because of the sorts of
5 things that go on in the correctional system. That
6 was my point.
7 CO-CHAIRPERSON SULLIVAN: Well, if I might
8 follow with a related question, do you know what
9 percentage of those patients with mental illness, with
10 HIV in the correction system have access to mental
11 health services?
12 DR. ANNELLE PRIM: I don't know the
13 percentage of those with mental illness and HIV/AIDS,
14 and I don't have a percentage for you of how many have
15 access to mental health services.
16 There are mental health services in some
17 correctional settings, but they tend not to be of high
18 quality, and there are some places where there is
19 minimal to no care. So this is a challenge for the
20 nation because, as you know, once people are released,
21 they are not welcomed with open arms in our
22 communities, and even some of the community based

1 mental health providers are not excited to receive
2 these individual and treat them. So that's a big gap
3 there.
4 Thank you very much.
5 DR. BENY PRIMM: I would like to recommend
6 some biased applause for my daughter.
7 (Laughter and applause.)
8 DR. REZNIK: We're going to take a short
9 break. We had originally scheduled a ten-minute
10 break, but our next presenter needs to be at another
11 meeting at 11. So if you could please keep it to five
12 minutes and hurry back, I appreciate it.
13 Thanks very much.
14 (Whereupon, a short recess was taken.)
15 DR. REZNIK: Our next presenter is Abby
16 Block, who is the Senior Administrator to the CMS
17 Administrator or became Senior Advisor to the CMS
18 Administrator in October of 2004. She has played a
19 leading role in implementing the Title I and Title II
20 provisions of the Medicare Modernization Act. She's
21 worked extensively with health plans and beneficiary
22 advocacy groups to insure an effective transition to

1 the new Medicare Advantage and prescription drug
2 program in 2006.
3 We had the pleasure of hearing Abby Block
4 at the Treatment and Care Committee meeting earlier
5 this year, and I'm very proud and happy that she's
6 here once again to fill us in on the Medicare
7 prescription drug benefit and how it's going to impact
8 people living with HIV and AIDS in the United States.
9 MS. BLOCK: Well, thank you very much, and
10 of course, Dr. McClellan sends you all his very best
11 wishes. He's on a bus somewhere in New Jersey, and as
12 many of you may have heard because the news coverage
13 was very good, the President formally kicked off our
14 outreach campaign right here in this building on
15 Thursday and then went to Minnesota with the Secretary
16 for some follow-up, and today is Florida Day. and so
17 Dr. McClellan and the Secretary are, as I said, on a
18 bus somewhere in Florida reaching out to seniors and
19 to their families as we begin the formal enrollment
20 effort for this new, very exciting 2006 Medicare
21 prescription drug benefit.
22 So just a quick overview for those of you

1 who aren't already familiar with it. I'm sure most of
2 you are. As you know, the Medicare Prescription Drug
3 Improvement and Modernization Act of 2003 was passed
4 in December of 2003, and beginning in 2004, we
5 initiated the prescription drug card or the discount
6 card and also saw a significant enhancement of
7 Medicare Advantage plans in the program.
8 In 2005, preventive benefits were
9 initiated for the first time in the Medicare program,
10 and those preventive benefits have a very strong link,
11 of course, to the prescription drug benefit since
12 prescription drugs can play such a huge role in
13 preventing more serious events really at all levels in
14 the cycle of care for patients with all kinds of
15 problems, including severe chronic illnesses.
16 In January of 2006, the prescription drug
17 benefit formally goes into effect, beginning January
18 1. Right now, in June, CMS is engaged in a huge
19 effort with the Social Security Administration,
20 getting people who are eligible for a low income
21 subsidy information and forms to help them sign up for
22 that benefit. It's a huge benefit for low income

1 subsidy eligibles, and that effort is going on right
2 now.
3 Enrollment in the new program begins
4 November 15th of 2005, and not only will Part D plans
5 or prescription drug plans be available, but many,
6 many additional Medicare Advantage plans, both
7 regional PPOs and local plans all over the country.
8 Some of the key dates that we're looking
9 at at this point in the process. The final bids were
10 due to CMS on June 6th. We received many, many, many
11 bids both on the MA side and the MAPD side and the
12 stand alone PDP side, and the response, to say the
13 least, has been robust.
14 We're not giving out exact numbers at this
15 point because the bids need to be analyzed and
16 negotiated, the benefit packages reviewed, and until
17 the actual contracts are signed, we don't really have
18 accepted participants. The date for signing those
19 contracts will be some time in mid-September.
20 So everyone at CMS is working very hard at
21 this moment in time reviewing those bids and seeing
22 what they look like.

1 In October plan marketing starts. The
2 Medicare and You handbook becomes available. It will
3 be in the home of every Medicare eligible in October,
4 and dual eligibles, that is, the Medicare/Medicaid
5 dual eligibles, in October will be auto-assigned to a
6 PDP plan. They will be notified in October of what
7 plan they've been auto assigned to, and in that
8 notification they will also be told that they have the
9 option of changing to any other plan of their choice,
10 and they will, of course, be able to do that during
11 the regular enrollment period.
12 But we wanted to make absolutely sure that
13 nobody would have a gap in coverage, that is, none of
14 the Medicaid eligibles who will be losing their
15 Medicaid coverage on January 1. They will absolutely
16 be enrolled in a Medicare prescription drug plan
17 before January 1 so that they have continuity of
18 coverage.
19 The formal open enrollment period begins
20 on November 15th and ends on May 15th of 2006, and
21 that May 15th date is just for the first year of the
22 program. In subsequent years, the open enrollment

1 period will be from mid-November to December 31st.

2 As you probably know, there is in the
3 statute a standard Medicare prescription drug benefit,
4 and I want to stress that this is just the standard
5 benefit because plans have all kinds of opportunity to
6 modify that benefit so long as it's actuarily
7 equivalent to the standard benefit. That is, it can't
8 be less than the standard benefit.

9 And so what we're looking at is
10 considerable variation on the part of plans, and in
11 addition to that, there is in place a payment demo
12 which gives the plans even more latitude in terms of
13 how they can design their benefit packages.

14 So this is the standard, but there will be
15 considerable variation from this standard, and before
16 I give you this, I need to remind you that none of
17 this applies to dual eligibles; that dual eligibles
18 pay nothing other the $1/$3 prescription drug
19 copayment, and dual eligibles who are
20 institutionalized pay nothing at all. So this applies
21 to others than the dual eligibles.

22 The standard benefit is the $250

1 deductible up front, after which Medicare pays 75
2 percent of drug costs up to $2,250. The beneficiary
3 pays 25 percent of those costs. After that the
4 beneficiary will pay 100 percent of drug costs between
5 that $2,250 and $5,100 amount. At that point the
6 beneficiary's total out-of-pocket cost will be $3,600,
7 and then the catastrophic coverage kicks in. And
8 after that Medicare will pay about 95 percent of the
9 costs.

10 In terms of others than the full dual
11 eligibles, just as an example, for beneficiaries with
12 income up to 135 percent of the federal poverty level,
13 there are no gaps for beneficiaries with incomes at
14 that level. Only the area in red must be paid by the
15 individual, and the total out of pocket is the sum of
16 the two to $5 copays for up to $5,1000 worth of
17 prescriptions.

18 So there's a lot of help there in terms of
19 subsidy eligibles and low income eligibles. There's a
20 lot of help for people in those categories.

21 In terms of where we are, I'd like to tell
22 you a little bit about the road to implementation, the

1 progress that we've made so far, where we are, and
2 what's ahead.
3 As you probably know by now, the MMA
4 directed the Secretary to establish prescription drug
5 plan regions, and that process was separate from the
6 final regulation. On December 6th, 2004, CMS
7 announced the establishment of 26 MA regions and 34
8 PDP regions, and there's what the map looks like.
9 This is a map of the PDP regions, and each
10 of the territories, in addition, is it's own region.
11 I'm happy to say that at this point we have maple
12 bids. We have no expectation that there will be fall-
13 back plans anywhere in the country. We expect to have
14 full coverage everywhere, including the territories as
15 of this point in time.
16 And in addition to the very robust
17 response on the PDP side, on the MA side participation
18 has increased significantly. We are anticipating that
19 in 2006, actually by the end of 2005, where plan
20 contracts are already approved, we know already that
21 at least 80 percent of eligible beneficiaries will
22 have access to an MA or MAPD plan beginning in 2006.

1 So coverage had been extended
2 significantly, including coverage in rural areas.
3 CMS has released a lot of guidance in
4 addition to the final rule. Subsequent to the final
5 rule, we released very specific guidance on long-term
6 care coverage, on the transition process that will be
7 required, on fiscal solvency standards for the plans,
8 on prescription drug event data which is basically
9 claims data that we'll be monitoring very carefully to
10 have an understanding of what and how prescription
11 drugs are being used.
12 On employer waiver guidance that's for
13 those retirees who are covered by a plan provided by
14 their former employer.
15 We also -- and this is of special
16 interest, I know, to this group -- when we issued our
17 formulary guidance, we specified that there were six
18 drug classes of special interest. Those were the
19 anticonvulsants, the antipsychotics, the
20 antidepressants, chemotherapy drugs, HIV/AIDS drugs,
21 and immunosuppressants.
22 And we have required that all or

1 substantially all of the drugs in those categories
2 will be covered, and we've just release additional
3 guidance that clarifies that, and I can assure you
4 once again that in the HIV/AIDS category every drug
5 will be on the formulary.
6 And just as a special note with special
7 provision for the HIV category drugs, the plans will
8 not be able to use preauthorization for anybody
9 stabilized on these drugs of, in fact, for any new
10 prescriptions for these drugs. The only drug for
11 which preauthorization will be permitted is Fuseon,
12 and the reason for that is to insure from a patient
13 safety perspective that it is being prescribed at the
14 appropriate time in the treatment cycle, and there
15 was, you know, considerable news on that issue. So
16 you may already be aware of that.
17 In Part D, our goals were as follows. We
18 have a primary goal regarding access, and that is to
19 insure that plans are available nationwide, both
20 prescription drug plans and Medicare Advantage plans,
21 and we've been really successful in achieving that
22 first goal, I'm happy to say.

1 In terms of operations, our goal is to
2 insure that plans provide high quality service to
3 beneficiaries and are able to operate effectively.
4 That will be part of the review process as we look at
5 the bids and the proposals, and we'll be working very
6 closely with the plans to be sure that they can, in
7 fact, deliver the services that they're promising.
8 In terms of education outreach and
9 enrollment, our goal is to insure that the 42 million
10 Medicare beneficiaries can make confident decisions on
11 their prescription drug coverage, and that means a
12 huge, huge education and outreach campaign, which as I
13 indicated was officially kicked off by the President
14 here on Thursday, but which began really well before
15 that, back into April when we really started our
16 outreach seriously.
17 Forty-two million medicare beneficiaries
18 need to be educated so they can make confident choices
19 on their prescription drug coverage. That's a lot of
20 people, and the target populations include seniors in
21 general and people with disabilities who are Medicare
22 eligible. It includes the low incomes population, of

1 course, with special emphasis not only on the dual
2 eligibles who are working on with the states, but also
3 the low income subsidy eligibles who, as I mentioned,
4 were at this very moment working with SSA closely to
5 get them all the information they need to apply for
6 the subsidy.
7 Retirees, those are the people who are
8 covered by a former employer's plan, and the
9 population that's already enrolled in Medicare
10 Advantage plans.
11 The beneficiary target support list, this
12 is how it breaks down. Percentage-wise, about 5,
13 point -- I'm sorry. It's not percentage. It's
14 numerical.
15 The 5.7 million who are in Medicare
16 Advantage plans now, the 11.8 million who are covered
17 by a former employer's plan, 6.3 million people with
18 Medicaid, 7.7 million other people with limited means
19 -- those are the low income subsidy eligibles -- and
20 11.0 million who are the remaining general population,
21 and that's the group that's either covered by Medigap
22 or has no prescription drug coverage at all at this

1 point in time.

2 We understand that we need to increase the
3 percentages in the following categories. We need to
4 make beneficiaries aware of the Medicare prescription
5 drug benefit. There are some surveys out there that
6 say a huge percentage of beneficiaries are totally
7 unaware of the program, and that includes the Medicaid
8 beneficiaries. The survey or surveys were really
9 taken well before our outreach campaign began, and I
10 can assure you that beginning now there will be nobody
11 left in the country who will not be aware that this
12 benefit is available.

13 Beneficiaries need to believe that the
14 Medicare benefit has a positive impact on their lives,
15 which means an understanding that there is a
16 substantial federal subsidy in this program, and that
17 it is to everybody's advantage to sign up.

18 Beneficiaries need to understand that they
19 have to make a decision regarding enrollment. Unlike
20 Part B, it is not an opt out program. It's an opt in
21 program. So except for the dual eligibles who will be
22 auto enrolled, in order for people to receive the

1 benefit, they must sign up.
2 And they have to take action regarding
3 their drug coverage, and they have to actually enroll.
4 As I mentioned earlier, President Bush
5 kicked off the awareness campaign on Thursday, June
6 16th, here at HHS, and that began the nationwide
7 awareness drive. The President urged everyone on
8 Medicare to sign up. To quote him, he said the
9 message to seniors was when they have a form, when in
10 doubt, fill it out.
11 The President and Secretary Leavitt
12 visited Minnesota on Friday, June 17th, to continue
13 the focus, and Dr. McClellan and the Secretary are in
14 Florida today, again continuing the outreach campaign.
15 The general campaign message is that every
16 Medicare beneficiary will be eligible for drug
17 coverage that will help pay for the prescription drugs
18 you need. The coverage will pay for both brand name
19 and generic drugs. You've have a choice of at least
20 two plans, and there will be additional assistance for
21 those in need.
22 That's our campaign message, and we're

1 carrying that forward through every possible medium.
2 There will be targeted messages to
3 Medicare Advantage enrollees. What we're telling them
4 is you will get more drug coverage through your health
5 plan because of the prescription drug subsidy to
6 retirees with good coverage through their employer
7 plan. We're telling them your drug coverage will now
8 get new support from Medicare because employers can
9 receive a 28 percent subsidy for continuing their
10 current coverage and also have some other mechanisms
11 for continuing coverage if they choose to go a
12 different route than the subsidy route.
13 To people with Medicaid, we're telling
14 them they will get comprehensive coverage with
15 Medicare, and that comprehensive coverage is, as I
16 said, full coverage, no coverage gap, no deductible.
17 The only cost to people with Medicaid will be the
18 $1/$3 per prescription copay, which is written into
19 the statute.
20 For other people with limited means, you
21 need to apply for the low income subsidy, for
22 comprehensive coverage, and that application process

1 is going on right now.

2 To the remaining general population, our
3 key message is this is an insurance program. You need
4 to enroll for help with current drug costs and for
5 future peace of mind, and you save by enrolling on
6 time, that is, if you enroll before May 15th, then you
7 don't incur the one percent per month penalty that
8 kicks in after that date.

9 In terms of our time line, June to
10 September 2005, we focus on awareness and limited
11 income enrollment. We're building awareness including
12 national grassroots education campaign, and we hope
13 you all will be helping us with that.

14 The low income subsidy applications are
15 available. Community events on the low income subsidy
16 and on the drug benefit will be taking place, and
17 retirees will be enrolled and will be informed of the
18 opportunity through their employers.

19 October 2005 is support for the
20 prescription drug enrollment. "Medicare and You"
21 handbook will be mailed to all beneficiaries.
22 Specific plan information will be available, and the

1 plans will be starting their marketing campaigns.
2 People with Medicaid will be notified
3 about their Medicare plan enrollment, and we'll be
4 supporting enrollment through grassroots education and
5 counseling.
6 November 15th, as I've said, is the open
7 enrollment period beginning date. January 1st, 2006,
8 the prescription drug coverage starts. May 15th,
9 2006, the open enrollment period ends, and after that
10 there's a penalty just like for any other insurance
11 where you enroll late.
12 We've had a lot of ongoing training and
13 assistance for plan sponsors. There were major
14 training programs in Baltimore, quite a few of them.
15 Weekly calls that says through June -- actually the
16 weekly call schedule has been extended at least
17 through the end of August. So we'll be in touch with
18 the plans on an ongoing basis.
19 There will be some training on how to
20 submit claims data for Part D in July and August.
21 Payment and enrollment conferences in Baltimore in
22 August and September, and a retiree drug subsidy

1 national conference July 12th and 13th in Dallas,
2 Texas.
3 And I might also add we're starting
4 regular meetings with the states. We'll be meeting
5 with states on a regular and ongoing basis. Some of
6 that has already begun because it's really critical
7 for us to work closely with the states, particularly
8 in terms of the dual eligibles and also where the
9 states have SNAP programs which cover additional
10 people with limited income. So that's another ongoing
11 effort.a
12 Our field operations include a national
13 strategy with a local execution, and when I say "local
14 execution," I can tell you that that means literally
15 down to the county level. This has been broken down
16 county by county throughout the country so that there
17 will be literally outreach activities in everyplace in
18 the country.
19 There will be a huge community network
20 working through the CMS regions that are part of this
21 huge outreach effort, and there will be a layered,
22 coordinated outreach starting, you know, with the

1 national partners and getting down to the local level.
2 Partners will be targeted with application
3 materials. National partners are drilling down to
4 their local affiliates, and we have a time line, as I
5 keep saying, for the low income subsidies that's
6 carefully coordinated with the Social Security
7 Administration.
8 Partnerships, of course, are critical to
9 the success of the drug benefit program. They allow
10 CMS to work with organizations that are trusted by
11 beneficiaries. They help CMS to focus information to
12 specific audiences.
13 CMS and its many partners share the common
14 goal of helping people with Medicare get answers and
15 make better informed health care decisions.
16 We have started our collaboration, as you
17 know, with the HIV/AIDS community. We've coordinated
18 national level CMS regional offices, SSA local
19 offices, and states. Some of the activities that we
20 plan will be train the trainer activities. We're
21 going to facilitate information dissemination through
22 the state AIDS Directors, through HIV/AIDS specific

1 medical providers, through pharmacies, and we have
2 indicated -- I did it the last time I was here, and I
3 again extend our willingness to participate in any
4 national conferences that you all may have scheduled
5 where we could help in this outreach effort.
6 In conclusion, we've made great strides to
7 implement the drug benefit. We're encouraging
8 flexibility. We're willing to work with partners as
9 we move forward. We've established a variety of
10 mechanisms to answer questions, including training
11 events, Web materials, user group calls, and a Q&A
12 database.
13 And if any of you are not aware of it,
14 there is an extensive Q&A database up on our Website
15 where questions can be sent in. They're reviewed.
16 They're studied. Answers are prepared, and then the
17 answer or answers are then posted on the Website so
18 that they're available to everyone.
19 With that, thank you very much.
20 (Applause.)
21 DR. REZNIK: Do you have any time for
22 questions?

1 MS. BLOCK: Yeah, I have maybe five
2 minutes.
3 DR. REZNIK: Okay. Questions? Dr.
4 McKinnell.
5 DR. McKINNELL: Thank you for your
6 presentation and your work on implementation of
7 Medicare Modernization Act, the success of which is
8 important to all of us.
9 You're recognized the importance of
10 partnerships, which I think is absolutely critical.
11 Our research shows that people don't know very much
12 about this benefit. The more than they, the more they
13 like them.
14 And in your partnerships, I would
15 encourage you to include private sector that knows
16 something about marketing and communication and what's
17 the help available. And where I think it will impact
18 the program is in two variables: messaging and
19 charted audiences.
20 The better message seems to be not so much
21 CMS pays because CMS, in fact, doesn't pay. They
22 reimburse. They reimburse private plans, and I think

1 your private plans will come up with a much better
2 formula than Congress did, and that hasn't yet played
3 out. So I think that message is very important.
4 The other is the target audience. What
5 our research shows, the benefit has enormous
6 importance to the children of beneficiaries. So I
7 wouldn't leave them out of the equation.
8 MS. BLOCK: Well, thank you. As a matter
9 of fact, you're right on target with where exactly we
10 are. We're not only targeting the children of
11 beneficiaries; we're targeting the grandchildren of
12 beneficiaries. We're going into the colleges and
13 recruiting the grandkids who are so computer savvy to
14 work with their grandparents because tons of
15 information and very good decision tools will be
16 available on the Web, and it will be enormously
17 helpful to have computer users help with that effort.
18 We're particularly targeting, by the way,
19 the Boomer women who we think will play a key role in
20 working with their parents on this effort.
21 So we're exactly there. We're also
22 working with the industry. The industry has its

1 plans, you know, for its own outreach campaign. We're
2 working very closely with them, and I assure you since
3 I sense some doubt about the communications skills of
4 the federal government, we have excellent private
5 sector professional consultants working with us on
6 this outreach effort. It's a very professional effort
7 with enormous private sector input.

8 DR. REZNIK: Dr. Judson.

9 DR. JUDSON: One comment and a couple of
10 questions. This really is a huge new layer of
11 complexity which is going to be baffling to an awful
12 lot of people. The question is are the necessary
13 information systems in place yet to allow the enormous
14 new quantity of tracking to take place.

15 MS. BLOCK: I'm happy to say yes. The
16 information systems are, in fact, in place. They've
17 already been through extensive testing, and as best we
18 can tell at this point in time, everything is up and
19 running and will be ready to go.

20 DR. JUDSON: The other part of that, and
21 you addressed part of our group earlier, is that in
22 the tradeoff or the rationalizing between prior Ryan

1 White, Medicare and Medicaid programs for funding of
2 HIV care, how does this sort out again now? The new
3 benefit is taking over for what prior parts of funding
4 for HIV?
5 MS. BLOCK: Well, it's actually available
6 to everyone, including people with HIV, if they're
7 Medicaid eligible. If they fall into that dual
8 eligible category, then they really have virtually
9 first dollar coverage. The only thing that they pay
10 out of pocket is that $1/$3 copay.
11 For people with slightly higher incomes,
12 the subsidies range, but none of them have a coverage
13 gap. They pay that two to $5 per prescription copay.
14 In terms of contribution toward any of the
15 drugs that are not covered for people who would fall
16 outside of those categories, I think the issue that
17 you're asking about was whether funds that were used
18 to pay for the not covered parts of the Medicare
19 benefit could count toward the true out-of-pocket, or
20 TROOP, and that was a policy discussion that was had
21 very early on, and the conclusion was that no federal
22 funding could count toward true out-of-pocket, or

1 TROOP.

2 Other funding can. Any charitable
3 contributions, contributions from foundations, those
4 kinds of things can count toward the true out-of-
5 pocket, but not federal dollars.

6 DR. JUDSON: I just another way of asking
7 the question is: of the estimated $29 billion of new
8 taxpayer funding for this benefit for year 2006, is
9 any of that being double accounted through current
10 Medicaid, Medicare and Ryan White?

11 MS. BLOCK: No. So far as I know, none of
12 it is being double accounted.

13 DR. REZNIK: Abby, thank you.

14 One final question. Will patient
15 assistance programs through the pharmaceutical
16 industry count as true out-of-pocket expense?

17 MS. BLOCK: That's a really interesting
18 question, and it's one that we're still looking at.
19 We don't really have an answer to it yet because it
20 will depend on how those programs are structured.

21 The issue there really is if the
22 assistance is such that it's tied specifically to a

1 particular drug that is made by a particular
2 manufacturer, there is some problem with that. If
3 it's a general contribution or a generalized program
4 where it could legitimately, you know, be deemed a
5 charitable contribution, then we're fine with it, but
6 we have some issues and concerns with programs that
7 are specifically linked, that is, where a particular
8 drug manufacturer is offering some special discount or
9 program associated with the drug that they
10 manufacture.
11 So, you know, that's the issue that we're
12 looking at there.
13 DR. REZNIK: Abby, thank you for that, and
14 I know you have to leave.
15 (Applause.)
16 MS. BLOCK: Thank you very much.
17 DR. REZNIK: Okay. We'll be hearing more
18 from CMS on this because there still are many issues
19 out there. I was actually at the HRSA IAS clinical
20 conference before I came here, and the physicians are
21 still very confused as to what is covered and what is
22 not covered. So we're beginning the outreach process.

1 Our next presenter, we're going back to
2 mental health issues because we saw that there was
3 such incredible interest from our first presentation
4 by Dr. Primm. this is from Charles Curie. I think
5 I've got that name right, the Administrator of
6 Substance Abuse and Mental Health Service
7 Administration.
8 He was nominated by President George W.
9 Bush and confirmed by the U.S. Senate October of 2001.
10 As SAMHSA's Administrator, Mr. Curie reports to
11 Secretary Leavitt and leads a $3.4 billion agency
12 responsible for improving the accountability, capacity
13 and effectiveness of the nation's substance abuse
14 prevention, addictions treatment, and mental health
15 services.
16 I think it's also important to note that
17 Mr. Curie holds a Master's degree from -- the
18 Administrator of Social Services Administration is
19 also certified by the Academy of Certified Social
20 Work.
21 Thank you.
22 MR. CURIE: Thank you very much, David,

and good morning, everybody.

I want to thank you for that kind introduction and the opportunity to be here today. I'm pleased to join you this morning to discuss mental health, substance abuse, and HIV/AIDS.

And I think that we all agree that the research fundings that came out of CDC last week bring an even greater sense of urgency to our work. With over a million Americans now living with HIV< our service systems must rise to an even greater challenge, and our efforts to prevent new infections must continue to improve.

At SAMHSA, we're hard at work trying to find new ways to improve the quality and the availability of prevention and treatment services. The consumers of SAMHSA supported services are many of the same individuals who are at high risk of becoming infected or living with HIV.

These issues, what we do at SAMHSA, what you're focused on here today are so interrelated that I believe substance abuse prevention and treatment are HIV prevention and treatment.

1 And mental health services are a critical
2 element to the spectrum of HIV/AIDS services
3 delivered. So, in essence, what's going on at SAMHSA
4 is what's going on in HIV/AIDS prevention and
5 treatment, and if we're doing our job, striving to
6 attain our vision and accomplish our mission, it's
7 part and parcel of us accomplishing the mission around
8 HIV/AIDS prevention and treatment.
9 The outcomes and benefits are the end goal
10 of SAMHSA. Especially those I'll cover this morning
11 are many of the same outcomes and benefits that all of
12 us in this room are looking for in terms of preventing
13 and treating HIV/AIDS.
14 SAMHSA is the core box in the nesting box.
15 Addiction and mental illness have so many other
16 illnesses that stack right up around them. If we're
17 doing our job right, if we're doing substance abuse
18 prevention right, if we're doing substance abuse
19 treatment right, if we're doing mental health services
20 right, then we are reducing the spread of HIV/AIDS and
21 improving the lives of people living with HIV.
22 This year alone, SAMHSA is investing just

1 over $100 million in efforts to further develop local
2 capacity to provide mental health and substance abuse
3 treatment and prevention services for individuals
4 living with or at risk of contracting HIV/AIDS. These
5 funds are assisting states and local communities with
6 conducting outreach and training, addressing the
7 special needs of racial and ethnic minorities, and
8 with studying the cost associated with delivering
9 integrated care.
10 Just as Secretary Leavitt has continued to
11 make HIV/AIDS a priority for all of us and all
12 operating division within HHS, it is clearly a SAMHSA
13 priority. At SAMHSA we've aligned our budget,
14 policies and programs around a core set of priorities.
15 And I think you all should have received a
16 copy of our SAMHSA matrix, which gives you a visual of
17 SAMHSA priorities. If you don't have a copy, we'll
18 have some for sale in the lobby afterwards during the
19 break.
20 But this matrix clearly begins to outline
21 how we begin to approach our work. I call the blue
22 axis, which is the horizontal axis, the leadership

1 axis. These are set priorities, to make sure we're
2 doing the right things, and that's what leadership is,
3 is doing the right things.
4 I call the red axis, the vertical axis,
5 our management axis. That makes sure we're doing
6 things right. That's management, doing things right,
7 in the right way. So this matrix tries to represent
8 SAMHSA's priorities and focus in doing the right
9 things and doing those right things in the right way.
10 And if you might notice in terms of these
11 priorities, one of the reasons we developed this tool
12 and one of the reasons after I came aboard SAMHSA we
13 worked hard to focus on a few priorities is that we
14 knew that it was critical, and I know that it's
15 critical, especially in the mental health and
16 substance abuse arena with so many needs out there.
17 If you don't have a framework for your focus, it's
18 very easy to fall into the trap of trying to let 1,000
19 flowers bloom, fund a lot of different types of
20 initiatives trying to do a lot of good things, but if
21 it's not done in the context of a framework in terms
22 of trying to institutionalize what I call some solid

1 redwoods, because, after all, I recognize that I'm a
2 temporary steward in this position and I'll be here
3 only for a few years, and when I leave we need to make
4 sure there are some things that are solid.
5 And you might notice that one of those
6 major priorities specifically mentioned is HIV/AIDS
7 and Hepatitis C because it is so critical in the
8 substance abuse and mental health arena to be
9 addressing that. It's clear that these illnesses,
10 with many of our nation's most pressing public health,
11 public safety, and human services needs, have a direct
12 link to mental health and substance abuse disorders.
13 The obvious link is why HHS has put a
14 strong focus on prevention efforts and also building
15 treatment capacity. Over the past four years we've
16 worked hard at SAMHSA to align our resources. Right
17 in the middle of the matrix is our vision statement:
18 a life in the community for everyone.
19 And to realize that vision of a life in
20 the community, we need to accomplish a mission which
21 we've redefined as building resilience and
22 facilitating recovery. Again, the traditional mission

1 of SAMHSA is to assure access to quality prevention,
2 treatment, and assessment services, and that's still a
3 major part of our mission. I want to let people know
4 we've not wavered from that.
5 But we felt that the mission should
6 articulate the end game, that until people realize
7 recovery in their lives, until people are really
8 working toward and we're helping them build resilience
9 in their lives, they're not going to attain that life
10 in the community. And that's what we need to be doing
11 in everything that we fund, in everything that we do,
12 in policies that we develop, in how we frame things.
13 We need to be leading in a way to help build
14 resilience and facilitate recovery.
15 Stopping drug use before it starts is
16 foundational to that success, and it's also
17 foundational to the success in the prevention of
18 HIV/AIDS as well.
19 In partnership with other federal
20 agencies, states, local communities and faith-based
21 organizations, consumers, families and providers, we
22 are working to insure that every American has the

1 opportunity to live, work, learn, and enjoy a healthy,
2 productive, drug-free life.
3 Under the leadership of President Bush,
4 we've embarked on a strategy that's working. The most
5 recent data confirms that we are steadily
6 accomplishing the President's goal of reducing teen
7 drug use by 25 percent in five years. Now at the
8 three-year mark we've seen a 17 percent reduction.
9 There are now 600,000 fewer teens using drugs than in
10 2001. This is an indication that our partnerships and
11 the work of prevention professionals, the work going
12 on in our school systems, with parents, with teachers,
13 with law enforcement, with religions leaders and local
14 community anti-coalitions is paying off.
15 We know when we push against the drug
16 problem it recedes. And fortunately today, we know
17 more about what works in prevention, in education, in
18 treatment than ever before.
19 But we also know our work is far from
20 over. To provide a science based, structured approach
21 to substance abuse prevention, SAMHSA has launched the
22 strategic prevention framework, and you'll notice

1 that's another specifically stated priority on the
2 blue axis.
3 The framework allows states to bring
4 together multiple funding streams for multiple sources
5 to create and sustain a community based approach to
6 prevention. We now have a framework that can cut
7 across existing programs.
8 I've seen it time and time again first
9 hand. I've had the privilege to visit many cutting
10 edge prevention programs in many communities around
11 this country, and I've been tremendously impressed.
12 But I also have been extremely frustrated
13 when I leave because I see those prevention programs
14 scrambling for limited dollars, for multiple federal,
15 state, local, and public and private sector funding
16 streams all have specific and sometimes competing
17 requirements. All have different time frames in terms
18 of how long the grants or the dollars will last, and
19 in fact, my frustration also becomes even greater when
20 I sense prevention programs and spending more time
21 applying for grants than they're able to provide
22 prevention services to the community.

1 So in the Department of Health and Human
2 Services alone there's the Health Resources and
3 Services Administration, our good friends at HRSA.
4 There are our good friends at CDC. There's our good
5 friends at ACF. You'll be hearing from Wade Horn
6 later today on youth development. There's the
7 National Institutes of Health, and then there's the
8 Departments of Education and Justice, as well as
9 SAMHSA, that provide money for a range of prevention
10 programs in the local community.
11 These don't even include state, local and
12 private funding streams. The problem is with them
13 being so siloed going down to communities, many times
14 communities don't even know all of the dollars they
15 have to even develop a plan to leverage those dollars.
16 And, secondly, each one becomes almost a
17 trickling stream down to a specific program and ends
18 up having a minimal impact in communities.
19 With strategic prevention framework, we're
20 looking to bring those trickling streams into
21 providing an ocean of change in a community, to
22 leverage those dollars together, and I firmly believe

1 by focusing our nation's attention, energy, and
2 resources, we can continue to make even more progress
3 in reducing drug use and, concurrently, of course,
4 HIV/AIDS.
5 Whether we speak about abstinence or
6 rejecting drugs, including methamphetamines, tobacco
7 and alcohol, whether we're promoting exercise and a
8 healthy diet, preventing violence, preventing HIV/AIDS
9 or promoting mental health, we are really working
10 towards the same objective: reducing risk factors and
11 promoting protective factors.
12 SAMHSA has awarded strategic prevention
13 framework grants to 19 states and two territories.
14 The grantees are working systematically to implement a
15 risk and protective factor approach to prevention at
16 the community level.
17 Under these new grants participating
18 communities will implement a five-step public health
19 process known to promote youth development, reduce
20 risk taking behaviors, and build assets and resilience
21 and prevent problem behaviors.
22 This approach also provides states and

1 communities with the flexibility to target their
2 dollars in areas of greatest need. This strengthens
3 our ongoing efforts to use prevention dollars in ways
4 that are meaningful and relevant to at risk and
5 disproportionately affected populations right at home
6 and in the communities in which they live.
7 The success of the framework rests in
8 large part on the tremendous work that comes from the
9 grassroots community anti-drug coalitions. That's why
10 we're so pleased to be working with the Office of
11 National Drug Control Policy to administer the Drug-
12 Free Communities Program. This program supports
13 approximately 775 community coalitions across the
14 country.
15 Again, under the context of strategic
16 prevention framework, we're looking for each community
17 to be able to first come together, determine all
18 that's being funded around prevention in that
19 community from the different sources, and now that
20 we're administering drug-free communities, we'll make
21 sure they're at the table locally along with
22 everything else we fund.

1 And the other operating divisions within
2 HHS have indicated that they will do everything they
3 can to make sure what they fund in local communities
4 come to that table as well. Education and Justice
5 have expressed great enthusiasm about this approach
6 and working with us.
7 And once we have those folks together at a
8 community level and that community then embarks on a
9 process of identifying their risk factors that
10 contribute to substance abuse, that contribute to
11 seriously emotional disturbance, that contribute to
12 the juvenile justice problem, that contribute to
13 HIV/AIDS being a problem in the community; once those
14 risk factors are identified and then protective
15 factors are identified, they can embark upon a
16 strategy to invest those dollars in programs that have
17 an evidence base, that reduce substance abuse, that
18 reduce problems in those other areas that we're
19 discussing, and reduce the impact and have a baseline
20 to be able to judge the effectiveness in the future
21 and truly have a strategic prevention plan in their
22 community.

1 Along with launching this framework and
2 finding new and innovative ways to partner with
3 community based providers and faith based providers,
4 SAMHSA has taken a lead role in the Secretary's
5 Minority AIDS Initiative, or MAI. Through SAMHSA's
6 Center for Substance Abuse Treatment, our MAI programs
7 have provided funding for numerous community-based
8 organizations.
9 In FY '05, a total of 143 grantees
10 received over $61 million in MAI funding and tens of
11 thousands have been served. Through SAMHSA's Center
12 for Substance Abuse Prevention, our MAI efforts are
13 helping community based organizations to expand their
14 capacity to provide substance abuse and HIV/AIDS
15 prevention services.
16 Through this program, SAMHSA has awarded
17 130 infrastructure and planning grants in amounts
18 ranging from 100,000 to 125,000 over 200 multiple year
19 service grants in amounts from 250,000 to 350,000.
20 Our HIV/AIDS prevention activities also
21 include SAMHSA's rapid HIV testing initiative. SAMHSA
22 has several strong partners, including the National

1 Institute on Drug Abuse, NIDA; the Centers for Disease
2 Control; and again, HRSA, to name only a few who have
3 helped us design and launch the rapid HIV testing
4 initiative.
5 SAMHSA has secured a federal contract with
6 OraSure Technologies to supply rapid HIV test kits at
7 no cost to eligible service providers. We began the
8 implementation of the rapid HIV testing initiative
9 during fiscal year 2005, and to date over 200,000
10 rapid HIV test kits have been distributed.
11 And training on rapid testing is ongoing.
12 For example, 87 SAMHSA funded grantees and 16 opioid
13 treatment program providers have received training on
14 rapid HIV testing, prevention, counseling as well as
15 related data collection activities.
16 In fact, we really think it's very
17 important for those providers to have access because
18 of the high risk of the consumers who come to their
19 services have for HIV/AIDS protection.
20 We also know with certainty that HIV/AIDS
21 disproportionately impacts minority communities.
22 According to the latest statistics, minority

1 populations account for almost 60 percent of the
2 reported AIDS cases and injection drug use continues
3 to play a major role with HIV transmission.
4 In fact, the CDC reported that injection
5 drug use among African Americans and Hispanics counts
6 for over one-third of all AIDS cases. Even substance
7 use that does not require the sharing or reuse of
8 syringes or other blood contaminated equipment still
9 puts an individual at risk. The loss of judgment,
10 reduced inhibitions, poor communications associated
11 with the use of other substances of abuse, such as
12 alcohol, prescription drugs, elevate the risk of
13 HIV/AIDS and hepatitis infection as well.
14 Frustratingly, the CDC also estimates that
15 one quarter of the U.S. residents infected with HIV
16 are unaware of their HIV status. In fact, an
17 overwhelming number of individuals who have made the
18 effort to get tested at public funded sites never
19 return for the results.
20 Understanding this data, SAMHSA's rapid
21 testing initiative goes far beyond simply making
22 public funding available to test for HIV/AIDS. The

1 rapid testing initiative is being implemented as a
2 strategic intervention that will both facilitate the
3 early diagnosis of HIV among at risk minority
4 populations and will increase referrals to counseling,
5 treatment and other supportive care services.
6 And it's also going to provide counseling
7 to those who tested negative to further decrease the
8 risk of becoming infected. We are evaluating the
9 initiative to capture the number of test administers
10 as well as to determine if we improved in the early
11 identification of infection. In other words, we need
12 to find out if it's going to accomplish what we hope
13 it's going to accomplish, and so we're studying it
14 very carefully.
15 Along with the test kits, SAMHSA launched
16 a new program initiative in January this year called
17 substance abuse HIV and hepatitis prevention for
18 minority populations and minority reentry populations
19 in communities of color. Fortunately the goal is
20 shorter than the title.
21 (Laughter.)
22 MR. CURIE: The goal is to make sure that

1 community level, public and private and nonprofit
2 entities strengthen prevention services specifically
3 for minority populations and minority reentry
4 populations.

5 A total of $20.6 million is available to
6 fund up to a possible 82 awards in this fiscal year
7 and an average annual award ranging from 250 to
8 $350,000 per year in total cost, both direct and
9 indirect for up to five years.

10 SAMHSA is also piloting a new program to
11 expand sustained HIV and substance abuse prevention
12 education on the campuses of historically black
13 colleges and universities, Hispanic serving
14 institutions, and tribal colleges and universities.

15 I want to mention that these prevention
16 initiatives are operating in addition to the
17 prevention and HIV/AIDS early intervention set-aside
18 in the substance abuse prevention and treatment block
19 grant, and in addition to our currently funded and
20 ongoing targeted capacity expansion grants.

21 With regard to the block grant,
22 approximately 40 percent of the funds expended

1 annually by states for substance abuse prevention and
2 treatment come from the block grant. At $1.8 billion,
3 the federal block grant combined with state funding is
4 really the backbone of the substance abuse prevention
5 and treatment system in this country because that's
6 clearly where most of the dollars come from in terms
7 of the public arena for substance abuse treatment and
8 prevention.
9 There are specific provisions and funding
10 set-asides within the block grant, such as a 20
11 percent prevention set-aside and an HIV/AIDS early
12 intervention set-aside. Regarding that HIV/AIDS set-
13 aside, states with an AIDS case rate of ten or more
14 per 100,000 of the population are required to obligate
15 and expend a portion of their block grant for early
16 intervention services for HIV. And in FY '05, that
17 total is just about $60 million.
18 The block grant, with its set-asides, has
19 created the foundation and the infrastructure that
20 makes initiatives like rapid testing kits possible.
21 Sustaining that infrastructure is critical in order to
22 carry out our treatment and prevention initiatives.

1 The block grant required states to submit
2 detailed annual plans and explain how and why they
3 will spend their funds. Through this process, states
4 and communities get focused on prevention, early
5 intervention and treatment which moves us all forward
6 together from planning to provide services, to
7 achieving recovery based outcomes for all people the
8 block grant money reaches.
9 Along with the block grant, the targeted
10 capacity expansion grants also play an important role.
11 For example, the HIV prevention services and planning
12 grants I mentioned earlier provide multiple year
13 funding to community based and faith based
14 organizations. This grant program was designed to
15 enhance and expand substance abuse treatment and
16 outreach services, pretreatment and prevention
17 services in conjunction with HIV/AIDS services in the
18 community.
19 The grantees under this program are
20 establishing networks among substance abuse treatment
21 centers, medical personnel, mental health personnel,
22 and public health professionals to prevent further

1 spread of the disease and to provide high quality care
2 to infected individuals.
3 As our presence made clear, another way to
4 prevent the spread of HIV and hepatitis is to fight
5 drug addiction through treatment. President Bush made
6 a commitment to help more Americans get the treatment
7 they need. He made good on that promise with Access
8 to Recovery or ATR.
9 ATR was designed to expand treatment
10 capacity by increasing the number and types of
11 providers, including faith based providers who deliver
12 clinical treatment and/or recovery support services.
13 ATR is a voucher program that's based on consumer
14 choice. It allows consumers in need of treatment to
15 use their voucher to find and purchase the best
16 services for them.
17 This way recovery can be pursued through
18 many different and personal pathways. If you have 200
19 people in a room in recovery from substance abuse and
20 they tell their story, you'll have 200 different
21 stories of recovery, some common elements, but
22 recovery is clearly an individualized process.

1 So the challenge for government,
2 especially governmental bureaucracy which likes things
3 in nice, neat protocols, to operationalize recovery
4 can be a rather messy thing to do, can be a rather
5 challenging thing to do.
6 So Access to Recovery gives individuals
7 choice about options available to them to pursue what
8 pathway is best for them. The great news is interest
9 in Access to Recovery has been overwhelming. There's
10 a solid chance this coming fiscal year, I hope, if the
11 field rallies that we can receive a 50 percent
12 increase in funding from 100 million to 150 million.
13 I will say it doesn't look as promising at
14 this moment when the House mark came in with level
15 funding for 100 million and not the 50 million we
16 would like to see added because without any additional
17 dollars, there's no way we can expand it beyond the 14
18 states and one tribal organization that we're funding
19 currently.
20 So we're hoping that when the Senate comes
21 out with their mark and as the process continues, that
22 50 million that the President is asking for will be

1 realized because, again, we have quite a gap in terms
2 of the need for substance abuse treatment and
3 substance abuse treatment and access to care in this
4 country, and we can't let a year go by when we're
5 asking for 50 million new dollars not for that to be
6 realized.
7 So hopefully the field will rally and will
8 press and we'll see that $50 million that we need.
9 These new dollars will help thousands of people
10 seeking help find the help they need for their
11 substance abuse problem.
12 In turn, this will help many people in
13 their addiction and will help to further prevent the
14 spread of HIV or AIDS or help people gain access to
15 HIV services.
16 For those with mental health disorders who
17 are at risk or who have already contracted HIV/AIDS,
18 SAMHSA is working to make sure a life in the community
19 is possible for them as well. In fiscal year 2001,
20 SAMHSA initiated a grant program to address the unmet
21 mental health treatment needs of individuals who are
22 living with HIV/AIDS, who have a diagnosed mental

1 disorder, and who are also from minority communities.
2 Twenty community based organizations
3 received five-year cooperative agreements to expand
4 current service capacity through this program.
5 Additionally, SAMHSA has made it possible
6 for approximately 200,000 mental health care providers
7 to receive training through the mental health care
8 provider education program. This training helps
9 providers increase their understanding of how to
10 better address the mental health needs of people
11 living with or affected by HIV/AIDS.
12 I hope I've been able to shed some light
13 on the many ways in which SAMHSA's helping to stop
14 HIV/AIDS and hepatitis from devastating more lives.
15 If we continue to build on these initiatives, maximize
16 the power of the public health approach to prevention,
17 expand substance abuse treatment capacity, recovery
18 support services and continue to improve mental health
19 services, we'll be better serving those with or at
20 risk of HIV/AIDS and other diseases at the same time.
21 Ultimately, we'll be better serving all
22 Americans, including those in the criminal and

1 juvenile justice systems, our homeless, our adults and
2 our children and families.
3 And I do firmly believe as a compassionate
4 nation we can do no less.
5 I'd be happy to answer any questions you
6 might have. Thank you very much.
7 (Applause.)
8 DR. REZNIK: Dr. McIlhaney. I looked
9 straight over there first.
10 DR. McILHANEY: Dr. Curie, thank you.
11 That was an excellent presentation.
12 There's some data that would suggest that
13 unless you try to help people not get involved in any
14 risky behavior, you're not going to be very successful
15 in helping them avoid the risky behavior you're
16 focused on, such as substance abuse.
17 Are you aware of or do you have any
18 involvement in any pilot programs in which they're
19 trying to help people not get involved in any risk
20 behavior? In other words, programs to help to prevent
21 people from getting involved in drugs, alcohol,
22 cigarettes, sexual activity, as compared to programs

1 just trying to focus on substance abuse involvement?
2 MR. CURIE: Absolutely, and that's an
3 excellent question. In fact, strategic prevention
4 framework is really doing just that. We are clear
5 that the risk factors that exist in communities as
6 well as the behaviors that promoted substance abuse
7 also promote a range of other activities, and that
8 they're very much the same type of risk factors.
9 So we're very engaged with the youth
10 development efforts that are at play and the range of
11 faith based efforts, and we're looking for each
12 community under the strategic prevention framework to
13 bring all of the efforts that you've just described.
14 I mean, the vision that we have, and we've
15 seen communities do this, there were about 127
16 communities, I know, in Pennsylvania where I just came
17 from -- well, it's been a few years now. It feels
18 like I was just there. Time goes fast -- that
19 implemented a communities that care approach, which
20 basically while substance abuse was a primary factor,
21 all risky behaviors are looked at.
22 And, again, that's the scope we're looking

1 for for strategic prevention framework, and when
2 you're going to hear from Wade Horn later to day, I
3 mean, we think the partnerships we have with HRSA,
4 with ACF, with CDC addressing the realm of risky
5 behaviors has to be part of this. You can't just
6 separate them out.
7 DR. McILHANEY: Do you have any data
8 comparing programs that are focused primarily on just
9 one risk behavior, such as substance abuse as compared
10 to --
11 MR. CURIE: We probably could get some.
12 We could follow up with you and give you some data in
13 terms of the evaluation of programs to see, you know,
14 what type of clarity.
15 Many times, as you know, when a program
16 has been evaluated, it has been evaluated kind of
17 along the silo way in terms of these interventions.
18 We do have a national registry of effective programs
19 that initially started out to be primarily focused on
20 substance abuse prevention.
21 We're now looking for it to include mental
22 health promotion and also the treatment realm, and we

1 can send you that registry and the criteria used, and
2 that can give you this type of data.
3 Thank you.
4 DR. REZNIK: Our next question is from Dr.
5 Primm.
6 DR. BENY PRIMM: A great presentation.
7 Let me ask a couple of questions that are dear to my
8 heart, and that is what's going on with the block
9 grant, for example. How does SAMHSA monitor what has
10 been deemed as set-asides in the block grant that
11 states doing what they're supposed to do with those
12 dollars and whether they are distributing them in
13 terms of substance abuse treatment?
14 When there's a ten percent set-aside for
15 HIV, for example, are they also applying those dollars
16 to different modalities of treatment, particularly in
17 states like Louisiana?
18 My second question is about the prison
19 system. I note that the Center for Substance Abuse
20 Prevention has HIV/AIDS and HCV, and in the prison
21 system there are multiple problems concerning HIV and
22 Hepatitis C. What is the Center for Substance Abuse

1 Prevention doing in that area and what is the Center
2 for Substance Abuse Treatment doing in that area?
3 And what about the expansion of treatment
4 in those areas where those people are coming back to
5 the communities now and in North Carolina where
6 prisoners have been discharged to certain counties,
7 the incidence and prevalence of HIV goes up and
8 follow-up on those particular incarcerees and people
9 who are ex-incarcerees?
10 MR. CURIE: Thank you.
11 In terms of the block grant monitoring,
12 the way that is monitored, each state has an assigned
13 project officer and each state is to submit their
14 annual plan and then annual evaluation in terms of how
15 the plan was carried out, and that's monitored, again,
16 yearly by staff within CSAT and CSAP team primarily,
17 and evaluating whether they're attaining their goals,
18 whether they actually have set the goals, if they meet
19 the criteria, for example, for the set aside that they
20 have several benchmarks they need to reach.
21 However, and your question is a very good
22 one because block grant monitoring is very

1 challenging, and states view block grants primarily as
2 more flexible dollars as much as possible because, as
3 I stated earlier, when it comes to substance abuse
4 treatment, the block grant, the state match, what we
5 do at targeted capacity expansion, and then anything
6 else that a state may do on their own really makes up
7 the substance abuse treatment delivery system in this
8 country.

9 Medicaid is becoming somewhat of an
10 increasing partner in that area and arena, but it
11 hasn't been as substantial as, let's say, it has been
12 in mental health. So substance abuse really has been
13 relying on these funds.

14 What we're looking to do now is to
15 strengthen the accountability around the block grant
16 by holding them accountable to national outcome
17 measures, which we've developed ten domains, and we
18 can make sure that we share those domains with the
19 councils so that we can see what's emerging around
20 that which would measure outcomes in people's lives,
21 whether these dollars are really working toward
22 helping people not use, abstinence being a major part

1 of it, as well as people gaining employment. Do they
2 have stable housing? Are they staying out of trouble
3 with the criminal justice system? If they have
4 HIV/AIDS, are they receiving the medical support they
5 need ongoing and are they getting the treatment they
6 need?
7 And really being able to paint this
8 picture for the first time around these domains we're
9 going to have a state picture painted on an annual
10 basis, which will really bring the accountability to
11 light and, I think, strengthen our hand in that arena.
12 So that's something that we've made as a priority.
13 So while there has been ongoing
14 monitoring, we feel the need to strengthen it based on
15 those outcomes.
16 In terms of the prison system, we have
17 several initiatives that are in place especially
18 through CSAT. CSAP has been involved to some extent
19 in these, but CSAT has been the lead on our reentry
20 programs with Justice. Also we have worked very
21 closely with Justice around both drug courts as well
22 as mental health courts, and it gives us a forum to

1 address the high risk illnesses and diseases that go
2 along with addiction, such as HIV/AIDS.
3 I could circle back with you to let you
4 know what we're looking to plan around more of the
5 prevention area and arena, but those are the forms
6 that we primarily use.
7 For example, when someone is reentering
8 into the community, if they're under one of our grant
9 programs, we're working with Justice, and they have
10 HIV/AIDS. That's very much an issue that's address
11 then in terms of how they will receive ongoing care
12 and how prevention initiatives can continue in that
13 area and arena. So we can circle back also with what
14 we're looking at with CSAT.
15 DR. REZNIK: Just so you know, I have on
16 my list Jackie followed by Karen, Dr. Judson, and the
17 Reverend Sanders.
18 So Jackie.
19 MS. CLEMENTS: Thank you, Dr. Curie.
20 You did say that SAMHSA procured a federal
21 contract for tests at no cost.
22 MR. CURIE: Right.

1 MS. CLEMENTS: Eligible service providers,
2 what makes them eligible?
3 MR. CURIE: Well, what we have done, and
4 we actually have a question and answer sheet on the
5 whole HIV rapid testing arena that we're going to make
6 available to you that hopefully will address a lot of
7 these questions.
8 But our work primarily has been with
9 providers of treatment that they can use it as part of
10 their assessment when someone comes in and they've
11 been referred. So up front you can determine if the
12 individual has been infected, especially if they were
13 an intravenous user.
14 So there really has been no criteria used
15 financially except that they're in our system and that
16 they're beginning to receive treatment.
17 Also, we're working with the State
18 Departments of Health. In May we have what we called
19 our May initiative to make sure that any State's
20 Departments of Health in the states that wanted access
21 to this to make sure it was available through their
22 public health centers would have that available as

1 well.

2 So anyone who would be a client of the

3 public health system in a state or would become a

4 client in our substance abuse treatment delivery

5 system would be eligible.

6 DR. REZNIK: Okay. Next, Karen.

7 MS. IVANTIC-DOUCETTE: Thank you for your

8 presentation.

9 As I listened to the things that SAMHSA is

10 doing, you know, I still consider it kind of a top

11 down model where you're trying to get the biggest bang

12 for the dollars, and that some of the grantees are

13 really those that are interested in a very stigmatized

14 field.

15 One of the issues though is that each one

16 of these people is a person, and one of the things

17 that we also know is that a lot of the prevention and

18 care and treatment and effect in mental health

19 outcomes is done in the one-to-one, in the primary

20 care provider with the relationship and a trusted kind

21 of situation.

22 And I'm just wondering what SAMHSA is

1 going in this. You have these large programs. You're
2 looking at large aggregate outcomes, including
3 homelessness drop and things along those lines, but
4 what's happening on that personal one-to-one kind of
5 scale?
6 And just to put it in a framework for you,
7 I'm a primary provider, and I'm dealing with this on a
8 day-to-day basis, and one of the things, you know,
9 whether I'm dealing by bipolar, substance abuse, and
10 HIV all in the same package, but I'm getting good
11 outcomes, but my other providers don't get the
12 productivity release that I might get to do that.
13 So is there a provision to begin to move
14 SAMHSA, these large aggregate programs more down to
15 that field of support?
16 MR. CURIE: That's a great question. I'm
17 a firm believer that unless what you've just described
18 is going on at the individual level, we're not going
19 to realize the aggregate outcomes; that we need to
20 make sure that we're doing it right and that it's done
21 right at a local provider level.
22 We try to offer supports to local

1 providers through our various technical assistance
2 centers, and I'm finding all the time that it tends to
3 be that SAMHSA grantees know who are like our
4 addiction transfer technology centers are. We have
5 regional centers affiliated primarily with
6 universities, as well as we have what we call the
7 prevention technology centers, the CAPTS, which focus
8 on prevention, and then we have mental health
9 technical assistance centers, and through these we are
10 providing a range of not only information available on
11 Web sites, as well as information directly available
12 through clearing houses, but also training and ongoing
13 trainings that are available to work with providers to
14 help give and equip staff with what they need in terms
15 of effective interventions.
16 And let me make that all available ot you
17 to make sure you're all aware of how you can reach out
18 to those resources. Because I think we do need to
19 equip the field. I think one of the things that the
20 federal government can do quite well is provide an
21 economy of scale of information that a local provider,
22 especially in rural areas or more remote areas may not

1 have access to, and in this day and age of technology,
2 if we can provide more training and information and
3 really utilize our clearing houses and have them
4 utilized to a greater extent, I think it can foster
5 the type of things you're describing, and that's
6 available free of charge. Well, you paid for it
7 through your taxes, but it's available to the provider
8 free of charge.
9 DR. REZNIK: Dr. Judson.
10 DR. JUDSON: I think that when you start
11 off a new program or funding a new program that having
12 funding goals may be appropriate, but I think very
13 quickly as you understand the problem better, emphasis
14 needs to shift to evidence based outcome goals.
15 MR. CURIE: Absolutely.
16 DR. JUDSON: The parallel area that I'm
17 most familiar with in terms of substance abuse is
18 tobacco addiction over the many, many years, and I
19 thought it was useful to look at Steve Schroeder's
20 perspective on this. He's former President of Robert
21 Wood Johnson, which has spent a major part of its
22 funding effort over the years in tobacco prevention.

1 And when he looked at sort of the bottom
2 line for what worked, he concluded that there were
3 just two factors. One was in the economic arena,
4 where the cost of tobacco was very definitely related
5 to consumption, and the other was changing societal
6 norms in terms of where it's comfortable to do it,
7 where it's supported to do it, and that, in turn, led
8 to Clean Indoor Air Acts or environmental tobacco
9 smoke laws.
10 His feeling was that probably most of the
11 so-called educational or informational programs were
12 in the end marginally or ineffective. So when you
13 cite a 17 percent reduction in substance abuse during
14 the last four or five years, I'm fairly old now. So
15 I've watched political parties take credit for
16 anything that's trending in the right direction
17 whether it has any direct relationship to a funded,
18 targeted program and to disavow or put backwards to
19 some other political party when things go the wrong
20 way.
21 Is there anything that you're truly
22 enthusiastic about as being a cost effective approach,

1 applicable program to substance abuse that you think
2 has some causal relationship to the 17 percent
3 reduction?
4 MR. CURIE: That's a great question.
5 Here's my opinion based on what I've been with the
6 data. I think you can directly relate it when you
7 talk about changing the norms. I think a major
8 message has been going out in the last three years,
9 and especially when you see the battle with marijuana,
10 for example, and that's where we've seen a lot of the
11 decrease of teen use.
12 When the data is out there in terms of the
13 new information coming out from NIDA about the impact
14 marijuana is having on the brain and that begins to
15 work its way into school systems and beginning to
16 equip parents, I know when I'm out now I hear a
17 distinct difference, and some of this is my own
18 anecdotal experience, but it's things that I know that
19 we've been doing differently the last four years
20 trying to press the message, a strong message, much
21 along the tobacco lines because I think they were
22 successful in changing those norms, that marijuana is

1 already illicit. So are the other drugs we're talking
2 about primarily. Even under age drinking, alcohol is
3 illicit if you're under 21, if you want to look at it
4 that way.
5 So in terms of laws already on the books,
6 trying to point out that not only these things are
7 illicit, but they are truly harmful, and what we're
8 seeing in our household survey from year to year, that
9 the year before we're seeing the decline in drugs, we
10 are seeing the previous year an increase in the
11 perception that these drugs are dangerous among youth.
12 And so, again, I would never say that's a
13 causal relationship. It's a correlation that we're
14 seeing at this point, but in my mind it goes back to
15 when you push back against it and really make more of
16 an aggressive effort to say marijuana is harmful,
17 especially the young, developing brain, and it's
18 something we shouldn't even quibble about. We should
19 go for it.
20 Alcohol, the same thing. I think under
21 age drinking, to be honest with you, is our next press
22 because that's remaining stubbornly. It has plateaued

1 for the years, and we need to press that and have some
2 of the same things we did around tobacco apply there.
3 But that's my impression of what has made
4 a difference, and when I'm hearing teachers talk about
5 alcohol addiction, when I'm hearing -- or substance
6 abuse -- when I'm hearing parents now talk more about
7 it, I'm hearing a lot of the information we've been
8 trying to roll out start to come from people's lips
9 out in the public, and that's an indication to me that
10 that probably is a factor.
11 But one thing we really do monitor is
12 what's the perception of the danger of these
13 substances, that measure. And, again, what we see if
14 that increases in a particular year we can almost
15 anticipate there's going to be a decrease in
16 subsequent years.
17 DR. JUDSON: Thank you.
18 DR. REZNIK: Reverend Sanders.
19 REV. SANDERS: Thank you very much for
20 your presentation.
21 I'm especially appreciative of the Access
22 to Recovery strategy in terms of appreciating the

1 individualistic nature of addiction. In that regard
2 though, when I look at the statistics and your
3 reference to the way in which injection drug use
4 continues to play a major role in the spread of HIV, I
5 wonder where SAMHSA is these days in terms of
6 continuing to advance, you know, the research,
7 continuing to advance looking at models around clean
8 syringe initiatives.
9 I know a few years ago there was a lot of
10 evidence that there was some hope in terms of maybe
11 helping in terms of the spread of HIV. It ends up
12 being complex because obviously injection drug use is
13 something that you want to figure out how to get
14 people into treatment in relationship to, but at the
15 same time, you understand that those who are injecting
16 drugs are a big part of what's perpetuating the
17 problem around HIV.
18 I know some good research is being done,
19 and I want to know where you are no in that.
20 MR. CURIE: I know that we're working in
21 close partnership with NIDA on an ongoing basis in
22 terms of taking a look at what's really working in

1 terms of a science based approach to stop the spread
2 of HIV infections and, again, intravenous use is a
3 major mechanism that's used.
4 So we're continuing our partnership there
5 and helping educate providers in what they need to let
6 folks know as they come into service to try and help
7 them deal with it even before they're in treatment or
8 as they're engaging in treatment.
9 So we've continued those efforts with
10 NIDA.
11 REV. SANDERS: This is a short follow-up.
12 I think that one of the strategies that is important
13 to consider -- and I know some people at NIDA have
14 already been working on this. So this is a model of,
15 you know, a bridge to treatment.
16 MR. CURIE: Right.
17 REV. SANDERS: Because very often the
18 community that's involved in injection drug use is
19 under the radar screen of a lot of our traditional
20 strategists for bringing folks into treatment
21 settings, how you identify them, how you develop the
22 ability even of putting them in, and it seemed that

1 there is some evidence.
2 MR. CURIE: Well, and again, one of the
3 major links we have to bringing that evidence to the
4 front lines to provides is through the addiction
5 technology transfer centers I mentioned.
6 DR. REZNIK: And Dr. Sweeney.
7 DR. SWEENEY: Thank you.
8 Mr. Curie, as I was listening to -- I'm an
9 internist, geriatrician, and the question that I have
10 to ask you has not been well formulated, but I would
11 still like you to comment on it. It's something I
12 think about every morning almost driving to work past
13 a large men's armory, which is a shelter in Brooklyn,
14 New York.
15 And one of your mission sis a life in the
16 community for everyone, building resilience and
17 facilitating recovery, and then you look at the
18 programs and issues and you have co-occurring
19 disorders, mental health system transformation,
20 HIV/AIDS and hepatitis, and then we've talked about
21 mental illness and drug use, and I want to add lack of
22 preparation for life skills.

1 And the reason I say this is because this
2 looks like a model that we used to use a lot in
3 medicine that we worked only for people's recovery,
4 and we did not have a system in place as physicians
5 and other health care providers for helping people to
6 die, for example, with dignity.
7 So what I'm asking is: is there any
8 thought about relooking at having a place for people
9 in the community that might not be a shelter, but more
10 like a place that's long term for people who will not
11 recover, and to have the facilities for them to make
12 their life -- maximize any potential they have, but to
13 do it in a sheltered environment, not a state
14 hospital, but something that replaces the state
15 hospital.
16 Because many of the people who are in the
17 street now, homeless, in fact, have mental illness,
18 do, in fact, have mental illness. So I'm asking is
19 there any thought to doing it another way.
20 We have whole industry of homelessness
21 care that has been built up since the state hospitals
22 have been -- so the money is being used anyway to take

1 care of this population, but in a very ineffective
2 way, and whether or not there's any thought to redoing
3 this and rewording the goals so that those people who
4 won't recover, who are not going to be able to live
5 independently can get the supportive care in a
6 custodial environment or treatment custodial
7 environment, mental health and all of the services
8 they need, but be not warehoused in shelters, et
9 cetera.

10 And then an unrelated question is: do you
11 have any follow-up on how buprenorphine treatment is
12 going?

13 MR. CURIE: Okay. Thank you.

14 I think what you're bringing up here
15 describes well the conundrum we're all facing in the
16 field, and I think recovery is actually a major part
17 of the solution of what you've just described. I
18 think it's how we need to clarify and define recovery
19 and that people are at different levels of recovery.

20 There could be people who may never fully
21 recover as we might define recovery of getting back to
22 the point of having a full-time job, be reunited with

1 family, develop that life in the community that we're
2 talking about.
3 On the other hand, there are people that
4 I've seen both on the addiction side and the mental
5 health side that are living those lives now that ten,
6 15 years ago, 20 years ago we thought they would have
7 no shot at living that type of life.
8 So I think framing things in terms of
9 recovery helps us to begin to describe the end game of
10 what our responsibility is as a public health, to be
11 thinking in terms of more than just the initial
12 intervention.
13 Your point is extremely well taken though,
14 and I think it is something we have to grapple with,
15 and that is there are some individuals who may never
16 recover at that level. So we need to then, in
17 whatever system that we are funding and working with,
18 be thinking in terms of what supports are needed to
19 help an individual at their point of need of recovery
20 to help make sure they don't slide back further, but
21 that they're at the point of optimum functioning.
22 And I like what you said. We don't want

1 to go back to warehousing. We don't want to go back
2 and just find let's put these folks in an
3 institutional setting and we're meeting their basic
4 needs and they're kind of segregated from the rest of
5 the community, but what models are out there that you
6 can wrap around supports with people and perhaps there
7 may be different levels of setting depending on where
8 their level of need is.
9 But I believe recovery should be viewed as
10 people reaching, continuing to reach the next level of
11 recovery and they're in a recovering process, and I
12 think that's how we need to think about it, and I
13 think that begins to address also what you're thinking
14 of and talking about because we can't ignore
15 individuals who aren't attaining that level. In fact,
16 we need to prioritize those individuals in our
17 process.
18 Does that help in terms of at least
19 conceptually I know I'm talking here about how I think
20 we need to implement this.
21 The other thing I would go back to is the
22 state hospital. My initial background in mental

1 health, I was responsible for the ten state hospitals
2 in Pennsylvania, and three of those institutions were
3 closed while I was three.
4 We learned through the years that we kept
5 the money in the system when we closed the
6 institution. We developed supports and housing
7 supports, and wrap-around supports for people coming
8 out of the hospital depending on their level of need.
9 I think where we got in real trouble, when
10 you turn the clock back 20, 25, 30 years ago and
11 people were given a bus ticket and some medication and
12 told, "Here's a doc you should look up when you get to
13 your old neighborhood," or whatever, and that
14 perpetuated the homeless problem.
15 So, again, I think if we're going to do
16 resilience and recovery right, we're going to put the
17 right supports around people and meet them at their
18 point of need to help them move to the next level of
19 recovery that's possible for them, and I think that's
20 how we have to implement it.
21 Buprenorphine, I haven't received the
22 latest data in terms of outcomes. I mean, I'm hearing

1 good things in terms of results. I do know that we
2 have I believe it's approaching over 3,000 physician
3 offices trained. So the network is ever increasing.
4 The capacity has increased, and everything we're
5 hearing so far is looking like it's very much on
6 track.
7 I'm thinking it's something we may want to
8 bring to higher profile as we move along because I
9 think it's one of the best ways of increasing opiate
10 addiction treatment. Doing it through the out-patient
11 setting, I think it does fit with our goal of
12 facilitating recovery and doing it in a way that is
13 also less stigmatizing.
14 DR. REZNIK: I think you, Administrator
15 Curie.
16 I was going to ask Dr. Annelle Primm to
17 take questions, but we've run out of time. So I want
18 to thank Administrator Curie --
19 MR. CURIE: Thank you.
20 DR. REZNIK: -- and all of the presenters
21 from this morning for a wonderful treatment section.
22 Before I turn the program back to Joe, I

1 do think that Dr. Primm will be here. So if any of
2 the members have any questions, she has expressed
3 willingness to address those questions personally, and
4 again, thank you for a wonderful morning session, and
5 thank you, Joe.
6 (Applause.)
7 MR. GROGAN: I was just going to ask the
8 members to be in their seats by 1:00 p.m., and for
9 members of the public, there is a cafeteria on the
10 other side of the floor when you walk out past the
11 elevators.
12 Thank you.
13 (Whereupon, at 12:00 noon, the meeting was
14 recessed for lunch, to reconvene at 1:00 p.m., the
15 same day.)

1 AFTERNOON SESSION

2 (1:05 p.m.)

3 CO-CHAIRPERSON SULLIVAN: It's now time
4 for introduction of motion for action by the
5 committee, and we will ask each subcommittee chair to
6 present any motions that they wish the committee to
7 take action on.

8 And so we'll start with Prevention.

9 MR. MASON: Thank you, Mr. Chairman.

10 The International Committee will have one
11 motion that we're going to put forward, and I think
12 that we'll make copies available to members of the
13 council at some point, I think, in the afternoon.
14 There's a draft which we'll circulate, but it's a
15 resolution to eliminate taxes and tariffs on donated
16 medications, tests, and other materials used in the
17 diagnosis and treatment of HIV disease, is the title
18 of the resolution.

19 And I won't read the whole thing, but I'll
20 read the result because you're going to get copies of
21 it, but it talks about the fact that there are tariffs
22 and taxes on drugs that increase the cost and,

1 therefore, reduces access to people who need them who
2 can't afford them.
3 So it says, "Be it hereby resolved that
4 PACHA requests the Secretary of HHS to aggressively
5 pursue policy options that will lead to the
6 elimination of all taxes and tariffs on free, reduced
7 price, or donor funded medications, tests, and other
8 materials used in the diagnosis and treatment of HIV
9 disease."
10 Thank you, Mr. Chairman. That will be our
11 only motion.
12 CO-CHAIRPERSON SULLIVAN: Very good.
13 Thank you very much.
14 The Treatment and Care Committee, is David
15 in the room or Dr. Reznik? Well, we'll wait until he
16 returns.
17 The Prevention Committee, Dr. Sweeney.
18 Are there motions you'd like to put on the table?
19 DR. SWEENEY: Thank you, Mr. Chairman.
20 The Prevention Committee does not have a
21 motion. We have a much broader agenda than a motion,
22 which I have been told we cannot put forward at this

1 time. I think you have it at your seats. Does
2 everyone have a copy?
3 MR. GROGAN: Yes, everybody should have
4 gotten a copy.
5 DR. SWEENEY: It's a draft of principles
6 of the HIV/AIDS Strategy Prevention Subcommittee, and
7 it is not a motion, but a plan which we will need to
8 discuss in much greater detail than a resolution, and
9 we respectfully ask that everyone reads it and be
10 prepared for our discussion when our Chairman or Co-
11 Chairman -- thank you -- gives us the opportunity to
12 do so.
13 CO-CHAIRPERSON SULLIVAN: Very good.
14 Thank you very much.
15 And our third chair -- let's see. Dr.
16 Reznik has not returned.
17 MR. MASON: I don't think he has a motion.
18 He told me he didn't have one.
19 CO-CHAIRPERSON SULLIVAN: Oh, fine. We're
20 informed that he does not have a motion. So that
21 covers that item.
22 We're now at the time for 1:10, that is,

1 positive youth development and healthy choices. We
2 have Assistant Secretary for Children and Families,
3 Dr. Wade Horn, whom I had the pleasure of working with
4 when I was Secretary when he was Commissioner for
5 Youth, Children, and Families.
6 And his biographical sketch is in our
7 book, and he also was one of the founders of the
8 National Fatherhood Institute that focuses on
9 increasing the relationship between fathers and their
10 children and trying to preserve the family structure.
11 So we're very pleased to have Wade Horn
12 here who is going to tell us about positive youth
13 development.
14 Dr. Horn, welcome.
15 DR. HORN: Well, thank you very much.
16 First of all, it is a great, great
17 pleasure and honor to be with you again, Dr. Sullivan.
18 I had the pleasure of being in this room, I think, on
19 a number of occasions when you were gracing the halls
20 as Secretary of HHS.
21 For those of you who don't know, he's the
22 person who offered me my first job in federal service.

1 It is always a great pleasure to be with you. You
2 are one of, I think, the most important and
3 influential figures in health today, in the public
4 health arena, and it is always just an honor to be
5 with you. So it's great to be here.
6 I know some people here like Joe on the
7 committee and Anita and so forth. So it's great to be
8 with all of you as well.
9 As Dr. Sullivan said, I'm the Assistant
10 Secretary for Children and Families here at HHS, and
11 as such, I've been asked by Joe to spend a little bit
12 of time talking about strategies for dealing with
13 HIV/AIDS prevention when it comes to youth.
14 And so today what I'm going to do is begin
15 by highlighting some statistics, which I guess as most
16 of you are all too familiar with related to the
17 incidence and prevalence of HIV/AIDS among youth, then
18 talk a bit about the necessity of providing clear
19 messaging to young people on ways to prevent the
20 transmission of HIV/AIDS, and then talk a bit about
21 positive youth development.
22 And I understand that I've got 20 minutes

1 or so and then there will be some opportunity for
2 questions and answers; is that right? Great.
3 As I'm sure I don't have to tell members
4 of this committee, every day about 8,000 lives are
5 lost to the AIDS pandemic around the world. Millions
6 of people are, in fact, affected with the HIV virus,
7 half of which life in Africa.
8 An estimated five percent of those
9 infected with HIV are children under the age of 15.
10 In the United States more than 38,000 young people
11 between the ages of 13 and 24 have been diagnosed with
12 AIDS since 2000, and more than 10,000 young people
13 have died from AIDS.
14 In 2003 alone, an estimated 7,081 young
15 people were living with AIDS, a 37 percent increase
16 since 1999 when roughly 5,000 young people were living
17 with the disease, and in 2003 an estimated 3,900 young
18 people received the diagnosis of HIV/AIDS,
19 representing about 12 percent of the persons given the
20 diagnosis during that year.
21 And although young persons account for
22 only about two percent of the more than 524,000 total

1 deaths of people with AIDS in the United States, I
2 think, since 2000, I think that we all can agree that
3 that is two percent two many. As President Bush has
4 noted, and I quote, "HIV/AIDS is a direct challenge to
5 the compassion of our country and to the welfare of
6 not only our nation, but nations all across the globe.
7 It's really one of the great challenges of our time.
8 This disease leaves suffering and orphans and fear
9 wherever it reaches."
10 So given the magnitude of the problem for
11 young people, Joe has asked me to address the
12 following question: how can we spur behavior change
13 so that young people can avoid becoming infected with
14 HIV/AIDS?
15 My answer to that question is by adopting
16 the same strategy that the President has adopted for
17 preventing teen pregnancy and sexually transmitted
18 diseases more broadly, and that is what we need to do
19 is to find ways to empower teens to make healthy,
20 responsible decisions for themselves, including
21 healthy and responsible decisions when it comes to
22 sexual behavior.

1 In most cases that means encouraging young
2 people with a clear and consistent message about the
3 importance of remaining sexually abstinent until
4 marriage. That's because abstinence is the only 100
5 percent effective way to avoid pregnancy and sexually
6 transmitted diseases, including HIV/AIDS. And by
7 sending you a clear and consistent message about the
8 benefits of abstinence, we can help bring down the
9 numbers of young people with HIV/AIDS.
10 Now, the medical and social science
11 literature is clear that the earlier a teen begins
12 sexual activity and becomes sexual active or what
13 researchers call their sexual debut, the higher the
14 number of lifetime sex partners that person will have,
15 and the more sexual partners one has over the course
16 of their lifetime, the higher they are at risk for
17 contracting a sexually transmitted disease, and of
18 course, having a sexually transmitted disease is a
19 risk factor for HIV transmission.
20 So the key to helping young people avoid
21 HIV/AIDS, as well as other sexually transmitted
22 diseases, is to help them delay the onset of sexual

1 activity, preferably until marriage, but certainly
2 until they are at least out of high school.
3 President Bush believes that abstinence
4 and abstinence education is, in fact, a prudent
5 strategy when it comes to combatting unwanted
6 pregnancies and STDs, including HIV/AIDS, because it
7 sets a high cultural standard to which young people
8 can aspire, and in contrast to some who counsel
9 resignation to the issue of early sexual activity by
10 our young people, the President believes and at the
11 core of abstinence education is the idea that young
12 people, in fact, can control their behavior; that at
13 its core abstinence is about empowering young people
14 to live healthy lives so that they can avoid all sorts
15 of health risks, including HIV/AIDS.
16 As the President has said, "When our
17 children face a choice between self-restraint and
18 self-destruction, government should not be neutral."
19 So the value of abstinence education is it
20 presents a clear and consistent message when it comes
21 to sexual behavior. As a psychologist I know that the
22 best way to influence behavior is to provide clear and

1 consistent messages about that behavior. When
2 messages become confused, so does behavior.
3 An authentic abstinence message is one
4 that presumes that teens can, in fact, control their
5 sexual desires and impulses. Unauthentic abstinence
6 messages, in contrast, presume that kids are victims
7 of those desires that are beyond their ability to
8 control and that the best we can do is hand them a
9 condom or some other form of contraceptive to lower
10 the risk of either pregnancy or sexually transmitted
11 diseases.
12 Now, of course, this is kind of a "please
13 don't become sexually active, but just in case, do
14 this" message.
15 Now, it's interesting. We don't use that
16 "please don't, but just in case" message when it comes
17 to other kinds of high risk behaviors for young
18 people. We don't say, "Please don't drink alcohol
19 when you're under age, but in case you do, we're going
20 to teach you how to drink it safely." We don't say,
21 "Please don't smoke cigarettes, but in case you do,
22 let's talk about using low tar and nicotine

1 cigarettes." We don't say, "Please don't use illegal
2 drugs, but just in case, we're going to teach you how
3 to use a bong so that you don't spill the bong juice
4 on your lap," which by the way, was an actual message
5 given in a book in the 1970s when in the 1970s we were
6 confused about the need to give young people clear and
7 consistent messages about no use when it comes to
8 illegal drugs.

9 So what we need to do when it comes to a
10 variety of risks is be clear about what it is we want
11 them to do. Imagine if you will for a moment the
12 following scene. I travel a lot as I'm sure, Dr.
13 Sullivan, you do and many people here on this panel
14 do. I've been married for 28 years. Imagine the next
15 time I go on a trip. My wife meets me at the door on
16 the way out. She hands me my briefcase, and she says,
17 "Honey, we've been married 28 years. I know you love
18 me and I love you. I know that you trust me and I
19 trust you. I trust you will make good decisions for
20 yourself while you're on your business trip, but just
21 in case, I put a condom in your briefcase."

22 That is the kind of confused message that

1 I think we give our young people when we say, "It's
2 not a good idea for you to be having sex when you're
3 13, 14, 15, 16, and 17, but just in case, we're going
4 to teach you how to use condoms."
5 Clear and consistent messaging is
6 important if we want to influence behavior,
7 particularly if we're trying to prevent the behavior
8 from occurring in the first place.
9 Now, clear and consistent messaging is
10 especially important when it comes from parents.
11 Parents are pretty good about giving clear and
12 consistent messages in a lot of arenas. They're
13 pretty good about being clear and consistent about
14 things like the value of hard work. Parents don't say
15 things like, "Gee, you know, we'd really like you to
16 work hard, but here, let me give you some lessons in
17 how to sort of like shirk your duties."
18 They're pretty clear about messaging when
19 it comes to honesty. They don't say, "Gee, we would
20 like you to be honest, but boy, we're going to teach
21 you how to lie so you don't get caught."
22 Parents are pretty clear about things like

1 integrity, like the value of compassion for others.
2 When it comes to sending messages about their sexual
3 behavior, however, parents are often less likely to
4 understand how important it is for them to also be
5 clear and consistent in their messaging to their
6 children about sexual behavior.
7 Now, there's lots of reasons for this, but
8 in part it's because parents are unaware often that
9 they are, in fact, the most important influence on
10 their children's sexual attitudes, values, and
11 behaviors. There's a study published in Adolescence,
12 for example, that found in a sample of college
13 students that parents were rated as more influential
14 than friends, siblings, church, and school in shaping
15 their opinions, beliefs, and attitudes about sexual
16 matters.
17 A study recently by the Centers for
18 Disease Control found that 59 percent of teens say
19 their parents are their role models for healthy and
20 responsible relationship, and 45 percent of teens said
21 their parents influenced the decisions about sexual
22 matters more than friends do.

1 Indeed, a study by sociologist Arlen
2 Thornton published in the Journal of Marriage and
3 Family found that teen attitudes towards premarital
4 sex tend to mirror the attitudes they pick up from
5 their parents, and especially their moms.
6 So the bottom line is this. If we want
7 teens to make healthy choices about high risk
8 behaviors, including sexual behavior, we need to
9 communicate a clear and consistent message about what
10 we expect from youth, and that message needs to come
11 from parents, from community based organizations, from
12 the popular culture, and yes, even government.
13 Now, having been dubbed the Chastity Czar
14 by a few people in the media, it will come as no great
15 surprise either as a reflection of that title or from
16 the beginning of my talk that I am a strong proponent
17 of abstinence and abstinence education for young
18 people.
19 Having said that, I also recognize that
20 contraceptive services can play an important
21 supporting role in reducing the risks of HIV/AIDS
22 among those who are already sexually active. In fact,

1 HHS channels large amounts of federal funding into
2 contraceptive services and programs. Coupled with
3 state fundings, HHS currently spends an estimated $1.7
4 billion on a wide variety of contraception promotion
5 and pregnancy prevention programs through such
6 programs as Medicaid, Temporary Assistance for Needy
7 Families, Title X Family Planning, and the
8 preventative health and health services block grant.
9 But while acknowledging that condoms have
10 a role to play in preventing the transmission of
11 pregnancy and STDs, including HIV/AIDS, we should not
12 confuse what we should do when it comes to
13 intervention with what we should do when it comes to
14 prevention. And I think this is the problem at the
15 core of the controversy when it comes to working with
16 young people.
17 We confuse prevention with intervention.
18 We do something different to prevent young people from
19 taking drugs in the first place from what we do when
20 they are already taking illegal drugs. We do
21 something different with people who have started to
22 abuse alcohol than what we do to prevent them from

1 getting involved with abuse of alcohol in the first
2 place.
3 And it seems to me that we need to
4 separate out the prevention strategy from an
5 intervention strategy, and I think we can look to Asia
6 and Africa for some lesson here.
7 Uganda. As you know, Uganda is the only
8 country in sub-Sahara Africa that has achieved a
9 substantial decrease in HIV/AIDS infection, from 30
10 percent to ten percent today. Among pregnant women,
11 the rate of infection has dropped from 21 percent to
12 six percent, and among Ugandan women 15 years and
13 older, those reported having, quote, many sexual
14 partners, unquote, dropped from 18.4 percent in 1989
15 to 2.5 percent in 2000.
16 Now, while Uganda has a multi-pronged
17 strategy, encouraging abstinence until marriage,
18 including faithfulness, encouraging faithfulness
19 within marriage and condom use among high risk groups,
20 there are some who look to Uganda and invert the
21 pyramid, who say the success of Uganda is really about
22 condom distribution as opposed to A and B, abstinence

1 until marriage and faithfulness within marriage.
2 When, in fact, if you talk to those who
3 are responsible for implementing the Uganda model, as
4 I have and as I know many of you have, what they will
5 tell you is that they are not going into junior high
6 schools and having condom races with young people.
7 When they talk about condom distribution, they're
8 talking about distributing condoms to high risk
9 groups, prostitutes, for example.
10 And that's what I mean by an example of a
11 strategy which is not confusing intervention and
12 prevention. Prevention, they understand they need to
13 be very clear with young people about the value of
14 staying sexually abstinent until marriage, and for
15 those who are married to be faithful within marriage.
16 But for those who are engaging in
17 behaviors which we know are a high risk, they don't
18 say "condom." I've never heard of that word. But
19 they're very clear of the difference between
20 intervention and prevention.
21 In addition, I don't think we should give
22 up on young people simply because they have become

1 sexually active. Because I believe that contraceptive
2 services ought to be available to those who are
3 sexually active doesn't mean that we should say once
4 you become sexually active that is the only possible
5 intervention.
6 I'm a psychologist. I believe people can
7 change. You know, psychologists don't make money by
8 having clients come into their office and saying,
9 "Gee, you have a problem with X? Well, I guess you're
10 going to have a problem with X for the rest of your
11 life, nothing we can do about it."
12 But we presume that people can change
13 their behaviors, and if we believe that abstinence
14 until marriage and faithfulness within marriage is
15 key, then why would we say to somebody who is sexually
16 active, "Gee, I guess that's an option no longer
17 available to you"?
18 And so part of what we should do with the
19 sexually active is still give them a message about the
20 best and healthiest choice for themselves and not
21 simply assume that once someone has lost their
22 virginity, once someone has become sexually active

1 there is nothing we can or should do about that other
2 than provide them with contraception, as important as
3 providing them access to contraception is.
4 And the good news is that the abstinence
5 message is taking an effect. According to the CDC, 53
6 percent of all American high school students, a
7 majority, now report being sexually abstinent, up from
8 46 percent in 1991.
9 Now, that's interesting because you've
10 heard the argument. I guarantee you have. There's
11 nothing you can do about this. These are trends that
12 are just going to continue. There's not one thing any
13 of us can do. We can wish all we want, but we now
14 have empirical evidence that you can change trends.
15 You can change social trends.
16 And one of the ways you change social
17 trends is you develop clear and consistent messaging
18 about healthy choices and different ways of behaving
19 and not simply say, gee, once someone is engaging in a
20 certain behavior or once a social trend emerges
21 there's nothing we can do about it.
22 So without a doubt, in my view, abstinence

1 education plays a central role in promoting the sexual
2 health of teens, but a commitment to abstinence
3 doesn't occur in a vacuum. Rather, decisions about
4 responsible behavior are made in the context of
5 quality connections that teens have with their
6 families, with schools, with religious organizations,
7 and with their communities.
8 In fact, most of the social science
9 literature confirms that the more teens enjoy positive
10 relationship with their parents, with other adults in
11 their community, with religious and community based
12 organizations, with their schools, the more likely
13 they are to avoid all sorts of high risk behaviors.
14 This is why the Bush administration has adopted a
15 positive youth development approach when reaching out
16 and supporting young people.
17 When we do more to empower youth, we
18 release their potential to make good decisions for
19 themselves. That is the core of a positive youth
20 development perspective.
21 But this is not the way generally
22 government or we as a society approach young people.

1 Most of the time we approach young people as if they
2 were a series of problems to be solved, and so we say,
3 "Gee, we've got a dropout problem. Monday let's send
4 in a dropout prevention program."
5 "Oh, gee, we've got a smoking problem. On
6 Tuesday we send in an anti-smoking program."
7 On Wednesday, we say, "Gee, we've got a
8 problem with delinquency." You send in a program for
9 anti-delinquency.
10 And each of these is important. I am not
11 suggesting that they aren't, but youth are more than
12 just a series of problems to be solved. They are like
13 the rest of us. They are complex human beings that
14 have assets as well as challenges that they face in
15 their lives, and what the positive development
16 perspective says is that while helping them to make
17 good decisions about specific high risk behaviors,
18 including not to engage in sexual activity, that we
19 also have to empower them. We have to build their
20 connections with family, with schools, with community
21 based organizations, religious organizations, and we
22 have to treat them in a way that makes them feel

1 competent, empowered, and belonging.
2 This doesn't mean, again, that we shy away
3 from encouraging them to avoid drugs, alcohol, and
4 sexual activity. Of course we should. There's a
5 place for each of those programs even on Monday,
6 Tuesday, Wednesday and Thursday, but as we build these
7 programs, we should always build communities that
8 understand the need to support young people, empower
9 them, give them the sense of competence, give them the
10 sense of belonging and empowerment.
11 And that's why in the State of the Union
12 address in January President Bush proposed a three-
13 year, $150 million program to help families, schools,
14 and faith based groups reach out to young people who
15 feel isolated and alone, because we know those are the
16 youth that are most at risk for these behaviors.
17 And so the President and the First Lady
18 are talking about the need to give youth quality
19 connections and are seeking ways to strengthen a
20 variety of positive youth development programs
21 throughout our nation and in local communities.
22 So it seems to me that these are the two

1 most important components that we have to address in
2 helping young people make good decisions to avoid HIV
3 and AIDS. The first is to help them understand the
4 importance of staying sexually abstinent, preferably
5 until marriage, but certainly at least until they get
6 out of high school.

7 And secondly, we need to wrap abstinence
8 education programs into a broader, positive youth
9 development perspective so that youth will not just
10 avoid risky sexual behavior, but make good decisions
11 when it comes to other kinds of high risk behaviors as
12 well.

13 The President recently said this. He
14 said, "The decisions our children," and may I add here
15 "teens," "make now will affect their health and
16 character for the rest of their lives, and when they
17 make right choices, they are preparing themselves to
18 realize the bright future our nation offers each of
19 them."

20 I couldn't have said it better myself.

21 Thank you.

22 (Applause.)

1 CO-CHAIRPERSON SULLIVAN: Questions,
2 comments? Hank.
3 DR. McKINNELL: Well, thank you for a very
4 well thought through presentation. I suspect you've
5 done this a few times. That's good.
6 Let me introduce you to Dr. McIlhaney. He
7 and I have had discussions over, I guess, about two
8 years now, Joe, very polite and very nuanced around
9 the kinds of issues you raised, and the reason it has
10 sharpened my thinking is neither of us comes from the
11 extreme. It's hard to have a discussion between the
12 abstinence only and the condom only folks. That just
13 doesn't create progress.
14 And I do agree there's confusion at the
15 core, but I don't think it's so much prevention versus
16 intervention as it is the concept of personal health
17 versus public health, and in personal health it is all
18 about health and values and making the right choices.
19 I absolutely agree with you.
20 In public health, however, it's much more
21 about risk reduction. Now, that doesn't mean you
22 can't have an intelligence targeted strategy and a

1 prevention strategy for some and an intervention
2 strategy for others. The problem is they're all
3 sitting in the same classroom, and you can't tell one
4 from the other.
5 And I guess to conclude my kind of
6 thoughts here, I'd ask you your reaction to a study
7 that has recently been done, and I have a little note
8 in my desk that says, "In God we trust. All others,
9 bring data." And the data I saw recently was a study
10 by researchers at Yale and Columbia who looked at two
11 groups, some who had taken an abstinence pledge and
12 others who hadn't, and what I found interesting about
13 that is the behaviors were different. They were the
14 same in that 88 percent did engage in sex before
15 marriage in both groups, but those who had taken the
16 abstinence pledge engaged later. So there was an
17 impact on onset of sexual activity, but were less wise
18 in the choice of condoms and awareness of sexually
19 transmitted diseases.
20 So I wonder how you react to that kind of
21 data and the broader issue, which I think really is a
22 public health issue. It's certainly a personal health

1 issue, and we should all be advocating those values,
2 certainly as parents, but from a public health
3 perception, I'm not sure if it translates one to one.
4 DR. HORN: Well, first of all, I actually
5 think that what you have in your desk is a -- the
6 first person that said something close to that was the
7 late Gene Shepard who said, "In God we trust. All
8 others pay cash."
9 (Laughter.)
10 DR. HORN: It's hard for me to comment on
11 a study that I haven't seen, and what I would do is
12 actually invite you to send me that study and I would
13 be happy to share my reactions to you in writing,
14 perhaps even to the rest of the committee if you felt
15 that that's appropriate.
16 I do think that it creates confusion when
17 one presents the same information the same way to a
18 mixed audience, some of whom are sexually active and
19 some of whom are not, and that's the point I'm trying
20 to make, is that when you come in with a single
21 message -- I mean everything that I know as a
22 psychologist and everything I know from the empirical

1 literature when it comes to things like advertising is
2 you have to segment your audience, and different
3 messages mean different things to different subgroups.
4 And it seems to me that we all can agree
5 that a group that is sexually active is in some ways
6 different than a group that is not sexually active,
7 and if we accept that there are at least these two
8 groups, why not start to think about ways of giving
9 different messages and different messaging to them as
10 opposed to assuming that the same messages are going
11 to work with everyone.
12 And so that's my first reaction to what
13 you say. The second reaction to what you say is that
14 -- and, again, I'd love to see the data in this study,
15 and I'd be happy to react to that -- were it only the
16 case that the only thing that the group -- the only
17 messages that the group that got abstinence education,
18 were it only the case the only messages they got from
19 the onset of this study to when the follow-up data
20 were collected was an abstinence message, but turn on
21 the television. Go listen to some music. Go to the
22 theater and look at movies.

1 What we have is we have a popular culture
2 which sends a very clear and consistent message to
3 young people. Sexual activity among young people is
4 the norm and there are no consequences. That's the
5 message. It's clear and it is consistent.
6 The only difference between the group that
7 got the abstinence education and those that didn't is
8 somewhere along the line they had a little bit of a
9 voice that said, "Do you know what? It's not true
10 it's the norm and guess what. There are
11 consequences."
12 And so you know, part of this is how much,
13 you know, sort of counter-messaging needs to happen to
14 help protect young people from behaviors which we know
15 place them at risk.
16 One of the programs I run is the TANF
17 program. One of the fast tracks into poverty, long-
18 term poverty is to have a child out of wedlock. It
19 seems to me that we need to be very clear about
20 protecting oneself from that possibility. So you
21 know, it would be nice if we actually could do a study
22 where some people got a clear and consistent message

1 about abstinence and some people didn't, but
2 unfortunately that would require that we take the
3 young people out of the popular culture which
4 surrounds them every single day with different kinds
5 of messages.
6 CO-CHAIRPERSON SULLIVAN: Dr. Yogev.
7 DR. YOGEV: You know, it's interesting. I
8 agree with you and yet I disagree with you, and the
9 reason why --
10 DR. HORN: My wife says the same thing.
11 DR. YOGEV: Yeah, I know. But you already
12 raised me to a high level which I'm not sure I'll be
13 able to stand.
14 (Laughter.)
15 DR. YOGEV: Because I like your wife
16 because my wife would give me a condom after she send
17 me to my way. It would be even a bigger show of trust
18 in what I can do, and it seems like your wife is not
19 as trusting as mine.
20 (Laughter.)
21 DR. YOGEV: But you want to empower. I do
22 agree with the lesson on empowerment. We treat them

1 like a bunch of problems and we empower them, but
2 somehow you stop one step short of fully empowering
3 them.
4 You know, is one study that was mentioned
5 that was just recently published in Archives of
6 Adolescence, a study on those who commit to abstinence
7 who misinterpret what oral sex and anal sex mean, and
8 they increase because they did keep abstinence.
9 Uganda, which you just mentioned, which is
10 a great example and we should follow, it was true for
11 the beginning, and even there it was really more of
12 the "be faithful," but recently at least one study is
13 suggesting that we need an extension of it, and
14 unfortunately there is almost two groups, those who go
15 and say, "Well, well, abstinence? We need condom,"
16 and those who say, "Forget condom."
17 I am fortunately to talk to my kids and
18 say that. By the way, there is today in Washington
19 Post that 60 percent of those graduated from high
20 school have sexual activity already and 20 percent, 25
21 percent will have at least four partners by that time.
22 So there is no question in my mind that

1 your message of abstinence is very important, but to
2 suggest that you go to these people that you want to
3 empower against the whole popular culture, that they
4 will not be able to learn when to use the condom and
5 giving the condom is giving up on everything. Aren't
6 we short a little bit in our perspective and really
7 come with the whole package? Talk about abstinence,
8 increase abstinence, empower the parents because I
9 agree with you.
10 Unfortunately I'm in a part of Chicago
11 that only the single mom is not always there. So it's
12 really up to us to help, but if we take one of those
13 factors out, the abstinence and just the condom,
14 you're right. We're doing wrong.
15 But if we do only abstinence and ignore
16 that it doesn't work in the next ten generations till
17 we get the change that you're talking and continuing
18 that, we're going to do wrong to the public, and I
19 would encourage a little bit a combination of the two
20 in an appropriate way because I'll just give you
21 anecdotal example. In one school in which we were
22 asked to leave because of abstinence ground, which is

1 not allowed to talk about condoms, we found out that
2 increasing sexual activity which is not normal after
3 that because they are doing abstinence.
4 DR. HORN: Well, I appreciate your
5 thoughts, and I'm a child psychologist. What I care
6 about is helping kids arrive in adulthood healthy and
7 reasonably happy, reasonably productive, doing the
8 best they can with whatever potential God has given
9 them.
10 And my job as a child psychologist is from
11 birth until that moment when they enter into adulthood
12 to try to systematically reduce the amount of risks
13 that would prevent that from happening, and I
14 guarantee you two big risks is if you arrive in
15 adulthood with a sexually transmitted disease, many of
16 which are incurable, some of which can kill you or
17 will kill you, or if you become pregnant before you
18 become an adult and ready to take on that experience,
19 and so my job is to try and prevent as much of that
20 from happening in childhood and adolescence as
21 possible
22 I believe that part of that is being clear

1 and consistent in your messaging about whether or not
2 young people should be making choices that provide
3 increased risk for them. It's interesting that you
4 talk about giving them all of the information because
5 I do -- you know, I also was a college professor. I
6 think it's important to give people information and
7 help them make good decisions for themselves. I don't
8 think it's important for us not to be neutral about
9 that. I don't think we say here's all the
10 information. Now I really don't care. We've done a
11 gun safety course with you and we don't care if you
12 use that. I have no opinion if you use that. If
13 you're going to go rob a bank, you know, we have to
14 have a value attached to it. It does well as doing
15 gun safety.
16 Give them all the information. You know,
17 I speak to some young people groups, many of whom have
18 been through the so-called comprehensive sex
19 education. I have yet had a single person raise their
20 hand in all of my talks. My guess is you're all going
21 to now give me, you know, millions of testimonials to
22 the opposite, but I have not had a single youth yet

1 raise their hand who have gone through competence sex
2 education who could tell me what human papilloma virus
3 was. or that could tell me that condoms provide
4 according to the CDC no protection against it or that
5 could tell me that almost all cases of cervical cancer
6 are predated by human papilloma virus.
7 Now, it's interesting to me. You know,
8 are we really giving our young people all of the
9 information they need?
10 And so you know, it seems to me that, yes,
11 we need to respect young people. We need to give them
12 information and all of that, but there also are values
13 that it seems incumbent upon us as adults in the
14 society that also we give to our young people, and I
15 think one of the things that we have to be clear about
16 is the extraordinary risk to the future of young
17 people if they become sexually active and either get a
18 sexually transmitted disease or become pregnant.
19 So I'm glad we agree. I actually think we
20 agree a great deal.
21 CO-CHAIRPERSON SULLIVAN: Thank you.
22 Did you have a short follow-up?

1 DR. YOGEV: No, I just wanted to say we
2 agree. It just is exactly what we said. We need to
3 increase all of this information even with -- if you
4 tell people that get cervical cancer you can die or
5 whatever, more of them will choose not to have sex,
6 but if you got to this point and make the decision
7 which makes it difficult for you, here is the option
8 to make it a little bit safer. That's all I'm asking
9 for.
10 CO-CHAIRPERSON SULLIVAN: Ms. Ivantic-
11 Doucette.
12 MS. IVANTIC-DOUCETTE: Thank you.
13 I want to kind of follow up on a point
14 that Hank had made a little bit earlier, this notion
15 of personal health versus public health. You know, it
16 seems we're talking about changing behaviors, and you
17 probably already know this being a child specialist in
18 psychology, but one of the speakers we had about a
19 year ago talked about changing behaviors at the
20 critical points in sexual attitudes and behaviors, is
21 formed, you know, zero-three, three-six, and six to 14
22 years of age, and by that time your attitudes and

1 personal ways of thinking about sexuality are already
2 formed, and that that modeling begins in your family
3 and your family of origin, which is why they're a key
4 point.
5 But what I hear happening is that we're
6 putting a public health intervention on top of a
7 personal health behavior change issue. So we're
8 giving adolescents -- we're focusing and targeting our
9 message, positive behaviors, to a group that's already
10 past their attitude formation or development issue
11 with a message that is counter-cultural at a point in
12 development that they want to be like everybody else
13 in society.
14 So I'm just wondering what you're doing to
15 deal with the parents, you know, to talk. If they're
16 having serial marriages or unprotected relationships
17 within their families of origin, the kids are learning
18 those attitudes, you know. And I disagree that we're
19 modeling integrity and honesty and things in our
20 family. We cheat the government all the time on taxes
21 and other things. Kids learn those messages subtly.
22 They're subtle messages that are delivered on. So I

1 just wonder are there interventions that we should be
2 thinking about such as you were talking about earlier.
3 Public schools, couldn't we be having
4 parent forms that are mandatory to talk about that and
5 not necessarily just target on our adolescents at risk
6 with a limited message?
7 DR. HORN: I think it's a wonderful
8 observation and comment, and I agree with it
9 completely. I think I just gave a talk about how to
10 work with parents to help their kids make good choices
11 in their lives, including good choices about sexual
12 behavior, and what I say is start early and talk
13 often.
14 You know, a lot of parents think that, you
15 know, if they've had the talk, you know, once
16 they've done their job, and they often wait too late,
17 and one talk doesn't do it. They need to start early.
18 Now, obviously how you talk to a six year
19 old about sexual matters is different than how you
20 talk to a 16 year old, but it is very important for us
21 to help parents and empower parents to be able to talk
22 to their kids about this.

1 Often why parents don't do it is they
2 don't know how. They don't know how to bring it up.
3 They don't know how to talk about it. Sometimes they
4 don't talk about it because they're conflicted
5 themselves. They look at their own behavior when they
6 were younger and they say, "How can I, you know, kind
7 of urge my kids to be sexually abstinent before
8 marriage when I wasn't?" to which, by the way, I say
9 to parents, "Have you ever lied? Have you ever told a
10 lie?"
11 And every parent says, unless they're
12 lying, "Yes."
13 (Laughter.)
14 DR. HORN: And I say, "Well, does that
15 mean that when you talk to your kid about being honest
16 you say, 'Well, I can't talk to you about honesty
17 because I've lied once in my life'?"
18 I mean, it seems to me that, you know,
19 parents' job is not to use their children as
20 confessors, but to use their role as parents to help
21 their children develop well, avoid high risk
22 behaviors, and enter adulthood reasonably happy,

1 healthy, and productive, and that's their job.
2 And we've got to do a better job in
3 helping them understand that and equip them with those
4 skills. This department just did a Web site and a
5 bunch of publications, forparents.gov. I think that's
6 the Website address. That gives parents tips about
7 things like conversation starters, how to talk to kids
8 about these various issues and so forth.
9 And so I think that we do need to do a
10 better job because you are right. If all we do,
11 particularly in the context of this sea of what I
12 think are quite destructive messages to young people
13 about early sexual behavior being the norm and there
14 are no consequences for early sexual behavior; if we
15 wait until the kids are in high school and simply give
16 them a class, it helps, but it's not the whole answer.
17 We need to start earlier, and we need to use all of
18 the messaging that's possible, including pop culture.
19 It's not possible to tell our kids just to
20 turn off the TV 24 hours a day. I mean, I suppose
21 there are kids that don't watch the TV, but you know,
22 they do. My kids do, you know, and it's important

1 that we try to challenge the popular culture to give
2 different messages as well.
3 CO-CHAIRPERSON SULLIVAN: Ms. Clements.
4 MS. CLEMENTS: I'd like to go a little bit
5 further with the parenting issue you're speaking of.
6 I work in a community health center that provides care
7 to groups of people who would not normally have access
8 to care, and we do have an adolescent clinic, and most
9 of these adolescents come from broken homes. They may
10 have one parent. The parent that they have there does
11 not have the lifestyle skills to even make the right
12 choices themselves. Many of them are making bad
13 choices.
14 So when you talk about kids getting
15 messages and getting all informed and doing the right
16 thing based on what their parents are saying, many of
17 the parents are not there either. So they cannot get
18 that from their parents.
19 I think that oftentimes the messages that
20 we use for abstinence -- and I truly believe in
21 abstinence, but I think that what we've come to do is
22 to preach abstinence, and we're not teaching young

1 people how to be abstinent.

2 I can imagine that a young girl who has

3 never had sex before, when first approached will very

4 well say no, when secondly approached, may say, "Well,

5 I said no," when thirdly approached will say, "Well,

6 are you sure you love me?" and when fourthly

7 approached is maybe going to go for it because she's

8 not gotten the skills that she needs to stand up and

9 say no and walk away.

10 So you know, I think just saying no is not

11 going to work. I think that just depending on the

12 parents is not going to work because many of our

13 parents aren't prepared themselves, and I agree with

14 the empowerment piece that you speak about, empowering

15 our children, somehow getting to that point to empower

16 them to be able to stand and say no and feel good

17 about it and walk away.

18 DR. HORN: I agree with you. Let me just

19 say a couple of comments in reaction to what you say.

20 As Dr. Sullivan mentioned, I happened to found

21 something called the National Fatherhood Initiative.

22 In the interest of full disclosure, Dr. Sullivan was

1 one of our founding board members.

2 And the whole notion of that is to call
3 men to a higher standard of behavior, including
4 responsibility about their sexuality and also about
5 being involved with your kids, whether you live with
6 your kids or not, and the importance of being good
7 models for your children and talking to your children
8 about good choices. All of that is very important for
9 men and women, as fathers and mothers.

10 It's also why the President feels strongly
11 about the healthy marriage initiative, which is to
12 help couples form and sustain healthy marriages so
13 that there's less family break-up.

14 So we have to kind of do it all, you know.
15 And I agree with you about it's not a "just say no"
16 sort of message. The angriest I have ever gotten at
17 any reporter in my life was recently People Magazine.
18 They called me up. The reporter was very rushed, and
19 I said to her, I said, "This is not just a 'just say
20 no' campaign. It is about helping kids make good
21 decisions about," blah, blah, blah.

22 So what was my quote in People Magazine?

1 According to Dr. Wade Horn, it's a "just say no"
2 campaign. You know, it's exactly the opposite of what
3 I believe and it sounds like you believe. It is more
4 than that, which is why we're wrapping it into a
5 broader sort of notion about youth development.
6 So I start with the child. I'm very child
7 centered. Children live within the context of
8 families. Families live within the context of
9 communities. Communities live within the context of
10 culture, and when family, community, and culture are
11 aligned, kids do well. When families and community
12 and culture are all saying the same things, what
13 happens? People generally kind of behave in the way
14 that those messages are coming down to them.
15 Think about the change. I may be much
16 younger than you are, probably am, but I remember the
17 days when nobody used seatbelts, and what happened?
18 We had a change. Parents are now wearing seatbelts,
19 insisting their kids wear it. Communities have all
20 sorts of messaging about the importance of seatbelt
21 use. In the broader culture, you know, you can have
22 the most extraordinary, exciting, sort of crazy car

1 chase movie, and what's the first thing they do when
2 they jump in a car? They click on their seatbelt.
3 You know, when all of that is aligned, you
4 get behavior that is reflective of it, not completely,
5 not absolutely, but you increase the odds
6 tremendously.
7 The problem that I have is right now those
8 are not in alignment. Most parents do not want their
9 13, 14, 15 and 16 year olds to be having sex. Most
10 don't. The problem is we have, you know, a broader
11 culture that is far, far less clear about that, and
12 part of what abstinence education is trying to do is
13 to try to get in community organizations, such as
14 schools, a message that is more consistent with what
15 parents believe about sexual behavior when it comes to
16 their kids.
17 And a big challenge for this group, I
18 hope, is that you will challenge the broader culture,
19 the popular culture, you know, to stop sending these
20 very destructive messages.
21 CO-CHAIRPERSON SULLIVAN: Thank you.
22 Yes, Frank, and then Monica.

1 DR. JUDSON: I very much agree with the
2 way you have framed the questions and the issues. I
3 think where part of the misunderstanding comes from,
4 well, some of it is just from people who politically
5 don't want to understand or take a different position
6 altogether, are essentially against whatever the Bush
7 administration would come up with, and if they turned
8 pro condom, they'd probably be against condoms.
9 DR. HORN: You must be talking to my
10 mother.
11 DR. JUDSON: But I think one of the areas
12 that I've been sort of critical about as a scientist
13 looking at things broadly is that we'll see $180
14 million or something for abstinence, what are framed
15 in the media as abstinence only campaigns. Most
16 people don't have a clue what the real content of that
17 message is, and I have to say I don't either.
18 And then you find out that with no
19 evidence of efficacy, that we're now going to 210
20 million or so, which will get translated into the
21 negative press as despite no evidence of effect, the
22 President now asked for a 40 percent increase, still

1 probably not getting in the context that $200 million
2 isn't a huge amount in the United States for anything.
3 Then there's the overriding concern that
4 we have for all of these programs that are intended to
5 change human behavior and reduce human risks in
6 adolescents. Whether the schools have the time to do
7 that, whether they're effective, whether it's a
8 pregnancy prevention, sexually transmitted infections,
9 tobacco, substance abuse, when I look at the collision
10 between the continuing testing and monitoring for
11 reading and writing and so forth, that's become a huge
12 time conflict in our high schools. They can't do all
13 of this.
14 And if the feds. come in with a program
15 that offers a half a million dollars to deliver a so
16 many hour a month program on abstinence or sexual
17 behavior, something else has got to give, and the
18 principles and superintendents will often claim that
19 what's going to have to go is study halls for catching
20 up on math and reading and other fundamental things.
21 And finally there's the issue of whether
22 that's ever the place to change adolescent behavior.

1 The kids who are lucky enough to come from families
2 who have the parenting values and skills and so forth
3 that Jacqueline was referring to, they won't need
4 those, and the ones who don't, you could argue it's
5 not going to work. The impact just delivered by
6 teachers are simply paid to carry out a government
7 program for which a local school district gets paid,
8 that that's just not an effective set of motivations
9 or an effective context in which to change behavior of
10 children from sometimes dysfunctional families.
11 DR. HORN: I mean, those are very
12 thoughtful comments, and I appreciate that. Now, let
13 me sort of respond to a couple of things.
14 First of all, it's not true there's no
15 evidence that abstinence education works. There are
16 at least ten published studies that I'm aware of, four
17 in peer reviewed scientific journals that attest to
18 the effectiveness of abstinence education in helping
19 young people delay sexual onset.
20 In addition to that, it is not true, it's
21 just not true that there's this huge, huge alternative
22 literature attesting to the effectiveness of

1 comprehensive sex education.

2 You know, we sometimes say there is not a

3 great deal -- you know, there is not as much evidence

4 as we'd like about the effectiveness of abstinence

5 education, and I agree with you there is not as much

6 as I would like, and we need to do more research into

7 it to see whether the most effective ways to help

8 young people be sexually abstinent, but we rarely

9 challenge ourselves to produce this voluminous

10 literature that people say is out there or assume is

11 out there on competent sex education. It ain't so.

12 ASPB here did a comprehensive review of

13 what is available in the scientific literature of

14 scientific, valid studies and so forth, and the

15 results ain't great. They're quite mixed, a little

16 bit of evidence for positive effects, some evidence of

17 negative effects, and mostly no effects.

18 So if you're under the illusion that

19 comprehensive sex education has this great literature

20 out there showing how effective it is, it ain't so.

21 Now, guess what. When was the first

22 national effectiveness study of the Head Start Program

1 done? The last two years. In 1965 we didn't say,
2 "Gee, we can't commit this nation's resources to
3 helping poor people, poor kids arrive at school ready
4 to learn because we haven't done enough studies yet."
5 What we said in the political process is
6 it is unacceptable; the status quo is unacceptable to
7 have so many poor kids already disadvantaged in their
8 education, and so we are going to commit this nation's
9 resources to do something about it, and that's what we
10 did. We created Head Start in 1965.
11 If it is true that early and promiscuous
12 sexual behavior on the part of young people puts a
13 significant portion of our young people at risk -- and
14 I read those statistics early on -- why in the world
15 would we say, "But you know what? We really can't do
16 much about it until we have, you know, 100 different
17 studies that show unequivocally that, you know, these
18 programs are absolutely 100 percent effective."
19 It is a standard that is applied to this
20 series of programs. That's an education which is a
21 standard that is foreign to everything else I oversee,
22 and I oversee $46 billion. The standard that is

1 generally applied in government programs is we see an
2 issue that is compelling and that we as a nation make
3 a political decision, small P, to engage resources,
4 public resources to address it, and we don't generally
5 say, "And until we have unequivocal evidence of
6 certainty of the effectiveness of the programs that
7 we're going to hold off."
8 If that were so, my $46 billion would
9 shrink to about $1.70, and if I'm passionate about it,
10 I apologize, but I am passionate about this. I
11 believe that it is important for us. There are too
12 many kids out there whose futures are being seriously
13 compromised every single day, and as a child advocate
14 I just can't sit back and say, "Gee, that's
15 interesting, but we'll just kind of get there when we
16 get there."
17 I feel I have to say something. I could
18 be wrong. I entertain the possibility that I could be
19 wrong, and that's why I'm a strong supporter of
20 evaluation studies, because I want to know what's
21 effective, not just feel good stuff that I think is
22 effective, and my guess is you agree with me.

1 CO-CHAIRPERSON SULLIVAN: There's no
2 question that you are passionate about it.
3 (Laughter.)
4 CO-CHAIRPERSON SULLIVAN: Dr. Sweeney and
5 Dr. Green, and we'll ask you for brief comments if we
6 can. We are almost out of time.
7 DR. SWEENEY: I'll try very much to be
8 brief.
9 Thank you, Dr. --
10 DR. HORN: That was an instruction to me,
11 I think.
12 (Laughter.)
13 DR. SWEENEY: Oh. I was at a luncheon a
14 couple of weeks ago, and the keynote speaker was a
15 woman who just sold her real estate business for $4
16 billion, and I preface it that way to say she's not a
17 kook. She's unusual, and she wrote a book called If
18 You Don't Have Big Breasts Put Ribbons on your
19 Pigtails, and the subtitle of her book is "Use What
20 You Have."
21 And I bring that up because you talked
22 about in the community, the family, the general

1 society, and having the values aligned. In the
2 community where I work, Bedford-Stuyvesant, Brooklyn,
3 New York Times, 50 percent of males 16 to 64,
4 unemployed; 50 percent of the men in the prison in
5 this country, black males; dropout rate from high
6 school, over 50 percent; and the numbers go on.
7 Marginalized, racism, poorly educated, no
8 hope for the future, low self-esteem. Use what you
9 have. So I have in front of me a 16 year old who what
10 she has is youth, a nice looking body, and she's
11 sexually active. Do I use a public health approach or
12 a personal approach on this young woman who asks me,
13 "My boyfriend is coming out of prison. Can you tell
14 me what I can do to get pregnant because I've been
15 having sex since I'm 13 and I've never gotten
16 pregnant, and I've never used anything?"
17 So I raise that issue to try and show that
18 the decision to talk about abstinence in the context
19 of my community and my reality is very, very different
20 from the picture that is often presented, and I would
21 like you to comment on that.
22 DR. HORN: Well, you're exactly correct.

1 Kathy Eden has a book out. Kathy Eden is a researcher
2 that went into Newark -- no, Camden, Camden, New
3 Jersey. For those who are not familiar with New
4 Jersey, that is not the garden spot of New Jersey.
5 It's a very low income, very distressed, very much the
6 same kind of demographics in terms of the horrible
7 statistics you talked about when it comes to Bedford-
8 Stuyvesant.
9 And what she found was she found that
10 young people were getting pregnant because they saw
11 pregnancy and motherhood as the one avenue available
12 to them for meaning.
13 Now, that's interesting because it's
14 really interesting sort of implications for that. If
15 you say to that young woman who sees motherhood,
16 pregnancy as the only avenue towards meaning, "Here's
17 a condom. Make sure your partner uses it." What
18 you're essentially saying is, "Guess what. The one
19 avenue you have towards meaning in your life, we want
20 you to use this and cut it off."
21 But it's also a challenge to abstinence
22 because it's the same thing. If we say to that young

1 woman, "But be sexually abstinent and we're also going
2 to stop you from having that one avenue you see in
3 your life towards meaning," then there's nothing left
4 for that young person, which is why I talk about
5 positive youth development.

6 While I would still give that young person
7 a strong abstinence message, if we do it in isolation
8 without understanding the need in that community to
9 build structures that give those young people hope and
10 optimism for the future, there's no motivation for
11 them to either be abstinent or to use contraception
12 because the goal is motherhood, any sense of meaning,
13 or fatherhood, any sense of meaning.

14 And yet we know that that young person, if
15 that young person has a child out of wedlock at 15 or
16 16 or 17, the odds that they will escape that kind of
17 economic destitution are very small.

18 And so this is why I talk to much about
19 positive -- at least I hope I talked enough about
20 positive development because abstinence education is
21 an important piece of what we have to do, and I hope
22 people understand I am a strong proponent, but it's

1 not the only thing we have to do, and if it's the only
2 thing we do, we're not going to see the kinds of
3 results, particularly in communities that have the
4 kind of statistics that you describe.
5 CO-CHAIRPERSON SULLIVAN: Thank you.
6 And Dr. Green has a final question or
7 comment.
8 DR. GREEN: Yes, well, actually a comment.
9 First, thanks for your presentation. I'm somebody
10 who has spent a lot of time studying the Uganda model
11 and writing about it. I wanted to make a comment
12 about individual strategy versus public health
13 strategy that a couple of people have raised. This is
14 actually a comment from Norman Hurst who spoke to
15 PACHA last year. He did the review of condom
16 effectiveness for U.N. AIDS for 2003 and published his
17 findings and studies in Family Planning last year.
18 He has this to say. He said this in
19 discussions in E-mail after his article. He says as
20 an individual strategy, assuming he's talking about
21 himself, a sexually active adult, if he was going to
22 have risky sex, it would certainly make a lot of sense

1 for him to use a condom. He essentially reduces risk
2 greatly by using a condom rather than not using a
3 condom, and then when he would consider the other
4 option for a sexually active adult, fidelity,
5 monogamy, at the individual level that might not seem
6 like such a great idea because how does he really know
7 his partner is being faithful. He could be faithful
8 and his partner not.

9 In fact, a lot of people use this as an
10 argument against promoting fidelity. However, Norman
11 Hurst says when you look at the level of public health
12 strategy, things look a little different. Condom
13 promotion has been the primary thing that we have
14 funded and promoted globally in AIDS prevention, and
15 in looking at the African data so at least in
16 generalized epidemics, sub-Saharan Africa, and the
17 Caribbean condom promotion has not yet, 20-plus years
18 into the pandemic, paid off in lower HIV infection
19 rates at the population level.

20 In other words, promoting condoms and even
21 higher condom user levels have not translated into
22 lower HIV infection levels. Meanwhile the country

1 that has most promoted the A and B options, Uganda,
2 we've seen an unprecedented decline in national
3 prevalence by two thirds.
4 There are a couple of other countries,
5 Senegal, Jamaica, a few other countries that have also
6 given, you know, considerable emphasis to A and B
7 messages, usually B more than A, but A being
8 abstinence or delay, the primary message for youth.
9 That has paid off.
10 So things may look different depending on
11 whether you're looking at an individual strategy or a
12 public health strategy, and since we in this committee
13 consider policy and allocation of funds to programs,
14 we might do well to look at what's worked as a public
15 health strategy.
16 I don't know if you'd like to comment on
17 that.
18 DR. HORN: I am a great admirer of your
19 work in this area, and I would have nothing to add to
20 that.
21 CO-CHAIRPERSON SULLIVAN: Dr. Horn, thank
22 you very much for a very productive and very --

1 (Applause.)

2 CO-CHAIRPERSON SULLIVAN: Our

3 International Committee chairman, Abner Mason will now

4 take the chair.

5 MR. MASON: Thank you, Mr. Chairman.

6 With your permission I want to first add

7 one additional resolution which I overlooked. It was

8 brought to my attention by one of my members that our

9 committee has been working on a resolution on the ABC

10 approach for some time, and it has taken us a while,

11 but I think we have got a resolution that we're ready

12 to bring forward and present to the full council.

13 So I just want to add that. I only

14 mention one resolution. So there's going to be two.

15 Council members, you'll get a copy of it. You'll have

16 obviously a chance to review it, but I just wanted to

17 add that. I overlooked it earlier.

18 It's now my pleasure to introduce Roger

19 Bate, who is here to talk with us about taxes and

20 tariffs on drugs, and Roger is the resident fellow at

21 the American Enterprise Institute. He is Director of

22 Africa Fighting Malaria. He's a fellow at the

1 Institute of Economic Affairs, and those are just a
2 few of his appointments.
3 If you look in the binder, his list of
4 books and chapters from books and academic articles
5 and other writings are there for you to review, and
6 what you'll see if you take a look is that he has done
7 an extraordinary amount of work in areas that we work
8 on.
9 It's a pleasure for me to introduce him
10 because he is one of these people who manages to
11 combine a very, very keen intellect with a passion for
12 helping people in some of the poorest parts of the
13 world. That's a combination that we need to see a lot
14 more of, and so with that, it's my pleasure to
15 introduce Roger Bate.
16 DR. BATE: Thank you very much, Abner.
17 I think we have one or two technical
18 issues to resolve, but it's my pleasure to be here.
19 Thank you very much for inviting me to speak.
20 Last month because of pressure from AIDS
21 activists, academics, and others, Kenya dropped its
22 ten percent import tariff in essential medicines.

1 Today finance ministers from Uganda, Tanzania and
2 Kenya are meeting to discuss whether that tariff
3 should, in fact, be reinstated since it breached the
4 consensus approach that was agreed in January when the
5 East African and Customs Union came into force.
6 A stake I would argue is access to
7 essential medicines of thousands of the poorest
8 Kenyans, and of course, as a precedent setting
9 example, this will be important for many hundreds of
10 thousands, even millions of people across East Africa
11 because what is going on in Kenya is a microcosm of
12 what I want to talk about today, which is the specific
13 example, a specific problem of lack of access to
14 antiretrovirals and drugs for opportunistic
15 infections.
16 And the particular aspect that I'm going
17 to talk about is the imposition of taxes and tariffs
18 on medicines and medical devices in many developing
19 countries and the impact this has.
20 While we're waiting for the slides to come
21 up, I'll carry on because I can talk through the first
22 bits. Ah, here we are anyway. We're very close.

1 Few people in the poorest parts of the
2 world have ready access to good medical supplies. In
3 some countries, such as Uganda, that coverage is about
4 70 percent on average and is pretty good. Others,
5 such as Nigeria, access is as low, and disastrously
6 low, as about ten percent.
7 Thanks very much. Thank you.
8 The lack of access costs lives, millions
9 of them, and probably the most important reason for
10 lack of access is the significant poverty in these
11 countries, and the resulting lack of health care
12 infrastructure, but lack of political will is also an
13 important factor and it's something that can be
14 changed almost overnight.
15 It is, of course, the sovereign right of
16 any nation to raise revenues as it sees fit, but
17 having said that, given that so many people in these
18 nations do not have access to the most basic life
19 saving interventions, it does seem odd to flat tariffs
20 on the entry of these products and then tax them,
21 perhaps the most regressive forms of policy
22 intervention there is since it hits the sickest and

1 poorest people in the land.

2 It is my opinion and that of 16 NGOs at
3 the moment from 11 countries and also the World Health
4 Organization, which I'll move on to in a second, who
5 have not signed up to our initiative, but who are
6 broadly in support of that -- at least their
7 economists are -- that these regressive policies
8 should be repealed instantly.

9 In our working paper, which was published
10 just about two months ago, and it's very much a paper,
11 the working paper, because it's being updated
12 constantly as new data evidence arises. We look to
13 essential drugs accesses as defined by the World
14 Health Organization. The list we had to work from is
15 fairly old data so that we could compare and contrast
16 available, consistent tariff and tax data.

17 There is a lot of information about the
18 different types of categories. I learned more than I
19 really thought I was ever going to about the
20 categorization of pharmaceuticals and other products,
21 but we use the harmonized system, look to the
22 harmonized system which is produced by the Customs

1 Corporation Counsel. And we looked at, settled on
2 Chapter 29 and Chapter 30 categories of that system
3 which looks at finished pharmaceuticals and the parts
4 or the build-up chemicals to those pharmaceuticals.
5 We found partial data from many countries,
6 complete and reliable data for about 53. We simply
7 averaged the various category weightings, which has
8 led to some discussions about what should be the
9 correct weighting, and came up with a single figure.
10 Some country data was quite disaggregated;
11 others is less so.
12 We had a running debate with Richard Lang,
13 who is an economist at the World Health Organization,
14 who published a paper even more recently than ours,
15 about two or three weeks ago. This paper which is
16 great that has been published looks only at tariffs.
17 Ours looks at taxes as well.
18 I think that it's excellent that the World
19 Health Organization has published this because it
20 implicitly criticizes many of the member states of the
21 World Health Organization, and for that reason it is
22 courageous and correct to do so.

1 Because of the details of the issue, there
2 are many disagreements between Richard Lang and
3 ourselves, but as always disagreement is great in
4 scientific or economic discussions because it leads to
5 further analysis and a race to be seen to be correct.
6 So we hope that the conclusions of our
7 paper are, and I think there's more evidence than
8 there is at the moment, but it doesn't matter.
9 Ultimately their conclusions and ours are the same,
10 which is that these taxes and tariffs should be
11 removed.
12 So let's look at what we found. We have
13 here -- actually I've already covered most of the
14 points in that. I apologize for that -- 53 countries,
15 as I mentioned.
16 Okay. What did we find? Many of the
17 poorest African nations impose substantial tariffs and
18 taxes on medical products. As will become clear
19 shortly, it is more important to look at the tariff
20 rates than the tax rates. Taxes are no doubt
21 regressive, and I have examples where there are
22 significant problems with them, but it's the tariff

1 numbers that are the most problematic in terms of
2 denying access. Note especially near the bottom
3 Nigeria and India. These are countries with large to
4 huge populations, low access, and significant tariffs.
5 There are some highlights in this or
6 perhaps we should call them low lights, and Morocco,
7 for example, has a subcategory of Chapter 30 medical
8 products on bandages and gauzes, which is as high as
9 46 percent.
10 The Democratic Republic of the Congo and
11 Kenya have pretty high tariffs as well and other
12 taxes.
13 As I mentioned when I started speaking,
14 the East African Customs Union imposes a ten percent
15 tariff as of January. The one bit of good news that's
16 been coming out relatively recently is India, which
17 has incredibly high combined tariffs and taxes of 61
18 percent at its relatively recently budget reduced that
19 to 20 percent, although there is still -- and I said
20 this when I spoke to some of you about six weeks ago -
21 - there's still some disagreement about how the new
22 policy is being implemented since in some states the

1 old tax rates, close to 60 percent, are still being
2 applied.
3 Much like the 22 countries which are party
4 to the PhRMA agreement of the general agreement on
5 tariff and trade in the Uruguay Round, the Southern
6 African Custom Union imposes no tariffs on finished
7 medicines, which is very good news, in fact, in all
8 Chapter 30 items.
9 Many countries have low tariffs, although
10 any tariffs at all probably increase the probability
11 for corruption, given the way the tariff payments are
12 often collected. I can talk more about that later.
13 Antiretrovirals for HIV patients are often
14 exempted, increasingly so, which is good news, and
15 we're trying to compile a comprehensive list of that,
16 and I may ask for your help, the people in this room
17 today, in terms of compilation of that data.
18 But even where antiretrovirals are
19 exempted, most drugs for opportunistic infection are
20 not exempted, and neither are anti-malarial or anti-TB
21 treatments, which are often as we know the deadly
22 companion disease for HIV in developing countries.

1 So celebrating the ARV exemptions is
2 premature unfortunately, but the fact that the
3 pressure on poor countries as well as their own
4 enlightened self-interest, which of course is
5 ultimately more important, has exempted products and
6 shows that it can be done and further exemptions
7 should be encouraged.
8 It is important to recognize at this point
9 that the funding raised from tariffs and taxes on
10 medical products is not generally speaking spent on
11 health care in these countries, although it is largely
12 unclear, given the opacity of spending figures in many
13 of these countries.
14 Furthermore, even if it were allocated to
15 health as some governments have argued both to myself
16 and to many other people, it is not the most effective
17 or economically efficient way to raise funds, and just
18 on simply economic grounds, there are better ways of
19 raising funds if you want to spend more money on
20 health care.
21 Our tentative, and I stress that it is
22 tentative because of the changes in the data, quality

1 of access data, but from our econometric analysis we
2 found that income level was the most significant
3 positively correlated variable determining access to
4 drugs. Simply put, wealthier countries have far
5 greater access than poorer ones. That doesn't require
6 economics to tell you that really, but it does help
7 that it is confirmed by the econometric analysis.
8 However, tariff rates are highly
9 statistically significant as a negative determinant of
10 access. Countries with higher tariffs on average have
11 lower access rates.
12 The key finding, and I say this is
13 tentative because of the way the econometric study and
14 the quality of the data is concerned, but we found
15 that roughly speaking a one percent lowering of
16 tariffs could lead to an increase of access of one
17 percent.
18 And recall that for Nigeria, which has a
19 20 percent tariff rate, it only has an access rate to
20 pharmaceuticals of ten percent, and India has a 16
21 percent tariff rate now, maybe higher than that; it
22 depends on how it's being implemented, and only a 35

1 percent access rate.
2 These countries, as I mentioned, are
3 highly populous, and if this equation and relationship
4 are causal, as we believe it is, scrapping tariffs
5 would increase access for many millions of people.
6 Sales taxes are negatively correlated with
7 access much like tariffs. VAT, for value added tax,
8 in this slide, but the relationship is not
9 statistically significant. This is probably because
10 tax payments are collected broadly across the economy,
11 whereas tariffs are indicative generally of less free
12 and hence less wealthy economies, but also because of
13 the way that tariffs are collected, ships docking at
14 night, charges collected in more ad hoc fashions can
15 lead to, in fact, can stimulate forms of corruption.
16 Furthermore, revenue is received by small,
17 often more autonomous customs and excise units which
18 makes bribery probably more possible as well.
19 There is ongoing analysis which shows an
20 interesting association between tariffs and corruption
21 indices, but I haven't got room to talk about that
22 now.

1 But having said that taxes are not
2 statistically significant, they are obviously
3 detrimental, and they do place a burden on patients.
4 We looked at the tax paid on the average cost of
5 antiretrovirals for those people buying privately in
6 South Africa, and it shows that that costs about $12 a
7 month in tax rate. On that list or the list coming up
8 -- sorry. I think I've gone too far. There we go.
9 I'm sorry -- the list there shows what can be bought
10 for an individual for their family from just simply
11 the tax on antiretrovirals to private purchasers in
12 South Africa.
13 Antiretrovirals, of course, are very
14 expensive medicines or comparatively expensive
15 medicines, but even taxes on cheaper medicines still
16 has an impact, and remember the Kenya has 22 percent
17 tax on some pharmaceuticals and the rates vary
18 depending on what type of products, but there's no
19 doubt that this hits the most malnourished patients,
20 and as with tariffs, sales taxes on these drugs are
21 very regressive and should be repealed, and the World
22 Health Organization agrees with us as well on that.

1 It's not just the tariffs, but the sales taxes that
2 should be repealed, too.
3 Go on to that slide that we had a second
4 ago.
5 A less well documented problem is the non-
6 tax and non-tariff barriers because although there is
7 obviously a key input, drug safety is a vital issue.
8 Rigorously tested new drugs or drug combinations is
9 very fore. As we know from the discussion and debate
10 for even of a generic, non-FDA approved fixed dose
11 combination antiretrovirals, it seems that many
12 countries are delaying unnecessarily the approval of
13 new drugs. South Africa delays significantly. I
14 think it says up there 39 months. So over three
15 years.
16 Namibia had the disastrous situation of
17 requiring all reregistering of drugs approved before
18 1990 even though they had been approved in every
19 single European country, America and Japan and other
20 countries in the Far East. This is incredibly onerous
21 and costly for those people trying to reregister
22 drugs, which means that, of course, Namibia doesn't

1 have as many drugs reregistered as it should do, and
2 there are other examples. Just one from Nigeria
3 there.
4 That's about it. I will conclude by
5 saying that I hope that Patrick can get behind this
6 initiative, which is our no to taxes and tariffs on
7 drugs and devices initiative. The World Health
8 Organization independently, as I've already mentioned
9 a few times, has published on this topic and agrees
10 that these things should be removed.
11 Increasing numbers of nongovernmental
12 organizations are joining with us. As I mentioned,
13 currently there are 16.
14 Michael Marchman (phonetic) and Oliver
15 Sabber at the Global Fund and Friends of the Global
16 Fight are helping us gather information on drug
17 access. Jack Galbraith has already provided one
18 example to me of problems they have had, the Catholic
19 Medical Mission Board, when distributing drugs where
20 it's often not known that the tax and tariffs even on
21 antiretrovirals have been repealed so that drugs are
22 waiting in docks and causing significant problems.

1 The Global Fund incidentally has an
2 agreement which specifically states that the
3 assistance financed from donations will not be taxed
4 or have import levies on it, and we need more
5 donations policy based along those lines to encourage
6 countries to reduce or remove their tariffs entirely.
7 And then finally, of course, since I last
8 spoke on this issue about six weeks ago, the South
9 African Department of Health is arguing for the
10 removal of VAT on antiretrovirals and, in fact, on all
11 drugs, which is very good news, although they're
12 coming up against opposition because of the funding
13 questions and where government spending or, rather,
14 where government revenue is coming from from the
15 treasury in South Africa, but at least that discussion
16 is taking place, and as I mentioned, WHO has called
17 for tariff removal, too.
18 Senators Brownback, Landau, and Inhof have
19 introduced a bill on affected diseases which takes up
20 the idea in this regard, and Section 9 of the bill
21 would encourage donations from the United States going
22 to countries to remove tariffs and taxes. The bill

1 argues that these interventions are not necessary.
2 They only protect domestic industry and do not help
3 the poor in those countries, and we certainly agree
4 with that.
5 I hope I can deal with any questions you
6 may have. Thank you very much for inviting me to
7 speak.
8 (Applause.)
9 MR. MASON: Thank you. Thank you, Roger.
10 And now we'll take questions. We'll start
11 with Dr. Judson.
12 DR. JUDSON: Does PEPFAR have that within
13 their requirements or agreements with the 16 or 17
14 governments that are partners in this?
15 DR. BATE: As far as I know, it's
16 encouraged, but I'm not sure that it is actually
17 written into the agreement. I don't think it is.
18 There may be people who know more.
19 DR. JUDSON: Should it be? You were
20 saying it should be, but is there anybody who can take
21 the lead for that to see that American funding policy
22 is adjusted?

1 DR. BATE: I would have thought a
2 statement from Patrick would have helped very much in
3 that regard.
4 No, I think that, in fact, one of the
5 reasons the Global Fund has so many good provisions
6 within it, especially notably in this regard to do the
7 taxes and tariffs is because of input and pressure
8 from the United States. So it does appear odd, and I
9 apologize for not knowing the answer to your question.
10 If PET IV (phonetic) doesn't, as I don't
11 think it does have that, then it should, in fact, be
12 instigated immediately. I don't see that there's any
13 reason not to, at least in terms of pushing for
14 encouragement of that. If deals are already in place,
15 well, it would be unfair to withdraw those drugs, but
16 where new deals are being done and new donations are
17 being provided, it would make a lot more sense for
18 these countries to repeal those taxes and tariffs.
19 MR. MASON: Dr. Sullivan.
20 CO-CHAIRPERSON SULLIVAN: Well, first of
21 all, thank you very much for to me a very informative
22 presentation because this is an issue I was not aware

1 that existed. I have really two related questions.
2 One is on average what percentage of the
3 governmental revenues in these countries does the tax
4 and tariffs represent. You know, that is, how
5 important is it to these countries in terms of the
6 revenue issue?
7 And secondly, I think you're touched on
8 really my second question, and that is what
9 alternatives have been suggested or proposed. I think
10 you mentioned Senator Brownback and Inhof had
11 recommended the U.S. provide a substitute for those
12 revenues that are lost, but this seems so
13 counterintuitive. That is, why covenants would really
14 be, in effect, preventing access to medicines of these
15 citizens by imposing these taxes, but the question is
16 how important to these governments would their
17 treasurers say this is to them.
18 DR. BATE: First, clarification on the
19 Brownback, Landry, Inhof bill does not stipulate
20 compensation for the countries if they move it to
21 Britain. It's more to encourage them or more to say
22 that U.S. funding should not be going to the

1 governments that are, in effect, shooting themselves
2 in the foot or shooting people in the foot. I think
3 that's the impression.
4 One of the advantages I mentioned of the
5 debate that's going on between the World Health
6 Organization economists and my co-authors is actually
7 driven us to look at what revenues are delivered. I
8 can't give you chapter and verse on all of them, but I
9 know that from our analysis of the 53 countries that
10 the highest revenue, and it is significant from --
11 and I can't tell you if this is just tariffs. I think
12 it's tariffs and taxes -- is the Democratic Republic
13 of the Congo, which raises eight percent of its
14 revenue from tariffs and taxes on pharmaceuticals or
15 pharmaceutical products in general, which is a
16 substantial amount.
17 And therefore, they will probably be in a
18 potentially difficult situation where they could just
19 remove it overnight and this may be an instance where
20 they could be perhaps helped for the aid to compensate
21 so that could be provided, but as I said, on the other
22 hand, this is not an economically efficient method of

1 raising revenue. There are more economically
2 efficient methods, but in terms of capital gains
3 taxes, income taxes, and corporate taxes which are
4 doing the modeling, and I'm not a specialist in that
5 area, but I understand enough as an economist to know
6 that there are better ways of raising money.
7 So therefore, in most countries it is
8 much, much lower than eight percent. It is actually a
9 fraction of one percent, but the DRC is probably an
10 outlier in that regard.
11 But it can come up to one percent, maybe
12 even one to two percent of budget, and of course,
13 within that budget you're dealing with turf. You're
14 dealing with potential turf fights, you know, and so
15 obviously there are some people, sub-departments who
16 would actually lose out or perhaps members of those
17 sub-departments who would lose out, and therefore, it
18 hasn't been pushed through so far.
19 But what is encouraging is that South
20 Africa, for example, on its value added tax, we have
21 seen that members of the Department of Health have
22 said, yes, we'd like these taxes to be removed because

1 we know that they're regressive. So the more pressure
2 the more that is raised both in terms of carrot and
3 stick, if you'd like. Say perhaps more A could be
4 provided or perhaps there are better ways of dealing
5 with raising the revenue, but for some countries it
6 can be substantial. Perhaps DRC is way an outlier,
7 but it can be substantial.
8 CO-CHAIRPERSON SULLIVAN: I think that for
9 any government official in these countries it would be
10 helpful to perhaps not only challenge them, but
11 provide them with some alternatives because they are
12 always confronted with the issue of if, indeed, they
13 should give this up, and I think we all agree with
14 that. What are some of the alternatives that they
15 could consider? Because obviously if they are
16 significant revenues, that presents them with another
17 problem.
18 DR. BATE: I agree. In any governmental
19 decision, as I said, it's the sovereign right of any
20 nation to determine how it raises its revenue, and
21 there will be tradeoffs. There's no doubt that some
22 revenue is raised. Therefore, that revenue either has

1 to be lost or has to be replaced in some other way.
2 This can be done mutually in an economic
3 tax method that would raise the revenue far more
4 efficiently and far less regressively. But, of
5 course, advice in terms of how to do that can be
6 provided and aid perhaps as a short run measure to
7 overcome the loss in revenue could be provided, too.
8 Because ultimately it's not just the
9 amount of money that's raised. I mean, that can be
10 substantive, but the key point to realize here is that
11 you're often dealing with small amounts, relatively
12 small amounts of money, but you're dealing with
13 uncertainty. You're dealing with the idea that a
14 cargo of medicines turns up and perhaps the tariff on
15 it is only $1,200, say, but the fact is that paper
16 work has to be filled out, and you can end up having
17 drugs sitting on docks for weeks because of that
18 $1,200 because they're arguing as to whether it should
19 be paid or it should not be paid because it's an
20 exemption.
21 In some instances it may be tens of
22 hundreds of thousands of dollars, but the reality is

1 most of the time its not that much money, but it leads
2 to delay because it leads to uncertainty about are
3 these exempted and those drugs not, and that's why a
4 blanket repeal of these taxes and tariffs or at least
5 in terms of the tariffs should be pushed forward, at
6 least in my opinion.
7 MR. MASON: Any other questions for Roger?
8 (No response.)
9 MR. MASON: Thank you.
10 DR. BATE: My pleasure. Thank you very
11 much.
12 (Applause.)
13 CO-CHAIRPERSON SULLIVAN: Indeed, we are
14 ahead of schedule by about 35 minutes. Well, let me
15 see. No, about 40 minutes, but let me suggest that we
16 take a 15-minute break and we'll see if we are able to
17 move up the rest of the agenda, and if so, we'll be
18 able to finish early this afternoon.
19 So we'll take a 15-minute break.
20 (Whereupon, a short recess was taken.)
21 CO-CHAIRPERSON SULLIVAN: We have sent an
22 E-mail to Dr. Gottlieb, who is scheduled to present at

1 3:20. We've not heard back from him. So we may not
2 be successful in having him come early.
3 So I have one suggestion. If there are
4 members of the public who are on the docket for
5 presentation tomorrow who would like to present this
6 afternoon, we would welcome that. We really have 20
7 minutes that we can devote to that.
8 So are there any members of the public who
9 would like to present? Yes, please come forward,
10 identify yourself, and give us your testimony. You're
11 very welcome.
12 DR. MARTIN: Great. Thank you, Dr.
13 Sullivan and members of PACHA.
14 I'm Marsha Martin, Executive Director of
15 AIDS Action Council and AIDS Action Foundation, and
16 I'm very happy to be here to deliver AIDS Action's
17 public comment.
18 And, by the way, I was going to present
19 tomorrow. So we were going to try the public comment
20 that was going to be a PowerPoint. So you guys were
21 going to get your first comment PowerPoint, but it
22 won't happen.

1 So you have our official public comment in
2 this packet which we have given to you, which I just
3 will tell you very briefly has information about the
4 United States epidemic on your left-hand side, as well
5 as some of the challenges around the appropriations
6 recommendation, summary from our national
7 organizations responding to AIDS, NORA Coalition, and
8 then on the right-hand side you have what I'd like to
9 talk to you about which has to do with AIDS action
10 recommendation for reauthorization, changes to the
11 AIDS drugs assistance program.
12 There is a great deal of conversation
13 going on about reauthorization and AIDS Action
14 specifically is making a host of recommendations
15 related to the AIDS drugs assistance program.
16 But first let me just summarize for you
17 areas where the community has had unprecedented, I
18 believe, agreement around reauthorization, and we were
19 hoping that we might be able to hear from you all and
20 the administration on principles of reauthority, some
21 next steps.
22 But let me just share with you that the

1 community is in agreement I would say in about nine
2 key areas. One area is, of course, we want to see the
3 act reauthorized. There are some people who think
4 maybe we shouldn't reauthorize Ryan White, but we
5 think it should be reauthorized.
6 There is agreement around the primary of
7 medical care that is inclusive of methodologies to
8 insure access to care and treatment and insure
9 adherence; that we would like to see formula
10 allocations based on living HIV cases; that local
11 planning and local decision making should be
12 continued; that there is an agreement around an ADAP
13 minimum eligibility to be set at at a minimum 300
14 percent federal poverty; and that there's substantial
15 agreement regarding hold harmless recommendations, as
16 well as agreement around the need to continue funding
17 for under served communities and underserved
18 populations.
19 We would like to see increased and in some
20 cases true coordination of federal agencies and
21 resources, and we'd also like to see that there'd be
22 some support given to helping to identify people who

1 are positive, do some case findings, do some outreach
2 and recruitment in an aggressive way, bring people
3 into care, and then methodologies to help retain them
4 in care.

5 And these are areas that I think that if
6 all the community organizations, national and local,
7 were here today, you would find that there is
8 agreement around these key areas and we would
9 encourage the members of PACHA to join us in working
10 toward seeing that some of those key areas are worked
11 through in the reauthorization.

12 One place that I will tell you where there
13 might be some divergence of opinion is our AIDS action
14 proposal for addressing the ADAP crisis. It's in your
15 packet on the right-hand side, and we would like to
16 encourage you to become familiar with our ADAP
17 proposal.

18 It asks for a baseline formulary. It asks
19 for inclusion of all HIV related drugs to be on the
20 formulary, as well as provide an opportunity for
21 portability.

22 And then finally, we are recommending that

1 we move to an ADAP card that would provide information
2 on formulary, collect health outcome data, and be a
3 vehicle that we could use to start to monitor how well
4 we're doing in the epidemic.
5 So the materials are before you. We'd
6 like you to join us, and we'd like you to take this
7 ADAP card and put it in your pocket, and it has our
8 goals for reauthorization of Ryan White.
9 Thank you.
10 MR. GROGAN: Thank you, Marsha. Thank
11 you.
12 CO-CHAIRPERSON SULLIVAN: Thank you very
13 much. Dr. Judson, comment question?
14 DR. JUDSON: I'm sorry. Could you come
15 back to the microphone, please?
16 Just a couple of questions. Is AIDS
17 Action entirely about treatment?
18 DR. MARTIN: No.
19 DR. JUDSON: Ryan White?
20 DR. MARTIN: No.
21 DR. JUDSON: Is it also about prevention?
22 DR. MARTIN: Absolutely. We are very

1 supportive of prevention goals.

2 DR. JUDSON: Okay. Then virtually
3 everything you've requested here is for probably
4 stable or increased funding for existing programs.
5 Are there any programs where you would reduce funding
6 because you feel they haven't been effective in
7 accomplishing their goals and any new programs that
8 you think would be more effective in preventing HIV?

9 DR. MARTIN: Well, actually we make some
10 recommendations. If you take a look at the left-hand
11 side of the package I gave you, there are
12 recommendations for changes and increases to the
13 entire HIV portfolio, and they're based on work that
14 AIDS Action has been doing over the last 15 years in
15 monitoring the federal budget. And so we make a whole
16 host of recommendations around the federal budget both
17 for prevention, for research, and for care and
18 treatment. I was just speaking to reauthorization of
19 the Ryan White CARE Act because it's principally in
20 front of us now.

21 But, no, we have lots we could talk about
22 in terms of CDC, prevention outreach, what our

1 prevention goals are, targeting the conversation to
2 where it really needs to be, and finally really
3 addressing issues like testing routine and health care
4 settings with informed consent and being very clear
5 about what this epidemic looks like in this country
6 and beginning to manage it as well as begin to control
7 it.
8 DR. JUDSON: Thank you.
9 CO-CHAIRPERSON SULLIVAN: I'd also point
10 out, Dr. Judson, the sixth bullet point in this
11 brochure talks about prevention counseling. So that's
12 part of it.
13 Other questions, comments?
14 (No response.)
15 CO-CHAIRPERSON SULLIVAN: Thank you.
16 Any other members of the public who would
17 wish to present now to the committee? Yes, please
18 come forward, identify yourself, and proceed with your
19 presentation.
20 MR. ARNOLD: Sorry, Joe. I misled you,
21 but I guess I could get it out of the way, and I have
22 one copy here which I can leave for you and put in the

1 record.

2 Most of you know who I am. I'm Bill

3 Arnold. I'm the Executive Director of the Title II

4 Community AIDS National Network here in Washington,

5 D.C., and I'm also Director of the National ADAP

6 Working Group. I have appeared before this group five

7 or six times in the last few years.

8 In fact, attached to this, which I will

9 leave so it can go into the record, are my remarks

10 here in 2002, 2003, 2004, and earlier in 2005, and

11 substantially what I'm going to say now, which deals

12 with the current ADAP funding crisis is the same thing

13 that I've been saying before. So you will have heard

14 it again.

15 I've been watching the ADAP history from

16 the glory days of the successful AIDS drug cocktails

17 of late 1995 and early 1996 until today, which we are

18 kind of referring to as the ADAP resources dismal

19 swamp period in terms of resources. My remarks from

20 addressing PACHA in 2002, three, four, and earlier

21 this year are attached herewith and will be reentered

22 into the record one more time.

1 I suspect some in this room thought I was
2 crying "wolf" in 2002 and 2003 when I kept referring
3 to the funding shortage for ADAP. Unfortunately, I
4 was not. My message today is no different than it was
5 then, except it is some years later and the numbers of
6 HIV positive Americans affected is larger and growing
7 larger still.
8 As predicted consistently over the last
9 four years, the ADAP problem has continued, and it has
10 worsened. Official waiting lists have appeared and
11 grown. Unofficial waiting lists, which are sometimes
12 referred to as, quote, extended applications
13 processes, unquote, have shown up. Drug formularies
14 have been reduced. ADAP eligibility has been reduced.
15 Programs and patients' expenditures have both had
16 expenditure levels imposed and caps installed.
17 The pharmaceutical industry has helped
18 carry the inadequately funded ADAP program for the
19 better part of the last two years to well in excess of
20 $100 million. In many cases, industry's extra rebates
21 and additional ADAP crisis price concessions have
22 helped keep the entire ADAP programs open, but at

1 least our doors were open even if they were not able
2 to expand to meet the real needs.
3 President Bush found a much appreciated
4 $20 million last year to rescue -- I put that in
5 quotes -- 1,500 HIV positive Americans then reported
6 on officially that waiting list. But ADAP programs
7 now fear that this September when the President's 2005
8 funds expire these patients may have to be absorbed in
9 the ADAP programs which now already have new people on
10 new waiting lists.
11 Should ADAPs make people who are waiting
12 wait longer come September or should we just stop the
13 medications for the people who are covered by the
14 President's $20 million?
15 We face the possibility of both federal
16 and state Medicare-Medicaid adjustments and cutbacks
17 which can force thousands of HIV patients whose
18 medications were covered by Medicaid to look to ADAP
19 for HIV drugs. There are serious problems on how ADAP
20 will be able to interface with the new Medicare Part D
21 drug coverage in a cost effective and a patient
22 affordable manner.

1 In the meantime, the CDC tells us that we
2 have well over a million HIV positive people, a
3 substantial increase in our official figures.
4 We have extensive tested for HIV status
5 efforts in progress, making use of new HIV rapid
6 tests. However, we are in no better position to
7 guarantee access to care and successful heart
8 treatments to newly diagnosed Americans today than
9 when I sat in the Secretary's Office in this building
10 and said for the first but not the last time -- I
11 think that was 2002 -- that there was no short-term
12 answer to the HIV treatment access crisis other than
13 short-term funding.
14 MR. GROGAN: Bill, wrap it up.
15 MR. ARNOLD: There's only three more
16 paragraphs. It will show up in the record.
17 Like I said, I said it all before in 2002,
18 three, four, and five.
19 Thanks for the opportunity to speak again,
20 and who should I give this to?
21 MR. GROGAN: Thank you. You can give it
22 to me if you'd like.

1 CO-CHAIRPERSON SULLIVAN: Okay. Thank you
2 very much.
3 MR. ARNOLD: Thank you.
4 (Applause.)
5 CO-CHAIRPERSON SULLIVAN: Are there any
6 other members of the public who would wish to comment,
7 who registered to comment?
8 (No response.)
9 CO-CHAIRPERSON SULLIVAN: If not, we are
10 scheduled to hear from Dr. Gottlieb in about eight
11 minutes at 3:20. So I suggest you take advantage of
12 this to get coffee or make phone calls or talk among
13 yourselves, but 3:20 we'll resume.
14 (Whereupon, a short recess was taken.)
15 DR. SWEENEY: Thank you, everybody, for
16 being back more or less on time.
17 It's our great pleasure to be able to
18 present a talk, direct consumer marketing media
19 messaging in HIV prevention, and we have with us Dr.
20 Scott Gottlieb. And I know that we usually let you
21 read all of this on your own, but I will just do a
22 little, just one paragraph because it's noteworthy

1 that Dr. Gottlieb is a former Senior Policy Advisor to
2 the Commissioner of the FDA and to the Administrator
3 of the Centers for Medicare and Medicaid Services at
4 the Department of Health and Human Services.
5 At AEI Dr. Gottlieb researches FDA and CMS
6 regulatory policies. The development of new medical
7 technology and political and clinical trends in
8 medicine, Dr. Gottlieb is also the author of the new
9 Forbes/Gottlieb Medical Technology Investor and
10 Investment Newsletter.
11 He's a graduate of Mount Sinai Medical
12 School, and we present him to the group and thank him
13 for being here.
14 DR. GOTTLIEB: Thanks a lot.
15 My bio says I worked at both FDA and CMS
16 to make it sound like I had two distinct high level
17 senior jobs, but in fact, I worked for the same person
18 in both agencies. I conveniently leave that off.
19 I was asked today to present on media and
20 messaging in HIV/AIDS, to talk a little bit about the
21 history of direct to consumer advertising in this
22 space, and where I think policy could head to try to

1 improve the kinds of communications that you're seeing
2 in the marketplace.
3 I'm not an expert in direct to consumer
4 advertising by any means. I've worked on regulatory
5 issues in this realm at FDA when I was there and spent
6 a good deal of time thinking about how the agency
7 could improve the framework for advertising to help
8 make it more proactive or a more effective public
9 health medium, usually by eliminating some ambiguity
10 about what the rules were to give companies a clear
11 pathway to try to do these things, and so I want to
12 talk a little bit about that.
13 But first, a little history here. I think
14 one of the reasons I was asked to present today on
15 this topic was some recent issues in the media with
16 respect to some criticism of the DTC and the HIV/AIDS
17 space. This was a headline on June 14th, just
18 recently in the Los Angeles Times, which was a story
19 in response to the AIDS Health Care Foundation, the
20 nation's largest AIDS organizations with clinics in
21 the U.S. and all across Asia and Africa, expressing
22 disappointment in the news that the number of people

1 living with HIV/AIDS in the United States had
2 surpassed one million.
3 And the warning came from Michael
4 Weinstein, the president of this organization, and he
5 blamed what he called, quote, mixed messages from
6 Washington on preventive measures, but also said that
7 responsibility lies with the drug companies, he said,
8 whose, quote, high price direct to consumer drug
9 advertising campaigns downplayed the seriousness of
10 HIV, as well as with the FDA, that continues to allow
11 this irresponsible corporate behavior to go unchecked.
12 So it's a pretty strong statement, and I
13 think, you know, that's one reason that we're asking
14 this question today. What is the state of messaging
15 in this space? Has it contributed to the growth in
16 infection rates in this country? And what can we do
17 to improve this situation?
18 My own history here, this is an issue I
19 had thought about a long time ago, back when I was a
20 resident in training, and wrote an op-ed for the New
21 York Times at the time. It probably goes back about
22 seven or eight years, bemoaning what I thought at the

1 time was too much hyperbole on the part of some
2 doctors about their ability to, quote, unquote, cure
3 AIDS.
4 This was about the time that David Ho was
5 on the cover of Time Magazine saying that he's going
6 to cure AIDS, and I felt at the time that this kind of
7 robust talk was contributing to some complacency in
8 the HIV community, and I referenced in the New York
9 Times piece a very personal episode where I was stuck
10 with a needle in the emergency room, while working in
11 the emergency room one night, and had to go on triple
12 therapy for about three or four days until the patient
13 was ultimately tested positive.
14 And the three or four days was very hard.
15 It was hardly a normal life. Now, granted you
16 experience more of the side effects from combination
17 therapy up front. Most patients adapt to the side
18 effects, but it was anything but normal, and so a life
19 spent on these drugs is anything but normal and
20 shouldn't be postulated to be anything different by
21 the media or by physicians, and that was really the
22 thesis.

1 And so I'm sympathetic to some of the
2 views here, but I also think that history has changed
3 with respect to both what doctors are saying and
4 particularly with respect to what companies are
5 saying.
6 Now, that doesn't mean that there aren't
7 occasional episodes where the FDA or the consumers
8 feel that ad oversteps the bounds, and this is a very
9 recent warning letter that was sent out by the Food
10 and Drug Administration with respect to one ad. It
11 actually quotes from the letter.
12 It's actually an untitled letter, which is
13 significant because it means that the agency didn't
14 send it out as a true warning letter. Untitled
15 letters at the FDA don't go through the same legal
16 checks and balances, if you will, and some people
17 would postulate that they don't carry the same legal
18 weight. So things that to out as untitled letters
19 sometimes aren't really enforceable, which is
20 significant.
21 But nonetheless, there was a feeling on
22 the part of the agency, perhaps right -- I haven't

1 seen the ad myself -- that the ads had been overly
2 optimistic about what it was like to live with
3 HIV/AIDS and be on triple therapy.
4 So there are episodes even today, even
5 more recently where ads are perceived by consumers and
6 even by regulators to have crossed the boundary, but
7 it's worth noting a couple of things.
8 One, the number of warnings that have gone
9 out on HIV/AIDS drugs, and I tried to do a count, but
10 I didn't feel I had a full accounting of it and so I
11 didn't want to present it here today, but it has gone
12 down dramatically, and there really haven't been that
13 many more recently.
14 And more important than that, the rate of
15 advertising in this space has really gone down
16 significantly, and this is just some anecdotes,
17 statistics showing the drops over the late '90s into
18 the year 2000s. And the editor of Poz magazine, which
19 is one that has benefitted significantly from this
20 advertising as a financial matter, complaining in the
21 media about the drop to his revenue because of the
22 drop in advertising in direct to consumer advertising

1 of HIV/AIDS drugs.

2 And this is a quote from an advertising
3 executive, again, trying to elaborate on why perhaps
4 this has happened, and he postulates, as other people
5 do when you talk to them in the space, that the
6 companies themselves are reluctant to enter into
7 marketing or advertising arrangements that go direct
8 to consumers because of the backlash, which you saw
9 from the Weinstein quote.

10 I think that it's a little bit more
11 complicated than that. I think this has become, by
12 and large, a less competitive market for consumer
13 advertising. More people are on more tailored
14 regimens. So decisions are really being made by the
15 physicians and not by the consumers, which are the
16 people living with HIV/AIDS.

17 So DTC doesn't matter as much in this
18 market. There are fewer blockbusters. The
19 marketplace is split among more drugs. So you're not
20 going to spend as much advertising, and this is really
21 consistent with if you look at the cancer space, for
22 instance. We don't see a lot of cancer drugs direct

1 advertising to consumers. Really most of it is
2 physician directed because there's a lot of learning
3 that needs to take place about how to tailor these
4 cancer regimens, and most of the decisions are really
5 being made by the physicians because these treatment
6 decisions are highly specific.
7 So you know, companies like Genentech
8 don't advertise directly to consumers, and I think
9 that's happening in the HIV space as it becomes less
10 of a consumer choice about what drug you're on and
11 more of, you know, a choice that's dictated by a
12 pharmacogenomic panel or what have you.
13 So there are multiple reasons why direct
14 to consumer advertising has gone down, but we
15 shouldn't discount the fact that, you know, it's not
16 effective from an economic standpoint, but also from a
17 sort of public relations standpoint because there is a
18 lot of backlash in this space, and it seems like no ad
19 really meets the threshold, the test of what is
20 appropriate. You certainly don't want to pick a very
21 sick person in the ad, but then when you depict a
22 healthy looking person, that has usually caused

1 criticism.

2 I just wanted to back up briefly to talk
3 about the experience of advertising at the agency
4 because it becomes a question of, well, is this a good
5 thing or a bad thing that advertising has gone down in
6 this space. I would postulate a controversial
7 statement that it's bad, that more advertising would
8 be raising awareness and the lack of advertising, the
9 lack of public messaging on the part of the companies
10 is something that we should all bemoan.

11 I'll get back to why I feel that way at
12 the end, but just looking at some of the data that FDA
13 has generated, by and large most of the data supports
14 an important public health role for direct to consumer
15 advertising to the point where when we looked at
16 direct to consumer advertising when I was at the
17 agency and even spoke about it in the community, spoke
18 about it on Capitol Hill, spoke about it even to
19 critics of direct to consumer advertising, it really
20 never was a question of should we end it partly
21 because the courts already spoke to that question and
22 said very clearly that companies had the legal

1 authority to engage in commercial speech under the
2 First Amendment, but also because most people seem to
3 have realized that there is a positive role for direct
4 to consumer advertising, but that you know, where
5 people tended to disagree is on what's appropriate,
6 what kind of ads cross the line, what kind of ads
7 represent fair balance.

8 And so when you talk to consumers you
9 definitely saw a trend towards the advertising,
10 raising awareness in different diseases, prompting
11 consumers to go into the doctor, prompting them to get
12 tested, making them smarter health care consumers, and
13 as the ads got better and as more ads were focused on
14 disease awareness, and I think there was a very strong
15 push in that direction today on the part of the
16 companies, the learning that went on improved.

17 And when you talk to physicians, again,
18 you saw physicians confirming these findings. You
19 also saw physicians complaining -- I think I left that
20 bullet off because it didn't support my thesis. No,
21 I'm kidding -- you also saw physicians complaining,
22 you know, that they had to spend time talking to

1 patients about the drug they saw on TV and why it
2 wasn't appropriate, but that's not the worst thing for
3 a physician to engage the patient in that discussion,
4 and I think physicians who bemoan that are physicians
5 who like to go in and out of the room very quickly or
6 have a very limited amount of time to talk to their
7 patients.
8 I'm not as sympathetic to that as I am to
9 the idea that these ads actually drove patients then
10 to seek treatment or to see a doctor when they
11 otherwise wouldn't have because one of the very
12 difficult things in medicine is just to get patients
13 to be aware of their own symptoms and conditions.
14 Most patients are either very cognizant of
15 it and come in all of the time or are just oblivious
16 to it and only present when they show up in the
17 emergency room with the heart attack or the perforated
18 bowel or the bleed or whatever it is because they've
19 never seen a doctor or really paid attention to their
20 symptoms.
21 So I think that's the background on just
22 direct to consumer advertising in general. Now, when

1 you look at advertising messaging and advertising in
2 the space of HIV/AIDS, again, the literature bears out
3 a positive role. So the first study looked at paid
4 advertising for AIDS prevention, and this was done by
5 the CDC, again, where they were recommending targeting
6 certain populations, mostly young people, people who
7 are at high risk with not so much direct to consumer
8 advertising, but public health promotional PSAs,
9 promotional ads, things like that, help seeking ads,
10 disease awareness ads, and found a very positive role
11 for them, and the other two studies, too, seem to bear
12 out what I've been talking about.
13 And most of the literature in this space
14 really does support that, and where the literature
15 tends to bifurcate is what kind of ads raise awareness
16 the most, what kind of ads drive the most appropriate
17 awareness utilization, behavior on the part of people.
18 There's a lot of literature around whether
19 shock ads are more valuable in terms of driving people
20 to be tested or refrain from risky behavior than ads
21 that aren't shock ads, you know, and things like that.
22 That's where the debate usually lies, but there seems

1 to be no question that there's a role for public
2 messaging and perhaps also a role for advertising done
3 appropriately.
4 The problem, I think, is that as I said,
5 not only do you have withdrawal on the part of the
6 companies engaging in direct to consumer advertising
7 in this space, which again raises awareness of this
8 disease even existing, which it's hard to believe, but
9 awareness in high risk communities is waning and the
10 literature bears that out, but also there's a backing
11 off on the part of some of the not-for-profits that
12 early on in the AIDS crisis, which I'll show you in a
13 moment, engaged in a lot of public health campaigns, a
14 lot of public service announcements collaborating with
15 broadcasters and other media outlets to get out a
16 message about prevention, about seeking treatment,
17 about using condoms or other appropriate measures to
18 try to reduce the incidence of spread of this disease,
19 a backing away from that to the point where recent
20 investments, and this is one example, in public
21 service types of campaigns have focused on raising
22 people's consciousness about the international problem

1 and about their willingness to help participate in
2 international solutions, support contributions from
3 our own government to foreign governments, and things
4 of that sort.
5 And this isn't the only example. There's
6 been a couple of examples like this where the public
7 service campaigns are very broad based ones that have
8 been launched recently that have really focused on
9 this kind of a message rather than on a prevention
10 message or, you know, "don't engage in risky behavior"
11 message here domestically.
12 There's nothing wrong with this. This
13 could be very helpful in raising the world
14 consciousness to this disease and inspiring people to
15 engage in practices and to engage in efforts that are
16 going to help spread the blight or stop the blight --
17 excuse me -- but it's clearly a backing away from
18 where we were in the '80s and '90s, and you can
19 postulate all kinds of reasons why this would be, but
20 I don't think the fact that all of the public service
21 campaigns have been controversial and have been met
22 with some resistance and the direct to consumer

1 advertising and even the disease awareness that the
2 companies did, again, was met with criticism or
3 resistance. I don't think that should be lost in this
4 kind of debate and a discussion about why this is now
5 the trend and no longer to promote prevention and
6 disease awareness here domestically and promote a
7 message of not engaging risk behavior.

8 So how can we get the message back on
9 track, assuming we want to, and I think we do because
10 I think there's an important role for public
11 communications in helping to stop the spread of
12 disease here in the United States.

13 I certainly think that there's a role for
14 direct to consumer advertising. As I mentioned up
15 front, I think all of the literature on DTC ads in
16 other spaces validates the fact that the advertising
17 that the pharmaceutical companies engage in does, in
18 fact, promote awareness, does, in fact, prompt people
19 to come into their doctor, to potentially seek
20 treatment, and in this realm to see testing, making
21 people aware of the signs and symptoms of HIV diseases
22 so that they might be aware that they could be

1 infected just by doing their inventory of their risky
2 behavior and maybe the early symptoms of HIV disease
3 as opposed to waiting for, you know, full blown aids
4 to set in and they show up with, you know, Kaposi's
5 sarcoma or whatever the end stage manifestation of the
6 disease is.
7 So there is certainly a role for DTC
8 advertising, and there's also a very important role
9 for public service campaigns, and I think through Ryan
10 White, in particular, we can explore those more
11 aggressively, which I'll get to at the end.
12 So what can we do to make DTC advertising
13 a more effective tool? We've talked about some of the
14 criticisms that's been levied against it, and
15 certainly some of the ads that seem sort of
16 irrefutable that they cross some boundary of what is
17 smart advertising in this space if you're really
18 focusing on public health messages. You don't want to
19 show a robust person mountain climbing, you know, a
20 10,000 foot peak while they were on triple therapy.
21 It's not going to happen. So that's probably not an
22 appropriate ad. I think that was actually one of the

1 ads that ran back in the '90s that upset people.
2 I think there's more than the FDA can be
3 doing to try and promote better advertising in this
4 space, and I would hope that that would be part of the
5 discussion of this Commission, to look at trying to
6 promote some of those policy reforms at the agency as
7 part of your overall agenda.
8 So I think advertising promotes awareness.
9 You want more speech, not less. The FDA doesn't have
10 the authority to regulate the kinds of ads that people
11 find the most effective, which are the disease
12 awareness ads. It's really an FTC matter, and if the
13 company is not making any product claims, it's not
14 clear that it's really subject to any regulatory
15 authority.
16 But that said, those are the unbranded
17 ads, if you will, the ads that just raise awareness
18 about disease and about linkages between behavior and
19 disease, things like that. But looking at the product
20 specific ads, it could be useful if FDA had specific
21 guidance on the issues that have prompted other ads to
22 run afoul so they could issue therapeutic specific

1 guidance just on HIV ads if they wanted to try to
2 promote more effective ads and try to prompt companies
3 to be more conscious of what the guidelines are here.
4 So that's certainly one thing that the FDA
5 could be doing. So product specific advertising, if
6 you believe my thesis, product specific advertising is
7 down because of the uncertainty in this field.
8 And if you listen to the quotes from the
9 advertising executives, that would certainly seem to
10 confirm that, and so if there was less uncertainty
11 here, that might prompt more companies to engage in
12 more promotion that stayed within the strictures of
13 what the agency felt were the boundaries or seems to
14 align with what the community feels were the
15 boundaries, and the other positive impact that the
16 agency could have if it had product specific guidance
17 here, therapeutic specific guidance is that it could
18 help send a message to the marketplace and to
19 political leaders who often criticize these ads that
20 this is something that we want to promote as a public
21 health matter, advertising in this space, appropriate
22 advertising in this space.

1 And so the agency is making an affirmative
2 statement that there are ads, product specific ads,
3 that could be helpful.
4 So getting to the broader issue of how we
5 can promote an environment of more effective public
6 messaging tools generally, I think we can learn from
7 successful campaigns in other realms. The Office of
8 National Drug Control Policy, I think, provides one
9 very recent effective model for working with popular
10 media to engage in a public services type of campaign,
11 public service announcement type of campaign.
12 I think the PhRMA companies themselves,
13 especially in the current environment, are searching
14 for positive promotion agenda items, and certainly
15 providing opportunity for public-private partnerships
16 with the industry is something that this Commission
17 could think about.
18 And I think Ryan White funding generally
19 should be focused on treatment and prevention, and
20 prevention that also includes public service campaigns
21 and public messaging type efforts. I think Ryan White
22 should be focused on attacking the virus. It's a

1 limited source of funding and there's a lot of
2 infected people, and if we focus that limited money on
3 attacking the virus, I think we can get a lot more
4 bang for our buck, and by attacking the virus, I mean
5 suppressing the virus with treatment and preventing
6 the spread of the virus with efforts that promote
7 behavior that will help mitigate its spread.
8 So I wanted to just briefly touch on some
9 campaigns that have worked in the past. This is just
10 one from the Heartland, the Midwest AIDS Prevention
11 Project. This was the largest nonprofit, community
12 based organization whose sole mission was prevention
13 of HIV transmission, and in 1996 collaborated with a
14 number of other nonprofits in the area to target media
15 towards high risk populations and worked in
16 conjunction with some of the government authorities in
17 the region.
18 Another campaign that was deemed effective
19 was one orchestrated by the Ad Council, again going
20 back to 1988. This was launched at World's AIDS Day
21 on December 1st, 1998, and consisted of some
22 controversial ads that were probably more

1 controversial the day than they would be today, but
2 also some playful ads, some ads that would appeal to
3 younger people, people in more targeted populations
4 about not just promoting awareness of the disease, but
5 promoting awareness about the kinds of activities that
6 promote the spread of the disease.
7 And I encourage you to look back at both
8 of these. They're easy to find on the Web. It's
9 interesting that these ads, most of the follow-up work
10 that was done looking at that impact really validated
11 the campaign and found it to be highly effective.
12 Unfortunately in 2001, the Ad Council
13 shifted the focus of its AIDS campaign from prevention
14 through education to, quote, unquote, inspiring change
15 through awareness with the launch of a new campaign.
16 Now, that was done in partnership with the United
17 Nations Foundation.
18 So again, you see an effort of one that
19 was focused on prevention awareness, had a little bit
20 of shock value, targeted towards high risk
21 populations, particularly young people, people in
22 urban settings, pregnant moms who could have HIV and

1 should go get tested, to focusing on more of an
2 international let's collaborate, let's increase world
3 awareness and world funding for this.
4 Very important. You know, you wish both
5 can go on simultaneously. Unfortunately you don't
6 have a lot of partnership like the Ad Council, and
7 when they shift resources from one thing to another
8 you lose something in the process.
9 A third campaign I just wanted to
10 highlight, National Association of People with AIDS
11 sponsors a national AIDS testing day, which is June
12 27th, incidentally, coming up, and a lot of companies
13 support this. So this is a not-for-profit type of
14 group collaborating with industry to pay for and
15 promote a public services announcement.
16 That, again, doesn't have any product
17 specific information. Gilead is a big sponsor, and
18 they don't have any product specific information in
19 here, but again, promotes awareness in testing.
20 So industry can and should be involved,
21 and I think they want to be hopefully, involved in
22 these kinds of partnerships. They have certainly

1 shown a propensity in the past, and I think we should
2 leverage that.
3 And finally, I mentioned the Office of
4 National Drug Control Policy. This was in 1999, the
5 media campaign. There was a media campaign and
6 related programming surrounding activities that were
7 made possible by a unique collaboration among the
8 Office of National Drug Control Policy, NBC and AOL
9 arising from messages that came out of the National
10 Youth Anti-drug Media Campaign.
11 Basically ONDCP purchased advertising, and
12 it required a pro bono public service match from the
13 network. This was on NBC, and NBC created programming
14 around what at the time was a popular teen NBC, T-NBC.
15 I don't think I ever saw any of it, but apparently it
16 ran on the network during Saturday morning when teens
17 were more likely to be watching TV and also after
18 school and had tie-ins with some on-line media where
19 people could -- they had specific story lines in some
20 of their shows, and then they would run a public
21 services announcement afterwards and give teens a
22 place to go for more information or to chat on line

1 with experts.

2 And this, again, was deemed to be a
3 success, a little bit controversial at the time, but I
4 think in retrospect most of the efforts that have been
5 made to go back and look at it have really been
6 laudatory of the impact it had.

7 And then again, I had mentioned PhRMA
8 companies are searching for a positive promotion
9 agenda. You see PhRMA's code of conduct. You see
10 industry announcing certain measures like a moratorium
11 of one-year advertising by Bristol which I don't think
12 is probably a positive solution, but there are
13 positive solutions here, as I mentioned, with the FDA
14 guidance and some of the public-private partnerships
15 that could be pursued by a commission like this.

16 Finally, I mentioned Ryan White, and I
17 wanted to close on this point. I think the current
18 focus, not to criticize a program that has been very
19 successful and a very important public health effort
20 undertaken by this country and a very compassionate
21 effort, but certainly the current focus focuses a lot
22 of money on overall treatment of the patient and a lot

1 of ancillary health care that goes into not just
2 taking care of a patient who's infected with HIV
3 infection, but taking care of any patient.
4 That's a noble effort, but it might not be
5 the best effort when you have a limited amount of
6 resources and you really want to target this program
7 towards attacking the virus, and so how do you attack
8 the virus?
9 Well, you certainly attack the virus by
10 suppressing the virus in people who are infected with
11 it. Most of the literature bears out that even when
12 patients continue to engage in risky behavior after
13 they are on triple therapy if the virus is
14 sufficiently suppressed, the propensity to spread it
15 goes down dramatically, and so you're going to lower
16 the incidence of spreading the virus, although you can
17 argue by making them feel healthy, you'll put them in
18 a position where they can reengage in risky behavior,
19 but that's certainly not what you want to pursue as a
20 public health agenda, keep people sick so that they
21 can't spread a disease.
22 But what you can do is couple the effort

1 to suppress the virus with efforts to continue to
2 raise awareness about behavior that could spread the
3 disease, particularly in communities that haven't had
4 as long of a history with HIV and aren't as aware of
5 it, particularly the urban poor.
6 Like any other infectious disease, HIV is
7 becoming a disease of the urban poor, and where there
8 is less experience with and less knowledge. So target
9 public service messages there about what kind of
10 behavior could propagate the virus, target messages
11 about, you know, encouraging people to look for the
12 signs and symptoms or know when they might have been
13 exposed to seek treatment, to encourage people to seek
14 testing, to encourage people to just get tested if
15 they think they could have been exposed or could have
16 been in a high risk situation, and encourage people,
17 again, to come in and seek treatment and stick with
18 treatment when they are sick.
19 I think kind of agenda for Ryan White, one
20 that focuses on attacking the virus would really line
21 up the domestic program with the international effort
22 that's underway, which is really targeting the virus.

1 Especially in this country where there are a lot of
2 other services available to support patients overall,
3 not using the existing funding there to attack the
4 virus, I think, is not making the most efficient use
5 of those resources against AIDS.
6 And why this ties in here is because I
7 think when you talk about prevention and Ryan White
8 funding, prevention there really means doing more to
9 try to target high risk communities with a message of
10 avoidance of risky behavior and more testing. So you
11 get people who are HIV positive revealed so that they
12 can get into treatment and live healthier lives and be
13 less likely to propagate the virus.
14 Thank you for your time. I think I'm a
15 little bit short and so I'm happy to take questions.
16 Thanks a lot.
17 (Applause.)
18 DR. SWEENEY: Thank you.
19 We will take questions. We are a little
20 ahead of time. Dr. Green.
21 DR. GREEN: Yes. Thanks for your
22 presentation.

1 You mentioned in passing fear appeals, and
2 you had a 1989 reference I haven't seen before, and I
3 have just written an article about fear appeals. I'm
4 wondering what's your reading of the evidence about,
5 you know, do you feel that fear appeals perhaps
6 combined with self-efficacy motivates and sustains
7 behavior change or not?
8 DR. GOTTLIEB: Yeah. As I said up front,
9 I don't want to represent myself as an expert on
10 advertising or promotional messaging of any kind. My
11 colleague at AEI, Jack Calfey, would be very upset if
12 I represented myself as the expert on that because
13 he's the expert on that.
14 But I did review the literature. I
15 probably reviewed it selectively to be honest because
16 I don't know if I had the totality of the literature,
17 but the literature bears out the effectiveness of
18 those kinds of messages.
19 I don't know. Is that?
20 DR. GREEN: Yeah. There's a meta analysis
21 by Kim Witta, who is the co-author of my article. So,
22 yeah, what you said is what the literature shows, even

1 though it is a widespread belief to the contrary among
2 AIDS experts.
3 The second part of the question is the two
4 ads deemed successful, did they lead to a decrease in
5 incidence or prevalence of HIV?
6 DR. GOTTLIEB: It was felt if you look at
7 the analysis of the Ad Council campaign -- are you
8 talking about the public services campaigns I
9 mentioned?
10 DR. GREEN: Those two ads that you said
11 were deemed successful.
12 DR. GOTTLIEB: Yeah, I think one of them I
13 referred to was the Ad Council's campaign. There was
14 analysis done there that found that to be successful
15 to drive people towards behaviors, you know, greater
16 awareness of the disease, more propensity to seek
17 testing.
18 And the other one where there was some
19 follow-up analysis done was the Office of National
20 Drug Control Policies Campaign with NBC, and that was
21 seemed to have been successful in driving young
22 people, increasing their awareness of drug related

1 issues, driving them to have discussions on the
2 subject.
3 Those were the two where I actually had
4 available and could make available follow-up analysis.
5 DR. GREEN: Okay. So it didn't impact
6 incidence or prevalence, but it motivated --
7 DR. GOTTLIEB: It motivated appropriate
8 behavior.
9 DR. GREEN: -- behavior and awareness.
10 DR. GOTTLIEB: I think it would be hard to
11 -- you're probably more the expert than me, but I
12 think it would be hard to extrapolate from a single
13 public campaign unless it was highly targeted and you
14 had a very good control population to do that kind of
15 analysis.
16 DR. SWEENEY: I want to just see hands of
17 who has questions. I know Lisa does. Dr. Judson, Dr.
18 Sullivan.
19 Lisa, would you yield to Dr. Sullivan,
20 please?
21 DR. SHOEMAKER: Yes.
22 DR. SWEENEY: Dr. Sullivan.

1 CO-CHAIRPERSON SULLIVAN: Thank you. It's
2 more of a question and a comment, and I would preface
3 my comment by saying, first of all, I happen to be on
4 the board of Bristol-Myers Squibb. So you should be
5 aware of that.
6 My comment is in response to your comment
7 that the decision by Bristol-Myers Squibb not to
8 engage in direct consumer advertising for a year is
9 not a helpful outcome. So I guess my question is
10 this. Well, I happened to have been at a board
11 meeting last week. This was presented to the board
12 and this was felt to be a responsible response to the
13 criticism of the pharmaceutical industry for driving
14 consumer behavior in a way that many have criticized
15 in terms of consumers' lack of information for a
16 variety of prescription drugs that are available.
17 Having made that comment, I guess my
18 question is: what would be a better way for the
19 pharmaceutical industry to respond to the criticism
20 that they have been subject to for direct to consumer
21 advertising?
22 DR. GOTTLIEB: Well, I'll tell you why I

1 don't think it is a helpful response, and I was asked
2 about this many times in many private discussions, and
3 I've always been consistent in my view here. And
4 unfortunately I was never asked by Bristol or would
5 they have heeded my advice.
6 But I think there's a lot of --
7 CO-CHAIRPERSON SULLIVAN: Consider
8 yourself asked now.
9 (Laughter.)
10 DR. GOTTLIEB: I think there's been a lot
11 of capital expended over the years and a lot of money
12 spent, effort, good people putting their reputations
13 on the line to support the notion that direct to
14 consumer advertising could have a positive public
15 health impact. I believe that's true.
16 I believe the literature bears that to be
17 true, but selling that idea hasn't been easy and still
18 isn't easy.
19 I think when a company issues a moratorium
20 like this -- and I'm free to speak since I'm in the
21 private sector -- I think it sets back the whole
22 agenda. I think it says that advertising in the first

1 year of a drug being on the market is so bad we
2 shouldn't be doing it at all and there's no way to do
3 it responsibly. And I don't think that's effective.
4 I think that there is a way to do it responsibly.
5 There is a way to do it where it doesn't drive
6 marginal utilization, so that you don't expose people
7 who might not be getting a known benefit from the drug
8 to be subject to known side effects, and that's really
9 your concern about, you know, maybe advertising in the
10 early stages of a drug launch.

11 I think there are ways to do it so that
12 it's effective, and I think some companies right now
13 when you watch TV, you've seen a change in the tone of
14 the advertising, and some companies, I think are
15 finding a much more balanced, effective message that's
16 not turning off consumers, that's, I think, getting
17 regulators excited that there's new ideas out there,
18 that there's new ways to present information that
19 could be more effective.

20 So there is a right way to communicate
21 information even after a drug is newly launched. I
22 think the moratorium says that there's no effective

1 way to do it, and it sets back the agenda of those who
2 want to promote this as a public health tool, myself
3 included in that camp, and it also denies patients the
4 opportunity to hear effective messages.
5 So if you believe there's a positive
6 public health impact for messages even after a drug is
7 newly launched, why shouldn't those messages be in the
8 marketplace?
9 DR. SWEENEY: Lisa Shoemaker.
10 DR. SHOEMAKER: My question is: is there
11 any kind of campaigns that you know of that are
12 underway using famous faces?
13 There's one called RADD, which is
14 Recording Artists and Actors Against Drug Driving, and
15 it's very "bring it home" kind of advertising. Why
16 can't that be like used in this kind of field?
17 The majority of the population doesn't
18 have the intellect that's in this room when it comes
19 to HIV and AIDS. So they are really unaware of what,
20 you know, can and cannot happen to them, and that
21 might be one way of grabbing them. They still have
22 the "won't happen to me" attitude.

1 So is there anything that's underway now
2 that would be directed in that forum?
3 DR. GOTTLIEB: I don't want to represent
4 that I did an exhaustive survey of what's out there
5 because I didn't, but I talked to people who work in
6 PR and advertising in this space and didn't come
7 across specifically what you describe because it would
8 have been compelling. I would have been inclined to
9 include that. So I just didn't see it. It doesn't
10 mean it doesn't exist.
11 But, you know, if four or five advertising
12 PR executives couldn't think of it, it in all
13 likelihood doesn't exist.
14 DR. SWEENEY: Dr. Reznik.
15 DR. REZNIK: I got caught multi-tasking,
16 which is a bad thing.
17 One, I actually do think that there is a
18 benefit from direct to consumer marketing as far as
19 the disease awareness, et cetera, goes, and I do
20 appreciate that portion of your presentation. I think
21 there's not a person at this table who doesn't believe
22 that we need to prevent our way out of this disease,

1 not treat our way out of this disease.

2 My question is, and partly or mostly a
3 statement -- I'll be honest -- is why would you use
4 the Ryan White Care Act, which is the smallest of the
5 three federal payer sources? After Medicaid and
6 Medicare, it's little. It's two billion, but it's
7 small compared to address a prevention advertising
8 campaign when we have in my home City of Atlanta this
9 fabulous thing called the Center for Disease Control
10 with its hundreds of millions of dollars where
11 something like that should be located.

12 So why did you want to put it in the CARE
13 Act?

14 DR. GOTTLIEB: I thought you were going to
15 say the FDA should pay for it.

16 I think CDC should absolutely be doing
17 this, but I think philosophically when you look at
18 Ryan White, I think philosophically, and I guess I was
19 taking a small shot at the philosophical beliefs
20 behind the Ryan White Act and I'm not ashamed to admit
21 that, but I think philosophically Ryan White should be
22 aligned with attacking the virus more than it is

1 today, and that puts a focus of that money on getting
2 drugs to patients, particularly patients who have
3 difficulty accessing drugs.
4 But also as part of that, I think if you
5 philosophically say that these resources are going to
6 be focused on attacking the virus, I think a piece of
7 that is prevention and needs to be prevention. It
8 might not cost any money. It might just take the
9 leadership of the program. I'm not sure of the
10 regulatory ways to do this. It might just take the
11 leadership of the program talking about it, saying for
12 this Commission, saying part of the agenda should be
13 thinking about these things. Maybe they were under
14 the auspices of the Ryan White Act as ways to partner
15 with not-for-profits that could engage in this and it
16 wouldn't cost a lot of money or any at all, or maybe
17 it's just a mandate to the different states from the
18 Ryan White program to try to think about these
19 things.
20 I mean, it could run a whole gamut of
21 effort on the part of that program to try to promote a
22 positive message about prevention that I think would

1 align the program philosophically with the idea of
2 spending the money to attack the virus.
3 DR. SWEENEY: Dr. Judson.
4 DR. JUDSON: In think through the
5 legitimate role of pharmaceutical companies in
6 prevention or advertising prevention, I've just always
7 felt that there was in most cases probably an
8 unbroachable conflict of interest there, and I'm not
9 saying this is bad. I totally believe in free
10 enterprise and private market economy.
11 But I think that all you can expect from,
12 the best you can expect from a pharmaceutical company
13 is that there will be situations in which promoting
14 prevention or public health will also help them to
15 increase market share for their products and perhaps
16 even profit margins. And where those two goals come
17 into conflict, you can't expect them to do it.
18 I wanted then to make a couple of
19 analogies between tobacco advertising, the tobacco
20 industry, and the pharmaceutical industry, but start
21 off right at the beginning saying the purpose of the
22 pharmaceutical industry is to create products that

1 make you healthier, where the unfortunate goal of the
2 tobacco industry was to create and market a product
3 that made people sick.
4 So that's a very fundamental difference,
5 but then getting back to some of the excesses in
6 advertising that have occurred for HIV drugs and I
7 think still occur, you said 1999. In march when I
8 returned from our PACHA meeting and the last time I
9 looked, there was a giant in the Denver International
10 Airport ad that had been there for at least three
11 years in one form or another showing an incredibly
12 healthy, fit, tanned, presumably gay man rapelling off
13 the side of a mountain, and it's still there. It was
14 in 1999.
15 And to me the best single analogy to that
16 advertising were the Virginia Slims ads, where you're
17 simply saying that having AIDS or HIV may actually be
18 something good or desirable. There's certainly
19 nothing negative whatsoever about the appearance of
20 having HIV that was portrayed in that ad. If
21 anything, everything about it was to be desired.
22 So that's where you get into the roles of

1 restricting advertising. You give a false impression
2 or create, run counter to public health goals. Our
3 true public health goal is to have massive, large
4 scale, sustainable changes in human exposure behavior
5 to the virus, and where tobacco was to reduce both
6 supply and demand in both sides of the public health
7 equation, in California tens of millions of dollars
8 were converted into counteradvertising, and these
9 clearly used the fear factors. They let you know that
10 the tobacco industry directors and boards were not
11 your friends and were not interested in your well-
12 being in the long term. And then they tried to go to
13 every negative portrayal they could, from showing a
14 fetus smoking to your teeth falling out.
15 Those particular views are really not too
16 extreme for what HIV does to individuals, their
17 fetuses and so forth, and whether truly portraying the
18 negative outcomes that most people cannot afford to
19 get HIV infection. This is another analogy.
20 I was driving around Philadelphia not too
21 long ago, and I saw that Pennsylvania has these signs
22 up that say, "DUI, You Can't Afford It." The same

1 thing would be true for HIV were it not for Ryan White
2 or some of these other government programs.
3 So I think the negatives, the huge
4 negatives from economic to health to fetuses, we
5 really, really have to restrict the laborization and
6 promote the absolute true negatives that hopefully
7 will encourage people one way or another to avoid
8 exposure.
9 DR. GOTTLIEB: Well, a couple of comments.
10 I appreciate your thought very much.
11 To start off on the tobacco companies --
12 and I'm by no means an apologist for tobacco companies
13 as a physician, but you might as well accuse them of
14 what they did, which was to try to get people to be
15 long time users of a horrendous product not to make
16 them sick because once they became sick, they couldn't
17 use it anymore, and so it was more to get them
18 addicted.
19 but I'm very sympathetic to what you said,
20 and you know, my own speech on this subject, harkening
21 back to when I was a resident, I think, hopefully
22 reflects that I, too, found the public message that

1 the time to be counterproductive, promoting an overly
2 optimistic picture of what it was to be on triple
3 therapy.
4 And if you think that writing an op-ed
5 like that in the New York Times when you're a medical
6 resident and you're criticizing your attendings is
7 easy, it wasn't, and I got retribution for it, but
8 that aside, I'm surprised that those -- well, I'm not
9 surprised because you saw the Bristol letter that I
10 put up, and that was a recent ad, but I think the
11 number of ads of the kind you describe have gone down
12 dramatically. I'm actually surprised that companies
13 would still do it because they've had years of
14 backlash at those kinds of advertising, but I think
15 that's a place where, again, the FDA could step up and
16 issue therapeutic guidance, if this is an important
17 public health goal, if this is part of an important
18 public health agenda.
19 Because once the agency articulates in
20 guidance what it thinks runs afoul of the law and what
21 doesn't represent fair balance, it becomes very hard,
22 much harder for companies to cross those boundaries.

1 The lines become very clear. They're right.
2 We used to talk about creating bright
3 lines at the agency, and so as long as your bright
4 lines were within the boundary of what the law says
5 the agency could do, I think it pays for the agency to
6 be engaged in that, and so that's someplace where I
7 think a clearer statement by the agency could be
8 helpful in helping companies not only avoid the ads
9 that we think are violative, but also give them the
10 comfort to engage in ads that we think are a positive
11 public health effort.
12 Getting to your conflict of interest
13 issue, there's no question that there's at least the
14 appearance of conflict of interest here if not an
15 overt conflict of interest because the conflict is
16 that the more patients that get diagnosed with HIV,
17 the more patients who get on treatment, the more
18 profits the companies make.
19 That to me is a very healthy conflict of
20 interest. I mean, you have it in the HIV space to an
21 extent, and you probably had it early on. I don't
22 think you have it as much today, but certainly if you

1 make an analogy to Hepatitis C where Hepatitis C is
2 largely a silent disease, people don't know they have
3 Hepatitis C until they end up, you know, with end
4 stage liver failure and only a certain portion of
5 patients do.
6 So there there is a real interest on the
7 part of companies that make Hepatitis C products to
8 get patients diagnosed early so they can get on those
9 treatments and get cured of the Hepatitis C earlier in
10 the course of their disease perhaps.
11 And I think right now a lot of the
12 treatments are saved for patients who become more ill
13 with Hepatitis C. I think once you have on the
14 marketplace a very easy treatment for Hepatitis C that
15 could be given to patients early in the course of
16 disease and knock it out without a lot of side
17 effects, you're going to see disease awareness
18 advertising go through the roof because once you
19 diagnose the whatever millions of patients in this
20 country -- I don't know the figure offhand -- who have
21 Hepatitis C and you can give them a pill for two weeks
22 and it goes away, there's going to be a company. The

1 company that develops that drug is going to have a
2 real, real financial incentive to get people to, you
3 know, go to the doctor and ask for a Hepatitis C test.
4 That will be a very healthy conflict of interest.
5 And so I don't think the conflicts of
6 interest are necessarily a bad thing. I think they
7 help promote more effective communication in the
8 marketplace. So I wouldn't discount the value of
9 trying to tap into them and promote them along the
10 pathway that you think is the most effective in the
11 public health agenda.
12 DR. SWEENEY: We have three questions:
13 Hank, then Karen, then Jackie.
14 DR. McKINNELL: Scott, I would agree with
15 your statement that there's no benefit to companies
16 running ads that make people mad. So clearly there is
17 some area of what you call a boundary or a threshold,
18 but the problem is there's no bright line or agreement
19 on what those might be.
20 I would not rely on government to solve
21 that problem for us. The industry association, PhRMA,
22 is now working on guidelines for direct to consumer

1 advertising, in fact, what I prefer to call direct to
2 consumer education, and I think there's a number of
3 just kind of common sense points here.
4 One is you should educate the physician
5 before you educate the public. Now, it may well take
6 Bristol a year to do that. Others may be able to do
7 it a little more rapidly. So I'm not sure what the
8 right time is, but I certainly do agree that we should
9 be educating physicians before we educate consumers.
10 If you don't want to see erectile
11 dysfunction ads between six in the morning and ten
12 o'clock at night, I think that's right. I happen to
13 agree with that. So I think there's a number of
14 common sense thresholds or boundaries, whatever you
15 want to call it, that the industry is quite prepared
16 to accept voluntarily.
17 We're not quite sure what those are. So I
18 guess my suggestion would be particularly in this
19 field of HIV/AIDS what do you think those boundaries
20 should be, and if you have some ideas, and I'm kind of
21 speaking to the back of the room now, too, let PhRMA
22 know, and we'll take a look at them. If they're

1 reasonable, not portraying healthy people, apparently
2 normal, healthy people in HIV/AIDS ads I think is
3 absolutely right. People ought to not be misled by
4 what they see.
5 So if anybody has any suggestions, get
6 them into PhRMA and you may well see them turn up in a
7 code of conduct.
8 DR. GOTTLIEB: I spoke to some -- back to
9 your point about educating physicians, perhaps Bristol
10 doesn't have as big of a detailed sales force as
11 Pfizer, but --
12 (Laughter.)
13 DR. GOTTLIEB: -- so it will take them a
14 year to get around, but --
15 DR. McKINNELL: Just for the record, I
16 didn't say that.
17 (Laughter.)
18 DR. GOTTLIEB: With respect to your
19 statement about, you know, this group coming up with
20 some consensus or the community coming up with
21 consensus, I spoke to some D.D. Mack lawyers before I
22 came here, people who practice drug advertising law in

1 Washington, and they, you know, to a person said,
2 "Well, I wouldn't want FDA setting the norms of what
3 is good advertising because it's really not what their
4 legal mandate is."
5 They set boundaries. The boundaries
6 probably fall at least in this space, maybe others, in
7 a gap that isn't as narrow as what people here in this
8 group would feel is appropriate or people in the HIV
9 community or even the physicians community would feel
10 is appropriate because what we might feel is
11 inappropriate is perfectly legally permissible, and
12 the FDA, after all, can only regulate up to the point
13 of the boundary of the law.
14 And so when I talked to the lawyers, they
15 said to me, well, you should tell this group, you
16 know, it's fine to talk about guidance from the
17 agency, but you should tell this group that they
18 should have that discussion.
19 So I'm glad you said that, and I'm sorry I
20 left that out of my discussion. I think you ought to
21 follow it, too.
22 DR. JUDSON: Well, as a physician treating

1 AIDS patients for a long, long time, having a large
2 clinic, I thought about that, and I actually don't
3 think direct to consumer education about specific
4 anti-AIDS drugs is very useful, and I think it's such
5 a complicated area and there's so much literature
6 bearing on it, more all the time, that to come up with
7 recommended guidelines or treatment recommendations
8 for HIV requires huge, knowledgeable committees, the
9 input of a great deal of science, and that the direct
10 ads really can't add to that. All they can do is
11 provide patients with an extremely limited amount of
12 information that's often product specific and that
13 isn't going to help them receive the very best or
14 recommended treatment.
15 DR. SWEENEY: Dr. Judson?
16 DR. JUDSON: Yes.
17 DR. SWEENEY: You're out of turn.
18 (Laughter.)
19 DR. SWEENEY: Karen.
20 MS. IVANTIC-DOUCETTE: Thank you, Monica.
21 I took note that you are a proponent of
22 DTC as a public health tool, and I myself am not sure.

1 I don't know where really the boundaries are, but I
2 wanted to call your attention to one of your slides
3 that talks about the results of an FDA survey of 500
4 physicians in the U.S. about DTC and some of the
5 language in there seems more positive, like there are
6 more physicians that support DTC. At least I would
7 take that as a positive spin.
8 But you had a survey presented that said
9 many physicians believe that DTC advertising can play
10 a positive role. Do you have any information about
11 the percentage?
12 Some physicians thought that the ads made
13 their patients more aware of possible treatments. Do
14 you have any objective data on that?
15 Many physicians thought that the DTC ads
16 made their patients more involved in health care.
17 What is "many"?
18 And then 40 percent of physicians believe
19 that patients understood them well. Does this mean
20 that 60 percent did not feel the patients understood
21 well, or what do you have as far as objective data
22 with that?

1 DR. GOTTLIEB: Yeah, I apologize. I don't
2 have the breakdown of the numbers in front of me. I
3 actually took this language from congressional
4 testimony that was presented, and I did that quite
5 consciously, and probably the Congressman had the
6 back-up study available to me at the time. I just
7 didn't bring it today.
8 But I certainly didn't mean to mislead the
9 Commission. The 60 percent that wasn't the 40
10 percent, not all of them felt that the patient didn't
11 understand it, but they had various opinions that
12 would indicate that. So they felt that the patients
13 didn't fully understand the risks, didn't understand
14 the risks at all, were overly optimistic about the
15 benefits. So they had some kind of understanding that
16 wasn't in sync with what the physician felt was a
17 clear understanding of the drug's efficacy.
18 On the other stuff I'd be happy to provide
19 it or E-mail to have one on the Commission. I
20 mentioned that I left off a bullet there about the
21 doctors, which is probably the most negative thing you
22 can have a study about the doctors, feeling that

1 the -- well, there were two things that were negative
2 about the study.
3 One, feeling that the patients didn't come
4 away with a clear perception of the risks, which was
5 part of that 60 percent, and that the doctors felt
6 that they had to spend part of their patient
7 interaction or a good part of the patient interaction
8 in some cases trying to explain away the
9 misperceptions so that the drug wasn't the appropriate
10 drug for the patient when the patient felt that it was
11 after seeing the advertising.
12 And those were clearly the two most
13 negative expressions that came out of this survey, but
14 the survey is available publicly, and I'm sorry. I
15 didn't mean to leave the wrong impression on the
16 Commission.
17 MS. IVANTIC-DOUCETTE: That would be
18 great. If you could get that to us, that would be
19 great.
20 DR. GOTTLIEB: I did mean to make a point.
21 So I guess it's the same thing.
22 DR. SWEENEY: Jackie, and then Dr.

1 Sullivan.

2 MS. CLEMENTS: Okay. I have a real brief
3 comment. You know, when it comes to direct consumer
4 advertising, I think we need a fair balance because
5 certainly my pretty face on an ad after 20 years of
6 infection would not do much for prevention, but it
7 might do something for care and treatment and access
8 to care and adherence to medication. So I think that
9 it does serve some benefit to those one million
10 people, you know, that are living with HIV, trying to
11 remain healthy and the hope that they can remain
12 healthy with the meds that are out now.

13 So I think we need a fair balance.

14 DR. SWEENEY: Dr. Sullivan.

15 CO-CHAIRPERSON SULLIVAN: I just had two
16 quick comments, one for Dr. Gottlieb and one for Dr.
17 McKinnell.

18 DR. GOTTLIEB: Is this about the sales
19 force?

20 (Laughter.)

21 CO-CHAIRPERSON SULLIVAN: And that is you
22 mentioned the desire of having FDA perhaps give more

1 guidance to the tobacco industry about advertising,
2 and the reality is that the Congress has prevented the
3 FDA from doing that. The FDA has wanted to have some
4 regulatory authority over the tobacco industry, but by
5 congressional action, the FDA is prevented from doing
6 that.
7 And I guess for Dr. McKinnell I just
8 wanted to ask him if he has the remotest idea which
9 companies he has in mind that might do a better job of
10 direct to consumer advertising.
11 (Laughter.)
12 DR. SWEENEY: I just wanted to say Lisa
13 had asked whether or not there was anyone famous doing
14 ads for HIV medications, and the answer is yes, and I
15 don't know if you know the Magic Johnson Bristol-Myers
16 -- no, Glaxo. Oops, I didn't mean to say that.
17 DR. GOTTLIEB: Is that still going on?
18 DR. SWEENEY: I didn't even mean to say
19 who it was. Never mind.
20 Anyway, one of the issues with direct to
21 consumer advertising, and you might want to comment
22 because I'm one of those physicians who feel that the

1 patients who come in and want the little purple pill
2 when they really should take a Tums is really an
3 issue.
4 But what happened with the Magic Johnson
5 ad was that in a community where health literacy is a
6 really big issue, where people misunderstand, where
7 they're distrustful of the medical community to start
8 with, people thought when the ad said that Magic
9 Johnson had no detectable levels in his blood, they
10 thought it meant cured, and so when you are doing
11 direct to consumer advertising and you have one
12 message that's going out there, you are not taking
13 into consideration the various levels of linguistic
14 educational and cultural competency and can
15 miscommunicate information or mislead people, and
16 there are actually people now who think either he was
17 never positive or that he's been cured of HIV.
18 So that --
19 DR. BENY PRIMM: Or that he was has some
20 special medication.
21 DR. SWEENEY: Yes, that's right. That is
22 the other one.

1 So that I on television said that I
2 thought the ads were detrimental and that they should
3 come down, and they were changed, but not before the
4 damage was done that undetectable means cured.
5 So I would like you to comment on that,
6 please.
7 DR. GOTTLIEB: Well, I think that's
8 getting to the question of what is permissible from a
9 regulatory standpoint. I can't comment whether that
10 kind of statement runs afoul or whether the FDA even
11 issued a warning letter on that.
12 And if it doesn't cross the boundary of
13 what's legally not permissible, whether or not it
14 conforms to the consensus of the community, and a
15 statement from a Commission like this or the consensus
16 guidelines from PhRMA, whatever it might be about what
17 the messaging should be, and I think if you really are
18 serious about looking at trying to promote more
19 positive advertising in this space you need product
20 specific, therapeutic specific advertising because the
21 issues here are so much different than they are in a
22 lot of other diseases where a statement like that

1 wouldn't necessarily have a negative impact.
2 But certainly you're right. A statement
3 like that in this space could, probably does have a
4 negative impact because of misunderstanding that it
5 breeds, and it might not represent fair balance.
6 Just an observation on the DTC issue with
7 physicians, I think I'm still practicing, and I
8 certainly have my share of patients who come in and
9 ask for certain drugs by name, and I think it's just a
10 reality of life certainly because the courts have
11 clearly spoken to the companies that do this.
12 I think it's going to be a growing reality
13 of life because as you see the pharmaceutical
14 companies moving into more specialty focused product
15 areas with more of the marketing isn't to patients but
16 to doctors who made decisions about prescription
17 information, you're going to see more and more the
18 primary care drugs being delivered maybe even over the
19 counter, but certainly by companies that are more
20 engaged in consumer products.
21 And the consumer products companies aren't
22 going to have big sales forces. They're not going to

1 sell drugs to physicians. They're going to sell
2 directly to consumers. And so I think when you look
3 at the spectrum of advertising that we're facing in
4 the future, the next ten or 15 years, it's going to be
5 by different companies. It might be outside of the
6 regulatory purview of the FDA because more of these
7 primary care drugs will be driven over the counter,
8 and I think it's going to increase, not decrease.
9 And I don't think it's going to be the
10 actors who are advertising a lot today. I don't think
11 they'll be the ones advertising ten years from now
12 because they'll be out of the primary care drug space,
13 which is the space where you want to be advertising to
14 the consumer and not necessarily to the physician.
15 It's just an observation. It doesn't
16 impact this discussion, but I think as physicians if
17 we're really annoyed by these ads, we should be
18 speaking publicly as physicians about what we feel is
19 a positive message. I think that can have a lot of
20 impact certainly when the AMA speaks because it's not
21 a regulatory issue, although people would like to make
22 it a regulatory issue. It's not.

1 And when the regulatory agencies step in,
2 they are often running afoul of the law, and certainly
3 if it's an OTC product, the FTC has very limited
4 authority there.
5 And so if we don't want patients coming in
6 asking for products by name, we need to be speaking
7 out as physicians in the community.
8 DR. SWEENEY: One last comment from Lisa.
9 You have the last word.
10 DR. SHOEMAKER: I just wanted to clarify
11 myself when I was talking about RADD and famous faces.
12 I wasn't necessarily saying about people who were
13 infected with the disease, but also to have behavioral
14 changes, like RADD is talking about drug driving, to
15 not drive drug, that kind of thing, which brings
16 everybody into the realm that there's a possibility
17 that if you don't change your behavior you could get
18 this disease and also use it as a key for testing, to
19 get people who are famous faces to get tested and say
20 this is important to have done.
21 So I wanted to clarify myself. That's
22 what I meant.

1 Thank you.
2 DR. SWEENEY: Thank you very much, Dr.
3 Gottlieb.
4 (Applause.)
5 CO-CHAIRPERSON SULLIVAN: Thank you very
6 much, Dr. Sweeney, and the Prevention Committee for a
7 very helpful presentation.
8 It's now time for any final comments or
9 wrap-up for the day, and David Reznik has a comment.
10 DR. REZNIK: I do, and it's not actually
11 related to -- it's something I want people to think
12 about tomorrow. I just came from the HRSA
13 International AIDS Society clinical care update where
14 there was 400 physicians and mid-level providers,
15 mostly physicians there getting trained on the latest
16 information on HIV and AIDS.
17 And at the faculty dinner I had one of the
18 most interesting conversations I think I can remember,
19 and this is what I want people on the prevention and
20 treatment committee to think about for tomorrow.
21 There's a very prominent physician from
22 the National Medical Association who was at the

1 faculty dinner, and he was concerned that the Public
2 Health Service guidelines and the International AIDS
3 Society treatment guidelines were too low and that
4 there was a problem with more than one, multiple of
5 his patients and his colleagues' patients getting
6 reimbursed for treatment. These people had insurance.
7 They're written antiretrovirals, but the insurance
8 companies weren't paying.

9 So he is in charge of coming up with new
10 recommendations for the National Medical Association
11 on treatment guidelines, and the reasoning behind this
12 was that the man -- let's just use one example -- the
13 man was not willing to disclose his status to his
14 wife.

15 I think that the two groups have got to
16 get together and we have got to address this issue.
17 This was not just a sidebar conversation. This was a
18 significant conversation in front of people like
19 Michael Sagg and others that were there, and I think
20 it's an issue that we must find a way to address.

21 CO-CHAIRPERSON SULLIVAN: Thank you very
22 much.

1 Dr. McKinnell and then Abner Mason.
2 DR. McKINNELL: Yes, I would encourage the
3 Treatment and Prevention Committee to find a way to
4 get on the table the issue of routine testing because
5 it really seems to me crazy.
6 Somebody was here talking about a needle
7 stick late at night. It seems crazy to practice
8 medicine not knowing someone's HIV status in today's
9 world. It's like trying to practice medicine not
10 knowing somebody's blood pressure.
11 DR. REZNIK: We've got the CDC guidelines.
12 I mean, we need to reinforce it. I agree with you
13 completely.
14 DR. McKINNELL: But in the county
15 hospitals there is no testing unless people ask for
16 one. So it should be routine unless people opt out.
17 So if you don't want to have your blood pressure
18 taken, just say, "No, thanks." But it should be
19 routine that people are offered HIV testing.
20 DR. REZNIK: It says, "Know your numbers."
21 And that's one of the things that we need to do.
22 DR. SWEENEY: Dr. Sullivan, may I just

1 address that?

2 Hank, would you -- I just said Hank

3 because Dr. McKinnell just brought up that he wants us

4 to talk about routine. I will ask all of you to

5 please read the prevention outline before tomorrow

6 because it's on there. It takes about ten minutes to

7 read it unless you're a slow reader like I am, and

8 it's on there, routine testing.

9 DR. McKINNELL: Well, that's great, but

10 why can't we talk about it?

11 DR. SWEENEY: Oh, we can tomorrow. We're

12 going to tomorrow.

13 DR. McKINNELL: But we can't make it a

14 resolution, you said? I missed that maybe.

15 DR. REZNIK: We'll work on a resolution

16 because I've said twice here and I imagine at some

17 point I'm going to get fired from my health system,

18 but my health system, the Women's Urgent Care Center,

19 the Urgent Care Center, and the emergency room do not

20 do rapid testing. These are at risk, old CDC target

21 individuals who are going undiagnosed.

22 Now, I understand that something is up

1 with the CDC. They are going to do some kind of new
2 outreach, but it doesn't materialize, and as far as
3 I'm concerned enough is enough. We must have at least
4 -- and we're talking about doing routine testing in
5 private doctors' offices or in public health studies.
6 This is an old target. This is an urban public
7 health hospital system, and it's not just Atlanta.
8 It's Chicago, it's New Orleans, it's all over the
9 country.
10 MS. CLEMENTS: I'd like to say that in
11 North Carolina in a community health center we're
12 trying to, we would like to do routine testing. We
13 can't afford the tests.
14 CO-CHAIRPERSON SULLIVAN: Just a comment I
15 would like to make.
16 MS. CLEMENTS: Cost is an issue.
17 CO-CHAIRPERSON SULLIVAN: Is that this
18 committee previously heard from, I guess, one of the
19 companies, OraSure, and I think we in some way
20 endorsed the availability of the oral test as a rapid
21 test, but I gather what you're saying is that that --
22 and there may be other oral tests, too, or rapid tests

1 -- are not affordable. Is that what you're saying?
2 MS. CLEMENTS: Well, our clients can't pay
3 for the cost, and the community health center cannot
4 budget the cost. The Health Department gets a few
5 tests from the CDC. The State Health Department gets
6 a few from the CDC that's distributed across the
7 state, but it's not enough to give to the community
8 health center to do routine testing to all the clients
9 that present there. So it's a cost issue.
10 CO-CHAIRPERSON SULLIVAN: This is a
11 legitimate topic for tomorrow's discussion as a
12 follow-up to what we've done.
13 DR. REZNIK: I just wanted to add at
14 SAMHSA we had the presentation today, and it was very
15 proud that they had distributed 200,000 tests. That's
16 nothing.
17 MS. CLEMENTS: That's nothing.
18 DR. REZNIK: I mean, that's the point.
19 We're not where we should be with testing.
20 MS. HALL: Dr. Sullivan, those tests cost
21 about 13 to $15 per test and for the SAMHSA you have
22 to have a SAMHSA grant to be able to access those test

1 kits.
2 DR. REZNIK: And the training is issued
3 there, too.
4 MS. HALL: Yeah, the training is issued.
5 That's easy, but we are doing it, and it's costing
6 quite a bit. It's moving from $9 to $15.
7 CO-CHAIRPERSON SULLIVAN: I think Co-chair
8 Smith has a comment, yes.
9 CO-CHAIRPERSON SMITH: It would seem to me
10 that we might want to craft something in the form of a
11 resolution, tie it to the recent CDC numbers that are
12 increased above where any of us thought they were, and
13 make it a matter of priority.
14 CO-CHAIRPERSON SULLIVAN: Dr. Judson.
15 DR. JUDSON: Well, I think this is a
16 battle, Hank, that's been partly won, and it has been
17 won over time, but a few things remain to be done, and
18 I think there's general acceptance at CDC level and
19 most other prevention areas that there should be
20 basically at most opt out provisions for HIV testing
21 within almost all areas of routine care.
22 And this has occurred. I know that my

1 wife, for instance, who had no risk factors was tested
2 for HIV at age 45 through Kaiser. Ten years ago they
3 had already moved to that, and we have done so through
4 most of Denver Health and Hospital Services. It
5 became a routine opt out for all OB-GYN patients, OB
6 patients eight or ten years or so ago.
7 I think the advancing HIV prevention
8 program for CDC clearly has that as one of their three
9 or four key new areas. It is being generally accepted
10 as standard of care. That's where you win that
11 battle, is when all of the regulating or certification
12 agencies accept that as standard of care.
13 And then the final step is that the payers
14 are there. So that has to be taken payer by payer.
15 Kaiser will pay for it. Most HMOs will pay for it as
16 soon as it becomes standard of care, and they are
17 evaluated on it. If Medicaid and Medicare have not
18 done that, they should. We should see that that's
19 done.
20 CO-CHAIRPERSON SULLIVAN: Well, I clearly
21 think this needs to be addressed by our committee
22 tomorrow because if the cost is $13, that's no greater

1 than routine blood tests that are readily available.
2 So clearly for something that makes a big difference
3 in the lives of people, this would seem so.
4 Are there other -- oh, yes.
5 MR. MASON: Not on that subject, but it's
6 just a process issue. For resolutions, if we can get
7 them to people, some people wanted to have resolutions
8 in advance of tomorrow. So if we can do it, we'll
9 distribute them either later today or at the hotel
10 tomorrow or how do you want to?
11 A couple of people asked me about it. We
12 have two resolutions, and now it looks like there may
13 be a third one that hasn't been drafted yet.
14 MR. GROGAN: Well, depending on when you
15 can get them to me, I could send some over to people's
16 hotels, I suppose, but at the very least I could have
17 them ready the first thing in the morning to people
18 when they come back here.
19 MR. MASON: Okay.
20 MR. GROGAN: Just let me know after the
21 break when you think you can give me a copy.
22 MR. MASON: Okay.

1 CO-CHAIRPERSON SULLIVAN: Dr. Yogev.
2 DR. YOGEV: As long as we're talking about
3 standard of care, I think we need to really seriously
4 take the other element out, too, which is pattern of
5 notification. This is one of the few diseases that we
6 can save a lot of patients by pattern of notification,
7 and that should become an STD. We should make it a
8 disease and not a political entity. I would love to
9 see the prevention people adding that into the
10 discussion.
11 CO-CHAIRPERSON SULLIVAN: Dr. McKinnell.
12 DR. McKINNELL: Just to ask that a little
13 more broadly, if your goal was to reduce infection
14 rates to zero, what would you do? We should have an
15 answer to that question, and surely it would be
16 testing. Surely it would be tracking. It would be
17 all of these things we're talking about.
18 So let's look at what it would take to
19 reduce infections to zero.
20 CO-CHAIRPERSON SULLIVAN: Dr. Sweeney and
21 then Dr. Green.
22 DR. SWEENEY: We agree, and it's in there.

1 DR. McILHANEY: Wait until you read it.
2 It's really good. You're absolutely right.
3 DR. SWEENEY: There are things in there
4 that you have mentioned, and there are things that you
5 haven't mentioned, and there are things in there we're
6 not sure once you see them you'll want them in there,
7 but they're in there.
8 DR. GREEN: I had a comment about partner
9 notification because Dr. Yogev mentioned this. In my
10 book Rethinking AIDS Prevention, I have a description
11 of Jamaica's program of partner notification. They've
12 been doing this for years even though few other
13 countries do this, and the people who notify partners
14 of those found to be HIV positive pose as preventive
15 educators, and there were no complaints. There was no
16 evidence that anybody had been sort of outed or, you
17 know, that their status was made known to others in
18 the community because they did it that way. So it can
19 be done.
20 CO-CHAIRPERSON SULLIVAN: Thank you.
21 Yes, Dr. Yogev and then Dr. McIlhaney.
22 DR. YOGEV: On a completely different

1 topic, can I make a request to have less speakers at
2 the meeting and more time for questions? I think we
3 did a disservice to Dr. Reznik to be today the person
4 who cut. The most important part for me is the
5 discussion about the topic, and what happens too often
6 too many of us cannot express, ask questions, which
7 helps at least for me much more than something that's
8 too many topics.
9 CO-CHAIRPERSON SULLIVAN: If I might
10 respond to that, I agree with you. I see two issues
11 there. One, I think our speakers did not take too
12 long for their presentation, but I think many of the
13 questions were too long and with the statement, et
14 cetera.
15 But also many of the speakers took too
16 long, I think, in their answers. So the time was
17 eaten up. So I think if we might ask the committee in
18 the future to try and be sure that your questions are
19 concise, and, Joe, if you could give guidance to our
20 speakers that for the question and answer period
21 hopefully they could give us concise answers and not
22 really very long dissertations because that really

1 does take time away.
2 Thank you.
3 MR. GROGAN: I also give them all guidance
4 about how long their presentations should last and
5 have a fair amount of feedback with them about what
6 they're going to say and how much material they need
7 to present. So I try and make sure that they leave
8 time for Q&A, at least 15 or 20 minutes.
9 Sometimes people don't pay attention to me
10 and they go over.
11 (Laughter.)
12 MR. GROGAN: I know that's really hard to
13 believe for everyone here.
14 CO-CHAIRPERSON SULLIVAN: I think if you
15 get a gavel and a sword for the Chairman, we'll take
16 care of that problem.
17 Dr. McIlhaney. Yes, Ms. McDonald.
18 MS. McDONALD: Well, hello, everybody.
19 I'd certainly like to concur with limiting the
20 speakers. It seems to me that we as a body don't get
21 a chance to do enough real work. I think that we
22 certainly love the presentations and the presenters,

1 but I also would love to see us work in equal time to
2 really work on some very, very key issues, and so I
3 just will offer that as a suggestion.
4 CO-CHAIRPERSON SULLIVAN: Okay. Thank you
5 very much for that comment.
6 Are there any other comments?
7 (No response.)
8 CO-CHAIRPERSON SULLIVAN: Then I will see
9 if our Co-chair Anita Smith has comments. You will be
10 in charge tomorrow, so you might give us any guidance
11 for tomorrow, and then Joe will close us out.
12 CO-CHAIRPERSON SMITH: Okay. Thank you,
13 Dr. Sullivan.
14 Thank you, fellow committee members, for
15 sitting through a long day. It was a full day. I
16 think we had good discussion, a lot to think about.
17 I'm going to go back and resurrect those
18 America Responds to AIDS advertisements that I think
19 came out from CDC under your administration, Dr.
20 Sullivan, based on this last presentation. There's a
21 lot of good information that's already out there that
22 could maybe be reused.

1 As we think about tomorrow, please do read
2 the Prevention Committee insert that's in your
3 notebooks. It's in the left-hand pocket at the front.
4 If you don't have it, please see Dana or Delta
5 because it's very important for you to take a look at
6 that.
7 We will start tomorrow morning according
8 to schedule, and we'll be inserting something, I
9 think, on the agenda relating to testing day, National
10 Testing Day. Just a reminder for all of us and what's
11 being planned. It's timely. It's next week, and
12 something we all need to be thinking about and
13 participating in.
14 Thank you.
15 CO-CHAIRPERSON SULLIVAN: Thank you.
16 Before Joe comments, let me just make this
17 comment. I think these comments you have just made
18 are very helpful, but in spite of the issues we raise,
19 I think today's discussion, presentation was really a
20 very productive one. So I don't want anyone to leave
21 feeling otherwise, but we can improve on this by being
22 more concise.

1 But I do think that this was an excellent
2 day that we had.
3 Thank you.
4 Joe.
5 MR. GROGAN: I just have one relatively
6 minor announcement, which is that in the next couple
7 of days PACHA will be unveiling a new Website which I
8 hope will be much more visually appealing and useful
9 for the public and for the members, allowing the
10 public to register for meetings rather than call and
11 get routed through phone trees to figure out if they
12 actually have registered for the meetings and
13 registered for public comment, and try and get some
14 good links to various other HIV/AIDS resources in the
15 federal government.
16 So it's not active today, but it may even
17 be active tomorrow, and in the next few days or week
18 or so, it will be up and running, and I would
19 encourage you to check it out yourself and let me know
20 any suggestions or comments you have on how to improve
21 it because I'm trying to update it from what it was in
22 the past. I don't think they've been updated, you

1 know, in ten years maybe since it was last improved
2 upon.
3 So I hope you take a look at it. Thank
4 you.
5 CO-CHAIRPERSON SULLIVAN: Dr. McIlhaney, a
6 question?
7 DR. McILHANEY: May we leave our things
8 here?
9 MR. GROGAN: Yes, you can leave your
10 binders here.
11 CO-CHAIRPERSON SULLIVAN: If there are no
12 other questions or comments, thank you. We're
13 adjourned.
14 (Whereupon, at 4:50 p.m, the meeting was
15 adjourned, to reconvene at 8:30 a.m., Tuesday, June
16 21, 2005.)
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