MEASURING THE EFFECTIVENESS OF DRUG ADDICTION TREATMENT

HEARING

BEFORE THE

SUBCOMMITTEE ON CRIMINAL JUSTICE, DRUG POLICY AND HUMAN RESOURCES

OF THE

COMMITTEE ON GOVERNMENT REFORM

HOUSE OF REPRESENTATIVES

ONE HUNDRED EIGHTH CONGRESS

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MEASURING THE EFFECTIVENESS OF DRUG ADDICTION TREATMENT

TUESDAY, MARCH 30, 2004

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON CRIMINAL JUSTICE, DRUG POLICY AND HUMAN RESOURCES,
COMMITTEE ON GOVERNMENT REFORM,
Washington, DC.

The subcommittee met, pursuant to notice, at 2 p.m., in room 2247, Rayburn House Office Building, Hon. Mark E. Souder (chairman of the subcommittee) presiding.

Present: Representatives Souder, Cummings, Blackburn and Davis.

Staff present: Marc Wheat, staff director and chief counsel; Alena Guagenti, legislative assistant; Nicole Garrett, clerk; Tony Haywood, minority counsel; and Jean Gosa, minority assistant clerk.

Mr. SOUDER. The subcommittee will come to order. Good afternoon, and I thank you all for coming. Today we will continue our subcommittee study of drug addiction treatment, or as President Bush refers to it in the National Drug Control Strategy, "Healing America's Drug Users." It is estimated that at least 7 million people in the United States need treatment for drug addiction. Getting effective help to those 7 million people and getting them to accept that help is one of America's greatest public health challenges.

Everyone agrees that we should help drug addicts get effective treatment. What is far more difficult is to find a consensus on how to measure what effective treatment is, but it is vital that we find that consensus because in an era of tight budgets, we must be able to focus our limited resources on the most effective treatment methods.

Last year, President Bush took what I believe to be a very significant step in that direction when he unveiled the Access to Recovery Initiative. Beginning this fiscal year, the President's initiative will provide $100 million to the Substance Abuse and Mental Health Services Administration [SAMHSA], to supplement existing treatment programs. That amount of money is intended to pay for drug treatment for most Americans who want it but can't get it, many of whom can't afford the cost of treatment and don't have insurance to cover it.

If fully funded at $200 million per year as requested by the President, it could help up to 100,000 more addicts get treatment. The program also has enormous potential to open up Federal assistance to a much broader range of treatment providers than are used today. Through the use of vouchers, the initiative will support

and encourage variety and choice in treatment and could open up and support a significant number of new options for drug users to get treatment. Finally, and most important for our purpose today, the emphasis on accountability should help us make significant progress in the most difficult issues of drug treatment policy, finding and encouraging programs that truly work, helping and healing the addicted, as well as ensuring a meaningful and effective return on taxpayers' dollars spent on treatment.

Earlier this month, SAMHSA published a request for applications spelling out the qualifications for programs to administer the new funds and inviting those programs to apply. The RFA, request for application, contains new performance measures designed to help us determine what programs are working for the patients and which ones aren't. I am especially looking forward to discussing Access to Recovery Initiative with the person most responsible for implementing it, my fellow Hoosier, SAMHSA administrator Charlie Curie.

With SAMHSA up for reauthorization this year, I'm also eager to discuss with him the agency's plans for the future of drug treatment. We are also pleased to be joined by Dr. Nora Volkow, director of the National Institute on Drug Abuse at the National Institutes of Health, which is the Federal Government's pre-eminent authority on the nature of drug addiction and the science of drug treatment. We are pleased to be joined in the second panel by a number of experts in the field of drug addiction treatment.

We welcome Dr. A. Thomas McLellan, director of the Treatment Research Institute in Philadelphia, PA; Mr. Charles O'Keeffe at the Virginia Commonwealth University in Richmond, VA; the Honorable Karen Freeman-Wilson, executive director of the National Drug Court Institute in Alexandria, VA; Dr. Jerome Jaffe, professor at the University of Maryland in Baltimore, MD; Ms. Catherine Martens, senior vice president of Second Genesis in Silver Spring, MD; and Dr. Hendree Jones, research director at the Center For Addiction and Pregnancy in Baltimore, MD. We look forward to discussing these issues with you.

[The prepared statement of Hon. Mark E. Souder follows:]

Opening Statement of Chairman Mark Souder

"Measuring the Effectiveness of Drug Addiction Treatment"

Subcommittee on Criminal Justice, Drug Policy and Human Resources

Committee on Government Reform

March 30, 2004

Good afternoon, and thank you all for coming. Today we continue our Subcommittee's study of drug addiction treatment, or, as President Bush refers to it in the National Drug Control Strategy, "Healing America's Drug Users." It is estimated that at least 7 million people in the U.S. need treatment for drug addiction. Getting effective help to those 7 million people, and getting them to accept that help, is one of our nation's greatest public health challenges.

Everyone agrees that we should help drug addicts get effective treatment. What is far more difficult is to find a consensus on how to measure what effective treatment is. But it is vital that we find that consensus, because in an era of tight budgets we must be able to focus our limited resources on the most effective treatment methods.

Last year, President Bush took what I believe to be a very significant step in that direction when he unveiled the Access To Recovery initiative. Beginning this fiscal year, the President's initiative will provide $100 million to the Substance Abuse and Mental Health Services Administration (SAMHSA) to supplement existing treatment programs. That amount of money is intended to pay for drug treatment for most Americans who now want it but can't get it, many of whom can't afford the cost of treatment and don't have insurance that covers it. If fully funded at $200 million per year – as requested by the President – it could help up to 100,000 more addicts get treatment. The program also has enormous potential to open up federal assistance to a much broader range of treatment providers than are used today. Through the use of vouchers, the initiative will support and encourage variety and choice in treatment and could open up and support a significant number of new options for drug users to get treatment.

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as well as ensuring a meaningful and effective return on taxpayer dollars spent on treatment. Earlier this month, SAMHSA published a Request for Applications (RFA) spelling out the qualifications for programs to administer the new funds, and inviting those programs to apply. The RFA contains new performance measures designed to help us determine what programs are working for their patients, and which aren't.

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Commonwealth University in Richmond, Virginia; the Honorable Karen Freeman-Wilson, Executive Director of the National Drug Court Institute in Alexandria, Virginia; Dr. Jerome Jaffe, Professor at the University of Maryland in Baltimore; Ms. Catherine Martens, Senior Vice President of Second Genesis in Silver Spring, Maryland; and Dr. Hendree Jones, Research Director at the Center for Addiction and Pregnancy in Baltimore, Maryland. We look forward to discussing these issues with you.

Mr. SOUDER. Now I will now yield to our distinguished ranking member, Mr. Cummings, for his opening statement.

Mr. CUMMINGS. Thank you very much, Mr. Chairman, for holding this important hearing on measuring the effectiveness of drug treatment. I have often said it is one thing to treat drug addiction. It is another thing to be effective in treatment. As you know, Mr. Chairman, drugs kill 20,000 Americans each year, and drug abuse and the illegal drug trade contribute to most of the violent crime and social problems we experience here in the United States. Providing effective treatment to people who have become drug dependent is necessary to reduce the demand for illegal drugs that drives consumption and fuels crime and social dysfunction. The President has proposed substantial increases in drug treatment funding, including increases for the substance abuse prevention and drug treatment block grant, which accounts for 40 percent of public funding for drug treatment, and the new Access to Recovery Voucher Initiative for which State applications are being accepted this spring.

Under both, the block grant and Access to Recovery, drug treatment funding is being accompanied by new requirements for outcomes measurement and reporting in an effort to increase accountability and effectiveness in drug treatment programs funded with taxpayers' dollars. I have often said that the one thing that Republicans and Democrats appear to agree on is that the taxpayers' dollar must be spent effectively and efficiently. These are appropriate goals in addition to expanding the capacity of the drug treatment system to ensure that treatment is accessible to those in need. We should seek to ensure that the treatment we fund is the very best that it can be. The value of treatment cannot be overstated. Numerous studies attest to the effectiveness of treatment in reducing not only the consumption of drugs and alcohol, but also the social harms associated with addiction, including violent crime, property crime, unemployment, risky health behaviors contributing to HIV and hepatitis infection and so on.

And yet, public funding for drug treatment has been derided by some critics who view drug treatment programs as a revolving door for addicts who lack a moral commitment to abstinence. Addiction research tells us, however, that relapse is a component of the disease of addiction and a part of the recovery process for most recovering addicts. Moreover, temporary abstinence and reduced consumption are beneficial for the patient and the community in which the patient lives and treatment contributes to these intermediate steps as well as the ultimate goal of permanent abstinence. The National Institute on Drug Abuse publication, "Principles of Drug Addiction Treatment," a research-based guide, cites several conservative estimates showing that every $1 invested in addiction treatment programs yield a return of between $4 and $7 in reduced drug-related crime, criminal justice costs and theft alone. When savings related to health care are included, total savings can exceed costs by a ratio of 12 to 1. The guide further states that drug addiction is a complex illness that nonetheless is just as treatable as other chronic diseases in which patient behavior is a factor, including diabetes, asthma and hypertension.

Evaluations of treatment programs must take into account not only the complexity of the illness, but also the very different life circumstances patients in a variety of treatment settings in which patients receive treatment. The diversity and types of treatment programs poses a challenge to efforts to establish criteria that will allow for meaningful comparisons. Applying criteria in a manner that is fair and that yields useful evaluations is critical. We have two very distinguished panels of witnesses who will offer their insights on this important subject today, and I am happy that my State of Maryland is so well represented.

We are fortunate to have both NIDA and SAMHSA before us on this panel. And I want to thank you, Mr. Chairman, in particular for allowing Dr. Hendree Jones and Catherine Martens to testify today as minority witnesses on the second panel. Dr. Jones is research director for the Center For Addiction and Pregnancy at Johns Hopkins Bayview Medical Center in Baltimore. Ms. Martens is senior vice president of Second Genesis, a therapeutic communities program in Silver Spring, MD. Taking into account the perspectives of treatment providers is critical to the development of evaluation methods that will yield meaningful and useful information, leading to more effective treatment. And I am glad that we will hear these important perspectives today.

With that said, Mr. Chairman, I look forward to hearing the testimony of our distinguished witnesses and I hope that this hearing helps to move us forward toward the goal of reducing drug abuse and dependency in this great country. With that, I yield back.

[The prepared statement of Hon. Elijah E. Cummings follows:]

Opening Statement of

Representative Elijah E. Cummings, D-Maryland-7
Ranking Minority Member

Subcommittee on Criminal Justice, Drug Policy and Human Resources
Committee on Government Reform
U.S. House of Representatives
108th Congress

Hearing on "Measuring the Effectiveness of Drug Treatment"

March 30, 2004

Thank you, Mr. Chairman, for holding this important hearing on measuring the effectiveness of drug treatment.

As you know, Mr. Chairman, drugs kill 20,000 Americans each year and drug abuse and the illegal drug trade contribute to most of the violent crime and social problems we experience in the United States. Providing effective treatment to people who have become drug-dependent is necessary to reduce the demand for illegal drugs that drives consumption and fuels crime and social dysfunction.

The President has proposed substantial increases in drug treatment funding, including increases for the Substance Abuse Prevention and Treatment Block Grant, which accounts for 40% of public funding for drug treatment, and the new Access to Recovery voucher initiative, for which state applications are being accepted this spring.

Under both the block grant and Access to Recovery, drug treatment funding is being accompanied by new requirements for outcomes measurement and reporting in an effort to increase accountability and effectiveness in drug treatment programs funded with taxpayer dollars. These are appropriate goals. In addition to expanding the capacity of the drug treatment system to ensure that treatment is accessible for those in need, we should seek to ensure that the treatment we fund is the best it can be.

The value of treatment cannot be overstated. Numerous studies attest to the effectiveness of treatment in reducing not only the consumption of drugs and alcohol but also the social harms associated with addiction, including violent crime, property crime, unemployment, risky health behaviors contributing to HIV and hepatitis infection, and so on.

And yet, public funding for drug treatment has been derided by some critics, who view drug treatment programs as a revolving door for addicts who lack a moral commitment to abstinence. Addiction research tells us, however, that relapse is a component of the disease of addiction and a part of the recovery process for most recovering addicts. Moreover, temporary abstinence and reduced consumption are beneficial for the patient and the community in which the patient lives, and treatment contributes to these intermediate steps as well as the ultimate goal of permanent abstinence.

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The Guide further states that drug addiction is a complex illness that nonetheless is just as treatable as other chronic diseases in which patient behavior is a factor, including diabetes, asthma and hypertension.

Evaluations of treatment programs must take into account not only the complexity of the illness but also the very different life circumstances of patients and the variety of treatment settings in which patients receive treatment. The diversity in types of treatment programs poses a challenge to efforts to establish criteria that will allow for meaningful comparisons. Applying criteria in a manner that is fair and that yields useful evaluations is critical.

We have two very distinguished panels of witnesses who will offer their insights on this important subject today, and I am happy that my state of Maryland is so well represented. We are fortunate to have both NIDA and SAMHSA before us on panel one, and I want to thank you, Mr. Chairman, in particular, for allowing Dr. Hendree (AHN-DRAY) Jones and Catherine Martens to testify today as minority witnesses on the second panel.

Dr. Jones is Research Director for the Center for Addiction and Pregnancy at Johns Hopkins Bayview Medical Center in Baltimore. Ms. Martens is Senior Vice President of Second Genesis, a therapeutic communities program in Silver Spring. Taking into account the perspectives of treatment providers is critical to the development of evaluation methods that will yield meaningful and useful information leading to more effective treatment, and I am glad we will hear these important perspectives today.

With that said, Mr. Chairman, I look forward to hearing the testimony of all of our distinguished witnesses and I hope that this hearing helps to move us forward toward the goal of reducing drug abuse and dependency in this country.

##

Mr. SOUDER. I thank you for your statement. I ask unanimous consent that all Members have 5 legislative days to submit written statements and questions for the hearing record and that any answers to written questions provided by the witnesses also be included in the record. And without objection, it is so ordered. I also ask unanimous consent that all exhibits, documents and other materials referred to by Members and the witnesses may be included in the hearing record and that all Members be permitted to revise and extend their remarks. Without objection, it is so ordered. Now it is the policy of this committee and the full Government Reform Committee to swear in our witnesses, so if you would stand and raise your right hands.

[Witnesses sworn.]

Mr. SOUDER. Let the record show that the witnesses have answered in the affirmative. I apologize. I wasn't paying attention. Do you have an opening statement?

Mrs. BLACKBURN. No.

Mr. SOUDER. I was so intent on reading the materials in front of me, I apologize. We will start with Mr. Curie.

STATEMENTS OF CHARLES CURIE, ADMINISTRATOR, SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION; AND NORA D. VOLKOW, NATIONAL INSTITUTE ON DRUG ABUSE, NATIONAL INSTITUTES OF HEALTH

Dr. CURIE. Thank you, Mr. Chairman and members of the subcommittee. Good afternoon. I am Charles Curie, Administrator of the Substance Abuse and Mental Health Services, part of the U.S. Department of Health and Human Services. At this time, I ask that my formal written testimony be included in the record of this hearing. In the time I have with you today, I will describe how SAMHSA is working to promote and provide effective substance abuse treatment to people nationwide, and I will describe how we are measuring the effectiveness of those efforts. The importance of substance abuse treatment prevention services is undeniable. And I am pleased to be appearing here today with my colleague, Dr. Nora Volkow of NIDA, where partnership is critical in us accomplishing that goal.

According to our 2002 national survey on drug use and health, of the 22.8 million people aged 12 and older who needed treatment for alcohol or drugs, only 2.3 million of them received specialized care. Over 85 percent of people with untreated alcohol or drug problems said they didn't think they needed care. Of the 1.2 million people who felt they did need treatment, 446,000 tried but were unable to get treatment.

The result, continued addiction, lost health, employment and education and often criminal involvement. That is a huge human and economic cost. Yet we know Federal investments in substance abuse treatment and prevention are cost effective and beneficial. Treatment is effective. Recovery is real. SAMHSA's national treatment improvement evaluation study found a 50 percent reduction in drug use 1 year after treatment. It reported up to an 80 percent reduction in criminal activity, a 43 percent drop in homelessness and a nearly 20 percent rise in employment. Our findings are corroborated by other SAMHSA and NIDA studies. We are also work-

ing to prevent substance abuse in the first place. The President set aggressive goals to reduce youth drug use in America.

With effective prevention efforts, rates are dropping; 11 percent in the past 2 years among 8th, 10th and 12th-grade students, according to NIDA's most recent monitoring the future survey. That is roughly 400,000 fewer teen drug users in these 2 years. And that means the President's 2-year goal has been exceeded. Let me remind everyone what SAMHSA is all about.

In contrast to NIH, SAMHSA is not a research agency. We don't conduct or fund research. SAMHSA is a services agencies. That means taking our work and our substance abuse prevention and treatment services programs to where people are in communities nationwide. That's where our programs, policies and budget priorities are driven by the vision of a life in the community for everyone. That's why they're driven by a mission of building resilience and facilitating recovery one person at a time. And that is why each and every one of our program outcomes is being measured against the yardstick of recovery, resilience and that life in the community for every man, woman and child. Our vision and mission are aligned with those of President Bush and Health and Human Services Secretary, Tommy Thompson. We appreciate their leadership and support for our vision of a life in the community for everyone. Three concepts at the heart of today's hearing guide our work: Accountability, capacity and effectiveness [ACE]. We assess ACE by gathering and analyzing data about our programs. But we are not collecting data for the sake of collecting data.

Today we are asking why we are collecting the data and whether they measure outcomes that are meaningful for real people working to make recovery a reality. If they don't, they simply won't be collected. That's why we have been working with the States to change the ways in which we assess our discretionary and block grant programs. It is an approach that focuses questions and expectations on success and substance abuse treatment and prevention, measured in real-time outcomes for real people. The result has been the identification of and agreement on seven outcome domains, the very outcomes that help people obtain and sustain recovery.

First and foremost is abstinence from drug use and alcohol abuse. Without that, recovery and a life in the community are impossible. Two other domains, increased access to services and increased retention and treatment, relate directly to the treatment process itself. We measure whether our programs are helping people who want and need treatment get the care they need, over the duration they need it and with the social supports that are most beneficial to each individual.

The remaining four domains focus on sustaining treatment and recovery, increasing employment or a return to school, decreasing criminal justice involvement, increasing in stabilized family and living conditions and an increase in support from and connectiveness to the community. These measures are true measures of recovery. They measure whether our programs are helping people achieve and sustain recovery. By focusing our program outcome data collection on just these seven domains over time, we can foster continuous program and policy improvement. We can know

whether our efforts to move new scientific knowledge from NIDA to the front lines of service delivery or science to services efforts are working for people.

SAMHSA's addiction technology transfer centers are an example. They encourage the adoption of evidence based practices by alcohol and drug abuse treatment programs and providers. We work with NIDA to disseminate new knowledge specifically related to the results of NIDA research. We will know whether these efforts are paying dividends in reaching recovery and promoting and abstinence from drugs, giving people an opportunity to obtain sustained recoveries at the heart of the President's Access to Recovery Initiative. That is the first place we will use the seven domains to assess our outcomes.

As you know and has been indicated, Access to Recovery is a new substance abuse treatment grant program funded at $100 million in fiscal year 2004, and for which the President is seeking $200 million in fiscal year 2005. ATR fosters consumer choice, improved service quality and increases treatment capacity by providing individuals with vouchers to pay for substance abuse treatment they need. At the same time, SAMHSA has been working with the States to transform its substance abuse prevention and treatment block grant program into a performance-based system. To begin, States will be asked to voluntarily submit data on the seven domains as we integrate performance accountability into the system. SAMHSA has invested significant resources to help States build their State data infrastructures. We will work with them to promote better accountability not just for where the dollars are being spent, but how effectively those dollars are being used.

By focusing program measurement and management on the seven outcome domains, SAMHSA, States and communities and this subcommittee can gain a powerful tool to guide the policies and program directions of today and tomorrow. For the first time, we can paint a picture of the effectiveness of drug treatment as it relates to recovery. We will ensure that our programs remain focused on the real-time needs of people working toward recovery and a life in the community. Thank you for the opportunity to appear before the subcommittee. I will be pleased to respond to any questions at the appropriate time. Thank you.

Mr. SOUDER. Thank you very much.

[The prepared statement of Dr. Curie follows:]

TESTIMONY
of

CHARLES G. CURIE, M.A., A.C.S.W.

ADMINISTRATOR
SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES
ADMINISTRATION
U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

SUBCOMMITTEE ON CRIMINAL JUSTICE, DRUG POLICY AND HUMAN RESOURCES
COMMITTEE ON GOVERNMENT REFORM

U.S. HOUSE OF REPRESENTATIVES

March 30, 2004
Washington, DC

Mr. Chairman and Members of the Subcommittee, good morning. I am Charles G. Curie, Administrator of the Substance Abuse and Mental Health Services Administration (SAMHSA), part of the U.S. Department of Health and Human Services (HHS).

In this testimony, I will describe how SAMHSA and its State and community partners are working to provide effective substance abuse treatment to people who want and need it. Key to that effort is how we are measuring the effectiveness of those efforts.

The need for substance abuse treatment services in our Country cannot be overstated. According to SAMHSA's National Survey on Drug Use and Health, in 2002, 22.8 million people age 12 and older needed treatment for a serious alcohol problem or a diagnosable drug problem. Only 2.3 million of them received specialized treatment for an alcohol or illicit drug problem.

Over 85 percent of people with untreated alcohol and drug problems felt they did not require care. Further, of the 1.2 million people who reported that they did feel they needed treatment for their alcohol or drug problem but did not receive it, 446,000 reported that they made an effort but were unable to get treatment; 744,000 reported making no effort to get treatment. The result of these findings is continued substance addiction; potential loss of health, employment and education; and possible criminal involvement, all at significant human and economic cost. All of this requires us to acknowledge that we need to build more capacity while using the existing treatment infrastructure to better serve those who seek and need substance abuse treatment. With a historic focus on this objective by the President, Congress responded to this call and funded an innovative new program – Access to Recovery. Your focus now on quality of the system as a whole is both timely and important.

We have compelling data that show that Federal investments in prevention and treatment are a cost-effective and beneficial response to substance abuse. Prevention *does* reduce substance abuse. Treatment *does* help people triumph over addiction and lead to recovery. For example, SAMHSA's National Treatment Improvement Evaluation Study (NTIES), a congressionally mandated, 5-year evaluation of substance abuse treatment programs, found a 50 percent reduction in drug use among clients *one* year after treatment. Clients included in this evaluation study were from underserved populations and included minorities, pregnant and at-risk women, youth, public housing residents, welfare recipients, and those in the criminal justice system. NTIES also reported a nearly 80 percent reduction in criminal activity, a 43 percent decrease in homelessness, and a nearly 20 percent increase in employment.

SAMHSA's Services Research Outcomes Study (SROS), with a nationally representative sample, found similar outcomes five years following treatment.

Our findings are corroborated by other studies, among them, the Drug Abuse Treatment Outcomes Study (DATOS), a National Institute on Drug Abuse (NIDA) study of over 10,000 clients who received treatment in 96 programs in 11 large U. S. cities. NIDA found that,

following treatment, patients dramatically reduced their drug use, reduced drug-related criminal activities, and improved their physical and mental health.

As we acknowledge the state of the science with respect to addiction, we have come to the inexorable conclusion that addiction is indeed a disease. It is unlike many diseases in that a significant challenge to its diagnosis and successful treatment is denial. We also know that the earlier we diagnose the problem of addiction, the more cost-effective and successful are the outcomes. To help overcome that denial, SAMHSA has begun to invest in a program of early detection and treatment, a regimen of Screening, Brief Intervention, and Referral to Treatment. We know treatment works, and it is cost-effective. We also know that innovation in treatment is necessary to increase effectiveness, quality, and efficiency.

While substance abuse treatment is clearly effective, we must also work to prevent substance abuse in the first place. As you know, the President set aggressive goals to reduce drug use in America. Today, with effective prevention efforts, rates of substance use among the Nation's youth are dropping. The data confirm that the President's two-year goal has been exceeded. According to the HHS Monitoring the Future Survey, released this past December by NIDA, drug use declined 11% over the past two years among students in 8th, 10th and 12th grades. That finding translates into around 400,000 fewer teen drug users over the two-year period. This decline in substance use among our Nation's youth suggests that our work, joined with that of the Office of National Drug Control Policy, and the extensive community-based work of schools, parents, teachers, law enforcement, religious leaders, and local anti-drug coalitions, together, is having an effect.

THE SAMHSA ROLE

SAMHSA is working to improve how we approach substance abuse treatment and prevention, not only at the Federal level, but also at the State and community levels. During my tenure, we have restructured our work around the vision of a life in the community for everyone and our mission of building resilience and facilitating recovery.

To focus and to guide our program development and resources, we have developed a Matrix of program priorities and cross cutting principles that pinpoints SAMHSA's leadership and management responsibilities. These responsibilities were developed as a result of discussions with members of Congress, our advisory councils, constituency groups, people working in the field, and people working to obtain and sustain recovery.

The Matrix priorities are also aligned with the priorities of President Bush and HHS Secretary Tommy Thompson whose support for our vision of a life in the community for everyone we appreciate.

THE ACE PRINCIPLES

To accomplish our priorities SAMHSA is building our programs around three key principles: *accountability, capacity, and effectiveness* – ACE. These are the very issues at the heart of the hearing today.

To promote *accountability,* SAMHSA tracks national trends, establishes measurement and reporting systems, develops standards to monitor service systems, and works to achieve excellence in management practices in addiction treatment and substance abuse prevention. We are demanding greater accountability of our grantees in the choice of treatment and prevention interventions they set in place and in the ways in which program outcomes meet the identified needs for services. We will promote accountability from States that receive funds from the largest single funding source for treatment dollars, SAMHSA's Substance Abuse Block Grant, through the Performance Partnership Grants.

By assessing resources, supporting systems of community-based care, improving service financing and organization, and promoting a strong, well-educated workforce that is grounded in today's best practices and known-effective interventions, SAMHSA is enhancing the Nation's *capacity* to serve people with or at risk for substance use disorders

SAMHSA also helps assure service *effectiveness* by assessing delivery practices, identifying and promoting evidence-based approaches to care, implementing and evaluating innovative services, and providing workforce training. For example, our National Registry of Effective Programs – with over 50 known-effective programs in prevention and early intervention – provides a foundation on which States and communities can build to meet prevention needs and reduce treatment needs. And our Treatment Improvement Protocols (TIPS) bring the latest knowledge about effective interventions, including treatment for adolescents, co-occurring disorders, and treatment for older adults, to professionals in the field. By utilizing, in the broadest way possible, the medical infrastructure of the Nation to diagnose and refer those addicted to drugs and alcohol, we ensure that those who suffer from the disease of addiction are identified and treated as early as possible, thus increasing the likelihood of a successful recovery.

To measure our effectiveness and be accountable, we must have the capacity to gather and analyze data about our programs. We are continuing to build on our national surveys, such as the National Survey of Drug Use and Health, the Drug Abuse Warning Network and the Drug and Alcohol Services Information System, to measure our programs' effectiveness, and, at the same time, we are working with States to build the infrastructure to capture and evaluate those measures.

NATIONAL OUTCOME DOMAINS

Working in collaboration with States and other stakeholders, SAMHSA has reviewed our discretionary and block grant programs, examining their ability to capture and assess treatment and prevention outcomes. The result has been the identification of and global agreement on seven key outcome domains that emphasize real results for people with or at risk for mental and substance use disorders, instead of focusing on outcomes related to the effects on systems needs or regulatory requirements.

By using the same outcome domains and their measures over time to assess progress, States and SAMHSA can foster continuous program and policy improvement. By using the same national outcome domains across all of SAMHSA's State and community-based programs, we will be able to report nationally aggregated data in standard periodic and special reports. We will know, as will you, OMB, and the public, with significant precision, whether the service system is improving and whether we are meeting the President's goals to reduce substance abuse nationwide. Moreover, we will be able to identify – and you will be able to know about – gaps or issues that need to be addressed at the national level through program, regulation, or statute. Our grantees, and SAMHSA, in turn, will be accountable for positive results. Perhaps most critically, we will be able to see just how well we are promoting recovery and the vision of a life in the community for everyone.

Let me share, briefly, each of the seven domains on which we will gather outcome information related to substance abuse prevention and treatment:

- The domain that is most key to recovery is abstinence from drug use and alcohol abuse.
- Three of the domains also important to sustained recovery are – increased employment/return to school, decreased criminal justice involvement, and increases in stabilized family and living conditions.
- The remaining three domains – increased access to services, increased retention in treatment, and increased social supports and connectedness – relate directly to the treatment process itself.

Each domain represents an outcome that you, SAMHSA, and the American people expect from successful substance abuse treatment systems. More important, these are the outcomes that help people obtain and sustain recovery.

ACCESS TO RECOVERY

Providing people with the opportunity to obtain and sustain recovery is at the heart of the President's Access to Recovery Initiative. ***Access to Recovery,*** a new substance abuse treatment-related discretionary grant program, will foster consumer choice, improve service quality, and increase treatment capacity by providing individuals with vouchers to pay for the substance abuse clinical treatment and recovery support services they need. This program was funded at nearly $100 million in FY 2004, and the President has requested $200 million in his FY 2005 budget. Vouchers, coupled with other State-operated programs, such as the Block Grant program, provide an unparalleled opportunity to create profound change in substance abuse treatment financing, service delivery and accountability in America. Change will also be driven by the first time use at the Federal level of the seven domains previously discussed to measure and manage performance of this grant program.

Clearly, moving forward with these measures is a challenge for a variety of reasons. However, we already have identified and resolved many of the potential obstacles, in large part through the deliberate, iterative process between SAMHSA and the States. By keeping the number of key domains to a minimum – seven in this case – and by using domains for which measures already are in place in many States, we have relieved a potential burden on States and communities in providing performance outcome data.

OUTCOME DOMAINS IN REAL-TIME: KEY SAMHSA PROGRAMS

The utility of these seven domains extends across all SAMHSA grant programs, from the Substance Abuse Prevention and Treatment Block Grant program – the largest portion of SAMHSA's budget – to our discretionary grant programs.

We are looking at what data we now are collecting. We are asking why we are collecting it. And, we are asking how are we using it to manage and measure performance. If we do not use it, we need to lose it. Let me mention a few examples of just how we are changing our focus on measuring performance and accountability for substance abuse services.

Performance Partnership Grants: As you are aware, SAMHSA has been working at the request of Congress to move its Substance Abuse Prevention and Treatment Block Grant program into Performance Partnership Grants, with an emphasis on performance outcomes. Rather than design a stand-alone Performance Partnership program, SAMSHA is committed to improving the management of the block grant programs – and both State accountability to SAMHSA and our accountability to you – by focusing data collection and outcome assessment on the seven core domains described earlier and providing States with clear, but limited, requirements and standards for National outcome data collection.

Critically, States have shared in the identification of these domains, and, to a large degree, consensus on their use has been achieved. Clearly, State reporting on these outcome domains will need to be phased in over time. A careful and full assessment of State capacity in this area is being undertaken, as are ways to set State outcome goals and targets. At the same time, SAMHSA is providing targeted technical assistance on data collection, reporting, and analysis. During this transition, States will be encouraged to report outcome data on each of the seven domains on a voluntary basis.

Discretionary Grant Programs: As measures of program effectiveness, the seven domains also will be used to assess the performance of existing discretionary grant programs. Critically, this includes the new Access to Recovery substance abuse treatment program for which grant applications are now being solicited from States, Territories, the District of Columbia, and Tribal Organizations.

SAMHSA is firmly committed to bringing accountability for performance into each and every one of its programs. We concur with Congress that such accountability is at the heart of good program design and program management. We will judge our programs on their progress in achieving positive outcomes across each of these domains and hope you will judge SAMHSA's work similarly.

DATA INFRASTRUCTURE

Concurrent with these efforts, SAMHSA is shifting from cohort data collection to client-matched data for all of its grant programs, whether block or discretionary, collecting this data on a real-time basis. Consistent with applicable information technology architecture and privacy parameters, we have been building a data infrastructure at SAMHSA and are continuing to work with States to build their data infrastructures to promote better accountability not just for *where* the dollars are being spent, but how *effectively* those dollars are being used.

We have invested significant resources to help prepare SAMHSA and the States to report on these measures in substance abuse treatment and prevention, including prevention's Minimum Data Set and State Incentive Grant programs, and treatment's Treatment Outcomes and Performance Pilot Studies (TOPPS I and II), which built upon States' systems reporting data via the Treatment Episode Data Set (TEDS).

SAMHSA's Data Strategy Group is now developing final recommendations on these and other data investments to help ensure that our dollars and programs are working to achieve their intended goals of resilience and recovery for people with or at risk for substance use disorders.

CONCLUSION

By assessing program effectiveness and performance with the proposed seven domains of recovery, SAMHSA, States, communities and this Subcommittee can gain a powerful tool to guide future policies and program direction, thus serving as a key feedback loop to inform both program and policy. Only through performance measures can States be assured that the community-based substance abuse prevention, addiction treatment, and mental health services programs that they are supporting are working, and working well. Only through performance measures can SAMHSA know that it is working successfully to achieve its vision of a life in the community for everyone and its mission of building resilience and facilitating recovery. Only through performance measures can you assess whether SAMHSA is using its resources wisely to reduce the toll of substance abuse on the Nation.

Thank you for the opportunity to appear before the Subcommittee. I would be pleased to respond to any questions you may have at this time.

Mr. SOUDER. We will hear from Dr. Nora Volkow, Director of the National Institute for Drug Abuse at NIH.

Ms. VOLKOW. Good afternoon. Thank you for inviting the National Institute on Drug Abuse to join with our colleagues at SAMHSA and others to participate in this very important hearing. I am pleased to be here at my very first hearing before Congress. What I would like to do today is share with you what science is teaching us about the chronic relapsing nature of addiction and the impact it has had on how we treat patients and how we measure treatment effectiveness. Every one of us in this room is here because we want to do something about the tremendous burden that drug abuse has on our society. Illicit drug use costs our Nation $161 billion a year. But that number is very small compared to the impact that drugs can have on individuals, families and communities. Drug abuse can lead to crime, domestic violence, child abuse, among others. It is also a leading factor for many diseases, including HIV-AIDS, and hepatitis.

Fortunately, our investments in biomedical research to improve the health of all Americans are paying off especially how we approach and treat addiction. Research shows that addiction is a chronic relapsing disorder associated with long-lasting changes in the brain that can affect all aspects of a person's life. New advances are beginning to increase our understanding of the developmental nature of addiction. Addiction is a disease that starts in adolescence and sometimes even in childhood. The urgency to combat substance abuse and addiction is highlighted by the numbers; 2.9 million 12 to 17-year-old individuals are currently using illicit drugs. This is a time when the brain is undergoing major changes in both structure and function. If we do not intervene early, drug problems can last a lifetime.

For this reason, NIDA is encouraging new research such that pediatricians and other primary care physicians have the tools, skills and knowledge to screen every patient as early as possible. We are also working with our colleagues from SAMHSA and others to rapidly bring new treatments to providers. For example, a little over a year ago with the help of many of you in this room, we were able to bring the new medication buprenorphine to qualified physicians. For the first time, doctors can treat patients who are addicted to opiates such as heroin and Oxycontin in their own offices. Over 3 decades of research demonstrate that treatment works. We have summarized these findings in one of our most popular publications to date, the principles of drug addiction treatment, commonly referred to as the Blue Book. This Blue Book has been distributed to over 12,000 providers and provides the basic principles that research studies have shown to be necessary for successful treatment. As with other chronic illnesses, treatment for drug addiction in most cases is a long-term process. In fact, the effectiveness of treatment for addiction is similar to that of other chronic relapsing disorders such as diabetes, asthma, hypertension and heart disease and many forms of cancer. Indeed, treatment compliance, drop out rates and relapse are similar for all of these chronic diseases.

The chronic nature of drug addiction dictates the need for ongoing care. The importance of this strategy is illustrated by stories of after care in criminal justice settings. Studies in California and

Delaware have shown that when treating drug abusers while they are in prison and continuing to provide treatment and other services while they transition to the community reduces drug use by 50 to 70 percent. It also reduces the likelihood that their return to prison by about 50 percent.

However, without the after-care component, the effects of treatment largely disappear. In addition, because drug addiction is associated with disruption across multiple dimensions of a person's life, treatment requires that not just the drug use but also its consequences be treated, which can include medical complications such as HIV-AIDS and hepatitis, mental illness such as depression, anxiety, suicide, criminal justice involvement, unemployment and problems with family and social functioning among others.

Conceptualizing drug addiction as a chronic relapsing disease that requires ongoing treatment and that affects multiple dimensions of an individual's life that need to be addressed for recovery will require that we change the way we measure treatment effectiveness. We particularly applaud SAMHSA for focusing on the multiple dimensions of drug abuse outcomes because this is consistent with our scientific understanding of the complexities of this illness. Like other areas of health care, standardized measures of drug abuse treatment effectiveness have not yet been developed and I commend this committee for addressing this important topic. Thank you very much. I would be happy to answer any questions you may have.

[The prepared statement of Ms. Volkow follows:]

Testimony
Before the House Committee on Government Reform
Subcommittee on Criminal Justice, Drug Policy and Human Resources
United States House of Representatives

Measuring The Effectiveness of Drug Addiction Treatment

Statement of
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Director,
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National Institutes of Health,
U.S. Department of Health and Human Services

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Mr. Chairman and Members of the Subcommittee, thank you for inviting the National Institute on Drug Abuse (NIDA) to participate in this important hearing. I am Dr. Nora D. Volkow. I have been serving as the Director of NIDA for close to nine months and I am very pleased to have this opportunity to testify about the remarkable advances we are making in the treatment arena.

The reason we are here today is because we all want to harness our energies and resources to alleviate the tremendous burden that drug abuse places on our Nation. Drug abuse and addiction are major public health problems that impact us all. To put it in dollar figures, substance abuse, including smoking, illegal drugs, and alcohol, costs our Nation more than $484 billion per year. Illicit drug use alone accounts for about $161 billion. But the impact drug abuse and addiction have on individual lives, families, and communities is even more devastating and in comparison makes the dollar impact seem less significant. Drug abuse is inextricably linked with the spread of infectious diseases such as HIV/AIDS, STD's, tuberculosis, and hepatitis C, and is also associated with domestic violence, child abuse, and other violent behavior.

Fortunately, our investments in biomedical research to improve the health of *ALL* Americans are paying off. Scientific advances supported by NIDA are coming at an extraordinary rate and are significantly influencing the way this Nation approaches drug abuse and addiction. Foremost, research is continuing to provide new insight into the chronic relapsing nature of addiction. Understanding addiction as a chronic relapsing disease that involves the brain, behavior, the environment in which an individual is raised, along with genetic factors, is critical since it frames how we must ultimately develop strategies to treat this disease.

Research shows us that drug abuse and addiction are complex. It usually begins in childhood or adolescence, when the adolescent brain is undergoing dramatic changes in both structure and function. This is the time when individuals begin risk-taking behaviors, and without early interventions the abuse can worsen, progressing to addiction. This is one of the reasons we refer to addiction as a *developmental disorder* and why NIDA is initiating a number of activities to get pediatricians and other primary care physicians more knowledgeable about drug abuse screening and treatments.

New imaging technologies reveal the neurochemical and functional changes that occur in the brains of drug-addicted individuals. These same techniques also demonstrate that individual differences in the numbers of certain brain receptors can predict whether a person will find a drug to be pleasant or aversive. We also now have extensive knowledge on how most drugs of abuse affect the brain--the receptors they bind to, the circuits they activate, and the ways in which the brain can change following chronic exposure to a drug or multiple drugs. For example, almost every drug of abuse, including nicotine, marijuana, cocaine, heroin, and methamphetamine, elevates the level of a brain chemical or neurotransmitter, known as dopamine. Dopamine is elevated by natural rewards as well as by stress, and is part of a reward circuit. Addiction results from the repeated perturbation of reward circuits. There comes a point, where an individual's brain becomes so altered that normal rewards are no longer sufficient, judgment and decision-making circuits become impaired, and the individual's overriding motivation becomes seeking and taking drugs. NIDA is committed to understanding the brain mechanisms and circuitry that underlie the actual transition from the drug abuse state to the addicted state. Researchers are working to determine if the change is gradual or precipitous, and they are studying, for example, the role that the prefrontal cortex of the brain plays in driving behaviors, as well as the individual differences in vulnerability to drugs, to determine more definitively how taking a

drug repeatedly over time changes the brain in such a way that leads to the compulsive, self-destructive patterns of drug use that characterize addiction.

Research shows that addiction is similar to other chronic diseases such as type II diabetes, hypertension, cardiovascular disease, and many forms of cancer with respect to its onset, course, and response to treatment. Like these other chronic diseases, drug addiction can be effectively treated and managed over its course, but this requires treatments to be readily available and adhered to. Addiction treatment has also been shown to be an effective way to prevent the spread of diseases, such as HIV/AIDS and hepatitis. Drug injectors who do not enter treatment, for example, are up to six times more likely to become infected with HIV than injectors who enter and remain in treatment. Participation in treatment also presents opportunities for screening, counseling, and referral for additional services, which can all help to reduce the spread of diseases to the general population.

There is hope. Recovery is possible and is happening. It is happening in hospitals, recovery centers, therapeutic communities, clinics, faith-based programs, and self-help groups in every corner of the Nation. Effective treatment occurs in a variety of settings, in many different forms and for different lengths of time. We have found treatments that are delivered by qualified professionals using empirically validated medications and behavioral therapies and applied for adequate durations, followed by monitoring and after-care, have successful outcomes. In fact, recovery from addiction is an established reality, achieved through a variety of treatment modalities when they are matched for the needs of individual patients. Numerous studies have shown that addiction treatments are comparable in effectiveness to treatments for other chronic illnesses.

However, as with other chronic illnesses, long-term treatment adherence and lifestyle change can be difficult to maintain. One very important analysis of these issues was published in the Journal of

the American Medical Association (JAMA, October 4, 2000). The authors clearly show that addiction treatment outcomes are very similar to treatments for other chronic, relapsing illnesses such as asthma, hypertension, and diabetes. In almost every case where patients were prescribed medications for chronic illnesses, less than 50% continue to take those medications as prescribed; less than 30% of patients comply with prescribed behavioral changes such as weight loss, dietary restrictions or exercise regimens. The factors that led to rehospitalization for chronic diseases were the same factors implicated in relapse to drug use. In this analysis, treatment compliance, drop-out rates, and relapse rates were similar for all four diseases. Thus, though we've come a great distance in our understanding of treating chronic illnesses, we still have many challenges to confront.

The ideal outcome of addiction treatment is the complete elimination of drug use. Not only does abstinence improve the health of the individual, but it reduces the adverse consequences that drugs can have on the health and safety of families and communities. Therefore, a primary goal of addiction treatment is to stop all drug use. Addiction, however, is a complex chronic disorder that often co-occurs with problems in the domains of physical health, mental health, criminal justice, employment, and family and social functioning. All of these areas must be addressed, not just the drug use. Similarly, measuring the outcomes of drug treatment should not be limited to drug use levels alone, improvements in these other domains can contribute to recovery.

Our expectations for treatment are high. Not only do we expect treatment to eliminate drug dependence; but we expect it to return the patient to productive functioning in the family, workplace, and community. Because of the heterogeneity in patients, such as age, gender, types and severities of substance abuse problems, and mental and medical health problems, eliminating drug dependence is difficult and moreover it is imperative that treatment providers have an array of science-based treatments to offer patients, in addition to access to services and resources to address the complex

problems that patients bring to treatment. As with other chronic disorders, we should also expect that those who are addicted may require multiple episodes of treatment continuing over the course of the disorder. We need to study further how to improve abstinence rates and quality of care.

NIDA grantees continue to bring new treatments to the forefront, both behavioral and pharmacological. A little over a year ago, for example, NIDA's medications development program saw the realization of its ten-year research investment when it was able to bring a new medication for opiate addiction, called buprenorphine, to physicians treating patients for addiction. Thanks to NIDA's research investment, pharmaceutical company participation, agencies working together, and an Act of Congress, qualified physicians can now treat their patients in their own offices. Other pharmacological approaches influenced by NIDA research are nicotine patches and gum, bupropion, and LAAM. Also, numerous controlled trials provide evidence that behavioral treatment approaches can be effective in reducing drug use while also improving associated behavioral, familial, and psychosocial outcomes. These pharmacological and behavioral interventions are components of an overall treatment process that proceeds through stages in which the patient engages in the therapeutic process, learns skills needed for recovery, addresses problems related to drug use, and learns to sustain recovery. Many of these treatments that have been shown to be efficacious in pristine research settings are now being tested in real-life settings across the country through NIDA's National Drug Abuse Treatment Clinical Trials Network (CTN). The CTN provides a national infrastructure to bring science-based behavioral and pharmacological treatments for addiction into diverse patient and treatment settings across the country.

Treatment of drug addiction requires a continuum of care, based on the evolving needs of the individual over time. This can include detoxification as an initial acute first step to treatment, the treatment itself, and participation in self-help groups, for example, once treatment is completed. Most

effective drug treatments include an after-care component. For example, studies in states such as Delaware and California have shown that comprehensive treatment of drug-addicted offenders, when coupled with treatment after release from prison, can reduce drug use by 50-70% when compared to those who are untreated. Treated offenders are also 50-60% less likely to end up back in prison. These findings hold true for at least four years after release. Moreover, offenders who did not receive after-care in the transition back into the community, despite receiving in-prison treatment, had significantly poorer outcomes. Particularly for those who have the most serious problems, the most favorable outcomes are obtained following treatments that provide comprehensive services, often in a residential setting. To be effective, treatment should attend to problems of the individual that would otherwise jeopardize his or her recovery and participation as a productive member of society. This means that a continuum of care is crucial for success, including offering treatment and services to offenders with substance use disorders as they transition and after they return to life in the community.

It is not easy, nor simple to measure treatment outcomes; but it is also not impossible. We are committed to the President's management agenda. Program effectiveness must be measured and accountability for outcomes must be established. Typically measurement is done at the individual, not at the program level. To be able to understand the many factors that determine long-term outcomes in treating the chronic addictive disorder, researchers look at factors such as levels of drug use, criminal behavior, family functioning, educational achievement, employment, and medical problems. This kind of information is typically gathered before treatment begins, during the course of treatment, and at intervals over time following treatment. It is critical to assess the problems that patients bring with them as they enter treatment in order to compare the effectiveness of any given program with that of another.

A variety of instruments have been developed that can be used to assess patient needs and develop treatment plans. One well-known instrument is the Addiction Severity Index (ASI). The ASI, which has been developed and refined through NIH and Veterans Administration support over the past 20 years, is the most widely used and validated addiction assessment instrument in the world today. It provides the trained counselor with the tools he or she needs to conduct a structured 45-60 minute interview that has been shown over the years to provide valuable information that not only captures critical baseline data, but sets the stage for improved treatment outcomes. A computerized version is now being piloted in the United States as a way to collect information about clients entering federal treatment programs. Other measurement tools have been developed through federal research and are in the public domain.

These are some of the ways that treatment effectiveness is currently measured. Like other areas of health care, standardized measures of drug abuse treatment effectiveness have not yet been developed. To help in this development, NIDA offers a robust health services research portfolio that is teasing out the active and necessary components of an effective treatment program. Those that have successfully led the addicted through recovery. There is also some research being supported by NIDA and the Substance Abuse and Mental Health Services Administration (SAMHSA) looking at performance measures. Researchers are looking at data to determine which performance measures could be used to more systematically determine the effectiveness of treatment services and to promote quality and accountability in the delivery and management of drug abuse services by organized systems of care.

NIDA's goal is to improve the Nation's quality of addiction treatment using science as the vehicle. NIDA will continue to encourage research that supports the development of innovative treatments, including online treatments, and determine ways to measure their effectiveness. Improving

drug abuse treatment will ultimately depend not just upon the development of effective interventions, but also upon research to understand and to improve the overall treatment process.

Thank you. I will be happy to respond to any questions you may have.

Mr. SOUDER. I thank you both for your testimony. I believe your statement was very clear, Mr. Curie, but I want to ask it again for the record because as the administration moved in to several of these new initiatives, one of the most common questions was, were new grantees going to be treated differently in accountability than previous grantees? As I understood your statement, you said whether or not it was discretionary or block granted, you were looking for a continuity of measurement where all would be measured in similar ways?

Dr. CURIE. That is correct. We are able to operationalize Access to Recovery and we are asking States or tribal entities who are responding to that request for applications [RFA] to demonstrate how they will either entice or assure measurement from providers who are eligible providers to receive the voucher. At the same time, as we move ahead with performance measures on the block grant and other targeting capacity expansion grants, we are looking at the seven domains of common measurements to be required of all grantees. The primary reason is there has been consensus in the field that these seven domains represent recovery and represent measurement of someone who is in recovery, and that is really the goal of all of our services that we are funding.

Mr. SOUDER. Dr. Volkow just talked in her written testimony about the impact of comprehensive treatment. And in the written testimony, it also says that in the studies in Delaware and California, that offenders who are treated in prison are less likely, if they have comprehensive treatment, to end up back in prison. But if they do not receive after care despite receiving in prison treatment they have poorer outcomes. My question to you is, are we interconnecting the different programs at this point in the Department of Justice in what you are doing and what can we do to encourage more of that type of cooperation? I know, for example, in the Fort Wayne area, we both know well, they have Justice Department grants for continuum of care.

And Congressman Davis has a bill that I support on housing questions. But are we seeing these things coming together, because so many of us see people who have been in a treatment program and they go right back in and the question is how can we integrate and look at this more holistically from the Federal Government level.

Dr. CURIE. I think the answer is yes, we are making great progress in that area. We do have joint programs with the Department of Justice. For example, we are funding the treatment components of reentry courts. Fort Wayne is an example of a reentry court. And we have an understanding, a relationship with Justice, that our responsibility is to fund community-based treatment for individuals who are coming out of the justice system, and to collaborate on drug courts. And again, we have a commitment between both departments to continue to foster that relationship. I think we are all in agreement that the treatment and recovery support systems on the community based side of things need to be integrated, and you don't want to see a separate criminal justice and community-based system of care. But if we truly are working for individuals to have that life in the community, it needs to be part of the overall public health focus.

Mr. SOUDER. Before I followup with Dr. Volkow on that particular question, when you give block grant money to the States, is there any guidance to them that says we want this integrated with the drug courts, with other reentry programs and not just OK, we are pursuing this thing at the Federal level and these different agencies and you're pursuing this?

Dr. CURIE. For the block grant there are various directives and statute that are on the block grant. The States do have a lot of latitude. That's the very thing we are examining as we move to PPGs is how we can measure and incent, if you will, a system with further integration.

The other thing I might mention, there are block grant dollars, I know, in a wide range of States that are going toward treating individuals who are coming out of the criminal justice system. Also with Access to Recovery, nothing precludes the State, in fact, we have encouraged this one scenario, a State or a tribal organization may want to use the vouchers in connection with the drug court or the reentry court program and actually begin their voucher program with that specialty population. And we anticipate we are going to see those types of models proposed.

Mr. SOUDER. Dr. Volkow, have you seen any of these integrated studies? Are you setting up any tracking to see whether or not we are getting the results when we have a drug court, a reentry program and a prison treatment program or community-funded program? Are you able to see enough of these that you can start to research it and to see whether what was suggested in the State studies might, in fact, be true?

Ms. VOLKOW. One of our priority areas is how to actually develop knowledge that optimizes the way that we bring the prisoners back into the community. We have a strategy that, for lack of a better term, we are calling an "NIDA goes to jail" and it has multiple components. One of them is to generate the knowledge and to create the infrastructure. One of the things that we have started is what we call the Criminal Justice Drug Abuse Treatment Studies [CJDATS] and these are seven of our criminal justice systems working with academic centers to develop research protocols to optimize our reentry of the prisoner back into the community. Another component is to interact with SAMHSA, and also to interact with the Department of Justice to bring education about the signs of addiction and the treatments that are available. So that is the educational component.

And finally, the other aspects we are working with, which we are also addressing is the issue on research that unfortunately is common in the substance abuse area. Many of the individuals that end up in prison are frequently associated with co-morbid mental illnesses.

So that is another area where we don't have sufficient research. And in parallel to this initiative, there is also parallel one for the criminal juvenile offenders.

Mr. SOUDER. Can I ask one supplemental question? I know all the members are interested in this as well. I didn't mention, and nor did you, the Labor Department or the Education Department. Are we looking at any attempts to look at vocational education and/

or employment as part of this rehab where that would be integrated as well?

Dr. CURIE. Yes. In fact, one of the major domains, employment and education which reflect a dimension of recovery, we are looking at collaborating with labor. We are looking at potentially—I know a reentry program was proposed by the President which would be focused on just that and with the efforts between Justice and HHS at this point around bringing individuals back into the community to succeed. It would make a lot of sense to be engaged in that process to make sure we have a comprehensive approach. Also on a related side of the equation, on the mental health agenda side, we have an action agenda around transforming the mental health system, which will address co-occurring disorders which has a clear connect to addictive disorders. And with that, we have Labor at the table collaborating with us around models that work to help people gain employment.

Mr. SOUDER. Mr. Cummings.

Mr. CUMMINGS. Thank you all very much for being here. Ms. Volkow, tell me exactly what you mean—what is your definition of after-care? You said it is important that you have after-care. And I want to know what are the essential ingredients for what you deem to be effective after-care?

Ms. VOLKOW. The after-care for someone who has been in jail or after-care for any drug abusing person that ends up in a health care facility seeking treatment.

Mr. CUMMINGS. Both?

Ms. VOLKOW. What it basically requires is that it starts, and this is actually one of the things that has been clearly summarized in the principles of drug addiction and what has been, there is consensus that in the initial reentry of the person you are focusing on stopping the drug use while at the same time starting to engage the patient on realizing what are the positive and negative aspects of taking drugs. Once that individual recognizes his position on this stance, he is taken to the next step, which is to teach that individual what are the actions that he needs to do in order to optimize his chances to not take drugs.

So that is the first stage. Once that is achieved, the patient goes into what we call after-care and the patient is released into the community and that requires that there has to be followup and there are several programs that can be utilized. There is nothing like a recipe that works for everyone.

So the first thing that has to be realized is that the treatments have to be tailored for the unique circumstance and characteristics of the patient, and that will require that the several aspects that SAMHSA is focusing on are addressed. You need to address not just the substance abuse, but the integration of the individual and the support of the community, which ideally should include the family. And if the family doesn't exist, what does the integration require? If it is an adult, that they have employment. And if it is a younger person, that they are able to continue in the educational system.

At the same time, what science has taught us is that self-help groups are usually very beneficial. And in certain instances, the no-

tion of medication can help drug-addicted persons stay away from drugs.

And finally, but not because it is least important, unfortunately substance abuse is frequently coupled with morbid mental illness. And if the issue of mental illness is not addressed, they are very unlikely to succeed in getting that person out of drugs. That is what the after-care entails, being able to monitor all of these different dimensions that have unfortunately been affected by the drug addiction process.

Mr. CUMMINGS. I was waiting for you to say and you finally did say it, a job is helpful, isn't it?

Ms. VOLKOW. One of the things we have come to realize is that we are human beings. One of the most important aspects that motivates our behavior is to be part of a group; to be part of a community, and to feel that we are appreciated and we can contribute to that community. It is one of the most important aspects that motivates our actions in life. So when you bring a person into community and you make him feel he is part of it, you actually achieve a great deal through that process.

Mr. CUMMINGS. Mr. Curie, you were with us in Fort Wayne?

Dr. CURIE. Yes, I was.

Mr. CUMMINGS. If you recall when we were in Fort Wayne with the chairman, a lot of those judges came forward and talked about how they were so upset that State law—that is what they were talking about, I think—because somebody had a drug offense on their record, it had precluded them from getting so many jobs. And when I go to the inner city of Baltimore, I talk about that because they think it is only a problem in the inner city. And so then I just heard Ms. Volkow talk about how jobs are a part of getting that person back into society.

Are there any efforts to try and look at some of these State laws on the part of either of you? And I don't know if that comes under your purview, so we can get people to have some hope and able to get back and circulate in society, since that is such a crucial part of recovery.

Dr. CURIE. I am not aware of any formal reviews of looking at that. I think it would be a worthwhile endeavor to consider, especially since we are using recovery now as our framing of service delivery. Historically, and I think Dr. Volkow was, when she is talking about after-care, historically, I think from the public sector side of things, as we finance services, we have focused primarily on the treatment or the treatment intervention and not on the whole recovery picture. We have begun focusing on the whole recovery picture recognizing that relapse is less likely to occur if people are attaining those real life goals of employment, education, stable housing, connectiveness to family and friends, and connectiveness to the community. So as we are basically embarking, I would say, in a relatively new chapter as we look at what we are financing. I think the type of review you described would be worthwhile because historically you never heard us talking necessarily to labor or to education about how we help individuals build a life. We used to think that if we provided access to care and some forms of care, we are done with our mission. We are recognizing today that we are not finished with our mission.

Mr. CUMMINGS. Just one other thing. When I talk to people in my district who are recovering addicts, one of their biggest concerns is a job. And the more I think about it combined with what you just said, I mean, it really makes sense. One, they need another family. In other words, the family that got them on drugs, they need to get away from that group or they will be right back where they started. Two, I guess it does give them a sense of worth. Three, it gives them a whole lot more eyes looking over their shoulder, like the woman who is their boss or the person that they become familiar with and becomes a friend that they eat lunch with or people that go out and play baseball after work.

So basically what we are talking about is sort of a shifting from one lifestyle and trying to shift them over to another lifestyle, that includes new people and new opportunities to change and get away from what sent them there in the first place.

Dr. CURIE. Exactly. Goals, aspirations, you mentioned hope earlier. It is all part of it. Your experience parallels mine. When I ask a question of people what they need, people who have an addictive disease or disorder, they don't define that they need a clinical program. They define that they are looking for a job, a home and a date on the weekends to build a new life. And a job also strikes not only giving someone a sense of worth, but in our society, the basic question you're asked when you enter a neighborhood is what do you do? And if you don't have an answer to that question, already you're on a slippery slope in terms of acceptance in that community. So a job goes to basically identity in this society.

Mr. CUMMINGS. Just as a footnote when you are at a party and a fellow is talking to a young lady, she wants to know what do you do, do you work and have job.

Mr. SOUDER. Congressman Blackburn has been very involved in this before she came to Congress, and we had an excellent hearing in her district as well, a number of remarkable people in Tennessee.

Mrs. BLACKBURN. That is exactly right. Thank you, Mr. Chairman and to my colleague. He was speaking in terms of family and I was sitting here making some notes before he started speaking on that issue, abouit the importance of a family or an extended family or well-placed mentors. I do applaud our President in the fact that he has developed mentoring programs and that he is a supporter of faith-based initiatives. As the chairman mentioned, the hearing we did in our district and the very active work and participation that is taking place on that.

So I agree with what he is saying, that those life skills that many times our educational system no longer teaches. It is important that we have families and mentors to fill that void and to teach those skills to young people. I thank you both for being here and appearing before us. I appreciate it.

Dr. Volkow, I want to thank you specifically for using the front and back of your paper. We conservatives like to see that. It is wonderful that we doubled up there. You know just think what we could do to cut the use of paper in half if we used the front and back of the paper, so we thank you for that. A couple of questions that I do have looking through your testimony, Dr. Curie. I want to start with you first, please. As you reference the programs in the

studies that you have done, one of the things I am not seeing is the complete universe of individuals in your programs. I am going to ask these questions in bulk just to save time and let you answer them.

Out of the individuals in the program and the length of time they were in their programs, one of the things from the State level that we have learned is that short programs don't work, longer programs do work. Out of this universe, what is the recidivism rate and do you have any documented evidence on tying the length of the program to the recidivism rate? In looking at your accountabilities, and I appreciate your spelling out the seven domains, I think that is really excellent, do we know how much we are spending per individual to move them through this program?

And let me go ahead and finish here. When we look at the States, and both of you mentioned working with the States, as you move them through this, have you developed some type of software that you or some type of program that they are going to be able to submit this accountability data to you? And our grantees, if they are not accountable, is there a process for withholding money or moving them out of the program? I know that is a lot to throw out, but I have got 5 minutes, so I wanted to be sure I got out of all of these things before you.

Dr. CURIE. Understood. I can share with you information about specific programs and the link between longevity within the program and relapse and we have that mainly on specific programs, sometimes by State. There is no real comprehensive national picture of that and that is one reason we want the seven domains to be consistent among all grants because we think that will help us begin to paint more of a national picture.

Mrs. BLACKBURN. Mr. Chairman, I would like to request that we have that submitted for the record and for our review.

Dr. CURIE. And as we move ahead in terms of working with the States, State data infrastructure is a real critical issue. When you speak to the States, you understand that there are many demands on their particular State budget. At the same time, they have State legislators and Governors who want to have this information for them to make informed decisions. So there is an alignment of goals. We are providing both resources and technical assistance to States to help and develop the data infrastructure. Also working with States, there are certain States that have excellent data information systems that can be used as models for other States.

We are also looking to work with the National Association of State Alcohol and Drug Abuse Directors to accommodate that. But that is a priority and it is going to be essential in order for us to gain the data we need to measure performance.

Mrs. BLACKBURN. Thank you, sir. Go ahead. Thank you, Mr. Chairman.

Mr. SOUDER. Mr. Davis.

Mr. DAVIS. Thank you very much, Mr. Chairman and I thank you for calling this hearing. I have gotten very much into this whole business. In fact, I am leading an initiative effort in Illinois to get a referendum on the November ballot calling for drug treatment on demand. We have to get 300,000 signatures and we have gotten about 60,000 that I have in my office in a safe right now. Let me

tell you the headlines in the Chicago Sun Times on Monday, saying that Chicago is now No. 2 in the Nation in drug overdoses. Philadelphia is No. 1. Chicago is No. 2. And of course lots of folks thought that the increase would be in the inner city area of Chicago, but it is actually more prevalent in the suburban communities outside of Chicago and especially with teenagers using heroin.

And so it is a big issue and a big problem. One of the questions we find people are asking as we deal with our referendum effort is how effective is treatment, that is, if individuals get treated, then so what? What is the difference between the recidivism rate for those who are treated and those who are not? And we got into it really because there is such a close relationship between crime and drug use and abuse. I mean, most of the crime that we encounter is in some way, shape, form or fashion drug related or drug connected. And so we got to thinking that if we could reduce drug use, we also could reduce crimes and save ourselves a tremendous amount of money and human misery and other problems associated with it.

Is there a discernible difference in different kinds of treatment and their effectiveness? Do we have enough data to suggest that people who treat it one way, the recidivism rate might be one thing. If they are treated another way, it may be something different?

Ms. VOLKOW. Yes, there is some data for certain drug addictions, particularly for heroin, where we have compared the relapse rate for one type of treatment versus the other. And in the case of heroin we of course have methadone and buprenorphine, and indeed, studies have shown very, very clearly and cogently that treatment with these medications significantly reduces relapse and also the relapse reduction is significantly greater than basically other types of treatment intervention.

For heroin addiction, that is definitely the case. For other types of addictions, there is not enough research to compare one modality versus another. There are two aspects that I think are very, very relevant. When you compare one modality versus the other, you have to consider that not every addict is the same nor are their circumstances. And that's why I made the point that you have to be able to tailor the treatment accordingly to the needs of the individual. It is not going to be a transparent comparison in one versus the other.

Another thing I want to reiterate because it is extremely important and it has carried the field tremendously, is the notion that when you provide treatment and there is relapse, automatically it is felt that there was failure when, in fact, relapse may not be failure. When you are treating someone for hypertension, if the blood pressure has been stabilized for 6 months and 1 day it goes up, did you fail? You did not fail. You restart treatment. Even though relapse is part of the process, it does not necessarily mean that our medications have failed and that is one of the aspects that we have to start to change in the way we evaluate treatment. We are setting up the comparisons of different treatment modalities. We have the clinical trials network whose function it is to do exactly what

you are asking, to compare the different modalities and to optimize what is best for a given individual.

Mr. DAVIS. Thank you, Mr. Chairman. I have to run to another hearing, but I would like to ask one additional question if I could, and that is, is there enough information that we have been able to evaluate relative to faith-based efforts? And I mean we had an event Saturday and I had about 400 people in recovery and since I have been working so closely with them, I have learned so many things that I haven't really thought about in terms of who is addicted.

A lot of people seem to think that a lot of individuals who are addicted are thrill seekers and macho people and that many of the people who become addicted are lacking in self-esteem and somehow or another, whatever it is, they end up using. We were doing role playing and all of that to get them ready to go out and help get these signatures. And there were some individuals who simply could not ask a person to sign a petition because they could not look at them. And even when they would be talking they would be looking away. And of course, the faith-based stuff seemed to help with that somewhat. Is there any data related to the effectiveness of faith-based efforts?

Ms. VOLKOW. The answer is that there has not been enough research in this area. We are currently funding several grants that are specifically addressing the role of spirituality in the recovery process because most of the treatments that are available for drug addiction incorporate faith-based approaches into their systems. We are specifically requesting in all of our program announcements and request for proposals that faith-based organizations, we are encouraging them to apply for these funds.

Unfortunately, there is not enough research that has been done, but we are actually encouraging the community to come and request grants so that we can start to look at these questions that you are asking.

Mr. DAVIS. Thank you very much, Mr. Chairman, and I appreciate your leadership in this area.

Mr. SOUDER. If you have additional written questions that you want to submit, you can do that as well. If I could ask a followup on that faith-based point. We have been doing a series of field hearings around the country, both on narcotics and on faith-based. And one of the things we heard in San Antonio as well as Los Angeles and a few other places is that in faith-based drug treatment programs, one of the things that has been an effective measure, and disagree with me if this is incorrect, but I think most people agree that the more inclined a person is to want to get off their addiction, the more success there is, not saying that you have to have voluntary compliance or speaking about the program to make it more successful. But the more one is prepared to have a life changing experience, the more likely you are for success. And one of the roles of the faith based organizations is preparing their heart for a change in their life that prepares them for the drug treatment.

Is that one of the things you might be looking at in the research, and has that come up before?

Because that is a little different than saying it is precisely a drug treatment program. It is saying that because they are willing to

make a life change and they are transforming their life, that has prepared them now mentally to go through a drug program.

Dr. VOLKOW. What you are saying is correct. It is a basis of a therapy called transcendental therapy, and it has been shown to be effective not just for drug addiction but other types of behavioral disorders, where the main element is to make the person aware that they want to really incorporate the sense that they want to make a change in their life. This is an extremely important component of whether a person will succeed or not.

Yet at the same time, you also state that what we have shown, it does not necessitate treatment be voluntary, but the motivation of the person to change is indispensable.

As for your question about what is the role of faith-based organizations in helping drive the person to really accept and incorporate that need to change and willingness to change is one of the items that may indeed be playing a role. But we have to do the stories to demonstrate it.

The question scientifically is, what are the active ingredients that determine the benefits for faith-based approaches? And it is likely that one of them may be, but that is why we are doing the work. And we do not have answers yet. So one can just predict. From previous research, it does make sense that this is one of the variables.

Mr. CURRIE. I would say one common denominator among all programs, whether they are faith-based or they're not faith-based, could, again, be the seven domains being a way of judging outcome and effectiveness over time as well. And I think those domains can be utilized with a wide range of interventions.

Also, I think with faith-based approaches, recovery is such an individualized process. As Congressman Davis said, if there were 400 people in the room, there will probably be 400 different stories of recovery, some with common elements.

But the role that faith plays, sometimes, it is an upfront role as you just described. Sometimes, it's a role that, once they've been through a medically based program in order to sustain recovery in the 12-step program, the spiritual component of that helps them sustain recovery.

So I think faith can play a role at different levels in an individual's life, and again, I think the biggest challenge for us in using recovery as we are framing both public policy and public finance is that it is such an individualized process.

Mr. SOUDER. I want to ask one other question. The most spectacular failure, certainly in North America and possibly the world, is Vancouver, British Columbia, right now in their needle-exchange program. And now on top of having the world's highest HIV infection rate, they have this huge expanded market of actual heroin addicts. And now this high-THC marijuana, it has now corrupted several officials in their government. They are being prosecuted, going down the path of Colombia, more or less, and what happened in Mexico before those governments started to tackle it.

In Vancouver, they started this program in 1988. They are now up to 2 million needles that they are distributing on the street. And people call that harm reduction. And I wanted to have two clarifications here.

One is, there is a difference between harm reduction defined that way, which is more of a maintenance question. In other words, a heroin addict is getting a needle. The presumption is that you reduce AIDS, which has not necessarily been proven. The presumption is that you reduce AIDS, but you wouldn't treat the heroin. That is different than the treatment programs you are talking about. You are not talking about maintenance. You are talking about changing someone's addiction.

And the second thing I wanted to make sure that we were clear on is that do we have any data, or what percentage of people who actually get the needle exchange go to treatment? Or in fact, does giving them the needle perpetuate it, and then they do not see the need for treatment?

Dr. VOLKOW. Actually, it is interesting, because you were making the statement in the way that you were saying, which is absolutely correct, that just providing needles by itself is not helping anyone.

But what research has shown is that needle-exchange programs in the line of a comprehensive drug-treatment program have been shown to reduce HIV, and also includes the likelihood that these individuals will stay for treatment. So needle exchange by itself is not going to solve a problem. Not at all.

And it also addresses another aspect that is very relevant when we look at one thing. We sort of say we are looking at treatment. And the other aspect I view, which is very relevant, is that of prevention. So what is the message that we are sending with respect to prevention in terms of just exchanging needles?

And that is why, when we bring up that issue, we basically say what science has taught us is that needle-exchange programs in line with a comprehensive drug-abuse treatment program have shown in fact to reduce the cases of HIV when they are combined. Not by itself.

Mr. CURRIE. You are exactly right. The treatment programs we are talking about are not about harm reduction. In fact, when we talk about prevention and recovery, we are not talking about harm reduction but harm elimination. It's bottom line the risk factors you need to eliminate in the prevention scenario. As one attains and sustains recovery, they begin to manage their illness. They begin to manage their life. And that goes much beyond a harm-reduction vision.

Mr. SOUDER. I thank you both for your testimony, and we will probably have some written followups, not only from me but from other members in the subcommittee.

Thank you for coming.

Mr. SOUDER. If the second panel could come forward. As you come forward, if you could remain standing so that we could do the oath. If witnesses would raise their right hands.

[Witnesses sworn.]

Mr. SOUDER. Let the record show that each of the witnesses responded in the affirmative.

Thank you all for being here today. Our first witness is Dr. Thomas McLellan, director of Treatment Research Institute in Philadelphia, PA.

STATEMENTS OF THOMAS MCLELLAN, PH.D., DIRECTOR, TREATMENT RESEARCH INSTITUTE, PHILADELPHIA, PA; CHARLES O'KEEFFE, VIRGINIA COMMONWEALTH UNIVERSITY, RICHMOND, VA; KAREN FREEMAN-WILSON, EXECUTIVE DIRECTOR, NATIONAL DRUG COURT INSTITUTE, ALEXANDRIA, VA; JEROME JAFFE, M.D., PROFESSOR, UNIVERSITY OF MARYLAND, BALTIMORE, MD; CATHERINE MARTENS, SENIOR VICE PRESIDENT, SECOND GENESIS, SILVER SPRING, MD; AND HENDREE JONES, PH.D., RESEARCH DIRECTOR, CENTER FOR ADDICTION AND PREGNANCY, BALTIMORE, MD

Dr. MCLELLAN. Thank you. I was already told that one person wrote on both sides. I wrote on no sides, so I will just read it here.

I am Tom McLellan. I am a researcher in the substance-abuse treatment field from the University of Pennsylvania, Philadelphia, and the Treatment Research Institute there.

I am not an advocate and neither I nor my institute represent any treatment or Government organization. I offer evidence on the effects of treatments for alcohol, opiate, cocaine and amphetamine addictions based on my own work of over 400 reviewed studies and based on reviews. I'm the editor of the journal Substance Abuse Treatment, so I see many reviews of other work.

I have five very simple points to make. First, addiction treatment can be evaluated. It's not something that you have to wonder about. The same standards of evidence apply as apply to the evaluation of medications and interventions commonly done in the Food and Drug Administration. There are over 700 published studies of contemporary treatments so there is an evidence base.

Point two, effectiveness does not mean cure. We do not have a reliable cure. Yes, there are many people in the field who have become abstinent and lived productive lives. They are probably not going to be able to drink or use drugs socially again. So there is not a cure. On the other hand, evaluation perspective and a determination of effectiveness shouldn't just mean that the patient feels better.

The scientific basis for effectiveness means three things, as it's commonly evaluated. First is the significant reduction of the substance use. Alcohol, cigarettes, opiates, cocaine, amphetamine—significant reduction.

Second is improvement in personal health and social function. Basically, a reduction of the society's responsibility for the individual.

And the third piece of evidence is reduction in public health and public safety threats. And that is what we mean by effective.

Point three, not all treatments are effective. Some treatment programs are quite competent. Some aren't, like any other field. Certain treatments do not work. We have talked about them already. Detoxifications, for example, do not work unless they are followed by continuing care. Acupuncture does not work unless it is part of some other broader treatment.

Many contemporary treatment components have not been evaluated. They have simply been adopted well before modern methods have been brought to bear. And also many evidence-based treatments, treatments that were discussed by Doctors Volkow and

Curie, are not in practice because of financing and training issues, and I will discuss that later.

Better treatments have the following characteristics, in general. I am happy to answer specific questions but in general, longer is better, in an outpatient setting and one which includes monitoring. One of the Congressmen asked for one of the components, and monitoring is an important one.

Better treatments include tailored social and medical services. Better treatments typically involve family.

Fourth point, addiction treatment is not the same as it used to be, but the evaluation of addiction treatment is the same as it used to be. And it does not fit anymore.

Not so long ago, over 60 percent of addiction treatment was delivered in a residential facility someplace. You went someplace to that famous 28-day treatment, and the question was, how long do the good effects last? So you did a 6-month, 12-month post treatment evaluation. In general, relapse rates were 50 percent just about anywhere you went.

Now, addiction treatment isn't delivered in residential facilities anymore. Over 90 percent of addiction treatment in this country is done on the street in outpatient settings. People are ambulatory.

My point there is, it's too late to wait 6 months, 12 months after they are out of that kind of care. What you want to know is, are people attaining abstinence? Are they attaining employment? Are they being re-arrested? Are they using expensive hospital resources? That evaluation has not caught on yet.

The kinds of studies that have been done have to be able to give real accountability in the field, if you ask my opinion, now because that is where treatment is, it's on the street.

The final thing I have to simply say is that the basic infrastructure of the U.S. treatment system is in very bad condition. Program closures or takeovers are over 20 percent a year. Program directors make less money than prison guards and have fewer benefits. The great majority of programs have no full-time physician, no psychologist, no social worker. That is the majority of treatment programs in the country. Counselor turnover rates are comparable to the fast-food industry. The pay is terrible, and there aren't standards.

Though there are well-studied, excellent medications and therapies available, thanks to the work of the National Institute on Alcoholism and National Institute of Drug Abuse and CSAT, frankly, most cannot be adopted by the present system. This is a system that can't be regulated into effectiveness. It's going to have to have financing, incentives, to bring professionals into the field, to retain them, and it needs the kind of infrastructure that will provide the kinds of things that are associated with better treatments has to be available. And that concludes my testimony.

[The prepared statement of Dr. McLellan follows:]

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My testimony will be pretty plain vanilla. Three points
1 - Addiction treatment can be evaluated in a scientific manner using exactly the same procedures and standards presently used by the FDA to evaluate new medications and devices. There are over 300 published studies using these methods to evaluate various types of addiction treatments and the findings show that - when properly done - addiction treatments CAN be effective.

2 - Addiction treatment has changed in concept and delivery over the past 10 years and it has significant implications for treatment evaluation. Addiction used to be considered a bad habit and in the 1980's over 60% of treatment was provided in an inpatient setting for a fixed period of time. Discharged patients were expected to emerge "rehabilitated" and the evidence was sustained abstinence measured 6 - 12 months following treatment discharge.

Now addiction is considered to be much more like other chronic illnesses (evidence can be briefly reviewed if necessary) and today over 90% of addiction treatments are provided in outpatient settings for unspecified periods of time.

Consequently, the post-treatment measurement of outcomes in the traditional way is inappropriate, slow and expensive. Traditional post-treatment outcome evaluations cannot provide clinicians with information they need to iteratively improve care - or the policy maker with evidence of accountability about those issues the public is most interested in - crime, employment, ER utilization.

The clinical monitoring approaches used in the treatment of other chronic illnesses are also appropriate in the treatment of addiction. These approaches stress patient responsibility for disease and lifestyle management and the early detection of threats to clinical progress (relapse). These contemporary clinical approaches require modern information mangement techniques and systems that provide standardized, relevant monitoring information to the clinician and to the payors.

3 - The basic infrastructure of the United States addiction treatment system is in very bad condition. Program closures or takeovers are over 15% per year. Program directors make less than prison guards and have fewer benefits. The great majority of programs have no full time physician, no psychologist and no social worker. Counselor turnover is comparable to that of the fast food industry. There are no standardized data collection protocols designed for clinical use in monitoring patients.

Although there are now well-tested medications and therapies that could be helpful, there are very few physicians or trained therapists in these programs and there are significant reimbursement barriers to the adoption of these evidence based practices. This is not a system that can simply be regulated or audited into shape.

This system ultimately could meet the accountability requirements demanded by the public and could adopt the evidence based treatments developed by NIH - but ONLY if it gets investment to improve information management and to incentivize professional staff

DRUG DEPENDENCE AS A CHRONIC MEDICAL ILLNESS:

Implications for Treatment, Insurance and Outcome Evaluation

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This is abstracted from an article in the October 2000 issue of the Journal of the American Medical Association by the same authors

From

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ABSTRACT

Background: We consider evidence regarding drug "dependence" as a chronic medical illness - comparing its etiology, presentation, course and treatment response to three other chronic illnesses - adult onset diabetes, hypertension and asthma.

Methods: A focused literature review compared some of the defining characteristics of chronic illnesses (e.g. etiology, genetic heritability, and pathophysiology) and response to treatment (compliance and relapse) in addiction and the other chronic illnesses.

Results: Personal choice, family and environmental factors are involved in the etiology and course of all these disorders. Genetic heritability is also important and comparable across all disorders. Effective medications are now available for the treatment of nicotine, alcohol, and opiate - but not cocaine, amphetamine or marijuana dependence. Medication compliance and relapse rates are similar across all illnesses.

Conclusion: There is reason to consider drug addiction as a chronic medical illness. Contemporary medical treatments can reliably provide cost-effective reductions in drug use, and its attendant public health problems – but not cure. Drug dependence treatments designed to discharge patients upon resolution of the acute symptoms - have not been effective. Continued, outpatient management of drug use symptoms and their sequelae with medications and therapies can produce enduring public health benefits comparable to those seen in other chronic illnesses. The available data suggest that drug dependence should be insured, treated and evaluated in the same manner as other chronic illnesses.

Key Words: Drug Dependence Treatment, Chronic Illness, Outcome of Treatment, Genetics of Addiction, Relapse Rates Following Treatment, Compliance with Treatment

DISCUSSION AND IMPLICATIONS FROM THE REVIEW

Few of those who try drugs or even use drugs regularly, become "drug dependent." Although science has made great progress over the past several years, we cannot yet fully account for the physiological and psychological processes that transform controlled, voluntary use of alcohol and/or other drugs into uncontrolled, involuntary dependence on these substances. However, twin studies indicate a definite role for genetic heritability in alcohol and drug dependence. Neuropharmacological and neuroimaging research indicate that there is a predictable physiological course to dependence. Finally, research in diagnosis indicates that dependence can be reliably and validly differentiated from even heavy drug "use." In summary, evidence from the first part of the review indicated that drug dependence was generally similar to the three comparison conditions in terms of heritability, onset and clinical course.

However, arguments by analogy are limited. Even if there are elements of similarity between drug dependence and these three chronic illnesses, this comparison is not a basis from which to argue that addiction is an "illness" nor that medical treatments would be effective in reducing addiction. Thus in the second part of the review we examined evidence for the effectiveness of medications and medically oriented treatments for addiction. There are now many controlled studies of addiction treatments. The few examples exemplified the broader literature, showing evidence of significant reductions in drug use, improved personal health and significant cost offset (see 31, 33, 46 - 51). We also found evidence for potent and well tolerated medications for the treatment of nicotine, alcohol, and opiate (33, 55) - but not for cocaine, amphetamine or marijuana dependence (63).

Finally, as is the case in treatments for other chronic disorders, we found major problems of compliance during treatment and relapse following treatment among addicted patients. In fact, the same patient problems of poverty, low family support and psychiatric co-morbidity were predictive of non-compliance and relapse across all of these disorders (See 66, 69 – 71, 75).

Of course there are differences between addiction and the selected comparison illnesses. Unlike any other chronic illness, drug dependence results from illegal behavior. In addition, while behavioral changes in diet and lifestyle can reverse the early course of some forms of asthma, hypertension and diabetes, there is a later point in these illnesses where behavioral change alone is not sufficient for symptom remission and medications are required. In contrast, work by Vaillant and others has shown that some, even chronically addicted individuals can achieve almost full symptom remission without medical treatment, by eliminating alcohol and changing their lifestyle (79, 80). At the same time, few chronically addicted individuals achieve stable symptom remission without treatment.

Our review suggests that drug dependence – but not drug "use" - shares many of the features common to other chronic illnesses. Prior to discussing the implications of this suggestion, it is important to restate that we are well aware that even the numerous similarities discussed here are not adequate to prove addiction is an illness. At the same time, the noted similarities in onset, course and particularly, response to treatment raise the question why medically oriented treatments are seen to be appropriate and effective when applied to asthma, diabetes and hypertension – but seemingly inappropriate and ineffective when applied to alcohol and drug dependence. We think the discrepancy in perception is because contemporary addiction is not treated, insured or evaluated like other chronic illnesses. Again, a comparison of current treatment strategies is an appropriate illustration.

Contemporary treatment for drug dependence typically consists of an admission to a 30 to 90-day outpatient, specialty treatment program. Few of these programs provide medical monitoring or medication, concentrating instead on counseling and behavioral change strategies. The goal of these contemporary treatment programs has been to rehabilitate addicted patients and discharge them, as one might rehabilitate a surgical patient following a joint replacement. Outcome evaluations are

typically conducted six to twelve months following treatment discharge. A major (sometimes the exclusive) outcome in all these evaluations is whether the patient has been continuously abstinent after leaving treatment.

Consider a "rehabilitation" strategy applied to hypertension. Patients who meet diagnostic criteria for hypertension would be admitted to a 30 - 90 day outpatient specialty "hypertension rehabilitation program" where they would receive medication, behavioral change therapy, dietary education, and an exercise regimen. Because of insurance limits and the rehabilitation-oriented goals, the medication would be tapered during the last days of the treatment and the patients would be referred to community sources. An evaluation team would re-contact patients six months later and determine whether they had been continuously normotensive throughout that post treatment period. Only those patients that met this criterion would be considered "successfully treated" under this set of evaluation expectations.

We see three sets of implications that derive from this line of argument. For primary care physicians, this review suggests that addiction should be included as part of the regular medical school and residency curricula. Further, there should be efforts to adapt medical monitoring strategies presently used in the treatment of other chronic illnesses - to the treatment of addiction. Indeed, these types of strategies have already been initiated with some success (64). Research is needed to help both physicians and patients determine when to change from a "rehabilitation" strategy, in which the major goal is to help the patient leave treatment; to a chronic care strategy, in which the major goal is to help the patient accept and comply with ongoing treatment. It is an open question whether a rehabilitation strategy delivered in a specialty program, or a chronic care, disease management strategy coordinated through primary care, will provide the maximal benefits for addicted patients and to society.

For insurers, employers and those in health policy, our review offers support for recent initiatives to include addiction as part of insurance "parity" legislation. Like other chronic illnesses, it is clear that the effects of addiction treatment are optimized when patients remain in continuing care and monitoring. Thus, it may be appropriate to provide health benefits (even incentives) for continued outpatient, medication and behavioral management visits – without current limits or restrictions on the number of days or visits covered. It is likely that a chronic care, disease management approach to addiction would increase treatment initiation and engagement by reducing the stigma and alienation of segregated treatment. It is unknown whether an expanded insurance benefit of this type would reduce long term costs associated with the later stages of addiction – or merely increase utilization with no clear cost offset.

For clinical and evaluation researchers, this review suggests the importance of appropriate methods and reasonable standards in the evaluation of addiction treatments. It is likely that the standard "pre – post" treatment evaluation designs have underestimated the effects of addiction treatments by essentially ignoring the "during treatment" period and focusing instead on the post treatment period (See 46). As illustrated in the above example, such a design would be completely inappropriate for evaluations of hypertension, asthma or diabetes treatments. In this regard, it is interesting that the high relapse rates among diabetic, hypertensive and asthmatic patients <u>following cessation of their medications</u> have been considered evidence of the effectiveness of those medications, the need to retain patients in medical monitoring and the need for compliance enhancement strategies. In contrast, relapse to drug or alcohol use following discharge from addiction treatment has been considered evidence of treatment failure.

Mr. SOUDER. Thank you. We will now go to Mr. O'Keeffe from the Virginia Commonwealth University.

Mr. O'KEEFFE. Thank you, Mr. Chairman, members of the committee. It is a privilege to be here this afternoon.

Others testifying today will address more directly the measurement of the success of treatment effectiveness. I hope to provide the committee with a perspective on overall treatment policy. Together, these perspectives will, I hope, help the committee in its deliberations about the best strategies to improve drug addiction treatment.

The main point I wish to make today is that Federal policy is not optimal for the development and/or deployment of new treatments. There have been some recent improvements, but much more needs to be done.

As you know well, Mr. Chairman, because of longstanding strong Federal regulation, the system for treating opiate dependence has evolved as one separated, even isolated, from the normal practice of medicine. This has resulted in a disconnect between the findings of the research community and the practices of treatment providers.

In 1972, thanks to the work of the country's first drug czar, Dr. Jerome Jaffe, proposals related to the appropriate use of methadone as addiction treatment were included in the Nixon administration's initiative on drug abuse. This initiative established stringent regulations regarding eligibility for treatment, dosage to be administered, level of counseling, length of treatment and criteria for take-home dosing.

To prevent abuse and diversion of methadone, the subsequently promulgated regulation created a closed system that allowed treatment only through specialty clinics. And according to Dr. Jaffe, the drafters of the regulations did not intend for medication dispensing to be forever limited to a few large clinics. Although they recognized that access to treatment by individual physicians might be temporarily limited, they believed that the regulations would be revised as knowledge expanded and as opiate maintenance treatment became less controversial.

Sadly, this was not the case. Those temporary regulations remained and have been significantly expanded over the subsequent 30 years.

We learned in the 1960's that treatment could be effective. However, because the general portrayal of patients addicted to opiates as miscreants, treatment was confined to a small number of specialty clinics generally located in larger metropolitan areas and controlled by stringent regulations. This depiction of patients generally led communities to resist allowing treatment programs to locate in any but the least desirable areas. Physicians were reluctant to treat addicted patients because of the public perception of these patients, the treatment locations and the complexity of the regulations.

Consequently, a non-physician-oriented treatment system began to develop. Addicted patients became clients of programs that eventually developed a fortress mentality. Because treatment moved further away from the mainstream practice of medicine and more and more clients were seen by counselors and advisers instead of

patients seen by physicians, more and more regulations were needed to assure that appropriate treatment protocols were followed.

Treatment programs became increasingly insular under a maze of complicated rules, further distancing physicians and the health care community from the care of these patients.

Meanwhile, the research community lead by NIDA was making inroads into new treatment methods, pharmaceutical products and improvement in the treatment of co-occurring diseases. These developments led to new products, new uses for old products and new approaches to the treatment for this chronic, relapsing brain disease.

It is essential that Federal policy now ensures that these new emerging developments be transferred to the practice of medicine as quickly and as responsibly as possible so that more patients will have access to treatment.

Nearly 6 million Americans affected by this disease remain untreated. This untreated population continues to impose a significant burden on both the criminal justice system and the public health system. Both NIDA and CSAT have recognized this treatment gap and are working toward closing it.

These efforts are commendable, but the executive branch is constrained by legislative requirements, constrained by mandates and restraints, constrained by the patchwork of Federal and State regulations, which has grown so complex that very few physicians are willing to begin treating patients because of the infrastructure required by the rules.

In a sense, over time, we have created a monopolistic system which has arisen from the complex regulatory environment which now discourages new treatment providers from entering the field. We are discouraging treatment with evermore burdensome, monopoly building regulation.

Congress recognized this problem and enacted the Drug Addiction Treatment Act of 2000 which, for the first time in over 80 years, provides an opportunity for qualified physicians to treat addicted patients in their own office or clinic setting. While this legislation was a major step in bringing the treatment of addiction closer to the practice of medicine. And your bill, Mr. Chairman, will correct some of the oversights of data. We are clearly not at the end of the road.

There are crucial next steps, not the least of which is the daunting task of encouraging and enabling 5 million Americans to seek and receive treatment for their disease.

DATA began the process of de-stigmatization and its treatment, but it did not end that process. This committee can help ensure that policies, priorities and funding are all concessive to the effective treatment.

Perhaps, it's time for a re-examination of existing treatment policies and their consequential regulatory requirements that discourage adequate treatment. NIDA and the institute of medicine have the responsibility and access to the expertise to provide recommendation for sorely needed policy and regulatory change which they lack authority and incentive to make.

The public health as well as this committee would be well served by seeking their advice on legislation designed to remove existing impediments to effective treatment.

Thank you, Mr. Chairman.

[The prepared statement of Mr. O'Keeffe follows:]

Testimony of Charles O'Keeffe
Professor
Department of Preventative Medicine and Community Health
School of Medicine
Virginia Commonwealth University

Before the
Committee on Government Reform
Subcommittee on Criminal Justice, Drug Policy and Human Resources

March 30, 2004

Mr. Chairman, members of the committee, it's a privilege to be here this afternoon. My name is Charles O'Keeffe. I'm a professor in the Department of Preventive Medicine and Community Health in the School of Medicine and a member of the Institute for Drug and Alcohol Studies at Virginia Commonwealth University. These remarks are my own and not a position of Virginia Commonwealth University.

Others testifying today will address more directly the measurement of addiction treatment effectiveness. I hope to provide the committee with a perspective on overall treatment policy. Together, these perspectives will, I hope, help the committee in its deliberations about the best strategies to improve drug addiction treatment. The main point I wish to make is that federal policy is not optimal for the development and deployment of new treatments. There have been some recent improvements, but much more needs to be done.

As you know well, Mr. Chairman, because of longstanding strong federal regulation, the system for treating opiate dependence has evolved as one separated and even isolated from the normal practice of medicine. This has resulted in a disconnect between the findings of the research community and the practices of treatment providers and the health care community.

For the first half of the 20th century, a strict law-enforcement-centered policy for dealing with addiction prevailed, based on the belief that strict control of the availability of narcotics would result in the disappearance of the problem of addiction. The theory was that if there were no illicitly imported heroin and no excess supply of other narcotics, there would be no drug addicts. This highly restrictive policy was clearly less than successful in preventing opiate addiction.

Following seminal research by Drs. Dole, Nyswander, Kreek, and their colleagues at Columbia University in the early 1960's proving the effectiveness of methadone treatment for opiate dependence; some physicians began treating patients with this medication, both off label and sometimes under dubious research INDs. By the late 1960's, several thousand patients were being treated with methadone, and federal law enforcement agencies became concerned. The departments of Treasury and Justice continued to favor interdiction and believed that treatment was reckless; FDA did not find the data generated by the INDs sufficient to demonstrate safety and effectiveness; and social experts were concerned that the availability of pharmacologic treatment would decrease support for addressing issues such as unemployment, education, and adequate housing, and that such treatment failed to recognize the psychosocial and behavioral origins of addiction. Many recovering addicts who had achieved recovery in a drug-free residential treatment setting felt that pharmacologic treatment threatened that effective treatment method. Additionally, there were no standards of practice and some physicians were reported in the press to be prescribing methadone to patients who were not appropriate for treatment.

In response to congressional and community concerns, FDA established stringent regulations governing methadone INDs in 1971. This action allowed physicians to continue using methadone in a "research" context.

In 1972, thanks to the work of the country's first "Drug Czar," Dr. Jerome Jaffe, proposals relating to appropriate use of methadone as an addiction treatment were included in the Nixon administration's initiative on drug abuse. This initiative established stringent regulations regarding eligibility for treatment, dosage to be administered, level of counseling, length of treatment, and criteria for take-home dosing. To prevent abuse and diversion of methadone, the subsequently promulgated regulations created a "closed" system that allowed treatment only through specialty clinics. According to Dr. Jaffe, however, "The drafters of the regulations did not intend for medication dispensing to be forever limited to a few large clinics. Although they recognized that access to treatment by individual physicians might temporarily be limited, they believed that the regulations would be revised as knowledge expanded and as opioid maintenance treatment became less controversial". (Jaffe, 1975, 1997, 2003) Sadly, this was not to be the case. Those "temporary" regulations remained, and were expanded, over the subsequent 30 years.

We learned in the 1960's that treatment could be effective. However, because of the portrayal of patients addicted to opiates as degraded individuals with an incurable disorder, treatment was commonly confined to a small number of specialty clinics, generally located in larger metropolitan areas, and controlled by stringent regulations. This depiction of patients usually led communities to resist allowing treatment programs to locate in any but the least desirable areas. Physicians were reluctant to treat addicted patients, because of both the treatment locations and the complexity of the regulations. Consequently, a non-physician-oriented treatment system began to develop. Addicted patients became "clients" of programs that eventually developed a fortress mentality. Because treatment moved further away from the mainstream practice of medicine, and more and more clients were seen by counselors and advisors instead of physicians, more and more regulations were needed to assure that appropriate treatment protocols were followed. Treatment programs became increasingly insular under a maze of complicated rules, further distancing physicians and the general health care community from the care of these patients.

Meanwhile, the research community, led by NIDA, was making inroads to understanding the disease, developing new treatment methods, pharmaceutical products, and improvements in the treatment of co-occurring diseases. These developments led to new products, new uses for older products, and new approaches to the treatment of this chronic relapsing brain disease.

It is essential that federal policy now ensure that these new and emerging developments be transferred to the practice of medicine as quickly and responsibly as possible so more patients will have access to treatment.

The most recent SAMHSA Household Survey shows that while 7.7 million Americans are in need of substance abuse treatment, only 1.4 million patients are currently receiving it. Treatment is effective. Even less-than-ideal treatment is more effective than no treatment. Every treatment method can demonstrate efficacy. Individual patient response may vary from one treatment method to another, but the scientific literature is clear: treatment works.

Notwithstanding this evidence, over 5 million Americans affected by this disease remain untreated. This untreated population continues to impose a significant burden on both the criminal justice system and the public health system. Both NIDA and CSAT have recognized this treatment gap, and are working toward closing it. These efforts are commendable, but the Executive Branch is constrained by legislative requirements, mandates, and restraints; the patchwork of regulations has grown so complex that very few physicians are willing to begin treating patients because of the infrastructure required by the rules. In a sense, over time, we've created a monopolistic system which has arisen from the complex regulatory environment, and that system now discourages new treatment providers from entering the field, with the consequent effect of denying patient access to treatment.

Congress, recognizing this problem, as well as the NIDA-enabled research successes, enacted the Drug Addiction Treatment Act (DATA) of 2000, which for the first time in over 80 years provides an opportunity for qualified physicians to treat addicted patients in their own office or clinic settings.

While this legislation was a major step in bringing the treatment of addiction closer to the practice of medicine – and your bill, Mr. Chairman, will correct some of the oversights of DATA – we are not nearly at the end of the road. There are crucial next steps, not the least of which is the daunting task of encouraging and enabling 5 million Americans to seek effective treatment for their disease.

It is estimated that nearly half of the 2 million individuals who are currently in prisons or jails were in need of treatment for alcohol or drug abuse or addiction at the time of their arrest. Yet our penal system, with some notable exceptions, has not taken the opportunity to begin treatment that could stem some of the pervasive recidivism experienced in this population. An example of the exception to this dilemma is a successful program in Henrico County, Virginia, designed to do just that.

We know that the stigma associated with disease abates when effective treatments become available. It was not long ago that depression was an unmentionable malady whose victims dared not discuss it. Today, nearly all of us are aware of some friend or relative who has been effectively treated for depression. And that effective treatment is ongoing; it is not a single course of treatment that ends the disease. A couple of decades ago, epilepsy was a dread affliction that no one talked about. Today, epilepsy is a chronic recurring and treatable brain disease for which patients seek and receive effective treatment.

Drug addiction is a disease, Mr. Chairman. It is a chronic condition that, although it has complex causation, can be treated. Providing an environment conducive to offering treatment is critically important to assuring its success. Health care providers need to be trained to recognize this condition and to develop appropriate treatment plans tailored to each patient. Creating a social perception that recognizes addiction as a disease rather than bad behavior is one of our greatest challenges, second only to correcting the overly restrictive regulatory system. DATA began the process of de-stigmatizing addiction and the treatment of addiction, but it did not end that process. This Committee, in its deliberations on drug addiction treatment policy can help assure that policies, priorities, and funding are all conducive to effective treatment.

Perhaps it's time for a reexamination of existing treatment policies and their consequential regulatory requirements that discourage adequate treatment. NIDA and the Institute of Medicine have the ability, and access to the expertise to provide recommendations for sorely needed policy and regulatory change that they lack authority and incentive make. The public health as well as this committee would be well served by seeking their advice on legislation designed to remove existing impediments to effective treatment.

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DRUG and ALCOHOL DEPENDENCE

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Commentary

Accessing opiate dependence treatment medications: buprenorphine products in an office-based setting

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Drug abuse and addiction, including abuse of opiates, is one of the most significant public health problems facing the United States today. Moreover, several indicators suggest the opiate problem may be getting worse as the price of heroin decreases and its purity and availability continues to increase. Further complicating this public health issue is the fact that, as the number of untreated addicts increases, so does one of the largest vectors for the spread of HIV, hepatitis B and C, and tuberculosis into the general population. These trends, plus the fact that there are over 980 000 people in the United States known to already be addicted to opiates, with roughly 180 000 treatment slots available in opiate agonist treatment programs, demonstrate the tremendous need to expand both the access to and variety of treatments currently available to opiate addicts.

The good news is that our ability to treat addictions has never been greater. We have an array of drug abuse treatments that have been shown to be effective not only in reducing drug use, but also in reducing mortality and morbidity and their associated economic, health, social and public safety costs. The use of methadone for treating heroin addiction has been one of our greatest treatment success stories to date. Since methadone was approved by the US Food and Drug Administration (FDA) in 1972 for use as an oral medication, it has helped countless numbers of people improve the quality of their lives. Methadone maintenance decreases illicit drug use and crime, as well as curtailing the spread of infectious diseases such as HIV/AIDS among intravenous drug users.

Unfortunately, despite its proven effectiveness, methadone remains one of the Nation's only medical treatments that is not really readily available to those who need it. This critical issue of access to this treatment, as well as other opiate addiction treatments, is due in large part to the strict and archaic state and federal regulations and controls on these medications. The 1974 Narcotics Addict Treatment Act (NATA) restricts distribution of opiate agonist medications such as methadone to regulated specialty treatment programs. The bottom line is that opiate addiction medications are not being made readily available to those who need them most.

The current system for administering anti-addiction medications is too restrictive, especially as we continue to bring new medications to the forefront. This was most recently noted in November 1997 when the National Institutes of Health (NIH) Consensus Development Conference issued its statement on the "Effective Medical Treatment of Heroin Addiction". Overall the panel strongly recommended broader access to methadone maintenance and other treatment programs for people who are addicted to heroin. They went even further by saying that Federal and State regulations and other barriers impeding access to treatment should be modified significantly. Their statement concurred with a 1995 report by the Institute of Medicine, "Federal Regulation of Methadone Treatment," that access to treatment must be expanded.

As more and more effective treatments become available in the treatment providers' clinical toolbox, such as the long acting congener of methadone, levomethadyl acetate (LAAM), and the partial agonist buprenorphine, it is imperative that we have a more flexible and accessible system in place. Although the FDA approved LAAM several years ago, as of this writing it is only offered in existing narcotic treatment programs.

One viable option for expanding access to treatment with these drugs is to approve medical office-based

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agonist treatment of opioid addicts for those meeting certain criteria by a sub-set of appropriately trained physicians. In fact, permitting office-based physicians to provide such treatment was also one of the recommendations made by the NIH Consensus Development Panel. As the leading federal agency responsible for bringing new treatment medications and approaches to the national forefront, the National Institute on Drug Abuse (NIDA) has been supportive of activities that would expand access to treatment, including having newly approved medications made available to treatment providers including those in general practice settings. Having two new drugs approved by the FDA, buprenorphine and the combination dosage buprenorphine/naloxone, and available in office-based practices is a major step forward in improving the availability of safe and effective drug addiction treatment in this country.

A variety of recent changes in the way opiate treatment medications are controlled are cause for substantial optimism. The move from an FDA-based regulatory system to a Substance Abuse and Mental Health Services Administration (SAMHSA) run certification system is one step. Additionally, we will soon see buprenorphine and buprenorphine/naloxone administered through physicians' offices, as allowed by recent legislation (the Drug Addiction Treatment Act of 2000). The Center for Substance Abuse Treatment-based systems for training and accrediting physicians is highly encouraging. The various ongoing formal trials of ways physicians might administer drugs like buprenorphine from their offices is another.

Buprenorphine is currently a schedule III drug under the US Controlled Substances Act and its partial agonist quality should render it safer than full opiate agonists. Large scale, double blind, placebo controlled studies with buprenorphine have shown reductions in opiate use that are comparable to clinically effective doses of methadone. Also, the partial agonist actions of buprenorphine may have some advantages over methadone since it produces few or no withdrawal symptoms upon discontinuation of its use and the dangers of overdose are less. Moreover, adding naloxone further reduces the medication's abuse liability. For all of these reasons, buprenorphine and the buprenorphine/naloxone combination tablet are excellent medications for trained physicians to administer in the office-based setting. The combination tablet has a very low street value and low diversion potential. It is an important addition to drug abuse treatment where it can be administered in an office-based setting.

Buprenorphine-based products can be looked at as a way to supplement the existing provider system. They are not meant to replace the system, but rather to expand the range of alternatives currently available. They will be targeted to populations who either do not have access to methadone programs or are unsuited to them, such as relatively new addicts who are not typically accepted into existing programs until they have been addicted for at least 1 year. Getting them into a treatment program earlier will be more beneficial to the patient in the long run.

In summary, there is a significant need to expand access to opioid addiction treatment in this country. We have come a great distance in our approaches to understanding and treating drug addiction, but we still have quite a distance ahead of us. Bringing new drugs like buprenorphine from clinical trials into the clinical toolboxes of certified and trained physicians in their own office-based settings is a significant step in closing the treatment access gap.

NIDA is working intensively with the drug abuse professional community and colleagues at FDA and SAMHSA to improve how we treat addiction in this country. We can improve the quality and availability of treatment in the United States if we use the power of science to put treating addiction on equal footing with treatments for other chronic diseases.

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Review

From morphine clinics to buprenorphine: regulating opioid agonist treatment of addiction in the United States

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Abstract

The practice of prescribing opioid drugs for opioid dependent patients in the U.S. has been subjected to special government scrutiny for almost 100 years. From 1920 until 1964, doctors who used opioids to treat addicts risked federal and/or state criminal prosecution. Although that period ended when oral methadone maintenance was established as legitimate medical practice, public concern about methadone diversion and accidental overdose fatalities, combined with political pressure from both hostile bureaucracies and groups committed to drug-free treatments, led to the development of unprecedented and detailed Food and Drug Administration (FDA) regulations that specified the manner in which methadone (and later, levo-alpha-acetyl methadol, or levomethadyl acetate, (LAAM)) could be provided. In 1974, Congress gave the Drug Enforcement Administration (DEA) additional oversight of methadone treatment programs. Efforts to liberalize the FDA regulations over the past 30 years have been resisted by both the DEA and existing treatment providers. Additional flexibility for clinicians may evolve from the most recent effort to create an accreditation system to replace some of the FDA regulations. The development of buprenorphine, a partial opioid agonist, as an effective treatment for opioid addiction reopened the possibility for having a less burdensome oversight process, especially because of its reduced toxicity if ingested by non-tolerant individuals. New legislation, the Drug Addiction Treatment Act (DATA) of 2000, created an opportunity for clinicians with special training to be exempted from both federal methadone regulations and the requirement to obtain a special DEA license when using buprenorphine to treat addicts. Some details of how the DATA was developed, moved through Congress, and signed into law are described.

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Keywords: Buprenorphine; Methadone maintenance; Office-based pharmacotherapy; Opioid agonists; Regulations; Treatment; History; Policy

1. Early history of opioid-addiction treatment

The federal regulation of medical prescribing of opioids in the U.S. began with the Harrison Act of 1914. While the Harrison Act did not actually prohibit physicians from prescribing opioids for addicted patients within a legitimate medical context, the Treasury officials who were empowered to implement the Act vigorously opposed the practice and were successful in deterring physicians from engaging in it. By 1920, the American Medical Association (AMA) also condemned prescribing opioids to addicts, thereby opening the door further to the prosecution and conviction of physicians who continued to do so. This difficult situation for people who were dependent on opioids and for the practitioners who wanted to help them did not begin to change until 1964. It was then that Vincent Dole and Marie Nyswander first described their work treating heroin addicts with orally administered methadone (Musto, 1987; Jonnes, 1996).

Some of the milestones of those 50 years between the Harrison Narcotic Act of 1914 and the studies of methadone maintenance in 1964 include the rise and fall of morphine clinics (the last of them closed in 1923); the successful federal prosecution of physicians who prescribed morphine to addicts; and, following a period of relative stability in the 1930s and 1940s, a post-World

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War II rise in heroin addiction that led to new federal legislation increasing the severity of penalties for the use and possession of illicit drugs. In 1961, a report issued by a joint committee of the American Bar Association and the AMA questioned those repressive drug policies and encouraged research on opioid maintenance (Musto, 1987).

Throughout most of this period, and until he retired in 1962, Harry J. Anslinger headed the Bureau of Narcotics. Anslinger believed strongly that addiction would disappear in the face of severe penalties for the possession, use, or sale of drugs, and that getting rid of drugs, drug users, and drug pushers would solve the drug problem. Under Anslinger's influence, demonizing the drugs, especially heroin, became a key element of federal drug policy, and addiction to opioid drugs was portrayed as an incurable disorder that condemned its victims to a life of degradation (Musto, 1987; Courtwright, 1992).

2. Evolution of methadone treatment

The current system of opioid treatment regulations, as well as American attitudes towards addicts, were influenced not only by this history, but also by other equally important elements and events. These included a heroin epidemic that accelerated in the early 1960s; the rise of the therapeutic community movement, which convincingly demonstrated that heroin addicts were not beyond redemption; the Narcotic Addict Rehabilitation Act (NARA) of 1966, which established a federal civil commitment program modeled partly on similar programs in California and New York; and the work of Dole, Nyswander, and their collaborators at the Rockefeller Institute. Their work, from the early 1960s and onward, showed that heroin addicts who were maintained on oral methadone could give up heroin and lead productive, law-abiding lives (Glasscote et al., 1972; Gerstein and Harwood, 1990).

The data reported by Dole, Nyswander, and coworkers, and soon confirmed by others, showed that treatment in methadone treatment programs sharply reduced heroin use and criminal activity, increased gainful work, and resulted in generally improved health. Equally important, patients found the treatment acceptable, and several treatment centers began operation. Most of the treatment centers using methadone operated under Investigational New Drug (IND) applications issued by the Food and Drug Administration (FDA), and thereby claimed exemption from the policies of the Bureau of Narcotics, which still viewed providing opioids to addicts as illegal. It is of historical interest that Dole and coworkers at Rockefeller did not seek or obtain an IND, since they took the position that methadone was an approved therapeutic agent and that off-label use did not require an IND. From 1967 to 1970, the FDA liberally issued INDs for methadone research. Beginning in 1968, INDs were also issued for the study of LAAM, (levo-alpha-acetyl methadol, or levomethadyl acetate). By 1969, several thousand patients were enrolled in methadone maintenance treatment research programs (Jaffe, 1975; Gerstein and Harwood, 1990; Jonnes, 1996; Kreek and Vocci, 2002).

Yet, methadone was not well received in the early 1970s. Most federal agencies were hostile towards it or were at least skeptical about it. The Departments of Justice and the Treasury, still influenced by Anslinger's vision, saw methadone treatment as wrongheaded. Advocates for psychosocial programs within the treatment community derided it as a 'magic bullet' that was likely to lessen concerns about unemployment, housing, and the psychological and sociological origins of addiction; vocal groups of recovering heroin addicts saw it as both an irrational treatment and a threat to the therapeutic community movement; some minority activists described it as a government effort to control the behavior of young black men.

Even the FDA did not find the data that were generated sufficient to approve methadone as a safe and effective treatment for heroin addiction. Further, there was no rationale for determining how many INDs to issue and no practical mechanism to prevent their misuse as a cover for profit oriented prescribing of methadone unaccompanied by rehabilitative services. No standards had been established for what constituted minimally acceptable treatment, and no rules governed the amount of opioids that could be prescribed, or taken home, or for whom the treatment was appropriate, giving the recipients of the methadone INDs large leeway in making those decisions. Newspapers published stories about physicians who prescribed methadone for patients who were not seriously dependent on opioids; about methadone being diverted from the clinics to the street; and about children being poisoned by drinking methadone that was brought home legitimately by household members who were in treatment. Methadone maintenance also drew criticism from advocates and providers of 'drug-free' treatment, who saw it as another form of addiction, from law enforcement groups, and from minority groups who denounced it as 'genocide' (Jaffe, 1975; Jonnes, 1996).

In June of 1970, the FDA proposed a new ruling on methadone IND applications. Largely a response to the numerous Congressional and community concerns about the issues of diversion of methadone, iatrogenic methadone addiction, and accidental overdoses, the new IND regulations imposed such strict requirements on entry into treatment, dosage, and duration of treatment that they discouraged methadone use. With this ruling, which became final in April, 1971, the FDA avoided making a decision on whether methadone treatment was

safe and effective, but allowed it to continue 'thinly disguised as research.' These stringent regulations were of no help to the many heroin addicts who were seeking treatment but could only be put on waiting lists. The status of methadone treatment as 'research' made government authorities at all levels reluctant to provide funds to support its expansion.

Nevertheless, in June of 1971, the Nixon administration's initiative on drug abuse included the decision to accept methadone maintenance as an effective treatment, to develop ways of minimizing the real and perceived problems with its use, and to expand access to treatment for those who wanted it. The White House Special Action Office for Drug Abuse Prevention (SAODAP) worked with the FDA to revise the overly stringent regulations in order to achieve those objectives. First proposed in April 1972, the new regulations established the basic framework that governed the use of methadone and similar opioid agonist drugs in the treatment of heroin addiction for the following 30 years. These regulations created a hybrid IND–NDA (New Drug Application) that acknowledged the safety and efficacy of methadone maintenance as a treatment, but imposed a number of conditions on how it could be used. Those conditions represented a substantial and unprecedented departure from the usual practice of allowing licensed physicians to use their own professional judgment, guided by a drug's labeling, to determine how to prescribe a medication. Among other things, the 1972 regulations specified, according to various criteria including age and duration of drug dependence, who could be eligible for methadone treatment. They also specified the maximum initial dosages that could be used, the minimum amount of counseling that must be provided, and the factors to be considered when deciding on take home medication, such as how long a patient had been in treatment and whether drug tests showed any evidence of illicit drug use. The new regulations also created a closed system for methadone, restricting its availability to approved clinics and hospital pharmacies, with the aim of deterring those few individual physicians who, in violation of the 1971 regulations, continued prescribing methadone for substantial fees (Jaffe, 1975; Rettig and Yarmolinsky, 1995; Jaffe, 1997; Kreek and Vocci, 2002).

Each element in the 1972 regulations was intended to reduce or prevent problems that had been experienced under the largely informal pre-1971 IND system; or to correct the overly restrictive aspects of the 1971 regulations; or to assure concerned parties, including Congress, that methadone would be used in combination with, not as a substitute for, rehabilitation. In short, the 1972 regulations were designed to allow expansion of treatment while maintaining some control over quality of treatment. They described 'medication units' because they anticipated a time when clinics and individual practitioners would be linked to pharmacies and other sites that would be authorized to dispense drugs, such as methadone, for the treatment of addiction. The drafters of the regulations did not intend for medication dispensing to be forever limited to a few large clinics. Although they recognized that access to treatment by individual physicians might temporarily be limited, they believed that the regulations would be revised as knowledge expanded and as opioid maintenance treatment became less controversial (Jaffe, 1975, 1997). The regulations became fully effective in March, 1973. However, throughout 1972 and the beginning of 1973, some members of Congress and certain journalists continued to see methadone diversion as a serious problem. In June 1973, the Senate passed the Methadone Diversion Control Act of 1973, which became the Narcotic Addict Treatment Act of 1974 (NATA). This law, which was an amendment of the Controlled Substances Act (CSA), gave the newly created Drug Enforcement Agency (DEA) jurisdiction over the storage and security of drugs used in the treatment of addiction. It also required separate DEA registration annually of practitioners and treatment sites. The Secretary of Health, Education, and Welfare (now Health and Human Services [HHS]) retained the responsibility for setting standards for proper professional practice in the medical treatment of addiction.

Since 1970, clinicians have criticized the Federal regulations as a burdensome interference with the practice of medicine. Some claim that the paperwork burdens and constraints on take-home doses contribute to patients' dropping out of treatment (Dole, 1992). Although some of the criticism is valid, it often fails to distinguish between federal, state, and local regulatory burdens. State and local jurisdictions have also seen fit to enact legislation governing these programs, and some of those regulatory requirements are far more restrictive than federal ones. For example, some localities do not permit any take-home medication. Another criticism is that regulatory oversight is concerned exclusively with process, although actual treatment outcome can be measured. But regulations alone are not responsible for all of the problems methadone treatment providers encounter. Not to be overlooked is the impact of the more than 50% reduction (inflation-adjusted) in the level of financial support for methadone treatment programs in most parts of the country over the past 30 years (Gerstein and Harwood, 1990).

Alternatives to the current regulatory framework have been sought and proposed over the years. There is no federal legislation that requires the Secretary of HHS to issue *regulations* dealing with the medical treatment of 'narcotic addiction.' *Guidelines* could accomplish this task equally well. In 1984, Congress amended the NATA, and gave the DEA authority to withdraw registration from treatment programs or

individual practitioners for committing (in DEA's judgment) 'such acts as would render registration inconsistent with public interest.' Since one federal agency (DEA) already has the authority to revoke licensure, there may be no good reason to have any HHS *regulations*. However, if the use of opioid agonists in the treatment of opioid dependence were governed only by HHS guidelines or professional judgment, any oversight of the quality of treatment would be left to the discretion of the DEA and to the tort system (Molinari et al., 1994).

In summary, for most of the past 30 years the regulatory framework dealing with the use of opioids in the treatment of addiction in the U.S. has consisted of a dual oversight at the federal level (HHS and DEA), as well as various (and varying) regulatory requirements at the state and local levels. Although the FDA regulations were intended to be more flexible and responsive than legislation to changing conditions, prior to the major revision that was finalized in 2001 they had been revised only twice, in 1980 and 1989. Those changes were relatively minor, mostly having to do with urine testing, on-site services, and easing constraints on admissions. Despite complaints about over-regulation, when the FDA and the National Institute on Drug Abuse (NIDA) issued a proposal in 1983 to convert most regulations to 'guidelines', most of the treatment providers who responded to the proposal stated a preference for the existing regulatory system (Rettig and Yarmolinsky, 1995). In 1989, largely as a response to the spread of HIV among intravenous drug users, NIDA and the FDA published a rule regarding 'interim methadone maintenance'—the provision of methadone without rehabilitative services to addicts waiting to get into full service programs (Rettig and Yarmolinsky, 1995). The methadone treatment providers and some state authorities reacted unfavorably. Many treatment providers believed that interim maintenance would inevitably lead local, state, and federal governments to further reduce funding and to pay only for dispensing methadone (Rettig and Yarmolinsky, 1995).

3. Opioid-agonist treatment regulations—recent changes

The number of patients in methadone treatment programs has grown since the early 1970s, from about 20,000 to about 180,000 (Kreek and Vocci, 2002). Some states still do not permit methadone or other opioid agonist treatment regulated by the NATA. In 1993, when the FDA finally approved LAAM for the treatment of heroin addiction, multiple state and local legislative and regulatory barriers still prevented it from being used. Even where it was permitted its utility was compromised because the FDA regulations that prohibited take-home doses entirely. (New regulations that took effect in 2001 now permit take-home doses.)

In 1992, the Institute of Medicine (IOM) undertook a review of the Federal regulation of methadone and LAAM in the treatment of addiction. Their report, issued in 1995, concluded (among other things) that the current regulation by multiple agencies: (1) overemphasizes the dangers of methadone diversion; (2) burdens programs with unnecessary paperwork; (3) constrains clinical judgment; (4) reduces access to treatment; and (5) contributes to premature discontinuation of treatment. The IOM recommended that the current detailed regulations be replaced by practice guidelines and sharply reduced regulations (Rettig and Yarmolinsky, 1995).

In response to the IOM recommendations, the federal agencies that comprise the Interagency Narcotic Treatment Policy Review Board (FDA, NIDA, Substance Abuse and Mental Health Services Administration [SAMHSA], Department of Veterans Affairs [VA], DEA, and the Office of National Drug Control Policy [ONDCP]) undertook the work of substantially revising the HHS regulations. The DEA did not propose any changes in its authority to require special licensing and to oversee addiction treatment that uses opioid drugs. Originally, the new system was to have as its central feature a set of HHS regulations requiring programs or practitioners that use opioid agonists for addiction treatment to be accredited by an approved accrediting body, and establishing an upper limit on the amount of opioid medication that could be given to patients for use outside the clinic at any one time. Accrediting bodies would base their decisions on a set of treatment standards approved by the Secretary of HHS, and representing the best clinical thinking of experts in the field, subject to change as knowledge changes. It was recognized at the outset that value judgments and trade-offs are implicit in how standards of care are set. Setting high standards that require competent initial assessments, good medical care, and some minimal level of psychosocial support will limit access for some addicts where states, localities, or insurance carriers are unwilling to pay for those services. If the standards are not met, neither programs nor individual practitioners can be accredited, and the power to accredit becomes the power to destroy. Conversely, if standards are set quite low, the cost of delivering care will be reduced and access may increase; but then it becomes likely that some programs would be no more than opioid dispensaries staffed by the lowest cost personnel, and with considerable risk of hazardous prescribing practices and drug diversion. Unless federal and state priorities were to be reordered so as to provide much greater financial support for opioid treatment, setting standards, whether by guideline or regulation, will involve difficult value judgments.

Some changes have now been approved, but the effort to shift from federal regulations with their implied criminal penalties for violations to a system of peer review accreditation did not result in as much freedom for clinical judgment as those within HHS, who originally proposed the accreditation process, had hoped for. Pressures from already licensed methadone providers and the DEA left in place many of the regulatory constraints on clinical judgment, particularly with respect to the compliance burden placed on virtually all new patients regarding take-home medication and clinic attendance. While the new regulations eased considerably the maximum take-home dosages permitted for long term patients (in treatment for more than 2 years), new patients, regardless of level of stability or need for other treatment services, are still required to obtain nearly all their medication at the clinic for a period of several months. Furthermore, the burdens of meeting the accreditation requirements are likely to prevent individual physicians, no matter how well trained, from using opioid medications such as methadone or LAAM to treat opioid dependent patients in their offices, unless the physician is administratively linked to an existing opioid treatment program. In addition, the NATA still requires all physicians who might wish to treat opioid addicts with Schedule II opioid medications to obtain a separate registration for this purpose from the DEA, even if they intend to treat only a few patients.

Although these latest changes in the regulations, including the institution of accreditation, are far greater than those accomplished by the two previous revisions, their modesty and the time it took to bring them from initial proposal to reality gives testimony to the inertia in the system, the complexity of forces that influence it, and the power of the current stakeholders. The notion of a system of accreditation to replace the regulations was raised by Curtis Wright and Jerome Jaffe at a meeting of the Interagency Narcotic Treatment Policy Committee in 1995, shortly after the release of the IOM report on methadone regulation. It did not get final approval within HHS until some time in December of 2000. There were considerable reservations voiced at ONDCP. Following the Presidential elections of 2000 and the change in administration, a hold was placed on all regulatory change. The modifications of the methadone regulations did not go into effect until May 18, 2001 (N. Reuter, personal communication).

4. Buprenorphine: a new pharmacotherapy for opioid addiction

A major justification for the regulation, accreditation, and separate DEA registration was to minimize the diversion of opioid drugs from treatment programs. Among the most important concerns about diversion are the serious toxic consequences that ensue when non-tolerant individuals ingest dosages of methadone or LAAM typically used in treatment. As early as Jasinski et al. (1978) had noted the possible clinical utility of buprenorphine, a partial opioid agonist. By the early 1990s, it became clear that buprenorphine could be used effectively for the treatment of heroin addiction (Johnson et al., 1992; Ling et al., 1996) and that its partial agonist properties resulted in very substantially decreased toxicity even for non-tolerant individuals (Walsh et al., 1994, 1995). Under these circumstances, one major justification for maintaining the 'closed system' for medications used in opioid maintenance was largely eliminated. It was not so much that diversion of a partial agonist could be considered a trivial issue, but rather that with lethality from diversion of prescribed medication sharply reduced, a fresh look could be taken at the costs and benefits of making opioid treatment both more accessible and less stigmatizing by moving it from the clinics into the offices of individual physicians. It seemed possible that, under the right circumstances and once approved by the FDA for use in the treatment of opioid dependence, buprenorphine might be exempted from some of the burdens associated with the use of methadone and LAAM.

To achieve such an outcome, two major hurdles had to be overcome. First, buprenorphine would have to win FDA approval for the treatment of opioid addiction; second, some regulatory or legislative action was needed that would exempt it from the provisions of the CSA of 1970 and the NATA of 1974. It is important to point out here that from the perspective of Reckitt and Colman (now Reckitt Benckiser Pharmaceuticals), the company that originally developed buprenorphine as an analgesic and still controlled its use, the legislative effort to be described and the effort to develop and win FDA approval for its use in addiction treatment were seen as being inextricably intertwined. It was obvious from the experience with LAAM that winning FDA approval for a drug used in the treatment of addiction in no way assures its utilization if it also requires legislative changes in each of the 50 states. Also, from a corporate perspective it seemed unlikely that a drug confined to a limited number of clinics that were already comfortable using generic methadone would be used enough to justify the investment involved in taking buprenorphine through the regulatory process.

Reckitt and Colman knew it would be at least a 5-year project and that it would be committing millions of dollars to develop a product that had no patent protection remaining. The Board of Directors decided to approve the process nevertheless. It was apparent that, to recover any significant portion of corporate expenditures, two conditions would be needed. First, buprenorphine would need to reach the mainstream

practice of medicine—a goal that certainly seemed achievable in light of the IOM report on methadone regulation. Second, a period of market exclusivity would be needed to protect the product once FDA approved it. The Company faced three challenges. To address the matter of market exclusivity they needed to seek Orphan Drug designation. This was accomplished fairly quickly in 1994. The next challenge was to somehow amend the CSA of 1970 to allow physicians to treat patients with buprenorphine in the normal course of the practice of medicine. This change would result in an exemption from the NATA, which is itself a modification of the CSA. The third was to submit an NDA to the FDA and gain its approval. What follows here is the story of how the legislation that largely exempts buprenorphine from certain provisions of the CSA made its way through Congress to the Oval Office.

5. A need for new legislation

Reckitt and Colman was convinced by the history of efforts to modify the methadone regulations that amending treatment program regulations through administrative change would be a long and cumbersome process unlikely to reach the goal of moving treatment into the mainstream of medicine and expanding access for new patients. The company therefore chose to seek a change in the law. The original aim of the proposed legislative solution seemed simple and straightforward: to change the law to waive the current requirements for physicians prescribing opioids to treat opioid dependence. The proposed legislation would leave the methadone system intact but expand the possibilities for treatment. The original draft of this legislation, called the Drug Maintenance and Detoxification Act, was written by Charles O'Keeffe and Robert Angarola in October, 1995. That first draft stated simply that the requirements of the CSA did not apply when a physician treated no more than 20 patients with a Schedule V narcotic. As it turned out, this proposed legislation went through many changes and was not finally passed by Congress until 2000. It took more than 5 years to enact a very minor amendment to the existing legislation.

The high points of that journey make an interesting lesson about the process of change in our democracy. In 1995, representatives of Reckitt and Colman approached Capitol Hill offices to explain the issue as they saw it: there is a new product which, when approved, will have the potential to bring a significant number of new patients into treatment. But there will be no market for it and the medical community will not be able to use it because of current legal requirements. In several offices, staff members were very receptive.

Senator Carl Levin, who has had a long standing personal interest in expanding and improving addiction treatment, became a supporter. Senator Orrin Hatch and his staff on the Senate Judiciary Committee, which has jurisdiction over the Controlled Substance Act, was also interested. Senator Joseph Biden, who had previously introduced legislation to encourage the development of new addiction treatment medication, was most interested. Strong allies in the House of Representatives included Congressman Thomas Bliley, who was then Chairman of the Commerce Committee, which shares jurisdiction over the CSA with the Judiciary Committee. With their efforts, several key members of the Judiciary Committee and others on both sides of the aisle became persuaded that the proposed legislative changes would be good policy. Despite this promising start, it was not until the end of the 1998 congressional year that the Company could rally enough support to get something going. But 1998 was an election year and the end of the 106th Congress. It was clear that the bill could not be enacted using the full legislative route. Senate staff suggested an alternate approach: using what is called a 'must-do' vehicle: that is, attaching it to a bill not necessarily related to the subject matter, but one such as an appropriation bill that must be signed into law. Senator Hatch's staff, with agreement from the offices of Senators Levin, Biden and Moynihan, arranged to have the proposed change to the CSA tucked into a multiagency appropriations bill for Senate action. This required negotiating with HHS, Justice, and the White House over provisions of the bill. The parties reached agreement in late October 1998, about 3 years after the original draft was written. Although Chairman Bliley of the House Commerce Committee was willing to let this amendment pass as part of the appropriations bill, the senior Democrat member of that committee, Congressman John Dingell, was not. He objected to the process, not the policy. He said the Committee had never held hearings on the matter and had never formally considered the legislation, and this, he said, deprived the members of the Committee of an opportunity to examine the policy, understand it, and either agree or disagree with it. He also noted that appropriations bills are not the place to change health care policy. The provision was removed from the bill.

Shortly thereafter the bill's supporters in the Senate produced a new draft of the legislation. This time the Company and the involved congressional staffers tried to follow everyone's rules. They worked with virtually all of the interested parties, including the Clinton administration, FDA, SAMHSA, NIDA, DEA, and the departments of HHS and Justice. FDA was concerned that the system could get out of hand unless limits were placed on the number of doctors and patients who initially could participate in the system. DEA worried that they would not be able to get a handle on whether physicians were appropriately registered. SAMHSA was concerned about the impact on

their resources and about the potential impact on current methadone clinics. The College on Problems of Drug Dependence (CPDD), the American Methadone Treatment Association (AMTA), the American Academy of Addiction Psychiatry (AAAP), the American Society of Addiction Medicine (ASAM), the American Psychiatric Association (APA), the AMA, the American Osteopathic Association (AOA), and others in the field, also had concerns and suggestions.

The new bill was introduced at the end of January, 1999, by Senators Hatch, Levin, and Biden. It provided that physicians who were qualified to treat opioid-dependent patients would be allowed to prescribe certain FDA approved opioids without being subject to current regulations, so long as they certified to their qualifications with the Secretary of HHS 30 days in advance of treating such patients and treated no more than 20 at a time. The bill also provided that the new federal paradigm would not be pre-empted by the states for at least a period of 3 years, but gave the Secretary of HHS and the Attorney General ample authority to stop the entire program if there was significant abuse. It was passed by the full Senate in November. Still needed was a House bill and agreement between the House and Senate, but some people on the Democrat side of the House were still irritated by the ill-fated effort to put the matter into an appropriations bill the year before. Congressman Dingell had written to the Secretary of HHS, Donna Shalala, raising questions and concerns about the buprenorphine bill that needed to be addressed before there could be further movement. Fortunately, Secretary Shalala responded in support of the policy change. She argued for changing the regulatory framework of drug treatment, for destigmatizing treatment, and for the promise of new treatment products such as buprenorphine. This was a positive development, but it was not until the end of July of 1999 that a bill was finally introduced into the House of Representatives. A hearing was held on July 30th, and although one witness raised concerns about the impact of new treatment arrangements on the current methadone system, and another raised the issue of whether insurance would cover new treatments, the witnesses were otherwise quite positive. Significantly, Senators Hatch and Levin testified in the House of Representatives in support of the bill. Dr Westley Clark, of the Center for Substance Abuse Treatment (CSAT), testifying for SAMHSA, noted the importance of ensuring that states would follow any new federal oversight arrangement from the outset to make certain it caught hold. He cited the LAAM experience as an example of how not to get new interventions broadly adopted. Another 3 months passed before the Commerce Committee acted and the bill was ready for House consideration. During that time various changes were made to the bill, including, for example, greater specificity about what makes a provider 'qualified'. Although state preemption remained a concern for some members, the final language was believed to provide sufficient opportunity after an initial transition period for states to make different rules.

Meanwhile, a bill aimed at shutting down illicit methamphetamine laboratories had been introduced into the Senate by Senator John Ashcroft and was arousing interest and support. This interest was shared by many House members as well, and it now gained priority in both the House and Senate Judiciary Committees. Thus, before the Drug Addiction Treatment Act (DATA) of 2000, or the 'Buprenorphine bill', as it came to be known, could be released, some activities on methamphetamine, including hearings in members' home districts, had to be undertaken. Furthermore, the members wanted to ensure that the methamphetamine bill would sail through the legislative process. This required a considerable amount of negotiation about both bills among interested parties. The House finally considered the buprenorphine bill on July 18, 2000 under 'Suspension of the Rules'. Under this procedure, only 1 h of debate is allowed and no amendments are accepted. While it is more predictable than a process where multiple amendments can be offered, under this procedure a two-thirds vote, rather than a simple majority, is needed to pass a bill, and for this reason the committee was concerned that the bill not be controversial. The debate was held, the bill was supported, and it seemed poised to be passed by the House on a voice vote, when Chairman Bliley made a motion to require a roll call vote to take place later that day. Then another glitch appeared: the version of the bill printed in the Congressional record was different from the version that had been considered on the House floor. This administrative error meant the bill would have to lay over until the next day at least.

Although the Secretary of HHS had been supportive, the DEA had serious reservations, and the 1-day layover gave them another opportunity to voice their concerns. They immediately contacted the House Judiciary Committee and attempted to add a requirement for physicians to register separately with the DEA or to get DEA approval before prescribing. The effort failed. The bill passed the House the next day with a vote of 412 to 1. It was then placed on the Senate calendar, but before it could come to consideration, the Senate Judiciary Committee passed the methamphetamine bill and attached to it their version of the buprenorphine bill. The Senate now had its own bill, quite different from the House version, a methamphetamine/buprenorphine bill, which it passed and sent to the House on January 27, 2000. Although the buprenorphine amendment to the CSA had now been passed by both House and Senate, there was still no law on the books that actually changed policy.

Throughout this process, staffers in the offices of Senators Hatch, Levin and Biden were seeking other vehicles for both the methamphetamine and buprenorphine bills. Ultimately, both bills were included in another 'must pass'—a huge bankruptcy reform bill. The House and Senate were in conference on this bill. Bankruptcy reform was hardly benign and the conference was not without some rancor. Senator Levin was determined to pass the buprenorphine bill, with or without the methamphetamine bill. As the ranking member of the Senate Armed Services Committee, and with the concurrence of the chairman of that committee, Senator John Warner, he had the buprenorphine bill placed in the Department of Defense Authorization conference, attached to another 'must pass' bill to allow the military to continue to function.

In the spring of 2000, there were six versions of the buprenorphine bill making their way through the legislative process: two versions of a stand-alone buprenorphine bill; two versions of a buprenorphine/methamphetamine bill; a buprenorphine/bankruptcy bill; and a buprenorphine/guns bill. Then events took another amazing turn. On May 9, 2000, the House passed a bill, H.R. 4365, to 'amend the Public Health Service Act with respect to children's health'. Without fuss or fanfare, this combination of several children's health bills was scheduled for action. It was now Chairman Bliley's chance to seize an opportunity; so H.R. 2634, Bliley's buprenorphine bill, became part of what came to be known as the 'Children's Health Act'. The House passed their bill and sent it to the Senate. After some behind the scenes negotiations, the bill passed the Senate on September 22, 2000, with an amendment that was, not surprisingly, the Senate version of the buprenorphine bill with the methamphetamine provisions. That amended bill, of course, had to be sent back over to the House and reconsidered. The House passed the bill exactly as the Senate had passed it, as Public Law 106–310, on September 27, 2000. On October 17th, President Clinton signed it into law. It is of some academic interest that the bankruptcy bill and the defense authorization conference were still in play, so at the last minute the buprenorphine provisions had to be snatched out of those bills. The President vetoed the bankruptcy bill on December 19, 2000.

6. The drug addiction treatment act of 2000

The new law, the DATA of 2000, offers an opportunity to make significant changes in the way addiction treatment is delivered. The change could be of benefit to hundreds of thousands of patients addicted to opioids. Perhaps as result of this legislation, other companies will see more opportunity in the development of new pharmaceuticals to treat addiction. The last hurdle was the final approval of the buprenorphine NDA by the FDA.

Buprenorphine for the treatment of opioid dependence was approved on October 8, 2002. This approval marks a new milestone in the evolution of the American response to opioid addiction, but it does not mark our crossing into therapeutic utopia. There will be problems. With FDA's approval of buprenorphine we will have, concurrently, two distinct oversight systems that deal with the use of opioid drugs in the treatment of opioid addicts. One is the modified set of regulations that emerged from the hybrid IND–NDA that developed and evolved over 30 years to provide a framework for oversight of methadone treatment. That system, which applies to all Schedule II opioids, such as methadone and LAAM, now incorporates a system of professional accreditation to oversee some aspects of treatment quality. It would not be inaccurate to describe this system as a hybrid–hybrid. And it still includes, by federal regulation, numerous constraints on the free exercise of judgment by treating clinicians. The other oversight system is the set of conditions that will govern the use of Schedule III–V opioid drugs, such as buprenorphine, that are approved for the treatment of addiction by the FDA. In this system, the judgment of the clinicians, who must attain certain qualifications or special training in order to be exempt from certain requirement of the NATA, is constrained by the requirement to limit the number of patients treated at any one time and the restriction on group practices.

7. Future challenges

It is not clear at this time how these two concurrent systems will interact and what the impact will be on patient access to treatment or the array of services provided. It is anticipated that the changes in the older system (the hybrid–hybrid) and the availability of buprenorphine in the offices of qualified physicians will serve both to increase access to treatment and to ease the compliance burdens on patients, and that both of these conditions will result in substantial benefits to the public and patients treated. But the law of unintended consequences has not been repealed, and it will remain for future commentators to judge what has been brought by these policy changes.

Undoubtedly, there will be some diversion of buprenorphine, and there will be some overdoses. We hope that few, if any, are fatal. Some young people will try buprenorphine and find it reinforcing. Somewhere, someplace, these events will be reported on by the media. It is difficult to predict the spin that such news will be given. The published articles and the television programs will probably not mention that in France the widespread therapeutic use of buprenorphine for the

treatment of 70,000 heroin addicts seems to have reduced significantly the opioids overdose death rate (Ling and Smith, 2002). What the coverage might underscore is that, other than peer pressure, neither government nor the medical profession will have mechanisms to deal with the individual rogue physician who prescribes inappropriately or too generously. If such behavior persists there is, at the federal level, only the extreme measure of reconsidering the status of buprenorphine as a Schedule III drug, or of the provisions of the Drug Abuse Treatment Act of 2000. What happens, of course, will reflect the peculiar American ambivalence about the opioid addict as not quite a patient and not quite a criminal. Thus, Americans seem willing to tolerate occasional untoward events and misuse of drugs for treatment of hyperactivity or anxiety, but not those associated with treatment of opioid addiction. The most optimistic scenario is that the use of buprenorphine in office based settings will simply increase access and lead the United States to a more pragmatic attitude towards dealing with the consequences of heroin addiction—and that such pragmatism will be long lasting and will demonstrate what can be achieved by easier and less stigmatizing access to treatment. With continued support from NIDA and CSAT, the new era of clinical freedom will be just another step in the long national effort to achieve the right balance between investing in supply control and demand reduction.

Acknowledgements

Charles O'Keeffe is President of Reckitt Benckiser Pharmaceuticals. Jerome Jaffe retired from his position as Director of OESAS in CSAT in 1997. He was a consultant to Schering Corporation, in 2000–2001, which is licensed by Reckitt Benckiser to market buprenorphine in several countries around the world. In the early 1990s, he provided consultation to drug manufacturers Roxane and Mallinckrodt, which manufacture and distribute methadone and LAAM. Support for this work was provided through internal funds only.

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Mr. SOUDER. Thank you. Our next witness is the honorable Karen Freeman-Wilson, executive director of the National Drug Court Institute in Alexandria.

Thank you for being here.

Ms. FREEMAN-WILSON. Mr. Chairman and members of the subcommittee, I would like to thank you for the opportunity to represent the National Drug Court Institute and address this very important issue.

Dr. McLellan has already talked about the importance of measuring client outcomes during the course of treatment when it is still possible to alter the treatment plan for the client's benefit. I will not duplicate his discussion except to underscore my agreement that traditional approaches of measuring pre-to-post changes in client functioning have unfairly obscured the true effects of drug treatment services because they assess outcomes after treatment has been withdrawn from what is a chronic and relapsing condition.

Although it is the position of our organization that these and other observations heard here today are applicable to treatment in all contexts, I will frame my conversation in the context of our findings in the drug court arena.

Drug courts are a unique blend of treatment, case management, intense supervision and support services along with judicial case processing. The success or failure of participants in recovery depends heavily on their access to quality effective treatment in drug court.

There are a number of indicators that can be reviewed to determine whether treatment is effective in drug court. The first is the rate at which offenders report to treatment pursuant to a court order and the length of stay and the rate of completion once they arrive.

Next is the offender's abstinence from the use of alcohol and other drugs. Each drug court is required to monitor abstinence through regular, random and observed drug testing. This means that most participants are tested at least two to three times a week.

Another measure of the effectiveness of treatment in the drug court context is the ability of the offender to comply with aspects of the drug court program. Is the person actively engaged in community service? Are they actively involved in job search, vocational training or school? Are they attending self-help meetings? Are they appearing as ordered for court review hearings and meetings with probation officers and other court staff? Are they paying their fines and fees?

Another factor which may assist in the determination of whether treatment is effective is the status of the offender's personal relationships during the drug court program. Is there a spouse, significant other, parent or child who regularly accompanies the offender to court, probation and counseling sessions? How successful is the participant in improving their living conditions as indicated by living most of the time in their own apartment or house, with their families, in someone else's apartment, room or house, or in sober housing?

The measures discussed above address our evaluation of treatment while an offender is actively involved in the court process.

Another related measure is the completion of educational or vocational programs and elevation in job status after treatment. One of the most important factors to the success or failure of drug courts and treatment is the individual's decrease in criminal involvement or activity. That is measured generally by recidivism.

While all of the factors discussed above are important, some are easier to measure than others. It's relatively simple to maintain and compile statistics with drug testing. It's easy to review whether a person reports for treatment or engages in treatment.

In looking at the more challenging measures, you must ask: How do you gauge the quality of relationships? How do you look at the number of trips a family member takes to court?

In conclusion, there are a number of considerations that must be made in an effort to standardize measurements to achieve more effective treatment research. First, it's important to take any measurement at three key points in time: Before, during and after treatment, whenever possible. There is an inherent challenge involved in measuring indicators prior to treatment because there will be a need to rely heavily on self-reporting. I detail the other points and measures in my testimony.

In concluding, I would recommend that this committee call for the development and adoption of a core validated data set to be captured in all federally funded evaluation-and-research studies to drug abuse treatment.

I would also recommend that this committee put its weight behind the adoption and enforcement of best practice standards for drug treatment programs with suitable performance benchmarks that programs must meet in order to establish that they are providing evidence-based interventions with appropriate and documented treatment integrity. National organizations such as NADCP are ideally suited to review the research to establish performance benchmarks and to promulgate suitable standards for their respective disciplines.

Thank you.

[The prepared statement of Ms. Freeman-Wilson follows:]

Testimony Of The National Association Of Drug Court Professionals/
National Drug Court Institute[1]
Alexandria, Virginia

Presented by Judge Karen Freeman-Wilson (ret.)[2]

to the

Oversight Hearing: "Measuring the Effectiveness of Drug Addiction Treatment"

United States House of Representatives
Committee on Government Reform
Subcommittee on Criminal Justice, Drug Policy and Human Resources

Honorable Mark Souder, Chairman

Mr. Chairman and members of the Committee on Government Reform, Subcommittee on Criminal Justice, Drug Policy and Human Resources, I would like to thank you on behalf of the National Association of Drug Court Professionals for the opportunity to address this august body as you explore ways to measure the effective of drug addiction treatment. I request that my full written testimony be included in the record.

Dr. Tom McLellan has already talked (will be talking) about the importance of measuring client outcomes *during the course of treatment*, when it is still possible to alter the treatment plan for the client's benefit. I will not duplicate his discussion, except to underscore my agreement that traditional approaches of measuring pre-to-post changes in client functioning have unfairly obscured the true effects of drug treatment services because they assess outcomes after treatment has been withdrawn from what is a chronic and relapsing condition.

Although it is the position of our organization that these and other observations heard here today are applicable to treatment in all contexts, I will frame my remarks in the context of our findings in the drug court arena. Drug courts are specialized dockets in the judicial system that

combine treatment, case management, intensive supervision and support services with judicial case processing. There are a number of factors that distinguish drug courts from traditional courts, but the factors most relevant to this discussion is the requirement that each offender engage in treatment and support services as needed. The success or failure of participants in drug courts across the country and their ability to achieve long-term recovery depends heavily on their access to quality, effective treatment.

The first drug court in the United States was established in 1989. Today, there are over 1700 (1187 operational and 626 planning) in existence or in the planning stages. Because this is a relatively new concept, drug court practitioners and proponents are consistently reviewing ways to measure the success or failure of these programs; inherent in this review process is the need to measure the effectiveness of treatment. There are a number of indicators that can be reviewed to determine whether treatment is effective in the drug court context. The first is the rate at which offender's report to treatment pursuant to a court order and the length of each stay and rate of completion once they arrive. Next is the offenders' abstinence from the use of alcohol and other drugs. Each drug court is required to monitor abstinence through regular, random, and observed drug testing. This means that most participants are tested at least two-three times a week. Those who consistently test negatively are believed to be receiving effective treatment.

Another measure of the effectiveness of treatment in the drug court context is the ability of the offender to comply with other aspects of the drug court program. Is the person actively engaged in community service? Are they actively involved in a job search, vocational training or school? Are they attending self-help meetings? Are they appearing as ordered for court review hearings and meetings with probation officers and other court staff? Are they paying their fines

and fees? Is the participant attending, complying and progressing in ancillary services, referred to community service providers, to address issues other than substance abuse such as taking their prescribed medications and otherwise addressing identified co-occurring mental health issues? Are they attending parenting classes, anger management, life skills classes and other adjuncts to substance abuse treatment? Because each drug court participant is required to engage in treatment immediately, their compliance with the other aspects of the program that follow their entry into treatment also provide insight into whether the treatment is effective.

Another factor that may assist in the determination of whether treatment is effective is the status of the offender's personal relationships during the drug court program. Is there a spouse, significant other, parent or child who regularly accompanies the offender to court, probation and counseling sessions? Has the participant reconciled with family members after a period of estrangement? Is the person developing new, healthy relationships? What percent of clients report an increase in regular, positive contact with one or more family members and/or friends, including a sober peer group on an ongoing basis? How successful is the participant in improving their living conditions, as indicated by living most of the time in their own apartment or house; with their families; in someone else's apartment, room or house; or in sober housing?

The measures discussed above address our evaluation of treatment while an offender is actively involved in the court process. It should be noted that additional measures must be made after the person is released from treatment and even after their graduation from the court program. Some of these measures may be the ability to obtain and retain employment. Related to this determination and a way to quantify it is the amount of taxes that a person pays after treatment. Another related measure is the completion of educational or vocational programs and elevation in job status after treatment.

One of the most important factors to the success or failure of drug courts and treatment is the individual's decrease in criminal involvement/activity. This can be gleaned by looking at a person's arrest(s) and/or conviction(s) after treatment and after graduation from the drug court program at different intervals such as one, two and five years after program completion. There are other indicators after completion of treatment programs and graduation from court that can indicate the success or failure of treatment. It is helpful to look at the person's pro-social participation in the community. How do they give back? Are they involved in civic, social or other organizations that benefit their communities? Are they generally engaged with a positive peer group? Are they actively participating in recovery maintenance meetings such as AA, NA, CA long after the court requirements are met?

While all of the factors discussed above are important, some are easier to measure then others. It is relatively simple to maintain and compile statistics associated with drug testing. It is also easy to review whether a person reports for treatment, engages in treatment and finishes as an indicator of engagement. Separate, but closely related to this measure is the length of duration in treatment.

Although it might be a little more arduous, it is certainly possible to define recidivism and review court records to determine whether those who have successfully completed treatment in the drug court program have recidivated. It is also possible to review tax records to determine whether individuals have entered or returned to the workforce as taxpaying citizens.

It is much more challenging to quantify some of the other measures. How do you gauge the quality of relationships? Do you look at how many trips a family member makes to court? Do you compare who the person lives with before and after treatment?

In conclusion, there are a number of considerations that must be made in an effort to standardize measurements to achieve more effective treatment research. First it is important to take any measurement at three key points in time, before, during and after treatment whenever possible. There is an inherent challenge involved in measuring indicators prior to treatment because there will be a need to rely heavily on self-reporting. Second, it is important not to review any of the indicia discussed above in a vacuum. One can not measure efficacy of programs solely by reviewing recidivism or the results of drug tests. Many other quality of life factors must be taken together. It is also important to remember that in our quest for uniformity, we must take care in our comparisons—i.e. it is important to establish one measure for in-patient programs and another measure for outpatient programs. Third, much of the extant research on the efficacy of drug abuse treatment has relied upon large-scale, descriptive and correlational studies, such as the Drug Abuse Treatment Outcome Study (DATOS). These studies have been important in establishing such findings as the fact that longer tenure in treatment is associated with better outcomes. It is time now for a "next generation" of research using experimentally controlled designs that permit inferences of causality that are not permissible, scientifically speaking, from correlations. This is the same conclusion that was recently reached by the National Research Council of the National Academy of Sciences in its 2001 Report, *Informing America's Policy on Illegal Drugs*. I would request therefore, that this Committee call for the funding of scientifically rigorous experimental studies that directly answer questions of immediate practical and policy relevance for the drug abuse and criminal justice fields. Forth, It goes without saying that it is not possible to reach defensible conclusions from unreliable or invalid measures. If outcomes are measured poorly, or if they are subject to various biases such as clients' under-reporting, then the results merely add noise or confusion to the literature.

Moreover, if certain measures are used in some studies, and different measures are used in other studies, it will obviously not be possible to compare outcomes across studies, across jurisdictions, across modalities or programs, or across different target populations.

RECOMMENDATIONS

In light of the above observations, I would recommend therefore, that this Committee call for the development and adoption of a core, validated dataset to be captured in all federally-funded evaluation and research studies related to drug abuse treatment. I would also recommend that this Committee put its weight behind the adoption and enforcement of best-practice standards for drug treatment programs, with suitable performance-benchmarks that programs must meet in order to establish that they are providing evidence-based interventions with appropriate and documented treatment-integrity. National organizations such as NADCP are ideally situated to review the research literature to establish performance benchmarks, and to promulgate suitable standards for their respective disciplines.

Conclusion

After decades of failed efforts to reduce drug use and recidivism among offenders, recent initiatives such as drug courts are showing promise for improving outcomes in this intransigent population. Unfortunately, research methods have not kept pace with professional developments. Newer experimental methodologies are needed to reliably measure client outcomes, isolate the critical components of drug treatment services, identify specific types of clients who are best suited to specific types of services, and measure performance indicators before, after and during treatment that predict longer-term outcomes. These findings must then be incorporated into best practices and best policies for not only drug courts, but all community-based treatment programs. Thank you for your consideration.

[1] The National Association of Drug Court Professionals is a national voice, promoting drug court effectiveness and advocating for the creation of more drug courts and other problem-solving courts in the United States and abroad. Established in 1994, NADCP is the premier professionals for judges, prosecutors, defense counsel, probation officers, treatment providers, law enforcement officers and other professionals who regularly practice in drug courts. In 1997, the Office of National Drug Control Policy, Executive Office of the President, assisted in the establishment of the National Drug Court Institute (NDCI) as the training and education division of NADCP. NDCI promotes the drug court movement through education, research and scholarship.

[2] Judge Karen Freeman-Wilson is the Chief Executive Officer of the National Association of Drug Court Professionals and the Executive Director of the National Drug Court Institute in Alexandria, Virginia. She is nationally recognized as a leader in the anti-drug movement. She currently chairs the Indiana Governor's Commission for Drug-Free Indiana. Throughout her career, Freeman-Wilson has demonstrated her dedication to public service as Indiana Attorney General and Gary City Court Judge, Executive Director of the Indiana Civil Rights Commission, a Lake County deputy prosecutor and public defender. As judge, Freeman-Wilson started the first drug treatment court in the State of Indiana. She graduated with honors from Harvard College (1982) and from Harvard Law School (1985).

Mr. SOUDER. I need to correct the record with something because I was trying to sort it out, and it was in the footnotes of your testimony.

I was very confused when I read this: executive director, Alexandria, VA, because, I am saying, I think she was Attorney General of Indiana and on the Governor's drug commission. So first off, you are one of us, not part of this Washington group here. So I welcome a fellow Hoosier. I should have caught that earlier in my introduction of you, thank you very much for coming.

Dr. Jaffe is a professor at the University of Maryland in Baltimore. Would you elaborate, did I understand Mr. O'Keeffe to say that you were the first drug czar?

Dr. JAFFE. I have been called that, Mr. Chairman.

Mr. Chairman, members of the subcommittee, I thank you for inviting me to speak to you on measuring the effectiveness of treatment.

In January, Join Together, a project of Boston University School of Public Health, released a study called, "Rewarding Results: Improving the Quality of Treatment for People With Alcohol and Drug Problems." I had the privilege of chairing the panel that produced the report. I will offer some highlights of the report here and will submit the entire report for use by the subcommittee.

First, some preliminary thoughts on evaluation. First, how one evaluates or measures the effectiveness of treatment programs depends very much on the purpose for undertaking the evaluation. For example, an employer who wants to know if a program covered by the company's insurance plan is effective may be interested in knowing not only whether or not the problem drug or alcohol use is stopped but also how soon the employee can return to work.

Another agency may be more interested in knowing if treatment has resulted in decreased criminal activity.

Depending on resources and goals, one can obtain information directly by finding and interviewing patients or indirectly by analyzing data bases. It's also possible to look at surrogate measures of outcome, measures that correlate highly with good outcome, such as retention in treatment.

Federal agencies have put out a number of guidelines that, if properly implemented, could improve the overall quality of treatment. The guidelines aimed at improving quality are unlikely in and of themselves to do the job. They cannot compel high-quality treatment.

Crucial to high-quality treatment is a well-trained work force as well as better application of findings that have emerged and will continue to emerge from research.

But in the real world of treatment where there are about 12,000 programs, two major problems impede the implementation of those guidelines.

First, many programs are quite small and even many large ones lack the financial resources to put guidelines into practice.

Second, because the job is stressful and salaries are low, there is a high turnover of personnel, not only among first-line counselors and clinicians but also among program supervisors and managers. With such turnover, much of the investment that programs make in clinical and management training is lost.

The Join Together panel concluded that unless there are clear and continuing incentives to provide quality treatment, quality will always take second place to program survival or expansion. What is needed to drive quality improvement is a commitment by those who pay for treatment to reward good outcome. In other words, reward results.

Again, depending, the results can vary. Merely publicizing results can have the effect of stimulating pride in the better programs and stimulating a sense of urgency in the less effective ones. You can make the rewards more tangible by paying more to the better programs or directing more patients to those programs.

Implementing systems that look at outcomes will require additional resources. These shouldn't be carved from what is now available for treatment. Rewarding results should be seen as a means to improve outcome. It is not a pathway to getting more treatment for less money.

The Join Together panel recommends that rewarding results be defined as a national goal. On the road to reaching that goal, there are many technical and political obstacles to be overcome. And many upon different groups will have to be persuaded that it can be done and should be done.

I thank you for your time and would be happy to answer questions.

[NOTE.—The Join Together report entitled, "Rewarding Results, Improving the Quality of Treatment for People with Alcohol and Drug Problems," may be found in subcommittee files.]

[The prepared statement of Dr. Jaffe follows:]

Comments of Jerome H. Jaffe, M.D., Clinical Professor of Psychiatry, Division of Alcohol and Drug Abuse, Department of Psychiatry, University of Maryland School of Medicine, Baltimore, MD, and Adjunct Professor, Department of Mental Hygiene, Johns Hopkins University Bloomberg School of Public Health, Baltimore, MD, before the Congress of the United States House of Representatives Committee on Government Reform, Subcommittee on Criminal Justice, Drug Policy and Human Resources; Oversight Hearing, February 12, 2004.

Mr. Chairman, members of the Subcommittee, I thank you for inviting me to speak to you on the topic of measuring the effectiveness of treatment for drug addiction. It is my understanding that the Subcommittee is interested in strategies for improving treatment quality and how measuring results can contribute to that improvement

In January, Join Together, a project of Boston University School of Public Health, funded by the Robert Wood Johnson Foundation, released a report titled *"Rewarding Results: Improving the Quality of Treatment for People with Alcohol and Drug Problems."* The report was based on the deliberations of a panel of experts from various fields touching on treatment, background papers by nationally recognized scholars commissioned for the panel by Join Together, and testimony offered by dozens of interested parties. I had the privilege of chairing the panel and overseeing the preparation of the report. Because the contents of the report are so germane to the present interests of this Subcommittee, I will offer some highlights in my oral testimony and will submit the entire report for use by the Subcommittee as it sees fit. Before summarizing the report's main themes, I would like to offer some preliminary thoughts on the evaluation of drug and alcohol treatment.

First, how one evaluates or measures the effectiveness of drug and alcohol treatment programs depends very much on the purpose for undertaking the evaluation. For example, an employer who wants to know if a program covered by the company's insurance plan is effective may be interested not only in whether or not the problem drug or alcohol use has stopped, but also in how likely it is that recovery will be stable and how soon the employee can return to work. Another agency may be more interested in knowing if treatment has resulted in decreased criminal activity. Depending on resources and goals, one can obtain information directly by finding and interviewing patients, or indirectly by analyzing existing databases. It is also possible to look at surrogate measures of outcome, measures that correlate highly with good outcome, such as retention in treatment.

Large scale evaluations sponsored by the Federal government over the past 25 years have used direct patient interviews to look at multiple outcomes, such as use of drugs and alcohol, criminal activity, and the utilization of welfare and medical services. They have also looked at how long the effects of treatment persist after the period of active treatment ends, how various approaches to treatment compare in effectiveness, and what aspects of treatment contribute to outcomes. In the process, a rich store of knowledge has accumulated about the duration of treatment and the kinds of services that are likely to lead

to good outcomes. There is little doubt that good treatment leads to reduced drug use and other benefits to society.

Federal agencies have been working hard to improve the quality of treatment and have put out a number of guidelines that, if properly implemented, can improve the overall quality of treatment. But guidelines aimed at improving quality are unlikely, in and of themselves, to do the job. They cannot compel high quality treatment. Crucial to high quality treatment is a well-trained treatment workforce, as well as better application of the findings that have emerged – and continue to emerge - from research. But in the real world of treatment, where there are about 12,000 programs, two major problems impede the implementation of those reasonably well thought out guidelines. First, many programs are quite small, and many (even large ones) lack the financial resources to put guidelines into practice. Second, because the job is stressful and salaries are low, there is a high turnover of personnel, not only among first line drug counselors and clinicians, but also among program supervisors and managers. With such turnover, much of the investment that programs make in clinical and management training is lost.

When the Join Together panel looked at this situation we concluded that unless there are real and continuing incentives to provide quality treatment, quality will always take second place to program survival or expansion. What is needed to drive quality improvement is a commitment by those who pay for treatment to reward good outcome – in other words, to *reward results*. Again, depending on resources, the rewards can vary. Merely publicizing how the programs compare can have the effect of stimulating pride in the better programs and stimulating a sense of urgency in the less effective ones. It is also possible to make the rewards more tangible by paying more to the better programs or directing more patients to those programs. When this is done, programs delivering superior results will tend to flourish and those delivering poorer outcomes will either improve, merge with more effective programs, or cease to function.

In making the recommendation to reward results, the Join Together panel did not in any way intend to devalue the importance of increasing resources for the introduction of new technologies and stabilization of the workforce. There are hard-working and dedicated people on the frontlines of addiction treatment who are dealing with some of life's toughest problems with often threadbare resources. And despite such difficulties we often see good results. But until there are real rewards for getting good outcomes, those who make treatment decisions will not be motivated to ask continually: How are our patients doing? What are we doing that we could be better? Do we need to change what we are doing because evidence suggests that another approach would have produced a better outcome?

There is still no consensus about which types of treatment approaches are most effective in creating durable recovery from drug and alcohol addiction. However, when funding agencies begin to pay attention to outcomes, the public will be more likely to believe that treatment for drug and alcohol addiction does produce useful results, and the

credibility of treatment will be strengthened when it is competing with other public priorities for funds. Implementing systems that look at outcomes will require additional resources. These should not be carved from what is now available for treatment. Rewarding results should be seen as a means to improve outcome. It is not pathway to getting more treatment for less money.

The Join Together report contains specific recommendations to Federal and State agencies, employers, funders, and community leaders for rewarding results. No doubt, whether the method selected involves only providing a public report card or actual differential payment, objections will be raised to the idea of rewarding results. The major concern will be that each case is different, that programs or practitioners cannot be compared, and that practitioners or programs will "cherry pick" to avoid the most difficult patients. These objections cannot be lightly dismissed. Our panel recognized that mechanical approaches to program comparison may always remain imperfect. However, the panel is confident that care managers can use quantitative data together with site visits and patient input to form fair comparative judgments about program quality.

In both the private and public sectors there are already efforts to introduce performance measurement as a means to improve treatment quality for alcohol and drug problems. For example, the Department of Veterans Affairs (VA) is now obtaining data on addiction treatment delivered in all VA hospitals and clinics, making it possible to compare facilities in terms of performance. Differences in performance could result in funding adjustments. The Health Plan Employer Data and Information Set (HEDIS) is now introducing a few measures of how well alcoholism problems are dealt with, allowing employers to compare private health plans in terms of their performance in this area.

The Join Together panel was informed about the careful work of many, including the Washington Circle group, to develop consensus indicators of program quality. We appreciated these efforts and did not wish to duplicate them by developing our own set of indicators or measurements. We believe that the deep question is not to how to measure outcome or quality, but rather whether those with responsibility for paying for care will have the courage and management capacity to begin using available measures to reward results.

The Join Together panel recommends that rewarding results be defined as a national goal. On the road to reaching that goal there are many technical and political obstacles to be overcome, and many different groups that will have to be persuaded that it can be done and should be done.

I thank you for your time and ask that the full content of my remarks and the Join Together report, "Rewarding Results", be introduced into the record.

Mr. SOUDER. Thank you very much for your testimony.

The next witness is Catherine Martens, senior vice president of Second Genesis in Silver Spring, MD.

Ms. MARTENS. Thank you, Mr. Chairman, Congressman Cummings.

As the chairman said, my name is Cathy Martens, and I am the executive director of Second Genesis and a member of the Board of Directors of the Therapeutic Communities of America.

As a provider, Second Genesis appreciates the opportunity to provide the committee with our written testimony about measuring the effectiveness of drug treatment.

Second Genesis is the oldest therapeutic community-based substance provider in the Mid-Atlantic region and Maryland's largest provider.

As a successful nonprofit for over 35 years, we continue to serve the substance-abuse populations in Washington, DC, Virginia, and Maryland. We have criminal justice programs, programs for women and their children and a highly respected integrated program for clients with co-occurring disorders.

Society cannot continue to pay for the individuals who unsuccessfully cycle through various treatment options and criminal justice systems. In the Outlook and Outcomes 2002 Report from Maryland, an untreated substance abuser on the street costs society an estimated $43,300 a year. An incarcerated substance abuser costs $39,600 a year.

In contrast, 8-months of residential treatment at Second Genesis costs only $17,280, and for the remaining 4 months of the year and beyond, the recovering taxpayer is a productive member of society and a taxpayer.

Second Genesis clinical professionals have determined that the shorter the stay of the client, the more likely that client is to relapse.

Our own data collection demonstrates that 6 months after leaving residential treatment, 70 percent of long-term clients reported no alcohol or other drug use in the 30 days prior to that survey. The overall success rate of our program is 63 percent, significantly higher than that of the Maryland Statewide average of 47 percent for similar clients.

As a provider, we are largely publicly funded, which requires us to report to Government contract officers, foundations and other sources of funding, proof that the dollars that they have invested with us have produced concrete results. We use the HATS reporting protocol to report regularly and electronically to data collection systems for our contractors. The majority of this information is in actual real-time.

We collect information on our clients at admission, halfway through treatment, at discharge and 90 days post-treatment. However, in order to provide this outcome information, the burden of reporting has grown enormously. We are also responsible for staff training and other increasing costs associated with the outcome-based data collection.

Second Genesis has approximately 40 counselors that spend a minimum of 10 percent of their job completing outcome-related paperwork. This number does not include all of the other paperwork

that must be completed for each client. It becomes increasingly burdensome to dedicate staff hours and training to data collection at the expense of direct client treatment.

We are mandated to maintain this data to prove program effectiveness. Additionally, Second Genesis employs three full-time individuals who manage all aspects of this data collection and its analysis. However, funding to comply with Federal and other contractual mandates has not followed suit.

We collect information on all of the SAMHSA seven domains, yet it is the analysis of this data that is truly important.

In summary, substance abuse treatment programs should be constructed on and funded on evidence-based methodologies that are outcome-based and meet appropriate performance standards. According to Therapeutic Communities of America, any outcome measures should have the following considerations: addicted individuals must be placed in the appropriate level, type and standard of care to achieve positive and quality results. According to the NIDA research report, Therapeutic Communities [TC], for individuals with multiple serious problems, research again suggested outcomes were better for those who receive TC treatment for 90 days or more.

Treatment and any other performance standards must be client-based and should flow as a function of the client necessitating a coordinated and comprehensive continuum of care for that client. Any measure or performance standard should recognize that different treatment methodologies, should reflect the timeframe from which favorable impact outcomes are likely to occur. This consideration also includes modifications to treatment, when necessary, in working with special populations.

Any measure should recognize Therapeutic Community residential programs and permit at least 8 to 12 months of continuous treatment. Outcomes and measures should be no different in application to addicted individuals than any other chronic disease. Realistic goals for specific substance-abuse populations should be established. In the case of substance abuse, unlike any other illness, our system is often in danger of undertreating the client.

No Federal or State measurement or performance standard should be mandated without providing necessary direct funding, technical assistance and capacity building to the service providers.

Thank you for the opportunity to testify before you, and I would welcome any questions you might have. Thank you.

[The prepared statement of Ms. Martens follows:]

RESIDENTIAL AND OUTPATIENT TREATMENT
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Testimony of
Catherine C. Martens
Senior Vice President
Second Genesis, Inc.

Measuring the Effectiveness of Drug Treatment

House Committee on Government Reform
Subcommittee on Criminal Justice, Drug Policy, and Human Resources

U.S. House of Representatives
Washington, DC

Macrh 30, 2004

Chairman Souder, Congressman Cummings and Members of the Criminal Justice, Drug Policy and Human Resources Subcommittee of the House Government Reform Committee, my name is Catherine C. Martens, I am the Senior Vice President of Second Genesis and a member of the Board of Directors for the Therapeutic Communities of America (TCA). As a provider, Second Genesis appreciates the opportunity to provide the committee with written testimony for the February 12, 2004 hearing on measuring the effectiveness of drug treatment.

Therapeutic Communities of America (TCA) is a national non-profit membership association that represents over 400 programs across the country dedicated to serving those with substance abuse problems.

Second Genesis is one of the oldest therapeutic community-based substance abuse providers in the Mid-Atlantic region. We have been in existence for 35 years as a non-profit organization serving the substance abuse populations in Washington D.C., Virginia and Maryland.

We have impacted thousands of men, women, women with their children, adolescents and their families, and individuals with co-occurring disorders (i.e.: psychiatric and chemical abuse disorder.) to begin living productive lives. As a provider, our years of experience to confirm national, federally funded studies such as the National Treatment Improvement Evaluation Study (NITES) and the Drug Abuse Treatment Outcome Study (DATOS) conducted by the National Institute on Drug Abuse (NIDA).

Over the years we have found that the substance abusing population is growing at such a rapid rate that there are not enough treatment slots available to meet the demand. The challenge now is to provide evidenced-based treatment to the maximum number of America's substance abusing individuals and their families.

A recent study conducted by the University of Chicago confirmed that improvement is greatest when clients are in long-term residential treatment. NIDA studies agree that, illicit drug use and illegal activity are significantly reduced following one year of TC residential treatment. The most important consideration is the number of individuals we reach and the effectiveness of our treatment outcomes. Society cannot continue to pay for individuals to unsuccessfully cycle through various treatment options and criminal justice systems. For example, in the Outlook and Outcomes 2002 Annual Report for

Maryland, an untreated substance abuser on the street costs society an estimated $43,300 a year. An incarcerated substance abuser costs $39,600 a year. In contrast eight months of residential treatment at Second Genesis costs only $17,280, and for the remaining four months of the year and beyond, the recovering addict is an employed taxpayer.

Within Second Genesis we have found the shorter the stay of a client the more likely they are to relapse to drug abuse and criminal activity. Our own data collection demonstrates that six months after leaving residential treatment, 70% of clients reported no alcohol or other drug use in the 30 days prior to the survey. The DATOS shows that in long-term residential treatment, clients who remained in treatment for 3 months or longer had significantly better follow-up outcomes on a variety of criteria than did early dropouts or those treated less than 3 months. Post treatment outcomes continued to improve as treatment retention increased. We know from our own experience that treatment works and long-term treatment works best. Measurements should be based on evidenced-based research showing the importance of length of stay.

Providers of the therapeutic community model take into account the individual's needs throughout their entire treatment process and foster drug rehabilitation based on those needs. Therapeutic communities understand that substance abuse clients have multiple barriers to recovery, in addition to their drug use, that need to be addressed in order to achieve effective outcomes.

As a provider, our principles, philosophies and modalities reflect the Principles of Drug Treatment developed by NIDA. The services we provide facilitate individual recovery from substance abuse by providing information, support and guidance, and by insisting that clients take an active role in planning and implementing therapeutic activities for themselves, their peers, and their families. Our substance abuse programs are holistic in nature; they include programming services such as vocational services, educational opportunities, social skill building, family education, health related classes, support groups, parenting classes, childcare services and relapse prevention.

Second Genesis has followed the therapeutic community model for 35 years and the success rate with both mandated and non-mandated clients has been dynamic. Of the clients that we serve, 43% enter the program voluntarily while 57% are court mandated. Therapeutic communities strive to help individuals secure family unification and successful welfare to work outcomes. The overall success rate of our program is 63%, significantly higher than the statewide average of 47% for similar clients.

As a provider, we are largely publicly funded, which requires us to report to government contract officers, foundations, and other sources of funding who demand proof that their dollars produce concrete results. We use the HATS reporting protocols to report regularly and electronically to data-collection systems for the State of Maryland (e.g. SAMIS) and to the Baltimore Substance Abuse Systems. Most of this information is transmitted in real time. We collect information from our clients at admission, at the halfway point of treatment, at discharge and 90 days post-treatment. However, in order to provide research information, the burden of proof has been left at our door. Second Genesis is fully compliant with HATS software, procedures, rules, regulations, staff training, methods of data collection and tracking. We are also responsible for the hours of staff training, work hours, paperwork and all costs associated with outcome-based studies.

Second Genesis has approximately 40 counselors that spend 10% of their job on all associated paperwork needed for research data this number does not include all the other paperwork they must complete for each client. Second Genesis also employs two fulltime individuals to manage all aspects of collecting and interpreting the outcome data. It is becoming increasingly inefficient to dedicate staff hours and training to research and data collection; but it is a necessity to maintain this data to prove the effectiveness of our programming for the increasing mandated federal and state measurement performances. However, funding to comply with mandates is not provided.

Information required includes self-reports in major life domains, including confidence in staying clean and sober, employment status, and involvement with the criminal justice system. SAMHSA has suggested 7 domains from which to measure outcomes. Those domains are drug/alcohol use, employment/education, crime and criminal justice, family and living conditions, social support and access and retention/engagement. We collect information on all of those domains, yet it is the interpretation and the details in which those measures are judged that affect their validity and their substantiation as positive outcomes. NIDA funded research has given providers important information on what works in treatment. It is our hope that any measurement system developed is reflective of the research.

In Summary:

- Substance abuse treatment programs should be constructed on evidenced-based methodologies that are outcome based and meet appropriate performance measures.
- Substance abuse treatment programs and their staffs should meet recognized certification, accreditation and/or licensing standards.
- Federal public policy should be based on evidenced-based substance abuse programs that are client-based.
- Public policy should require intergovernmental agency coordination to serve the client with a continuum of care.

According to Therapeutic Communities of America, any outcome measures should have the following considerations:

Addicted individuals must be placed in the appropriate levels, type, and standards of care to achieve positive and quality outcomes. According to the NIDA *Research Report – Therapeutic Community*, "For individuals with many serious problems, research again suggests outcomes were better for those who received TC treatment for 90 days or more."

Treatment and any performance standard must be client-based and should flow as a function of the client necessitating a coordinated comprehensive continuum of care for the client.

Any measure or performance standard should recognize that different treatment methodologies should reflect the time frame from which favorable impact outcomes are likely to occur. This consideration also includes any modifications to treatment methodologies necessary when working with special populations within therapeutic communities.

Any measure should recognize therapeutic community residential programs and permit at least 6 months or more of continuous care essential when working with special populations.

Outcomes and measures should be no different in application to addicted individuals than with other chronic diseases. Realistic goals for specific substance abuse populations should be established. In the case of substance abuse, unlike most other illnesses, our system is often in danger of under treating the client.

No Federal or State measurement or performance standard should be mandated without providing necessary direct funding, technical assistance, and capacity building to the service provider. Any measurement system implemented needs to be cautious not to add increased burdens on the substance abuse workforce by turning the already declining number of counselors into data collectors and researchers.

Any and all performance standards, outcomes, and measures should be client-based, based on evidenced-based research and be respectful of the NIDA Principles of Drug Addiction Treatment.

For the record please refer to the complete written testimony submitted to the Committee by Therapeutic Communities of America.

Mr. SOUDER. Thank you.

Our final witness today is Dr. Hendree Jones.

Dr. JONES. Hendree.

Mr. SOUDER. Hendree Jones, a research director for the Center for Addiction and Pregnancy in Baltimore, MD.

Dr. JONES. Good afternoon, Mr. Chairman.

And a special hello to Ranking Member Elijah Cummings, who represents the patients and families in Baltimore City where Johns Hopkins Bayview Medical Center for Addiction and Pregnancy is located. And thank you very much for inviting me to testify.

I serve as the director of research for the Center For Addiction and Pregnancy [CAP]. It is located at Johns Hopkins Bayview Medical Center. And I am also a NIDA-funded researcher on drug treatment effectiveness. Additionally, my program is a member of the Maryland Addiction Directors Council and State Association of Addiction Services, a national organization of State alcohol, drug-abuse treatment associations and provider associations whose mission is to ensure the accessibility and accountability of quality drug and alcohol treatment and prevention services.

I have spent a lot of time thinking about how to expand and improve drug treatment effectiveness, and obviously, we need to close the tremendous treatment gap. We also need to invest in the best treatment options, ensuring that our science makes it onto the streets and makes it into everyday practice.

CAP's outcomes actually demonstrate that drug and alcohol treatment can be effective, and I want to share some of our latest successes with you: 75 percent of the women who are enrolled in CAP have drug-free deliveries and are drug-free 3 months after completing our treatment program; 81 percent of our children are drug-free at delivery; 70 percent of our women maintain custody of their children; 15 percent of our women actually decrease dependency on welfare; and 95 percent of our women actually remain HIV-negative while in treatment.

Our average CAP baby is born at a normal time, at a very healthy birth weight, with normal alertness. Investing in CAP treatment can actually save $12,000 per infant through a reduction in the neonatal intensive care unit stays.

CAP successes are actually typical of many treatment programs across the country that treat women with children. And let me tell you a little bit how we have been able to achieve those outcomes.

CAP was founded in 1991, and it is an outpatient as well as residential treatment program. And we have a number of ancillary support services, including the drug abuse treatment that we provide. We provide transportation to and from the program. We have onsite OB/GYN care and onsite pediatric care and also onsite child care for women attending the outpatient treatment. And we have intensive outreach services. So if a client doesn't show up for treatment, we are out there on the streets looking for the patient to bring her back in. And it is these ancillary support services that help us achieve our outcomes.

There are other recommendations I have for improving the quality of treatment services. The ability to conduct studies and actually measure outcomes will improve the quality of treatment. CAP has been able to conduct these studies because we have been fund-

ed by NIDA. And we have been able to look at specific treatment interventions, and this information has actually informed our practice and improved it.

Transferring science to service also improves the quality of care. And what we have learned from studies we need to be able to implement into a first-line, frontline provider service. Without the technology that was discussed by Dr. Volkow, including the Clinical Trials Network and SAMHSA's Addiction Technology Transfer Centers, the addiction treatment field will be much slower to accept these new technologies.

We also need to be funding new techniques, including emerging medications as well as medications and behavioral interventions, to put the best practice into place.

We need to be able to recruit and retain a qualified addiction treatment work force. The development of course work in medical and nursing schools is key to encouraging practitioners to recognize drug dependence or abuse as well as to know where to provide referrals for those patients to treat them.

We also need to not forget our recovering community who has long been the frontline providers in this treatment.

Finally, it would be good to develop loan forgiveness programs and repayment programs in order to facilitate people to stay in this typically low-paying field.

Funding access to the full continuum of care will certainly help to improve treatment quality. Patients are often not able to go from one level of care to the next, and CAP patients are certainly not an exception to this barrier. Funding the full continuum of treatment is very difficult for different jurisdictions given the pressure on the limited amount of funds that we have, as well as the limitations that exist on current funding mechanisms like Medicaid.

If we were to increase the fiscal year 2005 substance abuse prevention and treatment block grants, Access to Recovery programs, and target capacity expansion programs, we could help meet the pressing needs for treatment.

Additionally, better Medicaid coverage would also improve treatment for women with children. We need to be moving toward a system of uniform treatment-outcome measures across funding streams to help improve treatment quality.

Moving toward this system of uniform performance measures across Federal funding streams will help benefit providers by reducing the large paperwork demands that are increasing and help us to be able to more clearly react to the different types of outcomes that are demanded by potentially different providers.

These savings could hopefully help us reinvest in provider training and back into treatment.

When SAMHSA determines the performance outcome measures, I hope they will consult with the providers as well as the States because outcome data is first and foremost generated at the provider level.

Thank you very much for holding this hearing today and for highlighting the importance of drug treatment. My patients and the Center for Addiction and Pregnancy staff and I applaud you. And I would be happy to take questions.

[The prepared statement of Dr. Jones follows:]

3/30/04

Dr. Jones

Introduction

Good afternoon, Mr. Chairman ~~and members of the Subcommittee, with a special hello to~~ Ranking Member Elijah Cummings, who represents the patients and families in Baltimore City whom ~~my program, the Johns Hopkins~~ Center for Addiction and Pregnancy, serves. Thank you for inviting me to testify. ~~I request that my written statement be submitted for the record, please.~~

I serve as the Director of Research for the Center for Addiction and Pregnancy at the Johns Hopkins University Bayview Campus and as a NIDA-funded researcher on drug treatment effectiveness. Additionally, my program is a member of the Maryland Addiction Directors' Council and the State Associations of Addiction Services, a national organization of state alcohol and drug abuse treatment and prevention provider associations whose mission is to ensure the availability and accessibility of quality drug and alcohol treatment and prevention services.

I have spent a significant amount of time thinking about how to expand and improve drug and alcohol treatment services. Investing funding into the treatment system is critical, because the treatment gap looms large, both in my state and nationwide. However, in addition to closing this treatment gap, we must invest in the best treatment options, ensuring that our science makes it to the street and gets incorporated into everyday practice

we need to close

CAP's Outcomes Demonstrate that Alcohol and Drug Treatment Can Be Effective

Addiction is a serious and chronic health problem. CAP and many other treatment centers for pregnant women and women with children throughout the nation are addressing this problem -- and we are succeeding. Let me share some of our successes:

- **75%** of the women at CAP have drug free deliveries and are drug-free three months after treatment.

- **81%** of the children born to CAP patients are born drug-free.

- **70%** of the women at CAP maintain custody of their children.

- **95%** of the women remain HIV negative while in treatment.

- **15%** of the women at CAP decrease their dependence on welfare.

- The average baby born to a CAP treated mother is born **at a normal time**, at a **healthy birth weight** and with **normal alertness**.

- **$12,000 in savings** ***per infant*** is generated by CAP care through a reduction in NICU stays.

CAP's successes are typical of women's treatment services across the country according to federal studies of similar programs.

Treatment at CAP

Founded in 1991, CAP is an outpatient and residential program that provides a comprehensive approach to treating drug-dependent mothers and their drug-affected babies. In addition to providing clinical treatment, CAP provides a range of support services that include on-site child care, transportation, and intensive outreach services for clients who miss treatment. Including these types of services helps to improve the quality and success of the treatment at CAP and without these services CAP would not be able to achieve the types of outcomes that I have described to you today.

Improving Treatment Quality

There are several other recommendations for improving the quality of the treatment services:

- **The ability to conduct studies and measure outcomes can improve the quality of treatment.** CAP has been able to conduct studies, funded by NIDA, to determine the effectiveness of specific treatment techniques and this information has improved our practice. Providing funding for treatment programs to do this activity is essential.

- **Transferring science to services improves the quality of treatment**. Transferring what has been learned from studies through training and technical assistance improves treatment practice. Without science and technology transfer through vehicles

such as NIDA's Clinical Trial Networks and SAMHSA's Addiction Technology Transfer Centers, the addiction field would not be able transfer new treatment technology to the front-line provider.

- **Funding new treatment techniques, including emerging medications and ~~incentives~~ Behavior intervention also will facilitate putting the best practice into place.**

- **Recruiting and retaining a qualified addiction treatment workforce is key to the long-term improvement of treatment quality.** Development of course work in medical and nursing schools that trains and then encourages those practitioners to enter the addiction treatment field is critical. Also, improving training for and keeping the recovering community as front-line staff is essential. Finally, the development of loan forgiveness or repayment programs is critical for ensuring that individuals are

able to enter and remain in this typically low-salaried field.

- **Funding access to the full continuum of care will help to improve treatment quality.** Patients are not able to go from one level of care to the next easily because access to treatment is so limited. Funding the full continuum of services is extremely difficult for many jurisdictions given the pressure on the limited amounts of funds that are available and the limitations that exist on some of types of funding, such as Medicaid.

Increasing funding in FY 2005 for the Substance Abuse Prevention and Treatment Block Grant, Access to Recovery Program, and Targeted Capacity Expansion Program will help meet the pressing need for treatment services nationwide. Additionally, better Medicaid coverage also would improve treatment, especially for women and their children.

- **Moving toward a system of uniform outcome measures across funding streams should help to improve treatment quality.** Moving toward a system of uniform performance outcome measures across federal funding streams should benefit providers because it should help to reduce the administrative burden that providers face in having to meet different outcome requirements for different funders. These savings would hopefully be invested back into treatment and provider training – things that would help to improve the overall quality and effectiveness of treatment.

However, when SAMHSA determines the selected performance outcomes measures, it is critical that it consult providers as well as States, since outcome data is generated first at the provider level. It is important to gain provider perspective about the challenges of collecting data for each of the selected measures and also the individual issues it should take into consideration when collecting

data from specific types of programs, such as programs serving pregnant and parenting women.

Conclusion

Thank you for holding this hearing today and highlighting the importance of drug and alcohol treatment – my patients and I applaud you.

Thank you also for including my testimony. I would be happy to take any questions.

Mr. SOUDER. We have three votes. We have approximately 7 minutes left in the first vote.

Are all of you able to stay for a little bit longer? Nobody has a plane or anything? We are going to go vote.

It will probably be about 20 minutes until we get back unless we have to hold the vote open for a while.

The subcommittee stands in recess.

[Recess.]

Mr. SOUDER. The subcommittee will come back to order.

I want to thank each of you for your testimony and each of you for your years of work.

I want to start with two different categories. So let me start. Dr. Jaffe and I believe Mr. O'Keeffe both talked about how to put some incentives into the system for behavior. I don't know whether Dr. McLellan referred to that, too.

Could you describe a little bit more, you said, I believe it was Mr. O'Keeffe. Was it you who said regulation alone wouldn't do it; we need to have incentives? And Dr. Jaffe referred to incentives as well.

What exactly do you mean by incentives? Are you saying that you can't be eligible for certain programs unless you do this? That there would be a bonus if you did certain things? Longer stays? Different things?

And if we gave those, would it give incentives for programs to cherry pick, take the easiest to treat as opposed to the hardest to treat?

Dr. JAFFE. When you put incentives in for producing results, you always run the risk that those who are trying to get results will pick the easiest cases. This is true in medicine in general. It's probably true of life in general.

And one has to develop the methodology—there is some in place that is just not perfected yet—of adjusting for how difficult the initial cases are so that you can fairly compare practitioners or programs in terms of what they have achieved. And that is the one area where carefully comparing programs will need further investment to really make that a fair process.

When you ask about what incentives you can have, the incentives can vary.

They can vary from just posting the scores of programs in the city. It can appeal to pride. It can appeal to consumers, the people who are seeking treatment. They can vote with their feet. If you rank the hospitals in terms of their mortality rates for bypass surgery, you quickly find that people seek treatment at the hospitals that have the lowest mortality rates.

So you don't necessarily have to pay more, but clearly the providers, I mean the payers, whether it is the government or insurance plans or employers could begin to say, we pay more for better outcomes. The net effect of that is that those programs that give bad outcomes get paid less, and ultimately they are either going to have to merge with more effective programs or go out of business. That is what happens to any organization that delivers a less than adequate product.

The real question there, however, is whether or not at the State level there will be the political will to stop paying for a particular

program. Programs often develop their own political support. They are not without allies and the bureaucrat that tries to say, we are not going to pay you anymore because you are substantially below standard, may find he has a very short tenure in the bureaucracy. I say that having been on both sides of this issue.

Mr. SOUDER. I don't know if anybody else has a comment, but I would ask Ms. Freeman-Wilson, could you comment a little bit on that, coming out of the Gary area where, in the region, there are success stories and not success stories, but certainly Gary itself to some degree, East Chicago, have overwhelming challenges.

We are going through the very thing that Dr. Jaffe just talked about in education. What do you do when a school system is relatively disorganized and how do you get the political will? And what if the treatment programs were concentrated in that area and somebody didn't see how to do that? Yet, fundamentally, there are basic truths in trying to address the question, because we have been funding some programs which, we are all kind of familiar with, are less effective than other programs. But they have a bureaucratic momentum and a size and a number of people who have been through a comfortability with the insurance or connections.

How do we put this kind of accountability in and yet address the difficult questions that would be, for example, in northwest Indiana.

Ms. FREEMAN-WILSON. There are two examples in the Gary area that really speak to Dr. Jaffe's point. They are the Safe and Drug Free Schools program and the second is the drug court there, because what happened with both of those programs is that they did evidence some success. And that success was proven through a very clear evaluation process, one that was not only given to the participants and those who ran the programs, but those who also funded the programs both at the Federal level, at the State level and then, ultimately, the local level. Because the local officials, city and county officials were looked to pick up the funding, particularly for the drug court program, and they were willing to pick it up because it showed a reduction in recidivism, it showed more sustained treatment, and it also showed that after a year and after 2 years, that there was still a sustained reduction in recidivism.

The challenge in both the Safe and Drug Free Schools program and the drug courts and in other drug courts in the region has been the consistency of their treatment. I think that the numbers that were posted in Gary were there because of not necessarily the treatment, although the treatment was helpful, but also the use of nonconventional programs and self-help support groups like NA, like AA and like the presence of the Salvation Army programs.

So when the panelists here talk about the importance of treatment, I think that, and the challenges that you cited in the northwest Indiana region, I think that those are very evident, if you look at the type of treatment that is important to advance the cause forward.

Mr. SOUDER. Ms. Martens, what is your reaction, as a provider, to posting results that everybody could see, putting some form of accountability. How would we do this so that we didn't have incentives to kind of game the system to some degree?

Ms. MARTENS. In the State of Maryland, Congressman Souder, that is already being done. We are talking real-time outcomes. And actually we just got a RFP yesterday, which mandates providers to adhere to real-time data collection.

Mr. SOUDER. If I had a cousin who I wanted to send, I could look at the different treatment centers and have some sort of a common comparison across?

Ms. MARTENS. Not really, because there is no treatment on demand in Maryland, if you are not in the criminal justice system.

Mr. SOUDER. What if I wanted to pay for it?

Ms. MARTENS. If you wanted to pay for it, yes, you could find treatment. And I would liken it to the charter school initiatives, where the efficacy of what you do is judged, as Dr. Jaffe said. You are not going to choose a school for your child that has the highest failure rate in the city or the State.

One of the things I was going to mention to you that Maryland is doing, and I really commend the State for doing this, is that we have benchmarks to meet to get paid for each client. So you get paid a little bit at the beginning. And as that client goes through treatment and successfully completes, and there is a balloon payment in the end for your efficacy with that client. So you are really being paid for your outcomes with each individual client, which is a very interesting way for the State to get what they pay for.

Mr. SOUDER. I know Director Walters testified in front of this committee when we first began to look at how they were going to tackle the treatment initiative, and he was proposing to do that at the Federal level.

Dr. McLellan you said that you felt that some of our measurements weren't adapting for outpatient as opposed to inpatient. What is your reaction to what they have proposed there?

Dr. MCLELLAN. You'll get the kind of thing that Dr. Jaffe and Judge Wilson are talking about if you do post-treatment-only evaluation. If you evaluated first grade schools in the State of Maryland by the number of people who graduated from high school or college, you'd never figure out what was the best thing to do in first grade to make that happen.

The kind of model that Judge Wilson is talking about is much more iterative and proactive. Feedback occurs week to week to week. And just as in a medical condition blood pressure is a clinical measure, it is also an outcome. So you don't have somebody coming in from the outside taking the blood pressure. They take the blood pressure measure because it is both an outcome and it is a point that gives you decisions for the next thing that you do. If the blood pressure doesn't go down, you change.

So I think that is what I am talking about. You need the kind of immediate feedback, especially since 90 percent of your treatment is in an outpatient setting, those individuals, 60 percent of whom are coming from the criminal justice system, they are not away someplace in a program, they are in the community. So immediately you want to know, what is the urine test? Are they getting employed or are they getting job training? Are they hooking up with an AA sponsor? All the things that Judge Wilson talked about and it is possible to do.

Mr. SOUDER. That kind of leads to my other big category of questions. One of the more interesting things that happened back when I was a staffer, this must have been in the late 1980's. A number of my conservative Republican friends all of a sudden found themselves in the administration. And one of our principles was, well, we ought to block-grant things. We, as conservatives, believe we shouldn't have so much control and so many regulations.

We heard Ms. Martens say that the paperwork was becoming burdensome and that they were having to have all these different people instead of actually being practitioners and so on. And as we held an oversight hearing, all of a sudden my conservative friends were having so many of these regulations. Their comeback was, well, the only variable is accountability which we have been hearing about on this same panel, talking about too many regulations and we need more measurements and more flexibility to treat the patients.

Our dollars aren't increasing as fast as the demands.

But, by the way, we need more information and you are suggesting a very comprehensive evaluation type of approach. And part of the reason, I remember Becky Norton Dunlop, who was at the Justice Department at that time, said, what we found out was, when we didn't require all this type of thing, that most people were honest, but a bunch of people started ripping us off. And our theft and fraud rate went up so dramatically that it was more expensive than the paperwork burden. And, furthermore, the public wouldn't support this type of effort if when they hear these cases that were having some of this in, that is, dogging Medicaid or the food stamps program, where you find some person and they get on 60 Minutes or 20/20 and this person has been ripping off the Federal Government for this amount of money. So next, we put a whole bunch of regulations on for everybody in the system.

How would you suggest we do this? Because we want to make sure our dollars are effective. There isn't a Member of Congress, anybody on the street. Everybody I know who is on drugs has been through multiple treatment programs. And we go through this effectiveness thing and then we put a whole bunch of requirements on. How would you address this dilemma?

Dr. MCLELLAN. Just to start, I am certainly not the expert here, there is a big difference between paperwork, which everybody in this place will tell you is overwhelming. For example, in Philadelphia, it takes 3 to 4 hours worth of paperwork to get somebody into treatment, and it is paperwork, meaning that it is stuff that you fill out that you have no use for.

I am not talking about that and I don't think anybody here is either. I am talking about as a regular part of the treatment process, the counselors, the people who are working on the team, are measuring whether they are going to work, whether they are still using drugs, all clinical, just like the blood pressure. The blood pressure isn't paperwork in a hypertension clinic, it is critical. You have to know what is going on so you can make an adjustment.

That is the point that everybody is, that Judge Wilson keeps making, to use information to make decisions. That is not paperwork, and it shouldn't be burdensome.

Mr. SOUDER. Any other comments on that? In other words, if we could separate it out, these are the absolutely critical things for medical reasons, for drug treatment and these are things that we might need for tracking for financial reasons or insurance companies, one last question.

Ms. MARTENS. Dr. McLellan is absolutely right, the day-to-day paperwork that we do because treatment is holistic. Doctor is absolutely correct. I need to know what your drug test was yesterday, how was your family visit, are you getting your GED? These are very important things, and they are always part of treatment.

It is all of these other things that are now layered onto it that just take so much time that it really takes time away from direct client treatment.

Mr. SOUDER. I will say, I mean, you have helped clarify that those are the things that you need there, and then there are other things we need for waste and fraud reasons which you may refer to as paperwork. But quite frankly, I believe it was actually in this committee room when Chris Shays headed the Human Services Subcommittee in my first term I was vice chair on a Medicaid fraud case. And the hardest clients to serve are those who have no insurance, have no immediate family and have some chronic condition and have moved around.

We have a place in Fort Wayne, a health center that has a lot of these patients. And we were asking the GAO and the Inspector General, and we had HHS here and asked why they hadn't terminated this one company that had been found in court of defrauding the Federal Government of $1 billion. And they were in multiple regions in the country and our computers hadn't caught them under different names.

But the reason that HHS hadn't terminated them was because something like 20 percent of these highest risk people who nobody else would take, no nursing home would take, the State government really couldn't do it or they had to have a place to put the people, nobody would take them, so we were having this company that was bilking because they claimed the reimbursement wasn't enough—probably true—to cover the cost of it, so they started doing that type of thing.

And part of the reason we have the paperwork side for addresses, information, for tracking is that. But what we need to do is separate: here is the paperwork necessary for that part and what parts are medically necessary for drug treatment. And that has been helpful for me for clarification as we kind of tackle that.

I yield to Mr. Cummings.

Mr. CUMMINGS. Thank you very much, Mr. Chairman.

I thank all of you for your testimony. One of the things in listening to the chairman, I see all the money that we spend in government; and I hear the complaints from constituents, well, we spend money on certain things and then we don't spend money on other things.

I really want to have some sympathy with regard to the paperwork. I really, really want to, but it is very difficult. I see taxpayers' hard-earned dollars being paid to treatment facilities, doing a great job, by the way, but I also think that with those dollars comes a certain level of accountability.

And I know you are talking about two separate things. I heard you, Mr. Chairman, and I am not sure where the divide actually comes. But I want to go to you, Dr. McLellan.

One of the things you talked about, and it is a very interesting viewpoint; I really think that when the public watches this, they would be almost shocked, although I agree with you, that winning here is not necessarily getting somebody off of drugs forever. And I think we still have to educate the public to understand that. Because I think a lot of times the public sees a person on drugs, like a lady I saw in my neighborhood just the other day, who they once knew as a bright high school student and now they see them sitting on some steps, dirty, nodding, looking quite, you know, out of it.

And they say to themselves, you know, OK, I want to do something for that person, but if you told them that reducing the amount of drugs they use, perhaps getting a job, perhaps coming up with having good relationships with family and a support system could be part of the measurement of success, I think the general public couldn't fully understand that and comprehend it, because they want to see that person the way they saw them in high school when they were cheerleaders.

So I think we do have to educate the public about all the kind of measurements that you all talked about. And I think that because the public wants to see the dollars spent effectively and efficiently. And so it doesn't necessarily equal effective and efficient spending of dollars when they hear those kinds of measurements.

So I am just wondering, I mean, you have heard all of your fellow witnesses up here talk. I mean, are there any measurements that have been left out, anybody, that you didn't hear?

In other words, you talk about measuring tools, the things that you need to measure success. Have you heard of anything that has been left out that should be considered when measuring success? Because one of my concerns is—and I know we have a lot of great treatment providers, but one of my greatest concerns is that young people—I live in a district that has probably some of the highest addictions in the country. And I talk to recovering addicts and a lot of them will tell me they have gone to certain programs that they found out from going through them. And by the way, it gets out on the street which programs are, "real," and which ones are not. And they tell me that if they go to an unreal program, it can do more harm than good, but yet our Federal dollars are being spent.

So I am trying to figure out, you know, how do we make sure? It may take time to kind of sift away the fair programs and get the better ones out there so that people can have effective treatment. And I am just trying to figure out how do we do that. Do you all have any suggestions?

Dr. MCLELLAN. I can give you an example. I urge you to look at it. It is precisely the kind of program that Dr. Jaffe is talking about, and that is the State of Delaware. Now, it is a small State and it is a very interconnected State, but they basically gave up. They said, look, we don't know what to tell you to do, but we know what we want. And we are going to put criteria into play so that, I will summarize very quickly, your treatment programs, when you

open your doors, you will get 80 percent of your contract last year. However, if you meet the following criteria, you can make as much as 120 percent of your contract last year.

And I will summarize and tell you that several programs weren't able to do it. They closed. New places came and they were able to do it, and they are functioning now. And what the State is doing is, they are adding criteria. They started with retention, because it was the easiest to measure and all the programs agreed with it and that knocked out several programs. Now they are moving toward no new arrests. And if they are successful, they have a commitment from the Justice Department to put additional money into the treatment side, because it's worth it, it's worth it to the Justice Department, but only if they are able to make those—if they can buy success, in other words.

Mr. CUMMINGS. Anybody else have something?

Now, you all heard the testimony of the other two witnesses earlier and you heard my questions with regard to jobs. And it seems as if in most States people are placed in a position, particularly if they get a conviction where they are locked out of so many jobs. And I am just wondering, when you are trying to help somebody move forward, you know, there are a lot of barbers in Baltimore. I don't know why a barber, why it is such a big deal. I have met so many barbers who have had drug problems. Apparently, that is one field that is still open. And the reason you get to know them is because they talk about it.

Dr. MCLELLAN. They also teach barbering in jail.

Mr. CUMMINGS. And, see, that is good. I am glad you threw that in.

But if that person came out of prison and there was a law that said if you have, say, a drug conviction or you had some drug problems or whatever that you can't be a barber, then that person is precluded from making an income.

See, one of the problems that happens, and I don't know why people don't think about this, people have fines and child support. And I believe people ought to pay child support. I mean, there are a lot of things that go against the person and basically forces them back into jail or to addiction. In some kind of way, we have to grapple with that.

And Judge Wilson, I mean, in courts, I am sure you see that. A guy comes in or lady comes in and says, look, I am doing the best I can, but I can't get a job. And if I don't get a job, you are going to send me back to jail. Or, you know, the reason I went back to being involved in drugs was so that I could address making sure I pay my fines, pay my child support, pay whatever I've got to pay.

And then, even more so, a job becomes very significant. Am I right?

Ms. FREEMAN-WILSON. That is it exactly, Congressman Cummings. And there are two things we look at.

One is, when we talk to people about how they develop their court programs, we always encourage pre-plea programs because if you have a pre-plea program and you successfully complete it, then you are not saddled with the conviction.

But then as we move toward the discussion of reentry nationally, then we have to look at how the laws in the States affect the abil-

ity of the reentry participants to reenter society and become effective members of society. And so our organization along with a number of organizations, have embarked upon surveys of State laws, not just to survey those laws, but to look at ways to encourage legislators to begin to move those laws away from being punitive. Because if, in fact, you expect a person to reenter society, become a tax-paying citizen, how you saddle them with a conviction. Now don't get me wrong, there are some folks that need to have convictions on their records; we need that red flag on those records. But in many instances, it is not appropriate in the case of those individuals who have convictions for possession of drugs, for other property-related crimes, one-time convictions, so that we need to look at ways to have our laws in the States and to encourage the States to develop those laws in a way that you don't saddle the folks the first time around so that they can come out and get jobs, and pay support and pay taxes and all of those things that evidence them as members of society who are productive.

Dr. JONES. I would like to add something on a much more kind of grass-roots level.

One of the other hats I wear at Johns Hopkins is overseeing an after-care program for heroin-dependent individuals who have completed a 3-day or 7-day detoxification. It is a 6-month NIDA-funded after-care program, and we have four goals. And one of the main goals is getting that person a job.

Now, a lot of our patients have criminal justice involvement. And what we have found is that there are jobs available—perhaps not the best job. I mean, a lot of them are in barber shops, doughnut shops, working construction. But what we found is that these patients are particularly scared about even getting a job.

Some of them have even had a job. And working through that you know, let us put a resume together. These people never had a resume, and they are actually sitting down and filling out a questionnaire. We sit there with them and we say, can you come up with two people who could vouch for you? And sometimes they will remember, oh, yeah, I did that in the past and that was pretty good, I have a good contact here.

And then the next step, after they've filled out their resume is practicing interviewing skills, and we do it videotaped so they can see what they look like, learn how to answer questions.

And then we take them out, and we have what we call job fairs and we go to places that have hired our patients previously. So what we are doing is we're trying to build in small successes and maximize opportunities of the likelihood for them getting a position. And we do; 39 percent of our patients are actually employed. And a lot of them have criminal justice involvement.

So it is possible to overcome this, but it takes a tremendous amount of hand-holding and working through the steps to give them success.

Ms. FREEMAN-WILSON. Dr. Jones raises an important point and that is to engage the participation of the business community in this dialog. We can talk all the time about people needing jobs, but there are people who give jobs and unless they believe that someone coming out of her program or someone coming out of a drug court or out of a therapeutic community is a good employment risk,

and I would argue that they are better because you know, more likely than not, that those folks are drug free, whereas those who aren't being tested, who aren't in treatment, you don't have that guarantee.

But we have to engage the chambers of commerce. We have to engage State government. We have to engage the other larger employers, be they hospitals, manufacturers, in that conversation about employing not only the individuals who look good on a resume, but those whose resumes may be a little blemished.

Mr. CUMMINGS. I remember when I first started practicing law, one of the things I wanted to do was to see exactly how these 12-step programs worked. And I was just fascinated by the fact that when I went, just to see how they worked, they had these people sitting around talking about all their business. You know, it was interesting.

Dr. MCLELLAN. It is called "sharing."

Mr. CUMMINGS. That sounds a little bit more clinical. And I just wonder, how important is that to the things, to all your theories of effective drug treatment? How important is sharing? I am just curious.

Dr. MCLELLAN. It is not an opinion. There are studies to show it. It is very effective and it makes so much sense. Environments change people. So you have been to treatment programs, I can see that, and you can see the kind of environment that is there and you can accept that those people, while they're there, are honest and are industrious and have the values you want to see.

When they go back out to the environment that produced the drug abuse to begin with, or in concert with their genetics produced that, that is very likely to change them back, very likely unless they are involved on a regular basis. This is what they call "aftercare."

This is the continuing care that Dr. Volkow talked about; everybody here has talked about it. One of the best because it is cheap. Actually, it is free. It is everywhere, it's all the time. It is AA, NA, these 12-step programs. The fact is, only about a quarter of the people that are referred to them actually will go ahead and really lock up and then you have a guarantee. Those people do very well.

We need alternatives and we need new kinds of things for people that don't want to do that.

Ms. MARTENS. Congressman Cummings, I want to use one of our programs in your district as an example to you.

In all of your questions, you were asking, it is one thing for us to get a mom clean and sober. It is another thing, and I know you can appreciate this in Baltimore, a mom who reads at a third grade level, does math at a second grade level. She has been getting high since she was in middle school because her mom did it and her grandma did it and her dad has been locked up forever. Kid has so many problems.

We've got Hemmett Kennedy Kreger. So we're working on her GED while she's in treatment, case managing her to figure our what kind of skill set she would like to develop.

As Dr. Jones was saying, it's the little things. How to go to the office downtown and get your child's immunization record, that sounds easy to us; that can cause mom to think, I am going to get

high because I can't do that. These little things that we take for granted in our life have to be case managed throughout this entire treatment process. The mayor and I are working now because there are few places for us to put mom, in a house that does not trigger her addiction. She remembers the noise on North Avenue, she remembers the smell. She remembers what you look like, and you may be a trigger for her addiction.

If you don't treat the client holistically, a mom may not maintain her recovery, I think that is one of the reasons that therapeutic communities have been so successful because it involves every part of the client's life. Mom's relationship with her boyfriend may be a trigger for her addiction, so she can't go back into that neighborhood or live with her family. And if we don't look at the whole picture and find jobs, education, housing, and as Dr. McLellan was saying, the 12-step support system, you can't leave a Second Genesis program without having a sponsor in the community and already knowing where your meetings are going to be. Where is a meeting you can take your kids?

These may sound like really simple problems, but they are huge for a mom that may be in a fourth or fifth generation of the addiction cycle.

Mr. CUMMINGS. That is interesting. In Baltimore, there is an entire community of recovering addicts. They invited me to speak at something. I thought it was going to be like 30 people. It was like 700. And I realized that and I guess it is like another family.

So going back to what you were saying, Dr. McLellan, I guess it is a shifting. You shift over to this family where you are doing the 12 steps and you make new relationships and everybody is trying to, they are trying to get to recovery or trying to be recovered.

On the other hand, if they shift back into that old community, then again, as you were saying, something pulls them back in. And it could be one incident, because I remember one time I did a little tour, and there was a woman in Baltimore who had been off of heroin for 15 years. For 15 years. Had a great job, doing well. Had one incident that happened in the family, and she was back on. And it was incredible to me. And she said she stopped going to the 12-step programs.

So I think that we as a committee have to look at we are talking about generation after generation after generation. And it is so costly to try to treat the kids and treat everybody that, at some point, I think that is why we are so concerned about effective treatment, because like you said, this doesn't only affect the client, it affects everybody in their vicinity, which really says a lot.

Thank you, Mr. Chairman, for your patience.

Mr. SOUDER. I want to raise a point and see if anybody has any comment about this, because one of the most explosive issues we deal with here, the way we are playing it through, is the faith-based questions. Yet what becomes pretty clear to me is that to expand this program we need political support beyond a more traditional liberal Democratic community. If you don't have the conservative faith-based community with it, there isn't enough political support.

In Indiana, as Judge Wilson knows full well, it gets really nasty in political campaigns if you take a position that you ought to give

more flexibility for people who come out of prison and then one of them gets arrested. Right now, we have a situation where an Indianapolis news media has stated that 10 percent of the people at the Bureau of Motor Vehicles in Indianapolis are former convicts. Well, that was before they went to work there. There are other problems since they have gone to work there. That means, in fact, that they've hired people in that position, but politically, it is going to be a debatable issue this fall because that is a high number and it's lining a lot of Federal jobs.

There are barriers because it is so politically explosive. There is a big law-and-order type of mentality with it. And unless there is a way of including in jobs that part of the reason is that we have had 16 years of Democratic Governors, which I don't view as great, in Indiana. But they have been getting As on the score cards on faith-based because they came to realize, particularly in the minority community, that if they don't match it with suburban churches as well, we weren't going to get the support for the follow-through. Because an employer may be making, if he is guaranteed there is drug testing, the type of decision that you referred to, which is, he knows he has a clean employee.

But there are other risks. For example, a number of my friends who have hired people have had reoccurring problems because not everybody is rehabbed all the way. One of our major volunteer programs in Fort Wayne for people coming out of prison went broke because one of the people relapsed and stole everything they had. They stole their computers, stole a number of other things. They were too marginal. And they came back, a number of those people, not because they viewed it as a business, per se, but because they are faith motivated and felt they had a motivation.

And unless we can figure out how we are going to make some coalitioning between the Prison Fellowship and conservative Christian people to back up the kind of the institutional support from the government, it is going to be very hard to figure out how we are going to provide this comprehensive follow-through in jobs and the political support for adequate dollars. Because when we start to split these things off, it is ironic that we have these political divisions.

And our distinguished judge and attorney general of Indiana knows what we are talking about, because we have had some very tough debates in Indiana, and we continue to have them on this very subject. That makes it really dicey when any politician walks out there and says, we need to look for housing, we need to provide for job employment, we need to open up the opportunities. And then there is something that occurs or there is a backlash or somebody says, what do I have to do, commit a crime to get a job? And politically, we have to figure out how we're going to work this kind of stuff through, because we have put more money into treatment, but it isn't at the levels where we need.

And partly this is underneath it, particularly when you look at the after-care.

Dr. JAFFE. One of the major conclusions of our panel was that if you want to get broadened public support for the resources that you need to provide good treatment for those who need it, the public has to believe that treatment is effective.

Now, it's not ever going to be perfect. There is always somebody who is going to relapse even after 15 years. If 99 percent of people who leave prison don't do anything, somebody will take a job and steal from his employer. That is a virtual guarantee.

But if people are convinced that the people who pay for treatment are looking at the programs and making certain that they are all competent and that the programs that aren't effective are being eliminated, or at least they are not being funded with the taxpayers' dollars, they are going to be more willing to come up with those resources.

So what we saw was that evaluation and rewarding the effective programs is a way to build public support as this kind of treatment competes for resources against other priorities in the public sphere. There is not enough money for everything that needs to be done, and treatment needs to compete, we know that. One of the ways it can compete more effectively is to assure decisionmakers that all the programs are at least at some minimum standard of competence.

Mr. SOUDER. It is in the job's follow-through question, too, that part of the problem here is. If we took the targeted jobs credit and said that in the targeted jobs credit it should be those who are highest risk in the society for being unemployed, and I'll bet if we look at that, that we would find a fair percentage of those people have been through a drug treatment program.

So, theoretically, this could be turned on us saying the people getting the targeted jobs are the people who have committed a crime when we have high unemployment. What I am trying to get at is, unless we have a broader base of support that understands the concept behind this, both from the risk of crime to society, but also an obligation and an understanding that if these people can get rehabbed, they are going to be better in their family lives.

But politically we have a problem here, particularly, for example, we put in the targeted jobs credit that the people who have been arrested should go to the front of the line because they are the hardest to employ.

Ms. FREEMAN-WILSON. Congressman Souder, I would say the way to transcend that goal is to really convince the people who you referred to of the equal opportunity nature of this problem. It doesn't matter whether you are conservative or liberal, it doesn't matter where you live, it doesn't matter what you look like. Congressman Davis talked about it earlier when he said not only were they having problems in Chicago, but I know because we've worked with the drug courts in King County, IL. There is a heroin epidemic in the suburbs. So if we can get those groups, the church groups both in the cities and in the suburbs to take that message to the public—and quite frankly, some already know because it is happening in their homes—then I think we will have transcended that political albatross or potential political albatross.

Mr. SOUDER. Often it is, bluntly, put quieter in the suburbs because to go and buy the stuff in the lower-income neighborhoods and the crime and the related violence that comes from it is in the lower-income neighborhoods and often the parents in the suburbs are too busy to be in denial and don't want to be embarrassed. And

yet, it is kind of an interesting thing because trying to get that public is a whole other task we face. Any other closing comments?

Dr. MCLELLAN. I don't think anybody here is saying fund more of what we have. Take the opportunity to use measurement and to take the things that you know you want to buy and link those two together, and then I think that is going to knock the political albatross off your neck.

Ms. MARTENS. I think, Congressman Souder, when you asked about the faith-based communities, what we have used effectively is the potential of collaboration, because there is a great deal of stigma involved, as Judge Wilson was saying. To begin to get the faith-based community involved, we do mentoring programs with them, and we ask them to hold NA and AA meetings in their churches. They have parties in our women's and children's programs, and that begins to invest them in the process that, as Dr. Jaffe was saying, this is an equal opportunity destroyer. It does not matter who you are.

Especially with our programs in Baltimore, we are effectively using the faith-based community to be our partners. They don't want to be doing drug treatment. There is really a myth that, you know, the pastor in your church will be able to heal you. Wouldn't it be great if it were that easy?

Mr. SOUDER. Well, I want to make sure that we have in the record it is an equal opportunity, in other words, in the sense of people using drugs. But there is no question that the violence is not equally spread, that the dealing is not equally spread, that the impact on employment in groups that are already at high risk that have added to it, that when we are doing a returning offenders program in Allen County, the bulk of them are going into the lowest income, poorest housing areas where there aren't jobs and where the people are moving out of some of the school systems because drugs are in every school, as evidenced in our highest-income school in the county that has probably the biggest drug-dealing problem but there are more students.

They don't have the shootings in the school. There is, for whatever reasons, probably a higher percentage of parental involvement in the school, more income, different types of things. And I mean I can go into an urban school in Fort Wayne and say, how many have seen a shooting. I will see 75 percent—a shooting other than hunting for a deer—75 percent will say "yes." I can go into Homestead or Carroll or other schools that are in the suburbs or rural school and get none to 10 percent.

There is a difference in the impact of it, even though it is an equal opportunity destroyer, and most drug users in America are White, just like everything else. But it has a disproportionate impact because the families may not have the health insurance, may not have the support group around them, may not have the connection to get a job. So there is disproportionate negative impact, which is what we at the Federal Government have to be looking at.

One last question, why, if the programs aren't effective, hasn't the market in health insurance or the people that pay the insurance made some adjustment? In other words, why would they want to pay two or three times to send somebody through a program if

a program that lasted just a little bit longer would have had more success? Why hasn't the market adjusted?

Ms. MARTENS. The problem is so big, Congressman Souder. I will use our District of Columbia facility as an example for you. All of our clients come from CSOSA. They are federally mandated by CSOSA. CSOSA is putting our clients through a 28-day program. I have a man right now who is 82 years old and has been shooting heroin since he was 13 and he is in a 28-day program. I couldn't change one of my bad behaviors in 28 days, much less shooting heroin in my neck since I was 13.

Mr. SOUDER. If this was a private sector, you have private people.

Ms. MARTENS. Very few are private pay.

Mr. SOUDER. Are most people in drug treatment in private pay?

Ms. MARTENS. No. If you had a problem, Congressman, you know Father Martin's Ashley in Havre de Grace would probably be a very effective program.

Mr. SOUDER. I didn't understand. Did you say 80 percent at this point is public pay?

Dr. JAFFE. Thirty-eight percent, I think, in 1997. It is in our report. Thirty-eight percent, I think, is private sector and about 62 percent is now public sector with the bulk of that coming from the Federal Government directly or indirectly.

Ms. MARTENS. Block grant.

Mr. SOUDER. Thank you very much for your testimony today. It has been very important as we move through drug treatment and appreciate your cooperation. With that, the subcommittee stands adjourned.

[Whereupon, at 5:20 p.m., the subcommittee was adjourned.].

[Additional information submitted for the hearing record follows:]

Testimony
Of

Imani Walker

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THE REBECCA PROJECT FOR HUMAN RIGHTS
Washington, DC

Measuring the Effectiveness of Drug Addiction Treatment

SUBCOMMITTEE ON CRIMINAL JUSTICE, DRUG POLICY AND HUMAN RESOURSES
COMMITTEE ON GOVERNMENT REFORM

U.S. HOUSE OF REPRESENTATIVES

MARCH 30, 2004
WASHINGTON, DC

Mr. Chairman and members of the Subcommittee I would like to share my experience with addiction, treatment and recovery. I am Imani Walker director of Sacred Authority of The Rebecca Project for Human Rights. Sacred Authority is an alumni network of mothers in recovery.

I am a mother of four. While dealing with the grief of my mother's death coupled with the end of an eleven year relationship with my children's father, I spiraled downward into a deep depression. I began to self-medicate first with marijuana and when that no longer was enough to take the pain away I turned to crack cocaine.

I realized that my family and I were in serious trouble. Before using crack cocaine my main concern was how was I going to gain economic stability for my children without the help of their father. Once addicted to crack, I could no longer meet the daily needs of my children such as making sure meals were prepared and homework was done.

I sought help.

I first landed in a 28 day single adult treatment. While this treatment was good in that it educated me for the first time on the disease of addiction, it was not sufficient in addressing the needs of a family with substance abuse issues. The pathway to addiction for mothers is distinct in that 97% of mothers suffering with substance abuse issues have experienced domestic and sexual violence, post traumatic stress disorder and depression. I needed a treatment program where I could address the underlying issues of why I abused drugs in the first place in addition to why I couldn't stop.

I never got a chance to properly grieve my mother's death or the end of my marriage. I had never healed from the years of domestic violence that took place within the marriage. I needed help with housing. I was back in my family's home with my children. I needed marketable skills for economic stability. My children needed therapy to address the harm caused them by my addiction. I had an infant who needed early intervention services. We needed to heal as a family.

My treatment process was not successful until I was referred to a comprehensive family treatment program. I had been trying to access appropriate treatment for my family and me for a year and a half, and during that time I was sinking deeper into a world of despair, hopelessness and dysfunction.

At the family treatment program, I was allowed eighteen months to heal from the disease of addiction. The first three months were devoted to detoxification and learning how to make it through the day with out using drugs. The next six months focused on intensive group and individual therapy. I was able to get to the root causes of my addiction. I took parenting classes and my relationship with my children improved. I was referred to the housing specialist and moved into transitional housing and later permanent housing. My children received family and individual therapy. My infant was assessed by a pediatric, developmental psychologist and was placed in the Early Intervention Program. The next three months were devoted to Life Skills classes and working with a job placement specialist to determine career goals. The following three months were spent in a full time computer and office skills course where I gained marketable skills. The last three months were aftercare. There was serious accountability through out the whole process. I gave urine samples three times a week for the entire eighteen months.

I have been in recovery from drug addiction for over five years. My family is stable. I am employed fulltime and self-sufficient. My child who was an infant at the beginning of my treatment process is now a beautiful, bright 5 year old that is excelling in his kindergarten class. My family's experience

with treatment has proven to be preventative for my teenagers. All three have declared that "there is no point to using drugs".

We are now a stable family due to the comprehensive services and supports we received in family treatment. The program I attended is representative of family treatment programs nationwide. A recent Substance Abuse Mental Health Services Administration (SAMHSA) evaluation demonstrated that family treatment programs achieved success rates of 60 percent in parental sobriety (spring 2003). Family treatment is, unquestionably, effective.

But many other families do not achieve access to these effective programs. Only 5% of available treatment is comprehensive family treatment. According to the Child Welfare League of America, up to 80% of the families who come to the attention of the child welfare system are substance abusing. Unfortunately, child welfare workers can place only one third of these families in appropriate family treatment. My experience of seeking appropriate and effective treatment for a year and a half before finding family-focused treatment is not uncommon. Mothers like me should be able to access appropriate treatment before landing in the criminal justice system or having our children placed into the child welfare system.

QUESTIONS FOR THE RECORD

1. **What steps is SAMHSA taking to move to the use of the "Seven Outcome Domains" across all of its programs?**

Under the Access to Recovery Program States will be required to submit data on the seven domains and their performance will be measured using those domains and other criteria with regard to the management of the program. These same seven domains are being incorporated into all of our discretionary grants starting with this year's announcements.

With regard to the use of the domains in the block grant, States have shared in the identification of these domains, and consensus on their use has been achieved. Clearly, State reporting on these outcome domains will need to be phased in over time. We are moving quickly to begin this process with the 2005 SAPT Block Grant Application. A careful and full assessment of State capacity in this area is being undertaken, as are ways to set State outcome goals and targets. At the same time, SAMHSA is providing targeted technical assistance on data collection, reporting, and analysis. During this transition, States will be encouraged to report outcome data on each of the seven domains on a voluntary basis.

2. **How are the "Seven Outcome Domains" incorporated into SAMHSA's planning and metrics system in compliance with the Government Performance and Results Act?**

We are required under the Government Performance and Results Act and by the Office of Management and Budget through its PARTS program to demonstrate the efficiency and effectiveness of the programs we are responsible for and for the management of those programs.

By using the same outcome domains and their measures over time to assess progress, States and SAMHSA can foster continuous program and policy improvement. By using the same national outcome domains across all of SAMHSA's State and community-based programs, we will be able to report nationally aggregated data in standard periodic and special reports. We will know, as will you, OMB, and the public, with significant precision, whether the service system is improving and whether we are meeting the President's goals to reduce substance abuse nationwide. Moreover, we will be able to identify – and you will be able to know about – gaps or issues that need to be addressed at the national level through program, regulation, or statute. Our grantees, and SAMHSA, in turn, will be accountable for positive results. Perhaps most critically, we will be able to see just how well we are promoting recovery and the vision of a life in the community for everyone.

3. **What obstacles does SAMHSA face in implementing the "Seven Outcome Domains" as part of the Block Grant program? Where are you encountering resistance?**

In implementing the program there will be significant hurdles:

1. Agreeing on definitions of terms. Residential treatment in New Jersey is not necessarily defined the same way it is in the other 49 States.
2. Most States depend on long term grants or contracts with providers. These contracts set requirements on the contractor which will have to be reviewed in light of the uniform performance measures.
3. State, provider, and Federal personnel need to be trained in some cases on what a performance based system is, what data needs to be collected, etc. SAMHSA has begun this process for its staff.
4. Data infrastructure needs are important in the States. States need funds to pay for the upgrades and changes that will be needed to their data infrastructure and then to support the continuation of the data system. At the same time, States are trying hard to find the funds to pay for treatment.

We believe our approach offers the best hope of implementing a performance based system in the block grant program.

4. **What are some of the critiques of the indicators? How does SAMHSA propose to address these criticisms?**

These seven domains were developed in collaboration with States and other interested parties, and as you heard at the hearing, there is broad agreement on the use of these domains. The issues with the domains have been ones of implementation as stated before and largely with the Block Grant.

5. **Mechanisms do you have to audit these indicators and measures?**

In the use of the word "audit" we assume that you are interested in making sure that the States are using these domains and that they are reporting the data accurately.

When States are required to submit data on the seven domains, the governor will be asked to assure SAMHSA as part of the application for funds that the State will submit the data in keeping with the requirements of the agency. Each year the States must submit as part of their application for funding a report that will include the data required. In addition, SAMHSA conducts State performance audits to ensure that the State is doing what it says it is doing in their application, and a review of the data collection and analysis used by the State will be included in that audit.

6. **Your testimony refers to 50 programs in the National Registry of Effective Programs - how were these programs evaluated? How do their success measures compare using the seven outcome domains?**

To help professionals in the field become better consumers of prevention programs, SAMHSA created the National Registry of Effective Programs (NREP) as a resource to review and identify science -based prevention programs. Through NREP, evaluation materials submitted by candidate programs are rated independently by teams of experts on criteria associated with scientifically-defensible results. NREP sets a high standard for evidence or "proof" of program effectiveness; successful entry into NREP requires data from systematic evaluations employing an evaluation design and methodology that support a causal link between program intervention and outcomes measured. NREP review teams are comprised of at least three experts (senior researchers with methodological and content expertise) trained in advance on the set of approximately 18 methodological criteria.

Programs that achieve NREP recognition fall into one of three categories:
1) *Promising* programs provide useful, scientifically-defensible information about what works in prevention, but require additional evaluation documentation to meet NREP standards for effectiveness. To date, more than 50 prevention programs have achieved this designation.

2) *Effective* programs are prevention programs that produce a consistent positive pattern of results on the majority of intended recipients and have provided the evaluation documentation needed to meet NREP standards for effectiveness. To date, approximately 43 prevention programs have achieved this designation.

3) *Model* programs are effective programs whose developers have the capacity to disseminate their program to the field, and have entered into agreement with SAMHSA to provide materials, training and technical assistance to practitioners who wish to implement the Model program. To date, approximately 54 programs have agreed to take part in SAMHSA's dissemination efforts.

NREP-rated programs, including the Model programs, produce outcomes on factors that place people at risk for – or protect them from – problem behavior including substance abuse. Risk and protective factors enhance understanding of how and why youth initiate or refrain from substance use. Model programs produce outcomes on risk factors associated with individuals, peers, families, schools, and communities and report positive results on measures of drug use and alcohol abuse, thus cutting across the major Outcome Domains. ***Examples*** of outcomes reported by Model programs across five of the Outcome Domains include:

1) Abstinence from Drug use and Alcohol Abuse
   - Decreases in substance use among youth
   - Delayed onset of alcohol use and substance use among youth
   - Reductions of alcohol use by youth already engaged
   - Decreases in new anabolic steroid and ATOD use among high school male athletes
   - Decreases in prevalence of alcohol and tobacco use among young adolescents

2) Increased Employment/Return to School
   - Improvements in youth school achievement and retention
   - Increases in favorable attitudes toward and commitment to school
   - Increased rates of post-high school employment or higher education
   - Increased school bonding and attendance

3) Prevented or Decreased Criminal Justice Involvement
   - Reduced arrests and convictions
   - Reduced anti-social, aggressive and/or criminal behavior
   - Reduced habitual criminality and recidivism
   - Reduced number of adult arrests for drug dealing

4) Increased Stabilization of Family and Living Conditions
   - Decreases in family conflict, parental child-blaming and harsh punishment
   - Improved healthy communication and parenting skills
   - Increased family and parent-child bonding and family cohesion
   - Increased positive attachments to pro-social adults and peers

5) Increased Access to Services
   - Increased community involvement with youth
   - Increased accessibility to and use of social services/community resources
   - Increased community cooperation to promote norms that discourage underage alcohol use
   - Increased involvement of students to develop anti-tobacco community norms

Because these NREP-rated Model Programs address substance abuse prevention, there are no documented outcomes in the sixth domain of "increased retention in treatment." Examples of Model Program outcomes linked to the seventh domain of "increased access to services" --such as increased community involvement with youth and increased use of social services/community resources-- correspond to the outcomes domain "increased social support and connectedness.

7. **How many people are treated for marijuana abuse every year? What is the total cost per patient for such treatment? What are some of the best programs for treating marijuana abuse, and what makes them outstanding?**

In 2001, there were 251,000 admissions to the public treatment system for primary abuse of marijuana. Of these, about 88,000 were between the ages of 12 and 17; 82,000 were between the ages of 18 and 24.

Of people entering treatment for primary marijuana abuse, 4% (approximately 10,000) entered detoxification; 15% (approximately 38,000) entered inpatient or residential treatment; and 81% (approximately 203,000) entered outpatient treatment.

The average cost of treatment, derived from the Alcohol and Drug Services Survey, was $1,433 per episode of care (for outpatient non-methadone treatment).

The best treatment interventions for marijuana use were developed through the SAMHSA grant program "Cannabis Youth Treatment." Five outpatient treatment interventions were developed, tested and found to be more effective than any previous interventions for treatment of youth who are using marijuana. They ranged in length from 6-weeks to 3 months and included individual, group and family treatment approaches. The median cost of treatment for these five interventions was $1,413. Manuals have been developed for implementation of these interventions and are available free of charge from the National Clearing House on Alcohol and Drug Information.

The five treatment interventions were: Motivational Enhancement Therapy and Cognitive Behavioral Therapy for Adolescent Cannabis Abusers: 5 Sessions; Motivational Enhancement Therapy and Cognitive Behavioral Therapy for Adolescent Cannabis Users: 7 Sessions; Family Support Network for Adolescent Cannabis Users; The Adolescent Community Reinforcement Approach for Adolescent Cannabis Users; and Multidimensional Family Therapy for Adolescent Cannabis Users.

Breaking each down on other dimensions:

Intervention	Cost	# Sessions	Weeks of Tx
MET/CBT 5	1,126	5	6-7
MET/CBT 7	1,197	12	12-13
FSN	3,222	22	12-13
ACRA	1,413	14	12-13
MDFT	1,984	15	12-13

8. **Dr. Volkow, in her written testimony, said that the Addiction Severity Index (developed by NIH and the VA) has been refined for over 20 years to capture "critical baselines data...[which] sets the stage for improved treatment outcomes." As treatment programs**

are compared to one another, is baseline data like that derived from the Addiction Severity Index used to adjust the data of grantees that may taking in harder addiction cases?

We want to clarify that this concern is not about the seven domains themselves but of the use of the domains in judging the performance of individual facilities.

The Federal government as part of the Block Grant program and Access to Recovery will be holding States accountable, not individual facilities. It is expected, however, that the States will use the same measures to hold facilities accountable. In doing so the States will have to ensure that they take into consideration the characteristics of the people served and the environment in which they serve in judging the performance of the facility.

9. **Dr. Volkow's testimony pointed out the importance of continuity of care for ex-offenders who transition from prison to community re-integration. What is SAMHSA doing to measure the most effective programs for keeping ex-offenders drug free?**

SAMHSA believes that the ex-offender population would benefit immensely if the State were to focus on them with Access to Recovery funds. Under the program, each ex-offender would be evaluated as to the level of their dependence and the type of treatment services they need. They would then be given an opportunity to choose from among several qualified programs that offer that level of service. Of critical importance is that the program would be required to submit information on the individual to the State on the seven domains. These are the very same domains or areas of concern that would lead an ex-offender back into the community: abstinence from drugs, employment, stable housing, social connectedness, and reduced involvement with the criminal justice system.

10. **How can we best catch the vast majority of drug users in this country - occasional and first-time users - before they develop advanced addictions?**

SAMHSA has developed a comprehensive, focused Strategic Prevention Framework to prevent the onset and reduce the progression of substance abuse, including childhood and underage drinking. The Framework includes a 5-step, data-driven process, and utilizes a community-based, evidence-based, risk and protective factor approach to prevention. It helps Federal agencies, States, and communities identify common needs and risk factors, adopt assessment tools to measure and track results, and target outcomes to be achieved.

The Strategic Prevention Framework process: 1) profiles population needs, resources, and readiness to address the problems and gaps in service delivery; 2) mobilizes and/or builds capacity to address needs; 3) develops a comprehensive strategic plan; 4) implements evidence-based prevention programs and infrastructure development activities; and 5) monitors process, evaluates effectiveness, sustains effective programs/activities, and improves or replaces those that fail.

The Framework allows SAMHSA to focus on evidence-based risk and protective

factors, which have proven efficacy for preventing the onset and reduce the progression of substance abuse. For example, family conflict, low school readiness, and poor social skills increase the risk for conduct disorders and depression, which in turn increases the risk for adolescent substance abuse, delinquency, and violence. Protective factors such as strong family bonds, social skills, opportunities for school success, and involvement in community activities can foster resilience and mitigate the influence of risk factors. Risk and protective factors exist in the individual, the family, the community and the broader environment. Resistance to advanced substance abuse among occasional and first-time users is built by developing assets in individuals, families, and communities through evidence-based health promotion and prevention strategies. The result of this process is the identification, development, and publication of promising, effective, and model programs, practices, and policies.

In addition, SAMHSA has recently implemented specific efforts to prevent the onset and reduce the progression of substance abuse. These initiatives include programs for testing drug use in the workplace (now utilizing alternative specimen technology), programs focusing on young employees as they enter the workforce, and programs designed to identify and refer offenders before they re-enter society through rapid HIV drug testing kit protocol.

SAMHSA works to combine the Strategic Prevention Framework with evidence-based programs built on risk and protective factors to form a comprehensive systems approach that provides services to both individuals who have never used drugs and occasional and first-time users.

11. **How have advances in technology over the past 10-15 years helped in the delivery of treatment services? Can you specifically describe any new treatment systems that are based on new technologies?**

Significant advances in the overall delivery of treatment services for opioid dependence have occurred over the last few years as a result of legislative changes, scientific recommendations, and the Food and Drug Administration's (FDA) approval of Buprenorphine, a medication to treat opioid dependence.

In November 1997, a National Institutes of Health Consensus Panel recommended changes in legislation that would encourage treatment of opiate dependent individuals in primary care offices. The Drug Addiction Treatment Act (DATA), enacted by the Congress in 2000, permits qualified physicians to prescribe and dispense schedule III, IV or V narcotics approved for the treatment of opioid dependence. On October 8, 2002, the FDA approved two sublingual preparations of burpenorphine for treatment of opioid dependence. As a result of these events, physicians who meet the qualifications required in DATA 2000 and register with the Substance Abuse and Mental Health Services Administration (SAMHSA) are authorized to prescribe buprenorphine for the treatment of up to thirty opioid dependent individuals at any one time.

The introduction of buprenorphine for the treatment of opioid dependence has been the keystone

in the development of a new office-based treatment system that allows individuals addicted to opiates to receive treatment in physician offices. Prior to these recent advances, the use of opioid medications to treat dependence was permissible only in federally approved Opioid Treatment Programs (methadone clinics). Office-based treatment with buprenorphine is bringing additional treatment and care into the mainstream of medical care and thereby greatly expanding access to treatment and recovery to thousands.

SAMHSA has been the leader in training physicians and other allied health workers in the use of buprenorphine in opioid dependent persons. To date, more than 4,000 physicians have been trained in addiction care and the use of buprenorphine for opioid dependent individuals. More than 2,700 physicians have received a DATA waiver to prescribe buprenorphine in their office settings. In addition to meeting the training needs of physicians, April 2004 marked the unveiling of SAMHSA's first practical guide for physicians who wish to treat patients with buprenorphine. With recent advances in technology, SAMHSA is working with other federal agencies to improve the delivery of care in systems involving criminal justice, the aging and homeless populations as well as individuals with HIV/AIDS, hepatitis, and co-occurring disorders.

12. **The Residential Substance Abuse Treatment in State Prisons (RSAT) program in the Department of Justice provides grants to States to develop and implement substance abuse programs within prisons. The law directs the Attorney General to consult with the Secretary of Health and Human Services (HHS) regarding aftercare, and States are required to coordinate aftercare funding with existing comprehensive approaches provided by the Substance Abuse Prevention and Treatment Block Grant. How do you confirm this coordination and that the Substance Abuse Prevention and Treatment funds to States get used for aftercare for addicted individuals coming out of prison treatment programs?**

    Though this requirement is part of the RSAT, it is not a requirement under the Substance Abuse Prevention and Treatment Block Grant. Since it is not a requirement under this program SAMHSA is not collecting information regarding the use of SAPT funds for aftercare for this population. We recommend that the Subcommittee address this question to the Department of Justice which is solely responsible for implementation and management of RSAT.

13. **How will the Performance Partnership Grants and the Access to Recovery Initiative assure that States fund and guarantee service providers the necessary technical assistance and resources to implement any mandated performance measure or standard?**

    As stated before there are many obstacles to implementation of a performance based system and that is why SAMHSA is taking the steps it is in implementing such a system. We along with the States and other interested parties have to continue the working relationship that we have had over the past several years and work out way through each of these obstacles to ensure a successful implementation.

Two of those obstacles have to do with the funding needed to implement the program and providing the technical assistance needed to implement it. As a distinct underlying responsibility of SAMHSA's work as a service agency, our FY 2005 budget proposes a $66 million investment in data infrastructure and related technical assistance to the States for a cumulative total of $277 million from FY 2001 to FY 2005. This is in direct response to our new core operating mechanism that more closely looks at what data we are collecting, why, and how it can best be used to manage and measure performance. Our Data Vision strategy for putting data to work for us through controlled measures to make informed decisions is well underway.

14. **Will all the SAMHSA measurement guidelines recognize the different treatment modalities necessary to treat the addicted individual with special needs who requires extended residential care? And how?**

We want to clarify that this concern is not about the seven domains themselves but of the use of the domains in judging the performance of individual facilities.

The Federal government as part of the Block Grant program and Access to Recovery will be holding States accountable, not individual facilities. It is expected, however, that the States will use the same measures to hold facilities accountable. In doing so the States will have to ensure that they take into consideration the characteristics of the people served and the environment in which they serve in judging the performance of the facility.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
National Institute on Drug Abuse
Bethesda, Maryland 20892

May 6, 2004

The Honorable Mark E. Souder
Chairman, Subcommittee on Criminal Justice,
Drug Policy and Human Resources
House of Representatives
Washington, D.C. 20515-6143

Dear Mr. Souder:

I am providing the enclosed responses to the questions for the record that you sent to me in your letter dated April 7 as follow up to the March 30 hearing titled "Measuring Treatment Effectiveness."

Thank you for the opportunity to testify at this congressional hearing. If you need any additional information, please contact Mary Mayhew of my staff at (301) 594-6189.

Sincerely,

Nora D. Volkow, M.D.
Director

Enclosure

March 30, 2004, Hearing on Effectiveness of Addiction Treatment
NIDA Responses to Questions for the Record

Question 1: Dr. Volkow, your written testimony stated that the Addiction Severity Index (developed by NIH and the VA) has been refined for over 20 years to capture "critical baseline data...[which] sets the stage for improved treatment outcomes," and is now being adapted to a computerized version. Has this project found cooperation by the Department of Justice? How is this program being adapted for use with incarcerated populations?

Response: The Addiction Severity Index (ASI), which was developed and refined over the past 20 years through support from NIDA, is widely used by treatment programs across the country for admission assessments and for post-treatment clinical evaluations of improvement and outcome. The ASI is also often used in NIDA-funded studies involving offenders to gather information about substance abuse and criminal activity/risk. The Department of Justice has been working with NIDA to develop and implement the use of this instrument, though limited computer access in prisons and jails may prohibit the use of the computerized version of the ASI in many criminal justice settings.

Question 2: How has the success of treatment programs in a clinical setting using buprenorphine for opioid addicts compared with other forms of treatment?

Response: There are very few treatment programs using the buprenorphine products. Buprenorphine is largely being prescribed by physicians in office settings rather than dispensed in treatment programs. Buprenorphine is prescribed by licensed physicians in private practice and data on successes is not easily gathered. Also buprenorphine was only approved over a year ago so there has also not been sufficient time to compare its success with that of other treatments.

However, NIDA has conducted research on using buprenorphine products to treat opiate addiction in an office-based setting. To assess the safety and efficacy of buprenorphine or the buprenorphine/naloxone combination, researchers conducted a multi-site, randomized, placebo-controlled design in office-based settings. The initial phase of this study, which included 326 patients, was terminated early (i.e., before all participants had completed this phase) because of the robust effect of the medications in reducing opiate use and drug cravings. The longer-term study confirmed the safety and acceptability of the medications over time. This and other studies prove that treatment with these new medications is well tolerated and able to reduce use as well as craving for opiates.

Question 3: Your written testimony stated, "addiction treatment has also been shown to be an effective way to prevent the spread of diseases, such as HIV/AIDS and hepatitis." Proponents of needle exchange claim such programs link drug addicts to treatment. What percentage of needle exchange participants enroll in drug treatment programs and successfully complete treatment?

Response: Users of needle exchange or syringe exchange programs (NEPs or SEPs) are often hard to reach individuals with greater involvement in high-risk behaviors and many comorbid health conditions. Referral to drug abuse treatment is considered to be an important component of syringe or needle exchange services (SEPs/NEPs). In a survey of 127 SEPs/NEPs in the U.S. in 2001, over 80% reported that they provide referrals to drug abuse treatment.[1]

Federal and state medical confidentiality laws prohibit drug treatment programs from releasing treatment outcome data to a referral source in a way in which individuals might be identified, thus making it difficult to obtain follow-up data on client outcomes. Obtaining such data requires special arrangements between the referral source (e.g., the needle exchange program or NEP) and the drug treatment programs, and special informed consents from referred individuals.

In addition, recovery from drug addiction can be a long-term process and frequently requires multiple episodes of treatment, thus it is difficult to determine the percentage of persons who have "successfully completed" treatment in most research studies.

However, there are some studies that have reported treatment outcome data for drug users referred to treatment by NEPs. Brooner et al.,[2] found that patients referred to drug treatment by the NEP had greater severity of drug use at baseline than those referred by standard referral, but were comparable in terms of treatment outcomes (i.e., reduced drug use and criminal activity for profit) and retention in treatment (88% standard referral vs. 76% NEP referral).

Kuo et al. [3] evaluated program entry, retention, and early treatment response of NEP attendees referred to drug treatment using LAAM (levomethadyl acetate hydrochloride). Of 163 referrals, 114 (70%) entered the program, and 84% were retained at least 90 days.

Riley et al.[4] examined the characteristics of NEP participants who requested and/or subsequently enrolled in methadone treatment and found that, among 139 individuals who requested treatment, males were twice as likely as females to enter treatment. Health insurance ($p = .02$) and not living with children ($p = .01$) were associated with drug user treatment entry.

Finally, the Hawaii State Syringe Exchange Program is part of the state's comprehensive HIV prevention program, including voluntary counseling and testing, drug abuse treatment, and antiretroviral treatment for HIV positives, as well as syringe/needle exchange and pharmacy sales. The Hawaii program has made the necessary legal arrangements to obtain follow-up data on client outcomes and reports that a total of 74% of its referrals either successfully completed treatment or were still in treatment.[5]

1) Des Jarlais, D., McKnight, C., Eigo, K., Friedmann, P. 2000 United States Syringe Exchange Program Survey. Presented at the North American Syringe Exchange

Conference, Alberquerque, New Mexico, April 24, 2002. Also see: <http://opiateaddictionrx.info/survey2000/index.html>.

2) Brooner, R., Kidorf, M., Beilenson, Svikis, D., and Vlahov, D. (1998). Drug abuse treatment success among needle exchange participants. Public Health Reports : HIV Prevention with Drug-Using Populations: Current Status and Future Prospects, Vol. 113, Supp. 1: 129-139.

3) Kuo, I., Brady, J., Butler, C., Schwartz, R., Brooner, R., Vlahov, D., Strathdee, S. (2003). Feasibility of referring drug users from a needle exchange program into an addiction treatment program: Experience with a mobile treatment van and LAAM maintenance. J Subst Abuse Treat 24: 67-74.

4) Riley, E., Safaeian, M., Strathdee, S., Brooner, R., Beilenson, P., Vlahov, D. (2002). Drug user treatment referrals and entry among participants of a needle exchange program. Subst Use Misuse. 37(14):1869-1886.

5) Des Jarlais, D., and Shimizu, S. (2003) Hawaii Statewide Syringe Exchange Program: 2003 Evaluation Report.

Question 4: How would you draw a distinction between treatment and so-called "harm reduction"?

Response: The ideal outcome of addiction treatment is the complete elimination of drug use. Not only does abstinence improve the health of the individual, but also it reduces the adverse consequences that drugs can have on the health and safety of families and communities. Therefore, a primary goal of addiction treatment is to stop all drug use. Addiction, however, is a complex chronic disorder that often co-occurs with problems in the domains of physical health, mental health, criminal justice, employment, and family and social functioning. All of these areas must be addressed, not just the drug use. Similarly, measuring the outcomes of drug treatment should not be limited to drug use levels alone, improvements in these other domains can contribute to recovery.

Understanding addiction as a chronic relapsing disease that involves the brain, behavior, the environment in which an individual is raised, along with genetic factors, is critical since it frames how we must ultimately develop strategies to treat this disease. Treatment of drug addiction requires a continuum of care, based on the evolving needs of the individual over time. This can include detoxification as an initial acute first step to treatment, the treatment itself, and participation in self-help groups, for example, once treatment is completed. Most effective drug treatments include an after-care component. Particularly for those who have the most serious problems, the most favorable outcomes are obtained following treatments that provide comprehensive services, often in a residential setting. To be effective, treatment should attend to problems of the individual that would otherwise jeopardize his or her recovery and participation as a productive member of society.

NIDA's goal is to improve the Nation's quality of addiction treatment using science as the vehicle. The term "harm reduction" has various meanings depending upon the context in which it is used. It has political connotations, and is not viewed as a scientific term for any particular approach to addressing drug addiction. It is therefore not something NIDA can define or use in the context of its research mission.

Question 5: In Vancouver, Canada, illegal drugs and needles are widely available and accessible for IDUs. The city, in fact, boasts the largest NEP in North America. In 2002, nearly 3 million needles were distributed by NEPs in the City. Vancouver began its NEPs in 1988 and the number of new HIV infections among IDUs increased every year thereafter until peaking in 1996. A Vancouver Epidemiology Report released last fall found that both HIV and hepatitis C have now reached "saturation" among the IDU population, meaning few if any of who are not already infected are left to become newly infected. The City has the highest level of HIV infection in the developed world. Vancouver's response has been to establish legal injection sites where addicts can shoot up under medical supervision. Based upon the Vancouver experience, would you agree that NEP and harm reduction failed to prevent the City's HIV and HCV epidemics? Have other cities employing a harm reduction strategy encountered similar experiences?

Response: It appears from the information provided in your question that HIV and HCV infections were not successfully contained. The Vancouver NEP was not causally associated with higher risk of HIV infection.[1] The number of infections observed was similar to that which would be expected based on the underlying risk profiles of frequent NEP attendees, including unstable housing and hotel living, sex trade involvement, and incarceration within the previous 6 months.

Researchers in Vancouver have continued to investigate the ongoing injection drug use-related HIV epidemic there. The Vancouver Injection Drug Users Study [2-3] is an open prospective cohort of IDUs that began in May 1996. It observed 109 incident HIV infections during a follow-up of 31 months among 940 HIV-seronegative participants and identified injecting cocaine use as predictive of HIV infection in a dose-dependent fashion. There was a switch from predominantly heroin use to IV cocaine use in Vancouver. Compared with infrequent cocaine users, participants who averaged more than 3 injections per day were 7 times more likely to contract HIV. In addition, the time to HIV infection was accelerated among regular cocaine injectors independent of concurrent heroin use. Cocaine injection tends to occur in binges and increases the likelihood of needle sharing compared to the more stable and less frequent injection patterns of heroin users.

Difficulty accessing sufficient sterile syringes has been shown to be the primary risk factor for syringe sharing in Vancouver.[4] This, combined with the rapid shift from heroin to cocaine injection in that city, may help to explain why an HIV epidemic has been observed there despite the NEP. The Vancouver Injection Drug User Study analyzed data from 776 participants who reported actively injecting drugs in the 6 months before the most recent follow-up visit (January 1999 to October 2000). It found that, overall, 214 (27.6%) of the participants reported sharing needles during this period and in a

multivariate analysis that needle sharing was independently associated with difficulty getting sterile needles. The researchers report that, despite the availability of a large needle-exchange program and targeted law enforcement efforts in Vancouver, needle sharing remains a common and risky practice in this study cohort.

In response to the second part of the question, to date, we are not aware of any other cities employing a strategy of this nature that have encountered similar experiences as Vancouver. In fact, research has shown the converse, i.e., as part of a comprehensive HIV prevention strategy, NEPs are effective mechanisms for reducing the spread of HIV and other blood-borne diseases, including hepatitis B and hepatitis C. For example, Hurley et al.[5] reviewed published and unpublished reports from 1984 to 1994 on HIV seroprevalence among IDUs in 81 cities across Europe, Asia, and North America with and without NEPs. On average, seroprevalence increased by 5.9% per year in the 52 cities without NEPs, and decreased by 5.8% per year in the 29 cities with NEPs. The average annual change in seroprevalence was 11% lower in cities with NEPs (95% CI 217.6 to 23.9, p=0.004). Thus, in cities with NEPs, HIV seroprevalence among IDUs decreased on average, but in cities without NEPs, HIV seroprevalence increased, suggesting that NEPs led to a reduction in HIV incidence among IDUs.

1) Schechter, M.T., Strathdee, S.A., Cornelisse, P.G.A., Currie, S., Patrick, D.M., Rekart, M.L., & O'Shaughnessy, M.V. (1999). Do needle exchange programs increase the spread of HIV among injection drug users?: An investigation of the Vancouver outbreak. *AIDS, 13*(6):F45-51.

2) Tyndall, M., Currie, S., Spittal, P., Li, K., Wood, E., O'Shaughnessy, M., and Schechter, M. (2003). Intensive injection cocaine use as the primary risk factor in the Vancouver HIV-1 epidemic. *AIDS*, 17: 887-893.

3) Wood, E., Tyndall, M., Spittal, P., Li, K., Hogg, R., Montaner, J., O'S O'Shaughnessy; M., and Schechter, M. (2002). Factors associated with persistent high-risk syringe sharing in the presence of an established needle exchange programme. AIDS, 16(6): 941-943.

4) Wood, E., Tyndall, M., Li, K., Spittal, P., Kerr, T., Hogg, R., Montaner, J., O'Shaughnessy, M., and Schechter, M. (2001). Unsafe injection practices in a cohort of injecting drug users in Vancouver: Could safer injecting rooms help? *CMAJ,* 165(4):405-410.

5) Hurley, S., Jolley, D.J., Kaldor, J.M. (1997). Effectiveness of needle-exchange programmes for prevention of HIV infection. *The Lancet, 349:*1797-1800.

Question 6: According to a study published in the journal AIDS in 1997, "in Vancouver, NEP was introduced early, but access to drug and alcohol treatment, methadone maintenance and counseling services remains inadequate. As early as 1990, the lack of appropriate services for addiction treatment in British Columbia especially for cocaine users, was identified as a major barrier encountered by Vancouver's NEP attenders" and "this situation continues at present."

Response:
We understand that treatment services were and are inadequate. The cumulative scientific literature has shown that NEPS/SEPS, as part of a comprehensive HIV/AIDS prevention strategy, can be an effective public health approach to reduce the spread of HIV and other blood-borne pathogens in the community. Data also indicate that drug use is not increased among participants or community members, and that needle sharing networks are not facilitated by the availability of NEPS.

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May 7, 2004

VIA EMAIL
Congress of the United States
House of Representatives
Committee on Government Reform
Subcommittee on Criminal Justice
Drug Policy and Human Resources
2157 Rayburn House Office Building
Washington, DC 20515-6143

How well do you think SAMHSA's "Seven Outcome Domains" will capture treatment outcomes for drug addicts?

SAMHSA'S "Seven Outcome Domains" will capture treatment outcomes well because each domain is measurable and quantifiable. Drug and alcohol use can be measured through drug testing. Employment and education can be measured through the income earned and level of education achieved before, during and after treatment. Involvement with crime and criminal justice can be determined through the review of statistics, many of which are already collected. Family and living conditions and social support can also be determined by through the use of two to three questions that inquire about family relationships and social support. Access to treatment and retention/engagement in treatment are also easily measured. This information allows federal policy-makers to measure treatment effectiveness and adjust policy to achieve the most effective outcomes.

How Should the Federal government disseminate the measures of effectiveness?

We believe that any measures of treatment effectiveness must be founded and disseminated through performance-based contracts as a condition of funding, based on standardized outcomes. Providers should be contracted at 80% of their budget, with the rest of public funds contingent on the proportions of each measure met. Tying measures of effectiveness to funding will create a more competitive market and will ensure outcome measures are obtained.

What can be done to assist state in improving in the indicators of effectiveness?

The most pressing need lies with a state's ability to collect "real-time" treatment information in an automated way. States need funding and technical assistance to implement web-based Management Information Systems (MIS) so that all treatment providers can report daily information pertaining to assessment results, treatment plan information, treatment attendance, infractions/compliance and program responses, length of time to achieve abstinence. Drug testing labs can enter drug testing results and case managers can report on contacts with clients and referrals made. MIS provides real-time sharing of information and can be analyzed quickly to determine whether "during treatment" measures of effectiveness are being met by providers.

Should there be a collection of evaluation data from private providers?

We believe there should be uniform reporting of evaluation data from all providers in order to make comparisons among different modalities and systems of delivery (private, public, faith-based).

NADCP Responses Page 2

Congress of the United States
House of Representatives
Committee on Government Reform
Subcommittee on Criminal Justice
Drug Policy and Human Resources
2157 Rayburn House Office Building
Washington, DC 20515-6143

Some patients receive treatment from large programs; private providers treat others in clinical settings. What are some of the challenges in drawing a distinction in measuring the effectiveness in private treatment?

One of the challenges in measuring effectiveness between large and smaller programs is measuring the difference in treatment created by program size. Smaller programs are sometimes better able to give more specialized attention. Additionally, federal policymakers may also find it challenging to encourage private providers to use optimal treatment practices because they have few ways to influence private programs. One way to address this challenge is by highlighting the practices of non-private programs who utilize science-based treatment practices. It is also important to invite private providers to government-sponsored trainings.

Mr. O'Keeffe testified that federal policy is not optimal for the development and deployment of new treatments. What policy changes do you think would encourage that development?

One policy change would be the creation of federal policy that encourages collaboration among providers to develop and deploy new treatments. Many grants reward communities and jurisdictions that demonstrate cooperation among different organizations and disciplines for the purpose of delivering services. Using the same theory, federal grantors should encourage treatment providers to work together to explore new treatments and reward providers who do. While most rewards could be made through funding formulas, the federal government could also encourage collaboration by sponsoring treatment focus groups/roundtables and publications that explore new treatments such as the use of buprenorphine and other hot topics.

How do you coerce patients in denial into treatment?

Data consistently show that treatment, when completed, is effective. However, most addicts and alcoholics, if given a choice, would not enter a treatment program voluntarily. Those who do enter programs rarely complete them and among such dropouts, relapse within a year is the norm.

Accordingly, if treatment is to fulfill its considerable promise, drug involved offenders must not only enter treatment but also remain in treatment and complete the program. If they are to do so, most will need incentives that may be characterized as "coercive." In

the context of treatment, the term coercion – used more or less interchangeably with "compulsory treatment," "mandated treatment," "involuntary treatment," "legal pressure

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into treatment" – refers to an array of strategies that shape behavior by responding to specific actions with external pressure and predictable consequences. Moreover, evidence shows that substance abusers who get treatment through court orders or employer mandates benefit as much as and sometimes more than, their counterparts who enter treatment voluntarily. (Satel, 1999; Huddleston, 2000)

Four national studies, beginning in 1968 and ending in 1995, assessed approximately 70,000 patients, 40 to 50 percent of whom were court ordered or otherwise mandated into residential and outpatient treatment programs (Simpson & Curry; Simpson & Sells, 1983; Hubbard, et al., 1989; Center for Substance Abuse Treatment, 1996). Two major findings emerged.

First, the length of time a patient spent in treatment was a reliable predictor of his or her post-treatment performance. Beyond a 90-day threshold, treatment outcomes improved in direct relation to the length of time spent in treatment, with one year generally found to be the minimum effective duration of treatment. (Simpson & Curry; Simpson & Sells, 1983; Hubbard, et al., 1989; Center for Substance Abuse Treatment, 1996) Second, coerced patients tended to stay in treatment longer than their "non-coerced" counterparts. In short, the longer a patient stays in drug treatment, the better the outcome. (Simpson & Curry; Simpson & Sells, 1983; Hubbard, et al., 1989; Center for Substance Abuse Treatment, 1996)

"Unfortunately, few drug abuse treatment clients reach these critical thresholds. Between 40% and 80% of drug abusers drop out of treatment prior to the 90-day threshold of effective treatment length." (Stark, 1992, as cited in Marlowe, DeMatteo, & Festinger, 2003) and 80 to 90 percent drop out in fewer than twelve months (Satel, 1999, as cited in Marlowe, DeMatteo, & Festinger, 2003)

"Drug courts exceed these abysmal projections." (Marlowe, DeMatteo, & Festinger, 2003) Nationally, drug courts report retention rates between 67 and 71 percent. (American University) In short, over two thirds of participants who begin treatment through a drug court complete it a year or more later. "This represents a *six-fold* increase in treatment retention over most previous efforts." (Marlowe, DeMatteo, & Festinger, 2003)

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Drug court is the best vehicle within the criminal justice system to expedite the time interval between arrest and entry into treatment, and provide the necessary structure to see that an offender stays in treatment long enough for treatment benefits to be realized.

Drug courts are not the only method of coercing an addict into treatment who is in denial. Drug Free Workplace initiatives have a long history of using the coercive power of the employer to ensure entry and completion of treatment. Civil commitments and family interventions are also standard and effective means by which many addicts who do not want treatment, enter and complete treatment programs.

What perspectives do people in recovery bring to identifying treatment effectiveness?

Consumers of any service have exceptional perspectives on satisfaction measures. This is also true of people in recovery. Specifically, the actual consumers of treatment services can, if provided the right opportunity, provide consumer satisfaction information that is helpful in determining if a provider is fair, respectful, culturally competent, and helpful. The best way to gain this information would be to provide kiosks in the lobbies of treatment programs that are being measured. Kiosks currently allow customers in a number of settings (i.e. hospital emergency rooms, car dealerships, etc) to provide valuable, confidential information regarding satisfaction with services.

TO: The Hon. Mark E. Souder, Chairman
Subcommittee on Criminal Justice, Drug Policy and Human Resources

FROM: Jerome H. Jaffe, M.D.

RE: "Measuring Treatment Effectiveness"

Following is my reply to the additional questions you posed regarding the March 30, 2004 hearing entitled "Measuring Treatment Effectiveness."

1) How well do you think SAMHSA's "Seven Outcome Domains" will capture treatment outcomes for drug addicts?

SAMHSA's seven outcome domains more than adequately capture the outcomes of treatment. However, in practice there are both philosophical and practical problems with trying to cover these 7 domains. There is a real cost in finding patients and gathering the needed information. Further, unless there is some objective measure of the veracity of the answers obtained, (e.g., urine or hair tests for drug use, checking arrest records or pay stubs), there is always some questions about the accuracy of the findings. Second, it is not at all clear if it is appropriate to expect that treatment of drug dependence will achieve wide ranging changes in the behavior patients. This is a standard not expected of any other segment of health care –segments that are typically funded at far more generous levels. It is appropriate to expect that treatment programs reduce or eliminate drug use. If there are other benefits to society, these should be seen as extra benefits of treatment, not as a minimum expectation against which the effectiveness of treatment is measured.

2) How should the Federal government disseminate the measures of effectiveness?

The Federal government has, over many years, conducted costly studies of the effectiveness of treatment outcome. Generally when these are published the findings are expressed as averages. It is rare to find studies identifying outstanding exemplars of specific types of programs and disseminating both the results and circumstances, (the kinds of patients, the program resources and practices), so that other programs, States, and agencies with oversight responsibilities can use the results as benchmarks against which to measure themselves and the programs for which they have responsibility. It might also be instructive to single out, without specific identification, a few of the least effective programs as a challenge to the agencies responsible for the oversight of these programs.

3) What can be done to assist States in improving the indicators of effectiveness?

The States have two problems in measuring effectiveness. The first problem is a lack of resources and expertise. It is usually too costly to find and interview patients who have been treated, the method typically used in Federal studies of treatment effectiveness. Several States have developed methods of reviewing existing databases that already contain information relevant to treatment outcome, such as employment, arrests, Medicaid payments for medical services and hospital admissions, etc. In Alabama and Washington, reviews of already collected data were used to show how different treatment programs affected these measures for the months prior to and following admission. The data for the months prior to admission permitted the States to adjust for problem severity. It was clear in the case of Alabama that some programs were far more effective than others, even after adjusting for case difficulty.

The second problem faced by the States is how to use this information. It is often difficult to close a program that is underperforming either because starting another in the same locality is exceedingly difficult, or because the program has developed supportive political allies.

4) Should there be a collection of evaluation data from private providers?

It might be of value to potential patients of private programs to have available some reliable measure of a program's effectiveness. This is also true for all parts of our health care delivery system. But against the value of this information we must weigh the cost of collecting analyzing evaluation data. Based on my view of the state of knowledge about how to adjust for the severity of drug problems experience by patients entering drug treatment programs, I don't believe that this would be the best way to use limited resources.

5) Some patients receive treatment from large programs; private providers treat others in clinical settings. What are some of the challenges in drawing a distinction in measuring the effectiveness in private treatment? If so, what is it?

Programs that receive the bulk of their funding from public sources can be required to collect uniform information from patients admitted for treatment. This allows for some form of case difficulty adjustment when looking at the outcomes of those programs. I see no greater basis for the government imposing such standards of uniformity on private practitioners providing drug abuse treatment than on private practitioners providing other kinds of health services. Mandating such data gathering without financial support for the effort would raise the cost of treatment and make it even less accessible than it is currently.

6) Mr. O'Keeffe testified that Federal policy is not optimal ...
I did not hear Mr O'Keeffe's testimony and therefore I cannot comment on it.

7) How do you [get] patients in denial into treatment?

There are a variety of mechanisms that can motivate alcohol and drug dependent individuals who are ambivalent about treatment. These include the criminal justice system which can mandate treatment as a condition of continued freedom while on probation or while free on bail. Employers also have considerable leverage in persuading individuals with drug related problems to seek and stay in treatment. Family pressure is probably the most common factor that motivates people to seek consultation. New methods of interviewing designed to increase the motivation of ambivalent individuals to initiate change are now being taught and used by practitioners.

8) What perspectives do people in recovery bring to identifying treatment effectiveness?

Individuals in recovery can bring important levels of empathy to the treatment situation. The experience of being in recovery confers no special advantage or disadvantage in acquiring the skills and knowledge needed to obtain and interpret the information needed to measure treatment effectiveness.

House Committee on Government Reform
Criminal Justice, Drug Policy and Human Resources Subcommittee
Requested Questions on Measuring the Effectiveness of Drug Treatment

Response of Catherine C. Martens
Senior Vice President & Executive Director
Second Genesis

(1) How well do you think SAMHSA's "Seven Outcome Domains" will capture treatment outcomes for drug addicts?

I believe they do capture treatment outcomes well. However, it is also important for SAMHSA to gain a provider perspective about the challenges of collecting data for each domain. The administrative burden of outcome collection for most programs is enormous. Also it is important that the outcome measurements are not based on any one modality or type of treatment.

(2) How should the Federal government disseminate the measures of effectiveness?

Information should disseminate through State Alcohol and Drug authorities. However, once again we must be aware of the administrative burden that providers face in having to meet outcome measurements. Technical Assistance is a must in order to insure effective outcome collection. This will also have to be phased in over a number of years to be successful. There also will have to be new money for this. Our goal is not to compromise client treatment in order to capture needed outcome data.

(3) What can be done to assist states in improving in the indicators of effectiveness?

Substance abuse treatment outcomes are one of the most frequently researched topics in the substance abuse literature. The majority of these studies are based on a project-by-project effort by individual researchers. Many of these studies rely on a one-time measurement effort and are usually large studies affecting many providers nationwide, most are not related to ongoing outcome monitoring and management systems. I urge the continued funding of the National Institute on Alcohol Abuse and Alcoholism, the National Institute on Drug Abuse, and the Center for Substance Abuse Treatment. Once this research is complete we need to continue to transfer this information to providers through training, technical assistance and funding. Investing in ongoing client monitoring and management systems on a Federal, State, and local level is vital. It can provide an accurate assessment of treatment modality need. It can help match funding with identified need and thereby maximize resources. It can also provide policymakers with data for budget and funding increase requests. Also a good client management system improves cost savings through information sharing and less duplication of efforts and allows the client to be followed

through the continuum of care, which I believe will affect outcomes in a positive way.

(4) Should there be a collection of evaluation data from private providers?

Yes, there should be evaluation data for the purposes of research from private providers. As I state it my answer to question five for the most part the private providers and public providers deal with clients from different socioeconomic groups. The private provider deals with a more affluent group and the public provider with a less affluent group. It would be interesting to look at long-term outcome studies from individuals who suffer from drug or alcohol disorders and after treatment go back to adequate paying jobs, decent neighborhoods and in some cases more supportive family structures vs. the men and women who after treatment return to low paying jobs, high crime and drug infested neighborhoods and for the most part less supportive family structures. It is also important to collect private data to look at the cost effectiveness of treatment and success outcomes and at indicators such as severity of illness and recovery outcomes.

(5) Some patients receive treatment from large programs; private providers treat others in clinical settings. What are some of the challenges in drawing a distinction in measuring the effectiveness in private treatment? If so, what is it?

Substance abuse treatment revenue sources pay for services for groups with different characteristics. For example, private insurance tends to pay for services for substance abusers that are employed and by benefit of their employment. They come from a higher socioeconomic status and for the most part are more socially integrated, which helps with outcomes. The severity of one's disease will also dictate the type treatment necessary for success. Someone still in their original family and employment may need less structured or intensive care such as long-term residential. On the other-hand public funding sources such has block grants and Medicaid are payers of last resort. They for the most part fund services for substance abusers from lower socioeconomic groups with an overabundance of problems. Problems ranging from chronic unemployment lack of education, and involvement with the criminal justice system and this is just to name a few. A different outcome "Warrantee" should be made to the public purchaser in contrast to the commercial purchaser. Outcome data should be analyzed not only according to demographic characteristics, but also by funding sources. The challenges are coming-up with fair and realistic outcomes for both the private and public sector due to the aforementioned distinctions.

House Committee on Government Reform
Criminal Justice, Drug Policy and Human Resources Subcommittee
Requested Questions on Measuring the Effectiveness of Drug Treatment

(6) Mr. O'Keefe testified that Federal policy is not optimal for the development and deployment of new treatments. What policy changes do you think would encourage that development?

I do not believe that a Federal policy is optimal for the development and deployment of new treatments. Public subsidies represent the most important source of funding for facilities specializing in drug abuse treatment. Public subsidies are made up of state and local funds and Federal Block Grants. Other public sources of funding include Medicaid and Medicare. We in the field know that all of these are still not doing the job. According to the 2002 National Survey on Drug Use and Health, of the 22.8 million people aged 12 and older who needed treatment for alcohol and drugs, only 2.3 million of them received specialized care. Over 85 percent of people with untreated alcohol or drug problems said they didn't think they needed care. Of the 1.2 million people who felt they did need treatment, 446,000 tried but were unable to get treatment. The result: continued addiction, lost health, family disintegration, unemployment and often-criminal involvement. That is a huge human and economic cost. Yet we know investments in Substance Abuse Prevention and Treatment are cost effective and beneficial. Treatment is effective. Recovery is real. Also there is a Medicaid reimbursement inequity when it comes to substance abuse treatment. Medicaid pays for outpatient and a medically managed detox. Detox is not treatment! For the majority of the men and women who are accessing public funds for substance abuse outpatient treatment is inadequate for their first treatment of choice. Most Medicaid clients need long-term residential treatment, which Medicaid does not pay for because of the Institute of Mental Disease Exclusion. Medicaid eligible clients lose their eligibility for all medical services under Medicaid if they seek treatment in a long-term community residential substance abuse program. In January of 2004 Medicaid stopped paying for women and their children to enter long-term residential treatment in Maryland. To the best of our information, CMS now excludes payment for any long-term residential substance abuse treatment even if it has in the past been covered through a state waiver. Medicaid coverage for alcohol and drug treatment services should be enhanced by making all alcohol and drug treatment a required service under the Medicaid program. We need a Medicaid funding stream that is more stable. One that is not discretionary and subject to annual appropriations process. Also lifting the "IMD exclusion" which is one of the most serious roadblocks preventing low-income individuals from obtaining residential alcohol and drug treatment would increase appropriate services and produce better outcomes. Therapeutic communities fall under the IMD exclusion. We are attaching our national association's factsheet on this issue for more information.

(7) How do you engage patients in denial into treatments?

We can breakthrough denial by redesigning processes such as client intake, assessment, scheduling, and outreach and family involvement. Create a system that is less frustrating for both the client and staff. Outreach must include public promotion of recovery and treatment successes. First contact needs to be a trained and motivated professional. Intake and Assessment needs to be simple and centralized intake must employ the collaboration of statewide services. Therapeutic engagement must include the use of motivational interviewing with a non-judgmental attitude. All providers need to review their forms and eliminate duplicate questions that can frustrate both the therapist and the client. When someone is in denial frustration and inaccessibility can fuel his or her denial.

(8) What perspectives do people in recovery bring to identifying treatment effectiveness?

The term "recovery community" is a broad and encompassing term that includes persons having a history of alcohol and drug problems who are in recovery, those currently in treatment, those seeking treatment, as well as their family members, and other supporters and allies. "Recovery community" organizations help people in recovery, their families and supporters work together to identify, develop, and support needed treatment and recovery policies, systems, and services. Men and women who have experienced substance abuse, treatment, and recovery have a lot to offer treatment programs and the communities in which they reside. Because of their unique perspectives, they are able to speak out for services that are responsive to the needs of consumers and families. Men and women in recovery and their supporters need organized mechanisms through which they can provide support and encouragement to those in need of substance abuse treatment. No one is more able to speak to the efficacy of treatment than the person who has gotten another chance at life because of his or her treatment. Federal policy should support incentive programs such as loan guarantees and tax credits for an individual in recovery who is not credentialed have the option of a career ladder to enter the field as a qualified worker. There is a workforce shortage issue in the substance abuse treatment field that would benefit with a federal role that addresses the development of recovery individuals as counselors.

Questions for the Record

Hendree Jones, Ph.D.
Research Director, Center for Addiction and Pregnancy (CAP)
Johns Hopkins Bayview Medical Center

"Measuring Treatment Effectiveness"
March 30, 2004

1. How well do you think SAMHSA's "Seven outcome domains:" will capture treatment outcomes for drug addicts?

- SAMHSA needs to demand outcomes and evaluation from all funded programs on a yearly basis. Programs not producing improvement should not be re-funded.
- Objective measurement of outcome domains and standardization of data definitions should be adopted by SAMHSA grantees. Grantees failing to comply with these standards should not receive continued funding.
- Programs exceeding outcome benchmarks should be eligible to receive monetary rewards to help with expansion of program or dissemination of program model.
- Outcome evaluation needs to consider the severity of the patient population. Those programs treating more severe substance abusers may not be able to achieve the same outcomes as programs treating less severe substance dependent patients. If this is not done, programs will try to manipulate outcomes by "taking the cream of the crop" and not treating more severe patients. This could harm access to treatment for many patients.
- SAMHSA resources would be best utilized in programs that are based on the well established body of empirical evidence showing what types of treatments work (see NIDAs Principles of Drug Addiction).
- Examinations of outcomes should occur during treatment as well as post-treatment.
- Measures of flexibility of the program to address patient needs should be evaluated.

2. How should the Federal Government disseminate the measures of effectiveness?

- Treatment outcomes will improve if the public has access to an objective rating of treatment facilities. For example, an annually published listing of the top 100 best treatment programs would be helpful. Patients could easily see what the strengths and weakness of each program are and make more informed decisions about where to receive treatment.
- Encourage SAMSHA to demand objective outcome data from each grantee and make renewed funding based on standard benchmarks of successful outcomes.
- Addiction treatment is one of the *only* medical illnesses that is most often treated by non-credential personnel. The Federal Government should provide regulations about the training, education and credentialing of all treatment staff.

3. What can be done to assist states in improving indicators of effectiveness?

- States and localities should review their ability under provider contracts to assess their flexibility in rewarding results of patient improvement.
- Ensure the states and localities have access to data to make decisions about program funding status. Evaluations of programs should be conducted openly and with communication from staff, administration and include patient perspectives. Baltimore has a program called DrugStat that allows state/local agencies and providers to communicate together about outcomes. Objective outcomes are listed for each program in front of the entire group that breeds accountability, healthy competition and success.
- Having an external case monitor to review individual treatment plans to assure needs are identified and appropriate services are offered can help ensure more cost-effective outcomes.
- Provide guidelines on developing infrastructure for database systems that capture objective and clearly defined outcomes. These aggregate outcomes should be available to all interested parties including patients to help them choose the best program for their recovery.

4. Should there be a collection of evaluation data from private providers?

I see no reason why private providers should be held up to different standards than larger practices.

5. Some patients receive treatment from large programs; private providers treat others in clinical settings. What are some of the challenges in drawing a distinction in measuring effectiveness in private treatment?

- Treatment can be evaluated using same standards FDA uses to evaluate new medications.
- Good programs will have good outcomes regardless of setting.

6. Mr. Okeeffe testified that Federal Policy is not optional for development and deployment of new treatments What policy changes do you think would encourage that development?

- A public health crisis is looming with the lack of treatment for opioids. ONDCP estimated that there were 810,000 to 1,000,000 individuals addicted to heroin and even more abusing prescription medications. In 2002, SAMHSA estimated that there were 200,000 patients treated with methadone or LAAM, 3,000-4,000 in therapeutic communities and the number of patients in 12 step programs is not known. Obviously, there is a huge treatment gap that needs to be filled.
- Removing the 30 patient limit on physicians that prescribe buprenorphine will help address the treatment gap.
- Preventing new medications to treat illicit drug abuse from being segregated from general medical practice will help address the treatment gap. The illness of addiction is bad, not the patients that have it nor the medical staff that treat it.

7. How do you get patients in denial in to treatment?

- We use motivational interviewing developed by William Miller to help patients move from a resistant treatment stage to accepting and being motivated for treatment.
- We also believe that there is no wrong way to treatment and will ally with many community stakeholder (ministers, nurses, social workers, peers etc) to also teach them motivational interviewing tools to help patients see the need and benefits of treatment.
- Treatment on demand is critical to getting patients into treatment.

8. What perspectives do people in recovery bring to identifying treatment effectiveness?

- One can have the best treatment ever-developed in place for patients but if they do not see the benefit in it, on one will be treated.
- Patients who have completed treatment can help inform programs of the elements they liked or did not like and which areas need improvement or are excellent.
- Just as in all other areas of health care, patient satisfaction is important and should one of many factors considered for continued improvement of treatment.

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Mark E. Souder
Chairman
Subcommittee on Criminal Justice
Drug Policy and Human Resources
Committee on Government Reform
2157 Rayburn House Office Building
Washington DC 20515-6143

March 30, 2004 Hearing
Measuring the Effectiveness of Drug Addiction Treatment
Subcommittee on Criminal Justice
Drug Policy and Human Resources

Dear Mr. Chairman,

In further response to the questions posed I am pleased to provide the following;

(Question 6) Mr. O'Keeffe testified that Federal policy is not optimal for the development and deployment of new treatments. What policy changes do you think would encourage that development?

As I noted in my testimony, enactment of the Drug Addiction Treatment Act (DATA) went a long way toward increasing access to treatment and improving the outlook for the future, through the Act's recognition that drug addiction is a disease that requires the attention of specialty physicians and other health care providers and the ability of those providers to offer treatment in the setting of their own clinical practice. The intent of Congress to ensure that this new approach to addiction treatment was implemented in a careful way, to avoid diversion and abuse of the treatments themselves, was appropriate. However, it had an unintended consequence that has prevented this important statute from reaching its full potential.

The law required not only that providers certify to the Secretary of Health and human Services that they are qualified, by reason of training and experience, to provide addiction treatment, but also that they would limit that treatment to 30 patients at a time. The law expanded that 30-patient limitation so that it applies not only to each individual practitioner but also to every group practice. The unintended and unfortunate result of this is that group practices with dozens, or hundreds, of practitioners are limited to treating the same number of patients – 30 – as each physician in a solo practice. Thus, patients who receive their care from providers in group practices are less likely to be able to receive the addiction treatment envisioned by the DATA. All of the physician members of the group practice are limited, together and in the aggregate, to treating no more than 30 patients at a time.

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Interestingly, this problem exists not only for organizations we may think of in the traditional sense as "group practices" – ranging is size from small groups of 5 or 10 physicians to those such as Kaiser Permanente or Aurora, for example, but also at academic health centers affiliated with medical colleges, whose physicians are all members of the same "group practice." Thus, even these health care settings – which frequently offer some of the most cutting-edge health care in the country – find themselves hamstrung as regards the treatment of drug addiction. Nearly all of the clinical research conducted prior to approval of drugs covered by DATA was conducted in medical centers associated with medical colleges such as Yale, Columbia, U.C.L.A., Wayne State, and many more, yet these same centers of medical excellence are precluded by DATA from treating more than 30 patients at one time.

It clearly was not the intention of the DATA that addicted patients have less access to new medications simply because they receive care from a physician practicing in a group, or from a group-based or mixed-model health plan. Nevertheless, this effect is being felt today. The problem can be addressed by removing the 30-patient aggregate limit on medical groups. Such a change would enhance the new treatment paradigm established by DATA and, since the patient limitation would remain on individual treating physicians, would not increase the potential for abuse or diversion.

While the law allows for the Secretary of HHS to change the patient limitation by regulation, this is a most cumbersome and lengthy way to improve policy. Congress, however, has introduced several bills to change this inadvertent requirement. Enactment of that legislation (e.g., H.R. 3624, S. 2976) would correct it and ensure the policy works the way it was intended.

(Question 7) How do you get patients in denial into treatment?

For many years patients have resisted entering treatment for a variety of reasons including denial. In many cases, this denial resulted from fear of admitting that their drug use was inappropriate. Often these patients were reluctant to address the problem because of the stigma associated with the disease and their inability to have their disease addressed in the normal course of the practice of medicine, and their unwillingness to participate in drug treatment programs often located in unsafe and/or drug infested areas of inner-cities. For the past forty years physicians have been precluded from treating these patients in the privacy of their offices with the pharmaceutical products and treatment methods shown to be effective for opiate dependence. The Drug Addiction Treatment Act (DATA) established a new treatment paradigm which offers new opportunities for those patients to seek treatment. SAMHSA Administrator Currie has addressed the "treatment gap" identified by the White House Office of National Drug Control Policy, and that agency has moved expeditiously toward bringing more patients into treatment following enactment of this legislation. They have developed Guidelines for this new office-based treatment paradigm and more and more patients are entering treatment as a result of this congressional action. Unfortunately, many patients are still being denied treatment because their only source of medical care is clinics operated by medical schools, or large group practices that are currently precluded from treating more than 30 patients per institution because of the unintended effect of language of the DATA.

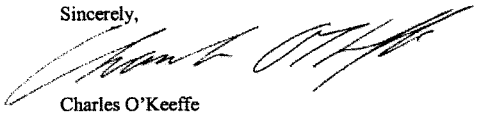
In a sense, the legislation which opened the door to treatment for so many has inadvertently prevented untold thousands of patients from receiving treatment they seek. Legislation such as that discussed during this hearing (H.R. 3624, S. 2976) will remove this unintended impediment and provide access to treatment to those currently seeking it but being denied acces to it because

of the patient ceiling inadvertently imposed on group practices. Providing acces to treatment for all treatment-seeking patients will significantly alleviate much of the fear and denial so often encountered in these patients.

Other witnesses are more qualified to respond to the other questions posed.

If I may be of further assistance to the Committee, please do not hesitate to contact me.

Sincerely,



Charles O'Keeffe
Professor
Preventive Medicine and Community Health
VCU School of Medicine
and Professor
Institute for Drug and Alcohol Studies
Virginia Commonwealth University

April 7, 2004

A. Thomas McLellan
Treatment Research Institute
600 Public Ledger Bld.
150 Independence Mall
Philadelphia PA 19106

Dear Dr. McLellan:

I would like to thank you for your testimony at our March 30, 2004 hearing entitled "Measuring Treatment Effectiveness."

Attached to this letter you will find some additional questions for the record. Please send your response electronically to malia.holst@mail.house.gov by May 7, 2004.

Again, thank you for your contribution to this Congressional hearing. If you have any questions, please contact Malia Holst at (202) 225-2577.

Sincerely,

Mark E. Souder
Chairman
Subcommittee on Criminal Justice,
Drug Policy and Human Resources

Enclosure

1. How well do you think SAMHSA's "Seven Outcome Domains" will capture treatment outcomes for drug addicts?

I think these domains are quite appropriate to cover the concerns of the patient (most important) as well as the various other important constituents (customers) who are regularly asked to support and pay for substance abuse treatment – including the family, the employer, the health system and the justice system.

It should be noted that the federal government (VA, NIDA, NIAAA and even SAMHSA) have all endorsed a clinical interview called the Addiction Severity Index (ASI) that is used by admissions personnel to capture the nature and severity of patients' problems in these same seven domains at the start of treatment (for the purposes of treatment planning). In addition, these same agencies have regularly re-administered the ASI in post-admission follow up interviews to measure patient progress in these seven domains. The ASI is reliable, valid, free and in the public domain (non proprietary). In addition there is software (free, public domain) that permits it to be collected and used rapidly. The problem is that the federal government has not required this or any other standard set of admission questions for the 13, 800 programs that currently receive federal funds. The result is that the field does not collect standard information and SAMHSA does not have ready access to information that it says it wants on those seven domains. Picking a single standardized instrument to collect information in these seven domains would essentially create clinical information standards in a field that clearly needs them and would set the stage for real-time information exchange and would permit standard outcome evaluation and comparison across all seven domains. My suggestion is the ASI for the reasons cited – but any standard validated instrument would be an improvement.

2. How should the Federal government disseminate the measures of effectiveness?

The reason that I suggested a standardized measure that would be used by all federal programs is so that there would be a unified way of collecting and reporting this information – without that there will be endless, unwinnable debates about the meaning of each domain. With that said – and given a standard measurement tool that captures each domain, there are many possibilities and all should be considered. A database could be provided to researchers (much like the National Household Survey database) and that would permit researchers and policy analysts full access to the raw data – many papers and reports will come from this.

For the public at large – I favor a "Consumer's Report" format. Using exactly the same filled-circle format that the public has come to understand, I would create a seven domain report for all states, cities and counties (maybe even individual programs). The standards of evidence for each domain grade (open, quarter filled, half filled, etc) would be easily generated from a

statistical formula that would take into consideration that some cities, counties, programs have more difficult patients. I could go into detail about how this is done but it is a pretty standard procedure – as long as you have standard data.

3. What can be done to assist states in improving in the indicators of effectiveness?

Sounding very much like a broken record here – a standard data collection instrument would at least open the door. However, even this is not enough. Our research group helps 13 states right now with this issue – and all these use a common instrument. One significant problem is that there is a need for training for all management people in the USE of data to make decisions. This may seem trite but it is quite real. This field has not had data available in a timely way and thus those in management positions at many/most state director offices, county authorities and certainly treatment program directors – simply do not understand how to read and use reports to change policy or practice. It is very similar to what happened in most other business sectors when the information spreadsheet became widely available. Most businesses had no clue about what to measure, how to measure it or once collected, how to use it. This became an important skill that managers and leaders had to develop. Remember that as recently as 2002 – less than half of the 13,800 treatment programs even had a computer. Now more have the computer but do not have standard information and do not know what thresholds on which variables are important in making decisions. Also they are only now getting used to trying a strategy, collecting pertinent data on that strategy for a pre-agreed time – and then re-considering the strategy. Our research group has begun to consult with mavens in other industries where there is demand for standard services in a tight budget with a workforce that is turning over rapidly and does not have a lot of training. We have turned to the fast food industry, the hotel industry and the car rental industry to learn how they collect relevant decision-critical information, how they present that information to decision makers, and how they teach mid level managers to use the information to make and re-consider decisions. This work is just not getting started but we can make our findings known as we go.

4. Should there be a collection of evaluation data from private providers?

The 13,800 providers in the nation are predominantly (about 70%) non-profit organizations that have predominantly (about 60 – 80%) public contracts. Almost all of the rest also have a mixture of public and private paying clients. The point is that I do not think the government has to REQUIRE anything from the few private providers. The government(s) (here I mean federal, state, county – health, justice, welfare) have such a large share of the business that their actions will essentially create the standards for the industry. Again – without any requirements – SAMHSA could simply add 1% bonus to the state block grants for any state that chose to collect data in a standard way – and report it in a timely way – on their seven domains. By the way, this would

save SAMHSA a great deal of money in terms of the time and labor necessary to process the state block grants. Once again, lack of standardized, relevant data delivered in a timely manner leads to significant delays and additional work for them and for states. Some leadership without coercion is needed here for the good of the whole industry.

5. Some patients receive treatment from large programs; private providers treat others in clinical settings. What are some of the challenges in drawing a distinction in measuring the effectiveness in private treatment? If so, what is it?

While I repeat that I do not think there is a real distinction between public and private treatment PROGRAMS (because of so many types of government funding even in private programs) – there is a very significant difference between what goes on in programs and what goes on in office-based private practice settings. There are many reasons for this. First, private practices are usually not inspected and some are not even licensed (other than through a professional society credential). There is tremendous range in background characteristics among those who practice office based addiction treatment. Look in your local phone book – you will see about 20 treatment programs and about 150 "addiction therapists." These individuals can be physicicans, psychologists, clergy, counselors, social workers, native healers, crystal therapists (no kidding), acupuncturists, etc. I think it is beyond the scope of this committee to get into this but it is a big problem because the are not regulated in very many ways. Leave it alone for now.

6. Mr. O'Keeffe testified that Federal policy is not optimal for the development and deployment of new treatments. What policy changes do you think would encourage that development?

The Drug Abuse Treatment Act (DATA) has lifted many annoying and unnecessary restrictions on access to new treatments and medications such as Buprenorphine. One unfortunate provision of that act (designed to limit some unscrupulous physicians from essentially selling Buprenorphine in an unregulated way) was to limit caseloads to 30 persons/patients. There is some limited abuse potential for Buprenorphine (not near that of methadone or of course street opiates) so it is not necessarily a bad idea to have some limits on patient numbers - <u>when applied to individual physicians</u> . However, the unintended consequence has been that it has also been applied to treatment <u>institutions or programs</u>. Thus, the addiction treatment section of the University of Pennsylvania (where I work) has over 30 physicians in a large clinical setting – we are only able to treat a total of 30 patients with Buprenorphine. If the restriction were simply broadened to each physician instead of treatment organizations it would be possible to expand access to this proven effective medication while assuring the public of some protections.

7. How do you patients in denial into treatment?

Not sure what is meant here but I guess it means what proven things can be done to overcome a patient's inherent unwillingness to believe they have lost control of their behavior and that they have a problem. By the way, this is one of the biggest problems facing the treatment of diabetes and hypertension – patients are unwilling to believe they have an illness or that they need to change their lives to accommodate to it. Anyway, there are proven therapies now (Motivational Enhancement Treatment) that can change a person in denial into one that recognizes there is a problem and wants to change it. This is one of the newer evidence based treatments.

8. What perspectives do people in recovery bring to identifying treatment effectiveness?

There are two perspectives they bring that are important and under recognized by providers and evaluators (in my opinion). First, unlike many in public policy those in recovery do not attribute all "substance related problems" to substance abuse – and conversely, they know that abstinence by itself is not adequate to resolve the other important problems that bother society. They have a "recovery" perspective in which abstinence in a necessary but not sufficient step toward the overall goal of employment, responsible living, productivity and happiness. This recovery is operationally defined by good scores on the seven domains of function.

Second, recovering people do not speak of themselves as having "recovered" they say they are in recovery. This is because they are aware that they are not cured – in the sense that they still retain a vulnerability to relapse and they cannot go back to normal drinking or casual drug use. In turn, because they are aware of this continued vulnerability they typically continue in treatment or in activities (AA, church, health clubs, social services, etc.) that are inconsistent with drug and alcohol involvement. One problem with contemporary treatments of all types is that they are time limited and designed only to address the acute problems of addiction (health and withdrawal and emotional instability) These are not adequate for a true recovery and this short term, acute care view is a contributor to relapse.