

U.S. DEPARTMENT OF HEALTH and HUMAN SERVICES

SUBSTANCE ABUSE and MENTAL HEALTH ADMINISTRATION
CENTER for SUBSTANCE ABUSE TREATMENT

"New Paths to Recovery"
Buprenorphine Community Education Forum
New York, New York

Hosted by SAMHSA/CSAT

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PERFORMANCE REPORTING

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1 On behalf of SAMHSA and CSAT, we will be
2 hosting this community forum and moderating it, and we
3 appreciate the host of the Department of Public Health,
4 in the interest of the City of New York, and your
5 participation.

6 So I want to thank those who helped put this
7 event together and who helped generate this audience. It
8 is my understanding that we had to turn away audience;
9 people were being called and being asked not to appear.
10 We regret that, but the fire marshals are very adamant
11 about certain things, like not too many people in the
12 room. Can we squeeze a few more? Nope, they weren't
13 listening.

14 So I want to salute the New York City
15 Department of Health and Mental Hygiene, Deputy
16 Commissioner Sullivan for all your help. Amongst their
17 staff, I want to recognize Stacy Lamon, the City Director
18 for Addiction Services, Ivan Quervalu, Director of
19 Training and Staff Development, and Ms. Sandra Mullin,
20 Deputy Commissioner of Communications.

21 I want to thank Ryan Miday, the Legislative
22 Director to Assemblyman Dinowitz, the 81st District, New

1 York State Assembly, for his help and interest.

2 Now, Dr. Harmison will proceed with the
3 beginning of this morning's activities.

4 DR. HARMISON: I would like to begin today by
5 introducing our first speaker, someone whose offices
6 provided such valuable assistance to SAMHSA and CSAT,
7 it's hard to say enough, Dr. Martha Adams Sullivan. She
8 is the deputy commissioner for Mental Hygiene Promotion
9 and Chemical Dependency of New York City's Department of
10 Health and Mental Hygiene, where she heads the
11 Buprenorphine Task Force and is playing a major role in
12 the initiative of buprenorphine treatment in New York.

13 I must say, before I have her come to the
14 podium and speak to you, that she has her DSW just like I
15 do, and it is wonderful to say hello to another fellow
16 doctorate of social work.

17 Dr. Sullivan.

18 **Remarks**

19 **Dr. Martha Sullivan**

20 DR. SULLIVAN: I would like to welcome each and
21 every one of you here this morning to our Forum: "New
22 Paths to Recovery." We are very pleased to work with our

1 partners at the State of the Office of Alcohol and
2 Substance Abuse Services, and of course with SAMHSA.

3 The Bureau of Alcohol and Substance Abuse
4 Services has as our mission to promote and protect public
5 health through developing, contracting, monitoring, and
6 evaluating alcohol and substance abuse services. We
7 monitor over 100 programs, and these services are
8 delivered by voluntary agencies, the public sector,
9 community-based organizations, and certainly the Health
10 and Hospitals Corporation.

11 As you all very well know, heroin and opiate
12 addiction presents a major public health problem
13 worldwide. In fact, there are approximately 9 million
14 people in the world who are heroin users, and about 1
15 million of those are Americans. The economic burden to
16 the U.S. has been estimated to be in the billions of
17 dollars, and of course the social burden is really
18 incalculable when we think of the devastation of families
19 and communities as a result of heroin addiction.

20 New York City has the unfortunate distinction
21 to be what could be called the heroin capital of the
22 world. About one-fifth of the U.S. heroin users reside

1 in New York City. This results in, or is at least
2 associated with, approximately 500 deaths annually in the
3 city. And of course, we also know that about half of HIV
4 transmission is related to intravenous drug use. In New
5 York City, about 40 percent of heroin users also are what
6 we call MICA patients. They have co-occurring disorders,
7 mental illness.

8 With the FDA approval of buprenorphine in
9 October, the Department has incorporated and made it a
10 real priority: the successful introduction and use of
11 this drug in New York City, because we see the potential
12 to impact a number of public health concerns. We see
13 buprenorphine, by the way, as an alternative, certainly
14 not a medication or a treatment approach to supplant
15 existing approaches which we know are certainly valuable
16 and work well.

17 Because of the priority that the Department has
18 faced upon seeing that this new treatment is available
19 and used successfully, we developed an action plan. That
20 action consists of three major components. One, is to
21 see that buprenorphine treatment is initiated in private
22 offices, in AIDS clinics, methadone clinics, the City

1 correctional system, to name a few.

2 We also want to develop systems to acquire data
3 that will really inform us as to how well we are doing at
4 building an infrastructure for this medication, and how
5 well we are doing at getting those people who are not
6 currently in treatment into treatment. That means we
7 need to know succinctly how many new providers, new
8 physicians are certified to be able to prescribe
9 buprenorphine, and how many new patients are coming into
10 the system receiving care who perhaps weren't before.

11 We may know that. In New York City, it is
12 estimated that about 200,000 to 250,000 people use
13 heroin, and yet our treatment system has actually about
14 38,000 people in treatment. Again, seeing buprenorphine
15 as an alternative, we hope that it is one that will
16 encourage some of those other people to enter treatment.

17 A third priority of the action plan is to see
18 that there are reimbursement rates and regulations
19 related to buprenorphine that will really support the use
20 of the treatment and will not discourage or become a
21 disincentive.

22 Some of the activities that we have engaged

1 upon to date have to do with, first, the development of a
2 white paper commissioned by Drs. Rosenblum, Johnson, and
3 Kleber. Dr. Kleber is on the dais, and I will take this
4 moment, also, to thank Dr. Kleber for all of his support
5 and advice and guidance of the Department from the
6 inception.

7 The white paper, I believe, was available for
8 you as you came in. It is considered a draft. We are
9 looking for feedback and comments. Please send them to
10 us. I think there are instructions there that you can do
11 so, even by an email.

12 We have also convened a roundtable at Gracie
13 Mansion to discuss the white paper, and we are very
14 pleased to pull together, I think, a rather stellar group
15 of providers, policymakers, physicians, people involved
16 in the regulatory and financing issues, to really discuss
17 the contents of the white paper, which was also organized
18 pretty much around the same topic areas as our action
19 plan.

20 In May, we also developed a Fact Sheet, because
21 getting the facts out in a simple, readable,
22 understandable form to the public, we felt, was very

1 important. That Fact Sheet is available at the
2 Department's website.

3 Many of you know that SAMHSA, in conjunction
4 with the State, organized a training in June, which about
5 100 physicians attended. So that, the ranks of those who
6 are certified to prescribe should be growing, and I
7 understand that there is another training scheduled for
8 November.

9 In closing, I just want to reiterate that our
10 department is squarely behind the successful introduction
11 of this new alternative. There hasn't been such a
12 significant alternative treatment for heroin addiction in
13 many years, but we want to see it done well, done
14 correctly. We are open for as much feedback from all of
15 you as possible. We certainly want to do this in a way
16 that works for patients. Particularly, as I said before,
17 we want to encourage all of those who have not so far
18 availed themselves of the treatment that is available to
19 do so.

20 So, thank you very much for coming this
21 morning.

22 DR. HARMISON: Just as Dr. Sullivan is familiar

1 with the public health dimensions of the problem of
2 opiate addiction, so too can our next speaker
3 thoughtfully articulate its public policy implications.
4 State Assemblyman Jeffrey Dinowitz has been in the news
5 and on the front lines of what has become, and most
6 assuredly must remain, a multi-level, comprehensive
7 effort to fashion and sustain policies which help
8 diminish the cost of addiction.

9 Elected to the New York State Assembly in 1994
10 to represent the 81st Assembly District, Mr. Dinowitz is
11 chairman of the Assembly State Committee on Alcoholism
12 and Drug Abuse, and serves on eight other committees.

13 Assemblyman Dinowitz.

14 **Remarks**

15 **Assemblyman Jeffrey Dinowitz**

16 ASSEMBLYMAN DINOWITZ: I looked at the list of
17 your speakers, and I am one of the few people on the list
18 who is not a doctor, unless you count juris doctor. I am
19 going to talk from a slightly different perspective, and
20 that is from policy and from a governmental and political
21 perspective.

22 I am the chair of the New York State Assembly

1 Committee on Alcoholism and Drug Abuse, and that
2 committee advocates on behalf of tens of thousands of New
3 Yorkers who are in need of alcohol and drug abuse
4 services treatment. The committee also participates in
5 developing state budget initiatives and drug abuse
6 programs, and oversees the New York State Office of
7 Alcoholism and Substance Abuse Services, OASAS.

8 Through our interaction with OASAS, as well as
9 advocates and professionals within the substance abuse
10 field, the committee plays an integral role in
11 identifying service needs to ensure the quality of
12 treatment programs throughout the State of New York.

13 Now, 2003 is my first year as chair of this
14 committee, and during that relatively brief time as
15 chair, I have been through a crash course in many issues
16 surrounding both the nightmare of addiction, as well as
17 the hopes of recovery through many treatment strategies.

18 Since becoming chair, I have been involved with
19 a wide range of issues, from working to curtail under-age
20 drinking, to establishing parity of reimbursement rates
21 between hospital and non-hospital methadone clinics, to
22 working to increase the beer tax in New York.

1 By the way, we did submit legislation to do
2 that this year, and we got a lot of cosponsors in the
3 Assembly for that legislation. It wasn't successful, but
4 I am going to keep plugging away on that. The revenue
5 for that would be dedicated to treatment and prevention
6 programs. Also, focusing on the fact that a high
7 percentage of addicts have co-occurring disorders.

8 But among the most important topics that
9 advocates for addiction treatment have brought to me time
10 and time again relate to heroin addiction, treatment
11 alternatives such as methadone, and the role New York
12 should play in addressing addiction in fostering the best
13 possible treatment options.

14 As I met with many experts over the past six
15 months, what was immediately clear to me was how complex
16 these issues are and the great differences of opinion on
17 a whole wide range of subjects within the addiction
18 treatment community. But through venues such as this,
19 which bring experts together, as well as policymakers who
20 share the goal of obtaining care for addicts, I am
21 certain we can work to find sensible solutions to help
22 those in need.

1 Now, early in my tenure as committee chair, it
2 became clear to me that among the illegal drugs being
3 used by New Yorkers, heroin poses, perhaps, the most
4 challenging set of prevention and treatment issues.
5 While it has long been a problem, heroin use is now on
6 the rise in New York and throughout the country.

7 Evident from testimony at an assembly here
8 which I chaired in May, addiction treatment programs are
9 encountering a new generation of opiate addicts, often
10 young, middle class New Yorkers who have discovered a
11 more potent, inexpensive, and easy to acquire heroin
12 which is available in communities throughout the state.

13 In the 1970s, New York attempted to stem the
14 rising tide of heroin addiction by enacting the
15 Rockefeller Drug Laws, and of course, that has been front
16 and center in the New York state legislature this year;
17 the Rockefeller Drug Laws, of course, being criminal
18 sanctions that impose very severe prison sentences in an
19 attempt to put a halt to illicit drug use.

20 In retrospect, there is bipartisan agreement
21 now that these laws are ineffective in stemming the use
22 of illegal drugs while causing a dramatic increase in the

1 state prison population. This consensus is based on the
2 belief that the state cannot solve the problem of drug
3 addiction simply by locking up addicts.

4 There is not, however, a bipartisan agreement
5 on how to change the Rockefeller Drug Laws. The New York
6 state assembly and the governor have each proposed
7 alternative strategies to deal with illicit drug use and
8 to reform these laws.

9 I think more than ever that addiction treatment
10 and prevention are gaining support as the appropriate
11 strategy for reducing the use of addictive drugs.
12 Research on pharmaceutical treatment of addiction has
13 been particularly well publicized recently.

14 I should say that I believe that we must
15 radically alter the Rockefeller Drug Laws to focus on
16 treatment of addiction programs as well as giving judges
17 discretion in how to deal with individuals that come
18 before them.

19 Now, recently in fact, when I first learned
20 that the FDA and the New York State Department of Health
21 have issued regulations that allow buprenorphine to be
22 used for office-based opiate addiction treatment, one

1 thing that struck me immediately was that, for the most
2 part, the approval of buprenorphine generated enthusiasm
3 and excitement. From medical journals to the pages of
4 "USA Today," buprenorphine was trumpeted as a cutting
5 edge medication that would forever alter the landscape of
6 addiction and recovery.

7 In light of all that excitement, I couldn't
8 help but wonder, does buprenorphine actually have the
9 potential to revolutionize opiate addiction treatment?
10 Will it or other drugs currently being studied eventually
11 supplant established opiate addiction treatment
12 modalities such as methadone maintenance? Further, I was
13 concerned about whether New York State was prepared to
14 take an active role in making alternatives to methadone
15 available to providers.

16 From my perspective as a state lawmaker,
17 several key facets of this discussion stand out in my
18 mind. For example, one aspect of the buprenorphine issue
19 that troubles me greatly is that, with both the state and
20 federal government budgets in crisis, I believe it is
21 absolutely essential that we know how much treatment will
22 cost and who will pay for it and make sure that we can

1 pay for it.

2 In New York and across the country there was
3 growing pressure to reduce Medicaid expenditures,
4 therefore giving the states dire financial straits. Is
5 it likely that the Medicaid system will be expanded to
6 cover new pharmaceutical treatments for addicts, be it
7 buprenorphine or whatever else in the future? We must
8 make funding available to do that which has to be done.

9 Of course, this is especially troublesome if we
10 agree that there is currently a population of addicts
11 unable for whatever reason to access treatment because,
12 after all, isn't it likely that many addicts will not
13 have private insurance and will need Medicaid to cover
14 the cost of their treatment? If Medicaid cannot be
15 adequately utilized, will there actually be any chance of
16 closing the treatment gap?

17 Another aspect of the buprenorphine issue which
18 I think is of critical importance in answering policy,
19 procedural, and professional questions is similar in
20 nature to that of operating methadone clinics. For
21 instance, since doctors and pharmacies now have the
22 authority to prescribe and dispense buprenorphine, what

1 specialized training will they need to manage addicted
2 patients effectively?

3 Also, there are currently systems in place to
4 identify and check methadone patients intended to prevent
5 abuse or diversion of medication. Will similar systems
6 be created to prevent the abuse of buprenorphine?

7 Finally, methadone clinics are currently
8 supposed to provide at least some therapy beyond just
9 distributing the drug. Will doctors who treat addicts
10 with buprenorphine be providing other supports for
11 addicts beyond just writing a prescription for
12 buprenorphine and then sending them on their way?

13 These and other questions and concerns were put
14 to a panel recently of respected experts on opiate
15 addiction at a recent roundtable sponsored by my
16 committee. The broadly varying answers showed that there
17 is great enthusiasm for buprenorphine but there was also
18 a testament to the distance we must travel before we
19 actually reach a point where there was agreement on how
20 opiate addiction can be effectively treated.

21 I am hopeful that the approval of buprenorphine
22 is a very important step on that journey and that this

1 conference will move us even further ahead. I should say
2 that I think that we have the potential to really have a
3 tremendous if not revolutionary effect in New York and
4 around the country in fact in treating drug addiction.
5 That is why I think so many people have greeted this with
6 such enthusiasm.

7 In closing, I should say that I am very pleased
8 to have been invited here because I think the exchange of
9 ideas and information is very important. I hope to work
10 with many of you in the immediate future as we continue
11 to look at buprenorphine as an answer to the problems
12 that face thousands and thousands of New Yorkers.

13 Thank you very much.

14 **Remarks**

15 **Dr. Sheila Harmison**

16 DR. HARMISON: Thank you, Mr. Dinowitz, for
17 your enlightening remarks.

18 I want to note by way of background that at
19 least two decades of substance use disorder treatment
20 have made one thing clear and that is that treatment
21 works. However, those of us in the addiction field have
22 seldom focused on the role of primary care physicians in

1 helping to find the answer.

2 We all know that substance use disorders are
3 often chronic conditions that progress slowly over time.

4 Primary care clinicians through their regular long-term
5 contact with patients over time are in an ideal position
6 to screen for alcohol and drug problems and to monitor
7 each individual's status. Historically this potential
8 has largely been untapped.

9 Fortunately, as you will hear today, there is a
10 new option for practitioners and their patients. Just as
11 Mr. Dinowitz and countless others have endeavored to
12 address the problem of drug addiction at the state
13 legislative level, so too have federally elected
14 officials made this day possible. Thanks to a great deal
15 of help from the U.S. Congress, doctors are now allowed
16 to prescribe and dispense a new anti-addiction medication
17 in the privacy of their offices.

18 Senators Carl Levin, Orrin Hatch, and Joseph
19 Biden have sponsored the Drug Addiction Treatment Act of
20 2000, DATA, which, for the first time in nearly 100
21 years, allows doctors to prescribe and dispense certain
22 narcotics for the treatment of opiate addiction. DATA

1 has made office-based opioid treatment a reality.

2 Buprenorphine holds out the promise of creating
3 an alternative delivery model that can be used in
4 mainstream medicine. It can help people addicted to
5 opiates stabilize their lives and get started on the path
6 to recovery. By being partners in this new delivery
7 system, primary care physicians and addiction specialists
8 can together identify and treat those in need.

9 The advent of office-based opioid treatment and
10 the availability of this new medication are important
11 developments as we seek to address the public health
12 imperative to reduce opioid dependency.

13 Consider for a moment that HIV/AIDS and
14 hepatitis C have reached epidemic proportions among
15 injectable drug users. Yes, seeing injectable drug users
16 and individuals who misuse prescription drugs is a
17 greater part of a primary care practice than one might
18 initially realize.

19 The twin epidemics of infectious diseases and
20 addiction to substances underscores the critical need
21 that primary care doctors collaborate with the public
22 health and addiction treatment centers. They illustrate

1 the degree to which treatment providers and professionals
2 across the medical disciplines must be prepared to
3 encounter substance use and co-occurring disorders.

4 It is towards these ends that we have convened
5 this community forum today. The individual and
6 collective professional experiences of our next three
7 speakers ensure that they are most familiar with 1) the
8 recent history of substance use disorder treatment; 2)
9 the importance of broadening access to that treatment;
10 and 3) how medication-assisted treatment options like
11 buprenorphine can and will expand that access.

12 Our next speaker is, I'm sure, familiar to many
13 of you. Dr. Steven Kipnis is medical director of the New
14 York Office of Alcoholism and Substance Abuse Service.

15 Dr. Kipnis.

16 **Remarks**

17 **Dr. Steven S. Kipnis**

18 DR. KIPNIS: It is really my pleasure to be
19 here for this forum, "New Paths to Recovery," and really
20 to start something that the federal government started
21 many years ago and also that New York State OASAS started
22 working on back in April of 2001, and that was our new

1 treatment option, buprenorphine.

2 One of the problems with not going first is
3 everyone has a little bit different numbers, so my
4 numbers say that in the United States there are upwards
5 of 800,000 opiate-addicted patients, anywhere from
6 800,000 to a million. Only 20 percent are receiving
7 agonist therapy at this time.

8 The reason for that is really varied. One is
9 stigma, the stigma of being an, quote, "addict" in
10 general and certainly an opiate addict. There is
11 community opposition to having a treatment center "in my
12 backyard." Certainly, regulatory issues. Heroin is
13 increasingly more pure and more available. Younger
14 people are starting to use heroin. Also, very important
15 to New York State is there is a paucity of methadone
16 programs in the rural areas.

17 The Addiction Medicine Unit of OASAS has worked
18 closely with New York State Department of Health and
19 Controlled Substance Bureau, New York City, and CSAT,
20 probably a little too close with CSAT as far as some of
21 our contacts can tell you.

22 We have made buprenorphine available to treat

1 opiate-dependent patients in New York State and hope that
2 it will continue to be a successful mode of therapy for
3 these patients.

4 My one great pleasure besides being here
5 speaking to you about buprenorphine is also to introduce
6 to you our new commissioner of OASAS, Dr. William Gorman.

7 Dr. Gorman comes to OASAS from a very impressive
8 background in substance abuse, treating mental health
9 patients, and also HIV/AIDS patients. He is a veteran of
10 the United States Army. He has a Ph.D. in pastoral
11 psychology, a doctor of ministry, masters of theology,
12 masters of educational psychology. What is really neat
13 for me is that he is an R.N., so someone in my agency
14 that I can actually commiserate with.

15 Anyway, I would like to introduce our new
16 commissioner, Dr. William Gorman.

17 **Remarks**

18 **Dr. William Gorman**

19 DR. GORMAN: State Assemblyman Dinowitz, Dr.
20 Clark, esteemed physicians, fellow members of the panel,
21 respected guests and participants. I am truly honored
22 this morning to represent the New York State Office of

1 Alcoholism and Substance Abuse Service at CSAT's "New
2 Paths to Recovery" forum on buprenorphine.

3 OASAS is committed to the use of addiction
4 medication in our licensed addiction treatment system.
5 It is one of the few states in the nation that has an
6 addiction medicine unit. The New York State system and
7 private practitioners have had limited exposure to the
8 effective use of medications in treatment of addictions,
9 except in withdrawal settings and our extensive methadone
10 clinic system, which continues to carry out significant
11 and effective treatment but is limited by a lack of
12 service availability in all areas of New York State.

13 Buprenorphine will, hopefully, allow these
14 patients that for logistical reasons cannot attend or are
15 clinically not suited for a methadone program to obtain
16 opiate-dependence treatment.

17 It is the responsibility of OASAS to work in
18 collaboration with other state agencies, professional
19 organizations, local governments, and medical
20 practitioners to help establish clinical protocols,
21 policies, training programs, and reimbursement mechanisms
22 which will support the use of any addiction medicine

1 which will produce a positive outcome for the patients
2 that we serve.

3 OASAS has started that process. We have
4 cosponsored two training sessions with CSAT, ASAM, IPPA,
5 New York City, and upstate New York at Rochester. We
6 have worked and continue to do so with the state
7 Department of Health with the Medicaid Unit and with
8 their Controlled Substance Unit. We have also worked
9 with the New York City Department of Health and Mental
10 Hygiene and will continue to do that to build bridges
11 with these different agencies.

12 We believe that successful use of buprenorphine
13 would be of great benefit for our state and this
14 treatment will be a judicious use of all of our
15 facilities to help our patients that we serve. It will
16 be a benefit, we believe, to our state, to the treatment
17 providers, and most importantly, for those we serve, our
18 patients.

19 Thank you.

20 DR. HARMISON: Our next speaker will provide
21 perspective from next door, so to speak. Carolann Kane-
22 Cavaiola is the assistant commissioner for the Division

1 of Addiction Services at the New Jersey Department of
2 Health. She has served on the Governors' Advisory
3 Council on Alcohol and Drug Abuse under three different
4 administrations.

5 Ms. Kane-Cavaiola.

6 **Remarks**

7 **Ms. Carolann Kane-Cavaiola**

8 MS. KANE-CAVAIOLA: The Division of Addiction
9 Services, as a single state agency, takes very seriously
10 our responsibility, our responsibility to our mission to
11 decrease abuse and dependence on alcohol and other drugs
12 and certainly in this whole area of new treatments for
13 heroin addicts.

14 It is very sad, but New Jersey continues to
15 show the highest rate in the number of mentions of heroin
16 admissions. Our programs, even before we are able to
17 collect the data, are talking to those in my office and
18 to me about the growth in our suburbs south and west of
19 our cities. I think it may be easy for you to understand
20 that we have a very different system of care in that most
21 of our towns are characterized by strip malls as opposed
22 to community centers, that our programs serve large areas

1 even though we have such a concentration of addiction.

2 We are going to begin in short order to have
3 many conversations with our partners in New Jersey about
4 incorporating this new technology into what we do. There
5 is a treatment gap; we understand that. We have to move
6 slowly and deliberately into this particular new
7 opportunity.

8 We are looking at our current treatment
9 settings but we are also needing to consider other
10 recovery-sustaining activities so that once we are able
11 to treat patients in an office-based approach that we
12 have the opportunities for them to continue. It is a
13 lifetime diligence to recovery.

14 I want to thank you for having New Jersey
15 present here today. I hope that we can continue having
16 these conversations. You are invited to our state at any
17 point in time, but I am absolutely committed to this
18 initiative.

19 Thank you.

20 DR. HARMISON: Thank you, Ms. Kane-Cavaiola.
21 It is great to have you here.

22 Next, I will have Dr. Clark briefly describe

1 for you buprenorphine as a medication that has profound
2 implications for primary care physicians, behavioral
3 medicine specialists, consumers of opioids, their
4 families and loved ones.

5 Dr. Clark.

6 **Remarks**

7 **Dr. H. Westley Clark**

8 DR. CLARK: What I am going to talk about is,
9 it is important, as Mr. Dinowitz pointed out, to have
10 people recognize that buprenorphine together with
11 behavioral counseling can potentially help thousands of
12 individuals using opioids to reclaim their lives and
13 their health.

14 Addiction treatment using opioid therapy has
15 been demonstrated to be effective; Dr. Sullivan pointed
16 that out. Less than 20 percent of individuals who become
17 addicted to opioids receive treatment.

18 One of the things I want to stress is that we
19 are not just talking about health -- New York, obviously,
20 has the leading problem with the issue of health -- we
21 are also talking about prescription opioid. That gets
22 lost, especially on primary care practitioners, because

1 they get to choose, well, we don't really treat heroin
2 addicts. At the same time, they are writing
3 prescriptions for hydrocodone, morphine, and oxycodone
4 and that sort of thing as if the problem belongs to the
5 public health department or some other department or the
6 other. It is a key issue that we are noticing and you
7 have noticed in Washington, this upswing in prescription
8 opioid abuse and dependence.

9 So, buprenorphine was promised to the primary
10 care practitioner not just for the detoxification and/or
11 maintenance for heroin but also as a mechanism by which
12 we can address the problems of those who are misusing
13 prescription opioids.

14 Dr. Crookston in Utah, when we did a community
15 forum there, stressed his use of buprenorphine as the
16 medication that he can use to transition older Americans
17 who are dependent on prescription opiates. It is a key
18 construct in this message.

19 So we need to get the message out, because I
20 don't think the primary care community recognizes that
21 they themselves have an issue. And it's not just, again,
22 imported drugs like heroin; it is domestically dispensed

1 drugs like morphine, codeine, hydrocodone, oxycodone. It
2 is a key construct that we need to keep in mind.

3 U.S. data from hospital emergency departments
4 indicates admissions for narcotic analgesics or
5 prescription drugs have increased steadily through the
6 mid '90s to 2001 to the extent that in 2001 ER visits
7 involving legal prescription drug medications for the
8 first time exceed those for heroin.

9 Now, the data here for New York City are not
10 like that, but the fact is, New York City has a problem
11 with prescription opioid abuse. Heroin is the dominant
12 theme here. In other places, like in Albany, or if you
13 look at western New York, prescription opioids actually
14 exceed heroin. So, again, it is a thing to keep in mind.

15 Our data reports 52,000 drug-related emergency
16 department admissions in New York City in 2001. The rate
17 in New York City for heroin, of course, is higher than
18 the population rate nationwide. There were 924 drug-
19 related deaths in the New York metropolitan area in 2000.

20 Of these, 713 of the deaths were overdoses.

21 The total number of primary heroin admissions
22 to state-funded and non-funded treatment programs in New

1 York City increased from 20,879 in 1999 to 21,616 in
2 2000, according to OASAS data. There were more
3 admissions for heroin abuse than for any other drug
4 during this period. There were 10,988 heroin admissions
5 in the first half of 2001 alone, indicating an ongoing
6 increase in the heroin admissions.

7 Data indicate the number of heroin-related
8 emergency room visits in New York City fluctuated, but
9 increased overall from 9,481 in 1997 to 10,644 in 2001.

10 The rate for 100,000 population in New York
11 City was dramatically higher than the rate nationwide.
12 Mortality data indicate there were 194 heroin-related
13 deaths in the metropolitan New York area in 2000.

14 In the New Jersey area, Newark area, there were
15 304 drug-related deaths in Newark, New Jersey, and
16 surrounding Essex and Morris Counties in 2001. There
17 were 190 mentions of narcotic pain medications associated
18 with these deaths, and 177 mentions of heroin and
19 morphine. The 304 deaths involving drugs in 2001
20 reflected an increase from the 250 recorded the year
21 before, continuing upward the trend for total drug-
22 related deaths. Again, not just heroin, the key

1 construct. We have to keep this in mind.

2 So when you relate to private practitioners,
3 you remind them they may be part of the problem and
4 buprenorphine offers a solution that allows us to deal
5 with everyone's concerns. The non-mortality data of
6 death, drug-induced, one or more of the drugs directly
7 caused the death, drug-related and drug abuse was a
8 contributing factor.

9 Now, obviously, we are limited by the data that
10 we have, but the data continue to show that we need to
11 work with New Jersey, we need to work with New York
12 State, as well as the various cities within each
13 jurisdiction to build the capacity and to implement the
14 most effective treatment services available.

15 Buprenorphine is not a revolutionary drug, so I
16 want to differ a little with Mr. Dinowitz. It is, as was
17 pointed out, a known agent. It allows us to bring
18 primary care into the delivery system. It allows early
19 intervention. We don't have to wait until someone has
20 mugged me or you, or somebody else, before we address the
21 problem.

22 I am getting up there in age, as Joe Nathan can

1 tell you. He was a fellow of mine way back when. I
2 would prefer early intervention to waiting until someone
3 has committed a crime and hurt somebody else before we
4 say, gee, we need to help them.

5 So what buprenorphine offers is the prospect of
6 early intervention. As we destigmatize drug treatment,
7 then what we can do is to encourage primary care to
8 screen at the office for intervention.

9 We are working at SAMHSA with multiple
10 communities, physicians, addiction counseling
11 professionals, behavioral scientists, pharmacists, and
12 others to acquaint them with buprenorphine and to ensure
13 that they become and remain valuable partners in treating
14 opioid addiction. It is critical that we have these
15 relationships.

16 It is wonderful that we have Mr. Dinowitz here.

17 I think New York State should be commended for having a
18 political person who is interested in substance abuse
19 treatment at this level.

20 We have at the federal level similar kinds of
21 ventures. We have President Bush, who has articulated
22 the importance of recovery. We have Secretary Tommy

1 Thompson, who has recognized the importance of prevention
2 and treatment. Of course, my boss, Mr. Charles Curie,
3 who has supported this effort, this new path to recovery
4 approach. Indeed, his focus is on recovery.

5 As a result of buprenorphine's availability, we
6 now can involve qualified primary care practitioners and
7 back them up with addiction medicine specialists like Dr.
8 Kleber over there. We have Dr. Lou Baxter from the State
9 of New Jersey, who is on our National Advisory Council.

10 So we have a process where, with existing state
11 license and DEA registration, we can train primary care
12 docs because one of the things primary care doctors
13 complain about is they don't have the skills and the
14 knowledge to do the screening. We have a process in
15 place.

16 New York has some unique rules that it applies
17 to the use of buprenorphine, but we believe that the most
18 important thing is that we have the primary care delivery
19 system involved in addiction treatment so that we can
20 have early detection, early intervention, and an
21 alternative achievement strategy that can occur in the
22 confines of the doctor's office so that by the time a

1 person discovers that they have a problem not so much
2 time has exhausted.

3 We are working with the American Society of
4 Addiction Medicine, the American Academy of Osteopathic
5 Addiction Medicine, the American Psychiatric Association,
6 and the American Association of Addiction Psychiatry. We
7 are also outreaching to the American Medical Association
8 and to the National Association of Addiction
9 Professionals because we recognize the importance of
10 counselors being involved in this effort, nurses and
11 pharmacists.

12 I don't want to underemphasize the importance
13 of pharmacists because the pharmacists will play a
14 critical role in this effort. We are outreaching to the
15 organized pharmacists so that we can address their
16 concerns and make sure that they have the necessary
17 information.

18 This is a radical new role. Not since USB1 has
19 the whole health care delivery system been poised to
20 address addiction rather than just clustering it off. We
21 have primary care docs who treat hypertension and heart
22 disease and who may feel that they have exceeded their

1 skills and abilities and refer them to specialists.
2 Hence, we should have a delivery system that is graded by
3 the degree and severity of the problems that a person
4 presents to that delivery system so that we don't have to
5 have a terribly costly system but we can have access and
6 we can have quality.

7 In your packets there is reference to our
8 website, <www.buprenorphine.samhsa.gov>. I encourage you
9 to use that website for information about buprenorphine,
10 about training opportunities. I urge you to call our 1-
11 800 number, 1-866-BUP-CSAT, with training and ways that
12 practitioners can begin this process. In New York we
13 have to register with OASAS.

14 The most important thing is that we get primary
15 care involved and that we get other addiction docs. To
16 date, CSAT has received data waiver notifications from
17 only 256 New York-based physicians. Of that number, 218
18 waivers have been approved. So basically, New York State
19 has very few compared to the number of physicians in the
20 state waivers. Some 163 of these physicians could be
21 identified from our SAMHSA buprenorphine physician
22 locator, which is also available on the website.

1 More than 80 of the physicians with waivers
2 practice here in the greater New York area. Again, there
3 are only 80 physicians in the greater New York area that
4 have waivers. So you have to ask, well, how many
5 physicians in the greater New York area are writing
6 prescriptions for fentanyl and morphine and oxycodone and
7 hydrocodone; is it only 80? Because, if it is only 80,
8 then you have a satisfactory number of docs. But I think
9 not. Then again, I may be wrong. I am interloper; what
10 do I know? I am just telling you about the numbers.

11 Seventy-six New Jersey physicians have applied
12 for waivers; 62 applications have been approved.
13 Information on the 62 New Jersey physicians can be
14 accessed on the Physician Locator.

15 A key issue is that there is this reluctance to
16 recognize the relationship between prescription drug
17 abuse and the complications of it. The law clearly says,
18 once I believe my patient is an addict, then I can no
19 longer treat that person with a scheduled drug except for
20 buprenorphine or send them to a methadone program. In
21 fact, across the country methadone programs are now
22 seeing more people with prescription drug problems and

1 narcotic problems than in the past. In fact, some
2 programs state that their new admissions are
3 predominantly oxycodone and hydrocodone rather than
4 heroin.

5 So, the issue for the City of New York and the
6 State of New York and the State of New Jersey is, is
7 prescription drug abuse a problem, as well as, is heroin
8 a problem? If so, then primary care needs to be involved
9 in the solution.

10 That is one of the reasons that we at SAMHSA
11 are taking the lead in educating physicians and the
12 public about buprenorphine. That is one of the reasons
13 we have launched our "New Paths to Recovery." We need
14 alternative strategies to deal with this issue.

15 We have been conducting these community forums
16 across the country. We plan to continue working with New
17 York and New Jersey. We have been in telephonic contact
18 as well as face-to-face contact with New York and New
19 Jersey. We want people to access our website.

20 We don't claim to think of our strategies as
21 the panacea. It is not. Health care is never a panacea.

22 It is a complex issue with behavioral components. You

1 tell people not to eat so much, you tell people to watch
2 their blood pressure, you tell people a lot of things,
3 and then we deal with it. As a psychiatrist, I recognize
4 that we don't always do what we are supposed to do as
5 human beings, but we deal with it.

6 So we have been working closely with the
7 National Institute of Drug Abuse and the Food and Drug
8 Administration and the Drug Enforcement Administration to
9 make sure that we can capitalize off the opportunities
10 that buprenorphine offers.

11 Scientific research supported by NIDA and the
12 Department of Veterans Affairs has demonstrated the
13 efficacy of using buprenorphine. We have Dr. Fiellin
14 here in the audience who has done a lot of work and a lot
15 of training and has published a number of papers. We all
16 recognize that what goes on in the laboratory and what
17 goes on in the streets are often different, so we have a
18 vested interest in making sure that we don't create a
19 problem in our effort to create a solution.

20 So we want to make sure that Mr. Dinowitz and
21 Dr. Sullivan are aware that we treat very seriously the
22 introduction of a new strategy. Everything has a down

1 side, but our hope is that the up side exceeds the down
2 side. If we have a community that is working together
3 and that is careful, we can mitigate the down side of
4 everything.

5 I am fond of saying, if it can be abused, it
6 will be abused. That is the case. When I found that
7 haldol was being abused, I figured, gee, if somebody is
8 willing to abuse haldol, they are willing to abuse
9 anything. So I use the fact that it can be used as a
10 reason not to do it. I used to shake my head when Ted
11 would come in complaining about people abusing haldol.

12 In any event, it is important for us to have
13 some basic pharmacological information. So I would like
14 to introduce Herb Kleber. He is a professor of
15 psychiatry and the director of the Division on Substance
16 Abuse at the College of Physicians and Surgeons of
17 Columbia University and the New York State Psychiatric
18 Institute.

19 He is a pioneer for research and treatment of
20 narcotic and cocaine abuse for more than 35 years. He is
21 the co-editor of the American Psychiatric Association
22 textbook on substance abuse treatment. He is on the

1 editorial board of scientific journals. He is previously
2 the executive vice president and medical director of the
3 National Center on Addiction and Substance Abuse. He
4 used to be a deputy director of Demand Reduction for the
5 Office of National Drug Control Policy.

6 He is a man of great experience, and I am
7 pleased to introduce Dr. Kleber.

8 **Remarks**

9 **Dr. Herbert D. Kleber**

10 DR. KLEBER: Thank you for those kind words,
11 Westley, and more importantly, thank you for your
12 energetic efforts to try and get physicians trained in
13 buprenorphine and to get it out there in the country.

14 I have been asked to present a brief overview
15 of buprenorphine, although I am sure there are a number
16 of you in the audience who may be even more familiar with
17 it. In fact, there was an NPR program about
18 buprenorphine this morning around 7:45 a.m., and one of
19 the people in the audience, Dr. Paul Cassadonte was
20 interviewed, along with Dr. Ed Salsitz and Terry Horton.

21 Of course, as Dr. Clark pointed out, we have
22 David Fiellin here from Yale who has been extraordinarily

1 active in trying to train new physicians in buprenorphine
2 as well as running a very good program in New Haven.

3 I should like to point out that it has hardly
4 been a rush to market.

5 [Laughter.]

6 DR. KLEBER: I wrote my first buprenorphine
7 paper in 1988. My colleague at Johns Hopkins, Don
8 Jaczynski, had written his first buprenorphine paper in
9 1978. So the wheels of justice grind slowly, but
10 sometimes things end up right in the long run.

11 I am delighted it is out here. One day we can
12 tell you about all the struggle it took to get it here in
13 terms of getting the bill through Congress. They
14 attached it first to the Bankruptcy Bill, and then, when
15 it looked like the Bankruptcy Bill wasn't going anywhere,
16 it ended up being attached to the Children's Health Bill.

17 So that is how buprenorphine got approved back in 2000.

18 So it has been a convoluted trip to get here,
19 but we are very hopeful that once it is here it can
20 markedly expand the options available because, as Dr.
21 Clark pointed out and as other speakers did, it is
22 estimated there are somewhere between 800,000 and a

1 million heroin addicts nationally. Some estimates are
2 that the number of prescription analgesic addicts is
3 twice the number of heroin addicts. So there is no
4 shortage of people out there who need this treatment.

5 I also want to express my gratitude especially
6 to Drs. Schedler and Sullivan from the Department of
7 Health in the city who, again, have been very energetic
8 about trying to get buprenorphine out there. Dr.
9 Schedler did say at that conference -- I don't know if he
10 wants to be remembered for that statement -- that there
11 are 40,000 opiate addicts in treatment in New York City
12 now, and by the year 2010 he wants 100,000 in treatment.

13 So I just want to get that on the record.

14 [Laughter.]

15 DR. KLEBER: He is trying and Dr. Sullivan is
16 trying very hard.

17 Finally, I want to point out that, for those
18 physicians who may be reluctant to begin people on
19 buprenorphine until they get more experience, we plan at
20 Columbia to open up an induction center in mid September
21 where we will start people on buprenorphine and evaluate
22 them. Then, once they are stabilized and we know what

1 they need in terms of psychosocial support, we will then
2 transfer them to various physicians in the city who have
3 the appropriate authority to prescribe buprenorphine. We
4 hope that will increase the number of physicians willing
5 to use buprenorphine and the number of patients in
6 treatment.

7 The two physicians who are going to head that,
8 Drs. McDowell and Gunderson, are in the audience here.
9 The brochure is out on the table which describes that
10 clinic.

11 We also hope, if the funding comes through, to
12 start sometime in the fall monthly training for
13 physicians in New York to train them in buprenorphine so
14 that they can get certified and, for those who are
15 already certified, to sort of have an up-to-date thing
16 dealing with some of the clinical problems they may run
17 into.

18 So we think that this is not a panacea. This
19 is probably not revolutionary; it is certainly
20 evolutionary.

21 How does buprenorphine work? It has a very
22 high affinity for the new opioid receptor, which is also

1 where heroin and morphine act. It competes with other
2 opioids at that receptor, and because of its very high
3 affinity, if they are already there -- so, if the person
4 is already addicted to heroin and you give them
5 buprenorphine -- it can precipitate withdrawal, so that
6 when you begin people on buprenorphine it is a good idea
7 to have them in mild withdrawal before you give them the
8 first dose.

9 So, when I start someone who is addicted to a
10 short-acting opioid, such as heroin, oxycodone, vicodin,
11 et cetera, I want them off opiates for at least 12 hours,
12 which will put them in mild withdrawal. Eighteen hours
13 would be even better, but that is a lot to ask for an
14 addict. If you want to get them to the office eighteen
15 hours off, you may have a long wait.

16 For people who have been maintained on
17 methadone, I like them to have had their last dose of
18 methadone at least 36 hours ago because of the long-
19 acting nature of it.

20 So you want people in mild withdrawal. You
21 give them the buprenorphine at that point. It relieves
22 that mild withdrawal and begins to occupy the receptor

1 and satisfy its needs so that it treats that mild
2 withdrawal patient. They feel better. You gradually
3 increase the dose, and within two or three days you
4 should have the patient stabilized.

5 It is long-acting. One of the advantages of
6 buprenorphine over methadone is methadone has to be taken
7 daily. Buprenorphine, because of its slow dissociation
8 from the receptor, has a prolonged therapeutic effect.
9 You can dose every 48 hours instead of every 24 hours.
10 You can dose with a higher dose every 72 hours, but I
11 don't suggest that because the data indicate that as you
12 approach that 72 hours people go into withdrawal. So I
13 think that 48 hours is probably about as far as I intend
14 to dose.

15 It has a ceiling effect on the opiate effects.
16 Because it is only a partial agonist, it doesn't give
17 you the full opiate effect, which makes it not as good a
18 drug to get high on and safer in an overdose. If you
19 take too much of heroin, of methadone, of any other full
20 agonist, you will die of respiratory depression.

21 The advantage of buprenorphine is it is a
22 partial agonist. As you increase the dose, you get a

1 ceiling effect on that respiratory depression, making it
2 much harder to kill yourself. Since the French
3 introduced buprenorphine for prescribing by general
4 physicians around 1996, they have cut the annual heroin
5 overdose death rate by about 75 percent. So it is much
6 safer.

7 It is not impossible to kill yourself. If you
8 work at it, you can. Most of the deaths that have
9 occurred in France have been from a combination of
10 buprenorphine and the benzodiazepines, drugs like Xanax,
11 Valium, because the benzos depress respiration by a
12 different mechanism. So you have a ceiling effect on how
13 much you can depress with buprenorphine and then you take
14 a drug that depresses it by a different mechanism and, lo
15 and behold, you are able to kill yourself.

16 The forms that buprenorphine will be available
17 in the United States are two. One is the Subutex, which
18 is just buprenorphine. The other is Suboxone, which is a
19 combination of buprenorphine with the narcotic antagonist
20 Naloxone. Naloxone is poorly absorbed orally so that --
21 if we could raise that a little bit so you can get the
22 bottom of the slide? You can't? Okay.

1 What it says at the bottom is, Naloxone is
2 poorly absorbed if taken orally. It blocks the opiate
3 effects if injected. So that, if you take the
4 buprenorphine, Suboxone as prescribed, you have very,
5 very little Naloxone on board. If, however, you inject
6 it, you have roughly 100 times more Naloxone. So this
7 provides a safety effect in terms of helping to make it
8 harder to divert the drug and more difficult to get high
9 from it.

10 The fuller agonists, like heroin, morphine,
11 codeine, methadone, have moderate binding to new
12 receptors. They are short-acting and they produce a
13 powerful opiate high. That is, the short-acting ones
14 like heroin produce a powerful opiate high. Long-acting
15 ones like methadone, especially taken orally, do not
16 produce as good an opiate high.

17 Bupe has strong binding to the receptor and
18 long-acting but relatively weak opiate effect. Now, the
19 practical aspect of that is that you cannot transfer
20 individuals from methadone to buprenorphine at all levels
21 of methadone. In general, buprenorphine seems to be at
22 best efficacious compared to about 60 milligrams of

1 methadone.

2 In terms of transferring people to
3 buprenorphine, in general they should not be on more than
4 30 to 40 milligrams of methadone. So if you have a
5 patient who is on 150 of methadone and wants to be
6 transferred to buprenorphine, they have to gradually
7 lower the dose of methadone until they get down to a
8 range that the buprenorphine will cover.

9 We are trying to figure out if there are other
10 ways around that, and we have a number of projects going
11 at Columbia and projects going at Yale, too, to try and
12 figure out are there safe and effective ways of
13 transferring people from methadone to buprenorphine at
14 higher doses of methadone. Right now they have to be at
15 low doses.

16 It is important to emphasize what other
17 speakers have said: buprenorphine is not going to be a
18 replacement for methadone. We have probably 25 to 30
19 antidepressants. We have a tricyclic antidepressant, we
20 have the SSRI's that increase the amount of available
21 serotonin, we have those that increase low adrenaline, et
22 cetera. If one antidepressant doesn't work, you don't

1 say, okay, we can't treat this man's depression. You
2 say, well, if this one doesn't work, maybe we should try
3

4 We have heard it said that methadone is a very
5 important part of a comprehensive rehab program, which
6 unfortunately a lot of the programs are not. We are
7 worried about that with buprenorphine. If you have a
8 program that provides appropriate psychosocial rehab in
9 addition to the medication, you have decreases in the
10 illicit opiate use. It normalizes the immune and the
11 endocrine system, it decreases criminal activities, and
12 it increases pro-social activities.

13 What about Naltrexone? Naltrexone, as we say,
14 is the ideal drug, only for the most part addicts aren't
15 interested in using it. It is long-acting. It is a
16 pill; it can last up to 72 hours. We probably have about
17 180,000 or so people on methadone in the United States,
18 and I think there are probably somewhere between 5000 and
19 10,000 people at best on naltrexone.

20 It can produce some mild GI effects early on,
21 which are probably residual withdrawal. The patients
22 have to be clean before they start. They have to be off

1 all opiates, depending on whether it was heroin or
2 methadone, for at least a week to almost two weeks, and a
3 lot of patients can't make that.

4 So it is hard to get on it, it may have some
5 mild dysphoria, and most importantly, it doesn't give you
6 any of the opiate effects. The advantage of
7 buprenorphine is it does give you some opiate-like
8 effects. So the hope is patients will be more interested
9 in taking it.

10 So, naltrexone right now has been primarily
11 used in patients who have a lot to lose. For them, it
12 has been quite effective. Doctors, nurses, lawyers who
13 -- I shouldn't say doctors; we know doctors don't abuse
14 drugs. Only lawyers.

15 [Laughter.]

16 DR. KLEBER: Lawyers who face sanctioning by
17 the bar association if they don't stop their opiate use.

18 In addition, there have been some interesting
19 studies in the criminal justice system where people on
20 probation were randomly assigned to naltrexone or to
21 extra counseling, and in six months the naltrexone group
22 had twice as many people still in treatment as opposed to

1 being returned to prison.

2 This gives you some idea of what we mean by the
3 potency of these different drugs. As you see, a full
4 agonist such as methadone fully occupies that receptor
5 and activates it whereas buprenorphine has only about
6 half of the activation of the receptor as compared to
7 methadone and naltrexone does not activate the receptor
8 at all. So that line down there at the bottom which is
9 naltrexone is flat.

10 How good is it for the treatment of addiction?

11 Well, it can be used for withdrawal. It is my favorite
12 agent right now for withdrawing addicts. It is much
13 easier than methadone or any other method. It has a
14 relatively benign withdrawal pattern itself, so it makes
15 it much easier to withdraw patients. In fact, in our
16 induction center first we were only going to do
17 induction; now we are thinking we will also do detox for
18 those people who want detox even though in general detox
19 is not very effective. My colleague from UCLA, Walter
20 Ling, has said heroin detox is good for many things but
21 getting off heroin is not one of them.

22 [Laughter.]

1 DR. KLEBER: So, the relapse rate from detox is
2 relatively high, but we figure if we detox these people
3 they will be back for maintenance when they find they are
4 unable to stay clean. A lot of people simply feel, hey,
5 if I could only get clean, that is all I need to do and I
6 will be able to stay clean. When they find out
7 differently, they will be back, wanting to be maintained
8 on the buprenorphine.

9 It diminishes cravings. It doesn't produce a
10 high; well, that is not totally true. If you inject it,
11 it does produce a high. It blocks heroin or it reduces
12 the effect and improves treatment retention. If you
13 compare it to trials versus methadone, basically the
14 bottom line of all of these three studies is that
15 buprenorphine is better than low-dose methadone. That
16 is, methadone at 20 or 30 milligrams. Buprenorphine has
17 higher retention rates and less positive opiate years.
18 It is about as good, maybe not quite as good, as 50 to 60
19 milligrams of methadone.

20 These doses of bupe, eight milligrams, that was
21 when they gave the liquid sublingual. The tablets are
22 not quite as potent in terms of absorption as the liquid,

1 so I think the standard dose pretty much daily is going
2 to be about 16 milligrams, and 16 milligrams of bupe will
3 be about equal to 60 milligrams of methadone as far as
4 holding capacity and negative yearnings.

5 This compares the various drugs as far as
6 positive yearns or negative yearns. What you see is
7 LAAM, which is a long-acting form of methadone which
8 lasts about three days, has the highest rate of negative
9 yearns. Next would be buprenorphine, and then a high
10 dose of methadone is about the same, and low dose of
11 methadone is much lower.

12 In terms of retention, what you see is that
13 buprenorphine was about the same as high-dose methadone
14 as far as retention and about the same as high-dose
15 methadone in terms of 12 or more consecutive drug-free
16 yearns. LAAM was the best, but LAAM is not very
17 available anymore. It was shown to produce certain
18 cardiac arrhythmias. As a result, the EU has pretty much
19 banned it in Europe and the FDA has said it can only be
20 used as a second-line treatment. So more and more
21 programs are discontinuing LAAM, which is unfortunate
22 because I think it is a good maintenance drug.

1 In terms of blocking hydromorphone, you see
2 again that the high doses of bupe, 16 milligrams or 32,
3 blocks the high from hydromorphone. At the low doses of
4 bupe, you don't see that blocking effect.

5 So, in summary, to wrap it up in the next 30
6 seconds, it is a partial agonist. It is about as
7 effective as methadone or LAAM, depending on the dose of
8 methadone. Lower level of physical dependency; it is
9 easier to withdraw from. Lower risk of respiratory,
10 therefore lower risk of overdose deaths. It can be
11 abused, especially if injected, but the addition of
12 naloxone should decrease the diversion to the streets.

13 The experiences in Europe and in Australia
14 suggest that it can be very effective in maintenance
15 therapy. Non-withdrawal decrease of opioid use, greater
16 safety, lower diversion potential.

17 Thank you.

18 DR. CLARK: Our first president is Dr. Clarita
19 Herrera. She is the president of the New York County
20 Medical Society. She is an internist in private practice
21 and is a clinical instructor in primary care at New York
22 Medical College at Valhalla, the past president of

1 American Medical Limits Association. She served two
2 terms as president of the AMWA chapter of New York City.

3 She has served on the governing council for the
4 International Medical Guidance Section of the American
5 Medical Association.

6 Dr. Herrera.

7 **Remarks**

8 **Dr. Clarita Herrera**

9 DR. HERRERA: Thank you for inviting me this
10 morning to participate in this extremely useful and
11 exciting program.

12 The New York County Medical Society is a local
13 district branch of the AMA. We are in Manhattan in one
14 of the five burroughs that do have a medical society. We
15 have currently 3500 physicians who are from different
16 specialties and subspecialties. Again, as a medical
17 society, we only have one continuing vision, and that is
18 toward improving and maintaining the health of the
19 general public.

20 How do we do this? We do this by making sure
21 that our physicians are well trained in areas that do
22 have an impact on the outcome of patient care. So I am

1 very pleased that I am here today representing my society
2 on this particular endeavor.

3 As a physician who has been in private practice
4 for 20 years in Manhattan, I would like to share with you
5 some of my own personal experiences in treating women and
6 men who are substance use abusers. Prior to opening my
7 private practice in Manhattan, I was one, I think, of the
8 first medical directors on drug dependency treatment
9 programs.

10 We opened the first drug treatment program in
11 Manhattan VA. That was in 1974 when our Vietnam veterans
12 who were addicted to drugs started coming home.

13 At that time, for those of us who have been in
14 drug treatment programs who have been old warriors, we
15 know that our medical armamentarium that were available
16 to us were very, very few. Methadone was one of them
17 which we used for detoxification and maintenance. For
18 those of you who have been in this program, you know that
19 it is effective but it is also very ineffective to many
20 of our drug-dependent patients.

21 The approval of buprenorphine for use in our
22 private offices is truly long in coming but certainly

1 truly welcome. In my practice, a dual diagnosis, which
2 you have heard before, of substance abuse disorder or
3 substance abuse or substance use disorder and mental
4 disorder is the rule rather than the exception. Treating
5 such patients is complicated and challenging to say the
6 least, especially in a private practice environment.

7 The data from the National Institute of Mental
8 Health Epidemiologic Area Program indicates that
9 comorbidity or co-occurrence of substance use disorder
10 and mental disorder is a dominant occurrence. Studies
11 have shown that about 50 percent of adult psychiatric
12 patients also suffer from substance use disorder.

13 A study from the UCLA showed the following: 50
14 percent of patients with a diagnosis of schizophrenia
15 suffer from substance use disorder; 27 percent of
16 patients with unipolar disorder are also sufferers from
17 SUD. In patients with bipolar disorder, which is a much
18 more common mental disorder, the incidence jumps to 61
19 percent. This co-morbidity seems to manifest itself
20 during the manic phase.

21 For primary care physicians, such as internists
22 like me or pediatricians who treat adolescents, dual

1 diagnosis can be beyond our scope of training. These
2 patients need an integrated service rather than
3 sequential service.

4 Somebody mentioned here today about the
5 importance of a team approach. If I were to treat a
6 patient in my office and give him or her medication
7 without the other infrastructure to support an overhaul
8 progress and treatment of this patient, then I think I
9 would be doomed to failure in terms of getting these
10 patients off the drug. So I hope this training that we
11 are about to experience in New York City will address
12 this particular issue.

13 Because these patients who are either dually
14 addicted or are dually disordered do get hospitalized
15 because they have either infections such as hepatitis C,
16 they do suffer from coronary artery disease -- I am a
17 cardiologist so I know it does -- and other surgical
18 problems, their treatment in a hospitalized setting
19 causes several critical problems.

20 First, the medical culture and treatment
21 environment is not always conducive to a positive outcome
22 for these patients with opiate dependence. Personal

1 belief system and prejudices may become barriers to
2 providing appropriate treatment to such patients. The
3 lack of knowledge on special needs of these patients can
4 lead to underdosing of opiates for pain control.

5 Because of my longstanding passion and
6 commitment to women's health issues, another issue that
7 is very close and dear to my heart is the treatment of
8 pregnant women. They do have special needs in terms of
9 medications and other services.

10 It has been mentioned that perhaps the misuse
11 of prescribed controlled substances may be a bigger
12 problem than heroin addiction, and I believe so myself.
13 Being a physician who writes controlled substances every
14 day, I have to admit that this has been a nightmare in
15 terms of how I should be able to control this type of
16 misuse and diversion of my prescription. So far I think
17 this is an epidemic that we have not really given enough
18 attention.

19 So I am here to learn, and I have learned many
20 things this morning. I am also very excited in telling
21 my physician members when we convene again in September
22 that this training program will be available to all of

1 us.

2 Thank you for inviting me.

3 DR. CLARK: Thank you, Dr. Herrera.

4 Our next president would be Lawrence Brown. He
5 is the president of the American Society of Addiction
6 Medicine. He is also a clinical professor of public
7 health at the Cornell Medical College and a visiting
8 physician at Rockefeller University Hospital. Among his
9 responsibilities is supervising the delivery of primary
10 care for patients with opioid addiction and conducting
11 biomedical behavioral research studies.

12 In addition, Dr. Brown provides consultation to
13 a host of private agencies, foundations, and government
14 entities, including the National Institutes of Biology
15 and Infectious Disease, the National Institute of Drug
16 Abuse, the Food and Drug Administration, and the Centers
17 for Disease Control and Prevention.

18 Dr. Brown.

19 **Remarks**

20 **Dr. Lawrence Brown, Jr.**

21 DR. BROWN: My friends and colleagues who know
22 me know that I like to bond with the audience. One way

1 to be getting that bonding is making sure that you are
2 both and all in the same room. So, good morning.

3 AUDIENCE [en masse]: Good morning.

4 DR. BROWN: Outstanding.

5 I am going to speak to you from at least four
6 perspectives. My grandmother has always told me that one
7 of the things in public speaking is tell people what you
8 are going to say, say what you are going to say, and then
9 tell them what you have said and then sit down. So I
10 hope to make my grandmother proud.

11 The first perspective is that I am a Brooklyn
12 boy, and I would like to --

13 [Applause.]

14 DR. BROWN: I would like to in fact invite
15 those individuals who reside or work in Manhattan and
16 those individuals who reside and work outside of New York
17 State to come to Brooklyn. We could have had a meeting.

18 I'm sure we would have been just as competitive as this.

19 [Laughter.]

20 DR. BROWN: Additionally, because of my
21 Brooklyn roots, that is one of the reasons why I am in
22 this field. I come from a community in New York where

1 unless there is some miracle, addiction will continue to
2 be a problem. It has been a problem in the past and is a
3 problem presently. That is probably one of the reasons
4 why I went into it, although some of my colleagues who
5 went through training with me probably would have never
6 known.

7 What is an internist trained in endocrinology
8 doing in this field? That is a question that I often
9 hear either directly or more frequently indirectly
10 because there is something about this field that people
11 do not want to engage in. That is why I think this day
12 is so important and in this setting makes it even more
13 important that we bring to the forefront the issue and
14 concern about the treatment of those with substance use
15 disorders.

16 Like my colleagues, I would echo that
17 buprenorphine is no panacea. In fact, in addiction
18 medicine, one of my other perspectives, is the fact that
19 it is like any other chronic potential relapsing
20 disorders. There are different ways in which to treat
21 patients.

22 We are among friends so we will share our dirty

1 laundry. In the addiction field when we try to fight the
2 abstinence-based program versus the medication assistance
3 programs, we all lose and our patients, more importantly,
4 lose. We need to recognize that for some patients this
5 is in fact the most effective therapy. Not for all
6 patients but for some.

7 Another one of my perspectives is dealing with
8 the Addiction and Research Treatment Corporation. I
9 began also, like my colleagues before, in that area. So,
10 thank the conveners of this meeting, the New York City
11 Department of Health, CSAT, and SAMHSA for the vision
12 that they have had in continuing to move us along. It
13 has been a long time coming and I have not been around as
14 long as Dr. Kleber. My gray hairs probably would tell
15 you that as well.

16 [Laughter.]

17 DR. BROWN: I haven't been here as long as he
18 has been, but it has been around.

19 DR. KLEBER: [Off mike.]

20 [Laughter.]

21 DR. BROWN: For those of you who didn't hear,
22 he said some nondescript information not valuable.

1 [Laughter.]

2 DR. BROWN: In fact, one of the things that is
3 useful about these meetings is it brings many of our
4 colleagues together, and to that regard I certainly want
5 to recognize many of my colleagues at the American
6 Society of Addiction Medicine. Dr. Baxter is on our
7 board and Dr. Fiellin has in fact provided the leadership
8 for the training for the American Society of Addiction
9 Medicine, which I am going to get into in a few seconds.

10 I am low tech because of a number of reasons.
11 One is I felt that it is useful for me to make sure that
12 I bond with the audience. If I have a PowerPoint
13 presentation, it is likely that that is going to take
14 some of your attention when I am the reason for being in
15 the first place.

16 [Laughter.]

17 DR. BROWN: So I decided to go low tech.

18 You might say, is he full of himself? If I am
19 not, who is going to be for me?

20 [Laughter.]

21 DR. BROWN: I want to also say the fourth
22 perspective is the American Society of Addiction

1 Medicine, which I happen to be honored by being the
2 president of at this time. I hope they are equally as
3 honored by me being the president. That is another story
4 for another day.

5 The American Society of Addiction Medicine has
6 been in existence since the early '50s and in fact is
7 celebrating its 50th anniversary next year in Washington.

8 We invite you all to attend. We think it will be
9 memorable because at 50 you don't come to work in a
10 night. I would attest to that myself.

11 It is also a medical society that is the
12 largest medical society dealing with the addiction
13 services. In fact, it is about 3000 physicians from all
14 ranges of types of addiction. Its purpose is to provide
15 access and to help to advocate for care for persons with
16 substance use disorders. We are comprised of physicians
17 of all specialties. As I mentioned to you, I am an
18 internist who became involved in the American Society of
19 Addiction Medicine. It offers a certification program
20 that has been accepted by many third party payers and
21 government for reimbursement for physicians who in fact
22 have that certification.

1 It does also have a patient placement criteria
2 that is used in over 27 states that is used as a variable
3 for which areas of care, what is the mix of services that
4 should be provided to persons with a substance use
5 disorder. In our good State of New York, it is offered
6 as an option for those of us who are OTPs of programs.

7 With respect to training, again I want to thank
8 David for doing such a great job. Our training program
9 uses investigators, people who have previously and
10 currently continue to investigate issues about
11 buprenorphine and in fact have written some of the more
12 stellar papers and the notable papers with respect to the
13 use of this in large patient populations.

14 In fact, most recently I myself in our agency
15 was involved in a protocol that included bringing
16 buprenorphine to the trenches. It has already been in
17 ivory towers, now let's bring it to the trenches where
18 patients want to get the care. That study is actually
19 going to press. It had some fantastic results which I am
20 not able to disclose to you since they will break my arm
21 since nothing happens in New York that doesn't get
22 outside of the city.

1 I also want to mention that it is a training
2 that is a face-to-face, where these trainers actually
3 talk about not only the scientific issue that you have
4 heard Dr. Kleber talk about in much greater detail but
5 also have case studies that go over what you would do in
6 these particular types of cases.

7 What we have found is that, like Dr. Clark,
8 there are not enough physicians who are involved in this
9 care. There are a number of reasons for that. One of
10 those is the lack of a mentoring system for physicians.
11 We believe that that is critical because physicians who
12 engage in this will need the mentoring, which leads me to
13 one of my pet peeves.

14 It is interesting to me that a physician in an
15 office-based setting has to go through this training
16 whereas a physician in OTP programs like many of us run
17 never have to go through the training -- to me, that is a
18 travesty -- unlike our good state across the water, New
19 Jersey, where they require some degree of training for a
20 physician to do this. So I am letting you know I am not
21 running for any political office, but that is one issue
22 that I am going to in fact ask our colleagues in medicine

1 and our colleagues in government to in fact make New York
2 State more consistent with the practice of medicine.

3 I really do appreciate this opportunity to
4 share this time with you. It is not often that I get an
5 opportunity to come down to 125 Worth Street, even though
6 you have to go through the side entrance if you don't
7 work here.

8 [Laughter.]

9 DR. BROWN: But I understand in the aftermath
10 of some tragedies that we have had recently that might
11 very well explain part of that.

12 I want to again say to you that this is a
13 fantastic opportunity for us. We need to encourage more
14 physicians outside of addiction medicine to in fact
15 provide this care because, clearly, there is unmet need
16 there. We need to in fact have many of you who are not
17 in the medical professions, as I trust many of you may
18 not have that burden, that you encourage your doctors.
19 Ask them, what is this story about buprenorphine?

20 I have patients who ask me about other
21 medications; why can't they ask about buprenorphine, what
22 do you think, to the doctor. That often pushes a

1 just going to try to do a whirlwind overview in about two
2 minutes.

3 Why don't addicts get treatment? From the
4 primary care perspective, my hunch is that docs don't
5 think addiction is treatable. You are in busy practices;
6 people are jumping through; you don't have a lot of time
7 to spend with your patients. Docs are primarily
8 practical people. So if you don't have an implicit
9 belief that addiction is a treatable illness, you are not
10 going to waste your time on it.

11 As I was once told during my internship, at
12 about 4:00 in the morning I had my fifth hit coming into
13 the emergency room. One of the nurses on the floor said,
14 "Dr. Rosenthal, I think Mr. Jones has a fever," to which
15 my senior resident turned to me and said, "If you don't
16 take a temperature, you don't have a fever."

17 [Laughter.]

18 DR. ROSENTHAL: Oh good. You got that one.

19 So, the issue here is about identification and
20 a belief that you can do something about it. What we are
21 all here about today is trying to impress upon you that
22 addiction is a treatable illness. It is not an illness

1 that is in a vacuum. Dr. Herrera and others talked about
2 the high co-morbidity of mental disorders with serious
3 medical sequelae of addiction, including HIV, hep C, et
4 cetera, et cetera.

5 So these illnesses don't exist in a vacuum.
6 Therefore, prevention and treatment of these illnesses
7 has serious impact in other realms of treatment. It has
8 a serious impact on hospital bed occupancy because of
9 people being ill.

10 So that is the first measure here, is that
11 addiction is a treatable disorder. Unfortunately, most
12 people coming through training never get taught about it.

13 Fortunately, with this particular foray into addiction
14 treatment, with this new weapon that we have in our
15 pharmacopeia, there is training available.

16 I represent a president of the American Academy
17 of Addiction Psychiatry. That is a group of about 1000
18 folks around the country who are researchers and office-
19 based clinicians, who are psychiatrists and also
20 affiliated members who are non-psychiatrists interested
21 in treating addictions.

22 AAAP -- you can find our website as AAAP.org --

1 ASAM, the American Psychiatric Association, and the
2 American Academy of Osteopathic Addiction Medicine all
3 have been providing training programs under the auspices
4 of CSAT across the country. We are going to continue to
5 do that to get people trained so they feel comfortable
6 and confident in treating opiate addiction in office-
7 based practices. It is necessity if we are going to have
8 any impact on this.

9 What I am trying to get you people to realize,
10 and I have a hunch I am preaching to the converted
11 because you are here, but you need to be emissaries. You
12 need to go get trained if you are non-physicians. As was
13 stated before by Dr. Brown, you need to urge the docs
14 that you work with to get involved, to find out about
15 buprenorphine, to start sort of getting on the gun here
16 about the availability and reality and practicality of
17 addiction treatment.

18 Once that starts to happen, you are going to
19 start seeing changes in stigmatization. One of the
20 things that our culture hasn't caught up to yet is the
21 fact that addiction is a treatable illness. It is still
22 severely stigmatized, which drives not only in terms of

1 access to care, which there aren't enough slots, but also
2 people in terms of treatment seeking. Because of the
3 stigma, people are ashamed, people don't reveal these
4 facts as they may reveal other facts in their medical
5 history to their primary care physician.

6 We need to make it accessible. We need to make
7 it inviting. Part of that invitation is when a doc has a
8 can-do attitude about it. When a doc says, "Oh look, you
9 have an addiction to heroin and we can do something about
10 this" without all of the overlay of, "Ooh, you are bad
11 and wrong, what's the matter with you?" and all of that
12 other stuff, but really thinking about it as a treatable
13 illness.

14 So, that's what I really want you to take away
15 from today, the fact that we have a real new addition to
16 what we can do. It doesn't work in a vacuum. People who
17 are getting buprenorphine are going to need access to
18 psychosocial services. It's actually in "DATA 2000" now,
19 that law that was mentioned before. It actually says the
20 doc needs to show that he or she can refer people for
21 appropriate psychosocial treatment. That, combined with
22 buprenorphine, can make a serious impact in someone's

1 career as an opiate addict.

2 That's pretty much what I wanted to say. One
3 of the other factors that we have had in addition to the
4 face-to-face trainings that have been provided by the
5 four organizations is the American Academy of Addiction
6 Psychiatry and the APA have also created a web-based
7 course and also CDs to teach you about buprenorphine.

8 So, if you are interested in that, you can go
9 to the CSAT website. You can go to the AAAP.org website
10 and find out more about this.

11 The idea here is we want to train as many docs
12 as we can. We want to get counselors and nurses and
13 psychologists involved and interested and supportive and
14 working with us to get the word out.

15 This isn't just about buprenorphine. This is
16 the beginning of a wave that could actually make a huge
17 sea change in our culture about how we view and treat
18 addictions. From the public health perspective, since
19 that is what we are really out to do, is promote the
20 public health and reduce morbidity and mortality, here is
21 a new way that we can really have a dent in things in a
22 big way.

1 Thank you for your time.

2 [End of proceedings.]

3 **Final Forum Thoughts**

4 DR. BROWN: In terms of whether these forums
5 are sufficient to draft physicians, I think they are part
6 of the recipe. We are going to need other ingredients to
7 include issues about informing and educating physicians
8 and medical societies, and medical specialty societies.

9 I think it is going to be important, also, for
10 patients to, in fact, ask questions of their physician,
11 because if anything drives physicians, it is the
12 questions of the patients.

13 DR. CLARK: The challenge remains in getting
14 physicians aware that they can participate in addressing
15 the issue of addiction in their practice. There may be
16 challenges getting beyond the stigma of the system that
17 occurs in the public setting, as was brought out by a
18 number of the people here today.

19 DR. KLEBER: I thought that the turnout was
20 terrific. We had a full house and people, in fact, got
21 turned away. I thought that the presentations were right
22 to the point.

1 DR. BROWN: With respect to SAMHSA, or the
2 Center for Substance Abuse Treatment, they have done a
3 splendid job of getting the word out. They have decided
4 that we have this opportunity, let's not mess it up,
5 let's not miss it, by putting it out in the streets, in
6 professional circles as well as in the public, to make
7 sure that everyone is aware that it exists.

8 Then it's a matter for the rest of us to, in
9 fact, come to the table. I think we will do that with
10 the continued encouragement of government, both federal,
11 city, and state, as well as private industry.

12 DR. CLARK: Continuing our efforts at educating
13 primary care physicians and looking at the professional
14 community as well as looking at counselors, pharmacists,
15 nurses, and others so that they know about the
16 availability of buprenorphine.

17 DR. KLEBER: The last I heard, there were about
18 2,000 physicians nationally who had received a waiver.
19 When we were talking about it a couple years ago, we had
20 hoped that by now there would be about 5,000. So we are
21 not where we want to be yet, and we need to redouble our
22 efforts to get there.

1 DR. CLARK: These forums give the community an
2 opportunity to raise their issues and raise their
3 concerns, and they give us an opportunity not only to
4 address those concerns but to catalogue them.

5 DR. KLEBER: I think we have to try a whole
6 variety of approaches, including forums such as these,
7 including what I heard this morning when I turned on NPR
8 -- there was a program on buprenorphine -- until we have
9 more physicians trained, until the major newspapers run
10 articles. I was pleased to see that there was a reporter
11 here today from the *New York Times*.

12 So, we need not one approach, we need a whole
13 variety of approaches to try and get both physicians
14 interested and opiate addicts interested in receiving the
15 drug.

16 One of the challenges is going to be getting
17 the non-addiction specialists involved in treating
18 patients with buprenorphine. That is going to involve
19 two things. One, showing them that they already have
20 people that could benefit from it in their practice.
21 These are the people that are being maintained on
22 prescription opioids such as hydrocodone, oxycodone, and

1 who would probably do better being maintained on
2 buprenorphine.

3 My hope is that once they get some experience
4 in maintaining these patients on buprenorphine, they will
5 then be willing to consider other people in their
6 practices that could benefit. They need to start looking
7 and saying, well, maybe I really haven't been doing as
8 much as I could to investigate whether such-and-such a
9 patient may be having problems with opiate addiction, and
10 maybe that's why they are not doing as well with their
11 diabetes or with taking their anti-AIDS medication, or
12 their other medication. We know that if people are
13 addicted they often get very sloppy in the way they take
14 medications.

15 So, after they have some successes under their
16 belt with patients they are familiar with and know that
17 they are addicted to opioid analgesics, my hope is they
18 will then reach out, start to think about addiction, and
19 look in their practice as well as new patients that they
20 might be able to help.

21 [End of tape.]

22 + + +