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TREATING ADDICTION AS A DISEASE: THE PROMISE OF MEDICATION-ASSISTED RECOVERY

HEARING

BEFORE THE

SUBCOMMITTEE ON DOMESTIC POLICY

OF THE

COMMITTEE ON OVERSIGHT AND GOVERNMENT REFORM

HOUSE OF REPRESENTATIVES

ONE HUNDRED ELEVENTH CONGRESS

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TREATING ADDICTION AS A DISEASE: THE PROMISE OF MEDICATION-ASSISTED RECOVERY

WEDNESDAY, JUNE 23, 2010

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON DOMESTIC POLICY,
COMMITTEE ON OVERSIGHT AND GOVERNMENT REFORM,
Washington, DC.

The subcommittee met, pursuant to notice, at 10 a.m., in room 2154, Rayburn House Office Building, Hon. Dennis J. Kucinich (chairman of the subcommittee) presiding.

Present: Representatives Kucinich, Cummings, Watson, Kennedy, and Jordan.

Staff present: Jaron R. Bourke, staff director; Claire Coleman and Charles Honig, counsels; Charisma Williams, staff assistant; Leneal Scott, IT specialist, full committee; John Cuaderes, minority deputy staff director; Jennifer Safavian, minority chief counsel for oversight and investigations; Adam Fromm, minority chief clerk and Member liaison; Kurt Bardella, minority press secretary; Seamus Kraft, minority director of new media and press secretary; Justin LoFranco, minority press assistant and clerk; Howard Denis, minority senior counsel; Ashley Callen and Sery Kim, minority counsels; and John Ohly and James Robertson, minority professional staff members.

Mr. KUCINICH. The committee will come to order. The Domestic Policy Subcommittee of the Committee on Oversight and Government Reform will come to order.

This hearing today will examine the scientific evidence supporting treating drug addiction as a brain disease and the development and use of medications to treat addiction and assist in recovery.

I am hopeful there will be other Members in attendance today. We are not only competing with General McChrystal today, but, even more significantly, we are competing with the World Cup.

So, without objection, the chair and ranking minority member will have 5 minutes to make opening statements, followed by openings statements, not to exceed 3 minutes, by any other Member who seeks recognition.

And, without objection, Members and witnesses may have 5 legislative days to submit a written statement or extraneous materials for the record.

In its 2006 legislation authorizing the Office of National Drug Control Policy, Congress specified two main policy goals: one, re-

ducing illicit drug consumption; and, two, reducing the consequences of illicit drug use in the United States.

But a neutral observer would have to conclude that this country's efforts to reduce drug consumption have largely failed. Rates of overall drug use have held steady, and so have the numbers of persons dependent on drugs and alcohol, a total of about 22 million people. It is estimated that 20 million people needed treatment for addiction in 2008 and did not receive it.

U.S. demand for drugs fuels an international illicit drug industry. It is estimated that 70 to 80 percent of the demand for certain highly addictive drugs is created by just 20 to 30 percent of users.

While we have spent billions of dollars a year trying to eradicate and intercept such drugs from coming to meet U.S. demands, the same cannot by said about our national efforts to curb demand where it begins, with the biological basis for addiction. Instead, untreated drug and alcohol addiction overburdens our health care system, and clogs our criminal justice system with people who should be in treatment, not behind bars.

As Dr. Nora Volkow of the National Institute on Drug Abuse will explain today, scientific research definitively shows that addiction is a treatable medical condition. Like people with any other medical condition, drug-addicted individuals need to have access to medications to treat the disease. By relieving withdrawal systems and reducing cravings, medicines have proven effective in helping individuals start and remain in behavioral therapy and achieve long-term recovery.

We will hear from several witnesses today on how medications help addicts to disengage from drug-seeking and related criminal behavior and become more productive members of society. Developing and using effective medications to treat addiction could make as big a difference in the individual lives of addicts as their widespread use could make in national drug control policy.

The Obama administration and the Office of National Drug Control Policy, under Director Kerlikowske and Deputy Director Tom McLellan's leadership, have taken a big step forward in U.S. drug policy by advocating for treating drug abuse as a public health issue. The 2010 National Drug Control Strategy supports the development of medications to treat addiction and recognizes that the effectiveness of addiction treatment has been hampered by the limited range of available medications relative to other chronic medical disorders.

Indeed, while the work of the NIDA has brought important advances in medication development this decade, including medications to treat opiate addiction and alcoholism, much work remains to develop and bring more addiction medications to market. The number of medications available for treating addiction is far fewer than other chronic illnesses. Currently, there are no approved medications to treat cocaine or methamphetamine addiction, despite promising new discoveries in clinical trial data.

While the scientific knowledge exists, it has not been translated in new medications. NIDA's budget, just over $1 billion and a small fraction of the national drug control budget, is simply too small to do this work alone. NIDA needs more support from the Federal

Government and the partnership of private industry to make progress.

But developing medications for addiction treatment is currently of little interest to the pharmaceutical industry. We will hear today from one former and one current pharmaceutical executive whose companies successfully partnered with NIDA to develop drugs to treat opiate addiction and alcoholism. They will address some of the market barriers private industry perceives to developing these medications and how the government can incentivize private industry to develop medications for drug abuse and addiction.

I hope today's hearing will shed some light on the importance of treating addiction as a medical illness worthy of medications and how we can support NIDA and private industry in order to make possible the research and development of medications which could transform the way we treat addiction.

Thank you very much.

And now I recognize the ranking member of the subcommittee, Mr. Jordan of Ohio.

Thank you for being here, sir.

[The prepared statement of Hon. Dennis J. Kucinich follows:]

Opening Statement
Dennis Kucinich, Chairman
Domestic Policy Subcommittee
Oversight and Government Reform Committee
"Treating Addiction as a Disease:
The Promise of Medication Assisted Recovery."
June 23, 2010
2154 Rayburn HOB
10:00 A.M.

In its 2006 legislation authorizing the Office of National Drug Control Policy (ONDCP), Congress specified two main policy goals: (1) reducing illicit drug consumption, and (2) reducing the consequences of illicit drug use in the United States. But a neutral observer would have to conclude that this country's efforts to reduce drug consumption have largely failed: rates of overall drug use have held steady, and so have the numbers of persons dependent on drugs and alcohol -- a total of about 22 million people. It is estimated that 20 million people needed treatment for addiction in 2008 and did not receive it.

U.S. demand for drugs fuels an international illicit drug industry. It is estimated that 70-80 percent of the demand for certain highly addictive drugs is created by just 20-30 percent of users. While we have spent billions of dollars a year trying to eradicate and intercept such drugs from coming to meet U.S. demand, the same cannot be said about our national efforts to curb demand where it begins – with the biological basis of addiction. Instead, untreated drug and alcohol addiction overburdens our healthcare system and clogs our criminal justice system with people who should be in treatment, not behind bars.

As Dr. Nora Volkow of the National Institute on Drug Abuse will explain today, scientific research definitively shows that addiction is a treatable medical condition. Like people with any other medical condition, drug addicted individuals need to have access to medications to treat the disease. By relieving withdrawal symptoms and reducing cravings, medicines have proven effective in helping individuals start and remain in behavioral therapy and achieve long-term recovery. We will hear from several witnesses today on how medications help addicts disengage from drug seeking and related criminal behavior and become more productive members of society.

Developing and using effective medications to treat addiction could make as big a difference in the individual lives of addicts as their widespread use could make in national drug control policy. The Obama Administration, and the Office of National Drug Control Policy under Director Kerlikowske and Deputy Director Tom McLellan's leadership, have taken a big step forward in US drug policy by advocating for treating drug abuse as a public health issue. The 2010 National Drug Control Strategy supports the development of medications to treat addiction and recognizes that the effectiveness of addiction treatment has been hampered by the limited range of available medications relative to other chronic medical disorders.

Indeed, while the work of NIDA has brought important advances in medications development this decade – including medications to treat opiate addiction and alcoholism – much work remains to develop and bring more addiction medications to market. The number of medications available for treating addiction is far fewer than for other chronic illnesses. Currently there are no approved medications to treat cocaine or methamphetamine addiction, despite promising new discoveries and clinical trial data. While the scientific knowledge exists, it has not yet been translated into new medications. NIDA's budget – just over $1 billion and a small fraction of the national drug control budget – is simply too small to do this work alone. NIDA needs more support from the federal government and the partnership of private industry to make progress.

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I hope today's hearing will shed some light on the importance of treating addiction as a medical illness worthy of medications, and how we can support NIDA and private industry in order to make possible the research and development of medications which could transform the way we treat addiction.

Mr. JORDAN. Thank you, Mr. Chairman. Thank you for this hearing.

From stronger enforcement of drug laws to treating those addicted to drugs, this country's commitment to fight the war on drugs is important and has taken on multiple forms. I applaud all the work and the efforts being made by those who are engaged in this struggle, particularly the individuals and families who struggle to combat addiction. It is the plight of these individuals which brings us here today to raise awareness of a new approach to fighting the war on drugs.

Historically, this country has treated drug addiction through behavior modifications—for instance, through counseling. Gradually, through research grants issued by the NIH, scientists have found drug addiction may be a result of brain disease and not solely a result of behavior—a condition which can be treated through medication.

As science changes our understanding about why people use drugs, the Federal Government needs to be careful not to endorse just one form of treatment over another but, instead, support individual choices in the type of treatment that is most beneficial, because, just as we learned this week, sometimes the drugs used to treat the addicted become another form of addiction.

On Monday, the CDC issued a report which found prescription drugs have overtaken illicit drug use as the number-one reason for overdose. Troublingly, the top three prescription drugs being abused—methadone is one of the most popular drugs used to treat drug addiction.

However we treat addiction, we must have a strong partnership with the private sector.

Mr. Chairman, I want to thank you for, again, holding this hearing. And I yield back the balance of my time.

Mr. KUCINICH. And I thank the gentleman for the points you just raised.

I want to start by introducing our first panel.

A. Thomas McLellan, Ph.D., is currently deputy director of the White House Office of National Drug Control Policy. As deputy director, Dr. McLellan serves as the primary advisor to the director on a broad range of drug control issues and assists in the formulation and implementation of the President's National Drug Control Strategy.

Dr. McLellan brings 35 years of addiction treatment research to the position, most recently at the Treatment Research Institute, a nonprofit organization that he cofounded in 1992 to transform the way science is used to understand substance abuse.

Dr. McLellan's contributions to the advancement of substance abuse research and the application of these findings to treatment systems and public policy have changed the landscape of addiction science and improved the lives of countless Americans and their families.

Dr. Nora Volkow, MD, is the Director of the National Institute on Drug Abuse [NIDA] at the National Institutes of Health, a position she has held since May 2003.

As a research psychiatrist and scientist, Dr. Volkow pioneered the use of brain imaging to investigate the toxic effects of drugs

and their addictive properties. Her work has been instrumental in demonstrating that drug addiction is a disease of the human brain.

Dr. Volkow has published more than 445 peer-reviewed articles and more than 60 book chapters. During her professional career, she was named recipient of multiple awards and was recently named one of Time magazine's "Top 100 People Who Shape Our World."

Dr. McLellan, Dr. Volkow, thank you for appearing before the subcommittee.

It is the policy of the Committee on Oversight and Government Reform to swear in all witnesses before they testify. I would ask that you rise and raise your right hands.

[Witnesses sworn.]

Mr. KUCINICH. Thank you.

Let the record reflect that both of the witnesses answered in the affirmative.

I would ask Dr. McLellan to begin and give a brief summary of your testimony.

Doctor, I would ask that you keep the testimony to under 5 minutes, 5 minutes at most, in length. Your entire statement is going to be included in the record, and it is much appreciated.

I would like to you begin right now, and then we will go to Dr. Volkow. Thank you, sir.

STATEMENTS OF A. THOMAS McLELLAN, PH.D., DEPUTY DIRECTOR, OFFICE OF NATIONAL DRUG CONTROL POLICY; AND NORA D. VOLKOW, M.D., DIRECTOR, NATIONAL INSTITUTE ON DRUG ABUSE

STATEMENT OF THOMAS McLELLAN

Mr. MCLELLAN. Chairman Kucinich, Ranking Member Jordan, distinguished members of the subcommittee, thank you for this opportunity to appear before you today, and I commend you for your attention to these critical public health issues that have been ignored for far too long.

I will begin with some definitions and facts about substance use derived from well-established science. This science will introduce what we think is a smarter way to address the Nation's drug problems, including expanded use of approved medications through our 2010 National Drug Control Strategy.

Now, in this hearing, I will use the term "substance" to mean alcohol; street drugs, such as heroin, cocaine, marijuana, and inhalants; but also pharmaceutical drugs, such as opiates, sedatives, or stimulants that have not been used as prescribed.

Now, approximately 23 million Americans suffer from either substance abuse or dependence which threatens their health, productivity, and relationships, ultimately eroding inhibitory control, turning drug-seeking into a compulsion, and erasing motivation for normally pleasurable human relationships.

Thanks to NIDA research, we now know that this is a biological process, characterized by progressive and long-lasting perturbations in the reward, motivation, attention, and inhibitory structures of the brain. In turn, we know the genetic heritability is a

significant factor in determining who among those who use go on to ultimately become addicted.

So, while we do not have a cure for addictions, we can manage these illnesses with the same favorable results obtained in chronic asthma, hypertension, or diabetes. And I think that's important. Specifically, we now have several FDA-approved medications for the treatment of alcohol and opiate addiction. In addition, we have very promising early results from clinical trials of other medications and of cocaine vaccines that could markedly reduce relapse.

But it is also a sad fact that the current addiction treatment system can barely incorporate even the already-approved medications. The reasons for this are both conceptual and historical. When the original addiction treatment system was developed about 40 years ago, addiction was not considered a medical illness, and, thus, addiction treatment was purposely segregated from the rest of medical care into then newly designed specialty treatment system, the so-called rehab programs.

In 2007, there were about 13,600 addiction treatment programs, treating over 2 million individuals at a budget of about $21 billion, the great majority of which were public funds. Recent data indicate that less than 1 percent of these funds go toward medication-assisted therapies.

Today, very few medical, nursing, or pharmacy schools provide even basic training in addiction treatment. Thus, only about half of contemporary addiction treatment programs employ even a part-time physician and less than 15 percent employ a nurse. Very few programs have a formulary, a proper electronic health record, or even an affiliation with a medical center. These are the minimum requirements one needs for effective medical management with pharmaceuticals.

Functionally, this means that physicians rarely make referrals or play a proper role in continuing care of recovering patients, as is so often the case with other illnesses. This is different from the rest of health care, and it is wrong.

Thus, the National Drug Control Strategy will not just upgrade the existing specialty care system, though that is very important; it calls for unprecedented expansion of training for health care professionals, as well as integration of early intervention and medication-assisted treatments in the approximately 7,000 HRSA-funded, federally qualified health centers and in Indian Health Service clinics. These two Federal systems treat about 22 million patients already and will provide an opportunity to properly implement medication-assisted treatments.

I hope these introductory remarks provide a context for how we plan to expand medication-assisted treatment within the President's 2010 Drug Control Strategy.

I have to say at a personal level that, for the first time in my 35-year career, we finally have effective interventions to prevent addiction before it starts, to arrest emerging cases of substance use, and to treat even serious cases of chronic addiction. We believe our strategy gives us a chance to use these interventions properly.

Thank you again for the opportunity to testify. I also ask that you include my full written statement into the hearing record. And I am happy to answer any of your questions.

[The prepared statement of Mr. McLellan follows:]

EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF NATIONAL DRUG CONTROL POLICY
Washington, D.C. 20503

"Treating Addiction as a Disease: The Promise of Medication Assisted Recovery"

House Committee on Oversight and Government Reform
Subcommittee on Domestic Policy

June 23, 2010
10:00 a.m.
2154 Rayburn House Office Building

Written Statement
of
Dr. A. Thomas McLellan
Deputy Director
Office of National Drug Control Policy

House Oversight and Government Reform Committee
Domestic Policy Subcommittee
June 23, 2010

Written Statement of Dr. A. Thomas McLellan
Deputy Director, Office of National Drug Control Policy

I. INTRODUCTION

Chairman Kucinich, Ranking Member Jordan, distinguished members of the Subcommittee, thank you for providing me with the opportunity to appear before you today to discuss medication-assisted therapies for substance use disorders. These medicines can drastically improve the way addiction is treated, and offer hope to the approximately 23 million Americans who need treatment. The Obama Administration recently released its inaugural *National Drug Control Strategy*. This balanced and comprehensive *Strategy* recognizes that prevention, treatment, and enforcement are all essential components of an effective approach to addressing drug use and its consequences. The *2010 National Drug Control Strategy* is the result of a thorough consultative effort with Congress, Federal agencies, State and local partners, and hundreds of individuals across the country. It serves as a bold call to action for all Americans who share in the desire and the responsibility to keep our citizens - especially our youth - safe, healthy, and protected from the consequences of substance abuse.

The *Strategy* sets specific goals by which we will measure our progress. Over the next five years, working with dozens of agencies, departments, Members of Congress, State and local organizations, and the American people, we intend to make significant reductions in illicit drug use and its consequences and costs. Our efforts are balanced, incorporating science and strategies to better align policy with the realities of drug use in communities throughout this country.

While medication-assisted therapies are the topic of this hearing, no discussion of treatment for substance use disorders is possible without a brief conversation of what steps can be taken to prevent individuals from reaching the point of addiction.

Studies indicate that most healthcare spending related to substance abuse goes to the avoidable, catastrophic consequences of addiction, rather than to its treatment. For this reason, the *Strategy* has placed an emphasis on prevention. Furthermore, if care providers consistently screen and intervene with early-stage substance abuse, the healthcare system can avert enormous human and economic costs.

Therefore, the *Strategy* – in concert with the recently passed Affordable Care Act - focuses on prevention in a number of ways:

- Increasing screening and early intervention for substance use in all healthcare settings;
- Increasing healthcare providers' knowledge and use of screening and brief intervention techniques through enhanced medical and nursing school educational programs;

- Increased reimbursement for screening and brief interventions in primary care;
- Increasing healthcare providers' knowledge and use of prescription drug monitoring programs as a patient care tool; along with curbing prescription drug diversion and abuse by expanding prescription drug monitoring programs, encouraging community prescription take-back initiatives, informing the public of the risks of prescription drug abuse and overdose, recommending disposal methods to remove unused medications from the home, and working with physicians to achieve uniform standards on opiate painkiller prescribing.

These steps will greatly reduce the public health threat posed by substance use disorders.

II. SCOPE OF THE PROBLEM

It is presently not known how, when, or why frequent or heavy use of a substance turns into addiction, but research continues on this fundamental aspect of the disease process. Importantly, we do know that once use becomes addiction, it is likely to be a chronic, complex, biological, and psychological illness that demands – but also responds to – the same types of therapies, interventions, and medications that are effective in managing other chronic illnesses.

With the passage of the Affordable Care Act, many more individuals will get medical help early, and, if indicated, be eligible for existing medications. This will not create additional expense to the healthcare system. Instead, it will be the opposite, because undiagnosed addiction and problem use is over-represented in every existing healthcare setting. Furthermore, these individuals use significantly disproportionate amounts of the most expensive healthcare services. Because of this, the expanded coverage will likely save precious healthcare dollars and improve the general quality of mainstream healthcare.

For approximately 23 million Americans, substance use progresses to the point that they require treatment. This is roughly the same number of American adults who suffer from diabetes. In the U.S., the only disease that affects more people is heart disease. Particularly problematic is the fact that of these 23 million, only 10 percent receive any type of formal treatment for their disorders. This represents the lowest treatment penetration rate of any illness.[1] For addicted individuals and their families, modern treatment can be a critical, even lifesaving resource, but only if it is readily available and of high quality. Unfortunately, the effectiveness of addiction treatment has been hampered by the limited range of available FDA-approved medications relative to other chronic medical disorders.

Even though there is compelling evidence that medication-assisted therapies are effective in treating nicotine, alcohol, and opiate addiction, as well as promising evidence for cocaine addiction, there are a number of obstacles that have hindered their application in clinical practice. Of particular concern is the state of our Nation's drug treatment system. Only 23 percent of facilities with a substance abuse treatment focus had 120 or more clients in treatment, while 17 percent had fewer than 15 clients in treatment. Most of these programs are small, not-for-profit organizations. Unlike treatment for any other illness, the great majority of drug abuse treatment in this country has been provided by specialty sector programs funded primarily through the

[1] Results from the 2008 National Survey on Drug Use and Health: National Findings, Substance Abuse and Mental Health Services Administration (SAMHSA), 2008, http://www.oas.samhsa.gov/nsduh/2k8nsduh/2k8Results.cfm

Substance Abuse and Mental Health Services Administration's (SAMHSA's) Substance Abuse Prevention and Treatment Block Grant Program, the Department of Veterans Affairs, Medicaid, private medical insurance, and other sources.

The most recent data available on the topic of staffing and training of personnel employed by specialty care treatment programs are from SAMHSA's 2003 The National Survey on Substance Abuse Treatment Services. Even though there has not been a similar study conducted since then, there is no indication that the staffing situation has changed significantly. The data revealed that only 54 percent of the programs had even a part-time physician on staff. Outside of methadone programs, less than 15 percent of programs employed a nurse. Social workers and psychologists were rarely mentioned. Substance abuse counselors are the major professional group employed at these specialty care facilities. While counselors play an important role in assisting people in overcoming addiction, persons suffering from substance abuse disorders need and benefit from the types of additional professional healthcare services that are routinely available to persons with other diseases. The large number of specialty care facilities that do not have affiliated physicians and nurses cannot write and administer prescriptions.

Staff turnover is yet another area of concern for many specialty care facilities. Among counselors, in 2003, the turnover rate was roughly 40 to 50 percent per year. And only 50 percent of facilities' directors have been at their current facility for more than one year. Such high turnover hinders the effectiveness of specialty care facilities, and denies patients with the chronic illness of addiction the continuity, structure, and direction they need to get and stay well. For these reasons, the FY 2011 Budget includes additional funding for the integration of behavioral health services (which includes addiction services) into two federally supported mainstream health systems (Health Resources and Services Administration's Health Centers and Indian Health Service-funded facilities). The Veterans Health Administration model is for services to be co-located or linked with other important services (e.g., mental health, infectious disease management, primary care), medical staff is well-trained in substance use disorders services, and patient information is coordinated among all of the patient's healthcare providers.

The *Strategy* also addresses improving quality in the existing specialty care system by promulgating the National Quality Forum Standards for Addiction Treatment through key agencies to promote: 1) the adoption of the full set of practices in the private and public sectors; 2) policy development, including alignment of payment/reimbursement and coverage and legal and regulatory policies; 3) development and implementation of measures based on each of the standards, their specification, and target outcomes; and 4) continuing research to improve standards so they do not become static.

III. EFFECTIVE TREATMENTS ARE AVAILABLE BUT NOT USED

Advances in neuroscience research are identifying promising directions for medication development. New medications include those that help in the acute management of withdrawal symptoms and those that reduce cravings for drugs on an ongoing basis. Recent scientific work has also indicated another particularly promising line of medication development: vaccines that block the ability of consumed drugs to reach the brain, thereby reducing their reinforcing power.

While these vaccines have different mechanisms of action, the clinical effect is to produce a competitive blockade of the euphoric and other effects of the target drug. This prevents the

addict from achieving the sought-after euphoric effect from the harmful drug and makes use futile for periods of about three months. Research continues in this very promising area, and we are committed to working with HHS's Food and Drug Administration (FDA), as permissible and when submitted, to encourage manufacturers to pursue medication development for patients with substance abuse.

While vaccines are still in development, there are already a number of FDA-approved medications that effectively treat addiction. One example is methadone, which is the oldest approved medication to treat opioid addiction. Methadone is an "agonist," which means it activates opioid receptors in the brain. It is orally administered, and a proper dosage of methadone will either block, or greatly reduce, cravings for illicit opioids, such as heroin, for 24 to 30 hours, while minimizing euphoric feelings. Methadone can be prescribed by any physician for the treatment of pain, but it can only be given for addiction treatment in State-licensed dispensing programs. It is therefore unique for its segregated and restricted dispensing mode.

Because opioid-dependent patients are among the most severely addicted, and because the current restrictions on prescribing methadone require them to be treated in segregated programs, methadone programs have always been controversial. However, hundreds of research studies have shown that methadone can be extremely effective in reducing craving for and use of opiates, particularly when the medication is provided in association with individual and/or group counseling, as well as other needed medical, psychological, and social services.

Buprenorphine is the newest medication available to treat opioid addiction. Buprenorphine is an orally administered "opioid partial agonist," which means it activates the opioid receptors in the brain, but to a much lesser degree than a full agonist, like methadone. The partial agonist nature of this medication confers many advantages over full agonist medications. First, it is less likely to cause an overdose. Also, it is not associated with the same level of withdrawal as a full agonist medication and patients may stop taking and experience less intense withdrawal symptoms. For these reasons, it has been possible to allow buprenorphine to be prescribed by trained physicians (e.g. an eight-hour course) in general medical settings such as primary care offices. This has resulted in broader access to care for opiate addicted patients.

Naltrexone is an orally administered "opioid antagonist," meaning that it attaches to the opioid receptors in the brain without activating them; and once administered, the medication prevents opioid drugs from having any effects. In short, it is an opioid repellant: once stabilized on naltrexone, a patient will not be able to feel the euphoric effects of any opioid (e.g. heroin, OxyContin ®, etc.). Naltrexone is best administered as a maintenance medication, two to three times per week for at least several months, combined with individual counseling and medical support services.

Naltrexone is also FDA-approved for use in the treatment of alcohol dependence. Alcohol-dependent patients maintained on naltrexone experience reduced craving for alcohol. If these patients do drink alcohol, the effects of the drink are blunted, usually leading to substantially reduced use. A long-acting formulation of naltrexone (a slow release injection) has been shown to be continuously effective in blocking alcohol effects for up to 30 days. In addition to naltrexone, there are two other medications that have been approved by the FDA: Acamprosate and Disulfiram. Acomprosate works by blocking craving and the withdrawal symptoms

associated with heavy drinking, while disulfiram causes aversive effects when drinking. There are also new medications, topiramate and ondansetron, currently under investigation. HHS's National Institute on Drug Abuse and National Institute on Alcohol Abuse and Alcoholism will continue their efforts to support medication development research and, in partnership with ONDCP, identify ways to increase private sector investment in addiction medication development.

It should be noted that, while all the medications described here are effective, effectiveness is magnified when the medications are provided in the context of proven behavioral therapies that are designed to increase patient motivation, recognize and deal with craving situations, and handle emotional and relationship issues that are so often a contributor to relapse. The most effective method of treating substance use disorders requires a holistic approach that incorporates both pharmacological and behavioral treatments. Medications, when combined with evidence-based behavioral therapies selected to best meet an individual's needs, create the optimal approach to treat persons with substance use disorders. Examples of evidence-based behavioral therapies include:

- Cognitive Behavioral Therapy;
- Motivational Enhancement Therapy;
- Community Reinforcement and Family Training;
- Behavioral Couples Therapy;
- Multi Systemic Family Therapy;
- 12-Step Facilitation; and
- Individual Drug Counseling.

In order to foster this more comprehensive approach, the *Strategy* focuses on:

- Expanding addiction treatment in community health centers and within the Indian Health Service;
- Supporting the development of new medications to treat addiction and implementation of medication-assisted treatment protocols;
- Improving the quality and evidence base of substance abuse treatment, including family-based treatment; and
- Fostering the expansion of community-based recovery support programs, including recovery schools, peer-led programs, mutual help groups, and recovery support centers.

Incorporating medication-assisted treatment into criminal justice settings is also important because substance abuse is one of the greatest predictors for incarceration. Nearly two-thirds of the inmate population in the U.S. meets medical criteria for an alcohol or other substance abuse disorder. In fact, prison and jail inmates are seven times more likely to have a substance-abuse disorder than the general population. To address this issue, the Department of Justice has introduced financial incentives, via grant programs, for criminal justice entities to integrate medication-assisted treatment into criminal justice diversion programs such as drug courts, as well as treatment programs in correctional facilities.

IV. HEALTH CARE REFORM WILL IMPROVE THE SITUATION

The recent healthcare legislation should improve coverage for, and access to, services for substance abuse disorders in the same primary care settings as now services all other illnesses. As noted, only about 10 percent of persons in need of treatment received care at a specialty treatment center. Many of those who do not receive care do not have health insurance or other means to pay for it. By helping more people get the help they need, the new law will go a long way toward closing the "treatment gap" and helping people on the road to recovery.

Features of the healthcare law that will benefit those in need of treatment for substance use problems include:

- Broader Coverage for Americans with Substance Use Disorders
  - Three million (16.3%) full-time workers without health insurance needed substance abuse treatment in the past year, particularly among 18-25 year olds (24.4%) and males (19.2%). Many of these Americans will receive insurance coverage that will help pay for substance abuse treatment.
  - Along with other steps the Administration is taking – such as proposing a $44.9 million increase in Fiscal Year 2011 funding to expand, improve, and integrate addiction treatment into Federally supported healthcare systems – this broader coverage could double the number of people who receive treatment.
  - With improved coverage for Screening, Brief Intervention, Referral, and Treatment (SBIRT) in primary care, more Americans will be screened for substance use problems and diverted from the path to substance dependence.

- No Denial of Coverage for Pre-Existing Conditions
  - Insurers will no longer be able to deny coverage based on pre-existing medical conditions, such as substance use disorders.

- Plans Must Cover Substance Use Disorders
  - The law requires a basic benefit package for all health plans in the individual and small group health exchanges.
  - All such plans will be required to cover mental health and substance use disorder services and to ensure benefits meet the "parity" requirements of the Wellstone-Domenici Mental Health Parity Act of 2008. (The Act prohibits plans from covering mental health and substance use disorders at a level lower than their coverage for other illnesses.)

- Greater Access to Treatment through Medicaid
  - In 2014, Medicaid eligibility will be expanded for families or individuals with incomes up to 133 percent of Federal poverty guidelines.
  - Many newly eligible beneficiaries will receive substance abuse and mental health services.
  - Participation in Medicaid will help more patients gain access to traditional healthcare benefits, such as medications and behavioral therapies in the treatment of addiction.

- Extended Coverage Under Parents' Health Plans
  - Young people up to age 26 – a population with a significant incidence of substance use disorders – who do not have their own health insurance, can obtain coverage under their parents' plans. Previously, health insurance for dependents in many States ended at age 19 or upon graduation from college.

- Substance Use Disorders Listed as Priority
  - ACA establishes a National Prevention Council, led by the Surgeon General, with substance use disorders as a national priority for the Council's report to Congress. The Director of the Office of National Drug Control Policy will serve as a member of the Council.
  - Mental health and behavioral health are listed as high priority area in the law's National Workforce Commission section.
  - The healthcare reform package is complemented by the Administration's FY 2011 Budget proposal, which seeks to increase funding by $7.2 million to train and engage primary healthcare providers to intervene in emerging cases of drug use.

Furthermore, the healthcare reform package is complemented by the American Recovery and Reinvestment Act (ARRA) of 2009, which appropriated $1.1 billion to HHS for comparative effectiveness research (CER), with $400 million of that funding allocated to the National Institutes of Health, $300 million to the Agency for Healthcare Research and Quality (AHRQ), and $400 million to the HHS Office of the Secretary.

VI. CONCLUSION

The development of medication-assisted therapies is expanding the clinical interventions available to better assist the millions of Americans with substance abuse problems. As reflected in the *National Drug Control Strategy*, the Administration is committed to expanding the use of effective medication-assisted therapies and the development of skilled professionals who are trained and qualified to administer comprehensive treatment programs that utilize behavior therapies, as well as, when appropriate, medication-assisted approaches. Thank you very much for the opportunity to testify and for the support of the Committee on this vital issue.

Mr. KUCINICH. Thank you very much, Dr. McLellan.

Dr. Volkow, you may proceed.

STATEMENT OF NORA D. VOLKOW

Dr. VOLKOW. Good morning, Mr. Chairman and members of the subcommittee. I am very appreciative, as director of the National Institute on Drug Abuse, to have——

Mr. KUCINICH. Dr. Volkow, could you pull that mic a little bit——

Dr. VOLKOW. Yes, certainly. I apologize.

Mr. KUCINICH. No, no, don't apologize.

I am going to ask staff that, at the beginning, before we start these hearings, just familiarize the witnesses with the mics. Thank you very much.

You may proceed.

Dr. VOLKOW. I apologize, because she did.

Mr. KUCINICH. No, please.

Dr. VOLKOW. My mistake.

Mr. KUCINICH. Go ahead.

Dr. VOLKOW. I do want to thank you for the opportunity to bring to you the opportunities and roadblocks that have come across in the development of medications for the treatment of drug addiction.

Drug addiction, as you all recognize, has a massive impact in our country. Just from nicotine addiction itself, we can account for 400,000 deaths every year. The economic costs are gigantic, half a trillion dollars, and that does not count the individual losses, as well as family and society of those involved with drugs.

Science has told us that drug addiction is a disease of the brain, that it is genetically determined, that the changes in the brain remain sometimes years after drug discontinuation, that it affects fundamental areas of the brain that enable us, for example, to exert control over our desires and emotion, which explains why a person that is addicted will compulsively take the drug despite catastrophic consequences to that person and their family.

However, from this knowledge, we have also learned that there are specific targets that we can now manipulate through compounds that, if properly translated into medications, could transform the way we treat drug addiction and have the potential also of transforming the way we prevent it.

I am going to just cite three examples to give you a perspective of how exciting the field is.

No. 1, addiction vaccines. There is data now currently that vaccines that are targeted toward specific drugs can be developed to generate antibodies that will neutralize the drug while it is in the blood, preventing its entrance in the brain.

An example is a vaccine, currently in phase three, developed for nicotine addiction, which has been shown to dramatically reduce nicotine consumption, either to complete abstinence or to reduce the amount of cigarettes utilized. Similar efforts are being done with cocaine vaccine and for a heroin vaccine.

Second one relates to a transformation in the way that medications are being delivered. An example is a medication, Naltrexone, which actually completely interferes with the effects of opiate drugs, like heroin or pain medications, to get into the receptors in

the brain. It has not been shown to be effective in heroin addiction because the patients just stop taking it. Now new methodologies have enabled to provide it in a doubled formulation that lasts 4 weeks. And preliminary results have shown that it dramatically reduces heroin consumption, 90 percent; that it dramatically increases retention in treatment, 75 percent; and it decreases craving by 50 percent.

The third example has to do with combinations of medications that may have been developed for other purposes. This strategy has been shown to be very effective in the treatment of many medical diseases, including cancer and HIV. And preliminary studies have proven its efficacy in the treatment of cocaine addiction and marijuana addiction, for which there are no FDA-approved medications.

However, as exciting as these discoveries and strategies may be, there are serious obstacles that threaten to put the brakes on their development. One of them is the exorbitant cost to bring a medication into the clinic. It's estimated to be approximately $2 billion for bringing one medication into the clinic.

Now, most of those costs are borne by the pharmaceutical industry for most of the medical illnesses in combination and in partnerships with the NIH. And this has been very successful. Just let's look at HIV. Since 1983, there have been 30 approved medications for the treatment of HIV that were possible because of the massive investment by pharmaceutical industry. Now let's contrast that with the number of medications that we currently have approved for nicotine, which is a drug for which pharma has made the biggest investments. Three approved drugs: nicotine replacement therapies, bupropion, varenicline.

So, why is it that we have not had investment of the pharmaceutical industry in substance abuse disorders? There are many factors that have been cited. Among them is stigma, but, very importantly, major economic disincentives. It is perceived that the market for addiction is small, when, in fact, it may not be. It is also clear that many of the substance abusers, because of the devastating effects of drugs, have lost their income, their work, and many of them are not properly insured.

So how do we then revert this situation? Which is actually, by the way, made even worse by the current decision of some of the major pharma in the world to actually decrease their investments on medication development for mental illness.

Now, why would that even impact us in the drug abuse field?

Mr. KUCINICH. Doctor, I am going to ask you to conclude your testimony, and then we are definitely going to get to you with questions that I think will help bring out the rest of it.

Dr. VOLKOW. Yes.

So, what we have seen is a massive amount of development and incredible opportunities to bring medication into fruition in the way that we treat and prevent drug addiction. For us to succeed we need to create partnerships with the pharmaceutical industry.

And, with that, I want to thank you for the opportunity. And I will answer any questions that you may have.

[The prepared statement of Dr. Volkow follows:]

Testimony before the
Subcommittee on Domestic Policy
Committee on Oversight and Government Reform
United States House of Representatives

Treating Addiction as a Disease: The Promise of Medication-Assisted Recovery

Statement of
Nora D. Volkow, M.D.
Director
National Institute on Drug Abuse
National Institutes of Health
U.S. Department of Health and Human Services

For Release on Delivery
Expected at 10:00 a.m.
June 23, 2010

Mr. Chairman and Members of the Subcommittee, as the Director of the National Institute on Drug Abuse (NIDA), part of the National Institutes of Health, an agency of the Department of Health and Human Services, it is a privilege to be here with my colleagues to present NIDA's perspective on the opportunities and barriers to the development of addiction medications and their integration into substance abuse treatment.

We have a public health mandate to stop the devastating scourge of drug abuse and addiction afflicting this country, and new medications to treat addiction could go a long way to achieving this end. It is a gaping need. A recent report from HHS's Centers for Disease Control and Prevention finds that drug-induced deaths, mainly from opioid pain reliever overdose, more than tripled from 4,000 in 1999 to 13,800 in 2006.[1] And cigarettes continue to kill roughly 440,000 people each year in this country[2]—yet the quest to discover treatments for nicotine addiction lags behind the efforts to develop medications for the diseases it causes. From 1987 to 2008, 174 medications trials were done for smoking cessation (46 supported by industry), compared with 1,490 clinical trials for lung cancer treatment (544 supported by industry).[3] The possibilities present in the knowledge we have accumulated, if translated into new medications today, could transform the way we treat addiction and even how we prevent drug abuse from occurring in the first place.

Science has shown, beyond a reasonable doubt, that addiction is a disease of the brain, and that our genes contribute close to half of the risk for becoming addicted. Addiction results from profound disruptions in the function of specific neurotransmitters and brain circuits. It involves an expanding cycle of dysfunction, first in the areas of the brain that process reward, followed by alterations in:

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[1] http: www.cdc.gov nchs data/databriefs db22.pdf; http: www.msnbc.msn.com/id/33091645 ns/health-addictions

[2] http: www.cdc.gov tobacco data_statistics fact_sheets health_effects effects_cig_smoking index.htm

[3] Pollock JD, Koustova E, Hoffman A, Shurtleff D, Volkow N. Treatments for nicotine addiction should be a top priority. Lancet 374:513-514, 2009.

- complex cognitive functions, such as learning (memory, conditioning, habits);
- executive function (impulse inhibition, decision making, delayed gratification);
- cognitive awareness (interoception); and
- emotional functions (mood, stress reactivity).

These circuits work together and change with experience. Eventually, with repeated drug exposure, they become recalibrated, tilting the balance away from volitional control over one's behavior toward behaviors driven by drug cues and drug cravings. The result is compulsive drug use, despite severe health and social consequences. In fact, that is the hallmark of addiction.

New Knowledge Presents New Medications Possibilities for Drug Abuse

This knowledge and other discoveries have given us numerous molecules and circuits that could serve as the basis for new approaches to medications development. Medications that target systems common to multiple addictions (e.g., stress-induced relapse) could widen the market for addiction medications and compel greater interest from pharmaceutical companies. In fact, the current pipeline of smart pharmacotherapeutic strategies embodies the translational potential of what we now know about addiction. For example:

Addiction vaccines. Vaccination is a centuries-old strategy in which the body is coaxed into producing antibodies that neutralize disease-causing agents (e.g., viruses, parasites, toxins). The concept behind this classic form of immunotherapy has only recently been explored and shown to be viable for treating addiction. In this case, antibodies are generated to specific abused drugs to bind the drug while it is still in the bloodstream, thereby reducing its entry into the central nervous system and blocking its pharmacological/behavioral effects. This approach, applied so far against nicotine and cocaine, has shown considerable promise.[4]. NicVAX, a nicotine vaccine developed by Nabi Biopharmaceuticals, is now in Phase III clinical trials for drug approval owing in

[4]Hatsukami et al., *Pharmacodynamics and Drug Action*, 2005; Kosten, *Archives of General Psychiatry*, 2009.

part to NIDA support using American Reinvestment and Recovery Act funds. Although not yet approved by the U.S. Food and Drug Administration (FDA) for safety and efficacy, preliminary results show that smokers who achieved high antibody levels had higher rates of quitting and longer stretches of abstinence than those given placebo (18% vs. 6% *complete* abstinence after 52 weeks). The vaccine was also well tolerated, with few side effects; and it reduced craving and withdrawal symptoms, which often prompt relapse.[5]

Long Acting (Depot) Medications (e.g., Vivitrol—injectable naltrexone currently prescribed for alcoholism). Recent clinical trials of Vivitrol for opioid dependence have produced spectacular results showing this compound could be of great help in situations where opiate replacement therapy is rejected or when the patients are hard to reach, because long-acting, or depot, medications have effects that last for weeks instead of hours and therefore promote adherence. Here, too, these results are under review by the FDA, but the drug is not yet approved for safety and efficacy. However, if approved, treatment with this drug could also be more cost-effective due to decreased clinical support with fewer clinical visits.[6] A study of Vivitrol among people addicted to heroin in Russia found a median 90% rate of opioid-free urines in the group receiving the medication versus 35% among controls; a 50% reduction in opioid craving versus no change for placebo; and a 75% longer retention in treatment for Vivitrol patients versus the control group.[7] Such promising results could greatly impact the public health in Eastern Europe and Central Asia, where the intertwined epidemics of injection drug use and HIV are fueling devastating disease and societal disintegration, as well as here in the United States, particularly within the criminal justice system, where NIDA is currently studying Vivitrol's effectiveness.

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[5] Ibid.

[6] Comer, S.D., Sullivan, M.A., Yu e, Rothenberg, J.L., Kleber, H.D., Kampman, K., Dackis, C., & O'Brien, C.P. (2006). Injectable, sustained-release naltrexone for the treatment of opioid dependence – A randomized, placebo-controlled trail. *Arch Gen Psychiat: 63(2),* 210-218.

[7] Krupitsky E. American Psychiatric Association Annual Meeting, May 26, 2010, New Orleans, LA

Medication combinations have emerged as a promising strategy for treating addictions. This includes marijuana addiction, which accounts for approximately 4 million of the estimated 7 million Americans classified with dependence on or abuse of illicit drugs.[8] Withdrawal symptoms—irritability, sleeplessness, increased appetite, drug craving—often prompt relapse in those trying to quit, but the combination of lofexidine (a medication to treat hypertension, approved in the U.K.) and dronabinol (an oral form of tetrahydrocannabinol (THC), the psychoactive ingredient in marijuana) has produced robust improvements in disordered sleep patterns, plus decreased marijuana withdrawal, craving, and relapse in daily marijuana smokers.[9] Preliminary data also suggest the safety and possible efficacy of combined buprenorphine and naltrexone,[10] for the treatment of cocaine addiction. Such findings are especially important since no medications currently exist for addiction to marijuana or addiction to cocaine.

Personalized approaches. Rapid advances in the science of genetics and related technologies are ushering in the age of personalized medicine, giving physicians and patients a greater understanding of health and disease at the molecular level. The field of pharmacogenetics, which deals with the influence of genetic variation on drug response in patients by correlating genetic polymorphisms and/or gene expression with drug efficacy, is opening up new worlds in addiction medicine possibilities. For example, a genetic variation has been identified that may help predict alcoholic patients' response to naltrexone (a μ-opioid receptor blocker).[11] Specifically, a functional polymorphism of the μ-opioid receptor gene, found in about 15 to 25 percent

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[8] Substance Abuse and Mental Health Services Administration. (2009). *Results from the 2008 National Survey on Drug Use and Health: National Findings* (Office of Applied Studies, NSDUH Series H-36, HHS Publication No. SMA 09-4434). Rockville, MD.

[9] Haney M, Hart CL, Vosburg SK, Comer SD, Reed SC, Foltin RW. Effects of THC and lofexidine in a human laboratory model of marijuana withdrawal and relapse. Psychopharmacology 197(1):157-68, 2008.

[10] McCann DJ. Potential of buprenorphine/naltrexone in treating polydrug addiction and co-occurring disorders. Clinical Pharmacology and Therapeutics 83(4):627-30, 2008.
Gerra G et al. Psychopharmacol Online First. Jan 9, 2006.

[11] Oslin DW, Berrettini WH, O'Brien CP. Targeting treatments for alcohol dependence: the pharmacogenetics of naltrexone. Addict Biol. 11(3-4):397-403, 2006.

of the general population,[12] has been linked to naltrexone's efficacy in treating alcoholism; similar findings are also emerging in the treatment of nicotine addiction.[13] As here, prescribing physicians may be able to improve and individualize patient treatment by taking genetic variation into account.

Current Obstacles Present New Opportunities for Innovative Solutions

New obstacles are appearing alongside existing ones, on both the medications development and service delivery fronts, that could restrain truly remarkable opportunities.

For instance, the cost of developing a new medication and bringing it to market can be, according to recent estimates, up to $2 billion.[14] NIDA needs to leverage research and technical assistance in partnership with private entities to help bring a medication to market. Securing pharmaceutical industry involvement has been difficult, due largely to perceived financial disincentives. Many pharmaceutical companies have traditionally shied away from medications development for illicit drug disorders because of a relatively small patient population who also tend to be in lower income brackets, lack health insurance, or rely on the State for their care. Added to this is the stigma that still attaches to illicit drug addiction, along with concerns about this population's compromised health overall, which may present drug safety and other liability issues that further discourage pharmaceutical involvement. However, the implementation of the Mental Health Parity and Addiction Equity Act of 2008 and the

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[12] Oslin DW, Berrettini W, Kranzler HR, et al.: A functional polymorphism of the mu-opioid receptor gene is associated with naltrexone response in alcohol-dependent patients. Neuropsychopharmacology 28: 1546–1552, 2003.

[13] Ray R, Tyndale RF, Lerman C. Nicotine dependence pharmacogenetics: role of genetic variation in nictone-metabolizing enzymes. J. Neurogenetics 23:252-61, 2009.

Uhl GR, Liu QR, Johnson C, Walther D, Rose JE, David SP, Niaura R, Lerman C. Molecular genetics of successful smoking cessation: convergent genome-wide association study results. Arch Gen Psychiatry 65(6):683-93, 2008.

[14] Adams CP and Brantner VV. Spending on new drug development. Health Economics 19:130-141, 2010; Estimating the cost of new drug development: Is it really 802 million? Health Affairs 25:420–28, 2006; DiMasi JA, Hansen RW, Grabowski HG. The price of innovation: new estimates of drug development costs. Journal of Health Economics 22:151-185, 2003.

increased accessibility to insurance coverage for those with lower incomes provided by the Affordable Care Act promise to expand access to substance abuse treatment and thereby open up the market for addiction medications. Moreover, capitalizing on new approaches that target brain circuits and molecules common to multiple addictions, including alcohol and tobacco, can also help increase market share, reduce stigma, and better engage pharmaceutical companies.

The reluctance of private companies to fully engage in the research and development of addiction medications has encumbered our ability to harness the full clinical potential of scientific discovery. But now, the problem is poised to worsen, as the pharmaceutical industry plans to reduce their investment in psychotherapeutics research and medications development.[15] Not only does this situation impede the development of medications for mental illnesses generally, but it contracts the pool of available medications for secondary uses, including to treat drug addiction. This is a serious trend in a country where approximately one in four adults suffers from a diagnosable mental disorder in a given year[16] and where, among the 9.8 million adults with serious mental illness, 1 in 4 also abuse or are dependent on illicit drugs or alcohol.[17] This high rate of comorbidity, together with fewer medications to treat both illnesses, could adversely affect the public health.

Getting Treatments to People Who Need Them

While developing medications to treat addictions is important, access to these medications as well as other substance abuse treatment services will be critical to improving outcomes for those struggling with substance abuse and addiction. It is a

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[15] Associated Press, March 2, 2010: "AstraZeneca shuffles, eliminates Del. R&D jobs."
The Motley Fool, February 26, 2010: "Drug Company Cost Cuts: Careful What You Wish For" (http://www.fool.com/investing/general/2010/02/26/drug-company-cost-cuts-careful-what-you-wish-for.aspx).

[16] http://www.nimh.nih.gov/health/topics/statistics/index.shtml

[17] Substance Abuse and Mental Health Services Administration. (2009). *Results from the 2008 National Survey on Drug Use and Health: National Findings* (Office of Applied Studies, NSDUH Series H-36, HHS Publication No. SMA 09-4434). Rockville, MD.

sad fact that more than 90% of the 23 million Americans in need of treatment for substance use disorders do not receive it.[18] In addition, many treatments, including nicotine replacement therapies, are not effective without behavioral therapies or social networks to help patients achieve abstinence. NIDA is actively engaged in efforts to change this situation, working through multiple venues, but especially the medical community and the criminal justice system.

The medical community

Substance abuse is a chronic, relapsing medical disease. To treat this disease effectively, we must—as a public health priority—promote the integration of addiction treatment into the rest of the health care system. Failing to do so denies addiction's probable complicity in and possible deleterious effects on other medical conditions or diagnoses. Mainstreaming substance abuse treatment requires that we engage primary care physicians, who are in a unique position to identify drug use early and prevent its escalation to addiction and/or to treat or refer patients with potential substance use problems. Yet physicians tend not to prescribe proven addiction medications or to proactively identify potential problematic substance use in their patients.[19] NIDA is working to change this circumstance through physician outreach and other initiatives.

Having addiction medications available could further engage the medical community in providing substance abuse treatment, helping patients recover from their substance use while also benefiting myriad other health conditions where drug use may affect the course and progression. We must therefore remain vigilant in our efforts to educate the healthcare community to properly screen for and treat substance use disorders.

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[18] Ibid.

[19] Mark TL, Kranzler HR, Song X. Understanding U.S. addiction physicians' low rate of naltrexone prescription. Drug and Alcohol Dependence 71:219-28, 2003.

Mark TL, Kassed CA, Vandivort-Warren R,, Levit KR, Kranzler HR. Alcohol and opioid dependence medications: prescription trends, overall and by physician specialty. Drug and Alcohol Dependence 99:345-49, 2009.

The criminal justice system

Criminal justice settings offer prime venues for implementing evidence-based treatments among a high-risk population. More than half of incarcerated individuals have a substance use history,[20] but rather than capitalizing on the opportunity to effectively treat this high-risk population, we continue to release prisoners without any provision or mechanism for follow-up treatment, in spite of known consequences: greater recidivism, relapse, and post-release mortality.

For example, more than 200,000 people addicted to heroin pass through American correctional facilities each year.[21] Opioid maintenance therapy (e.g., methadone or buprenorphine) exemplifies a treatment that has proven effective in treating opioid dependence and in reducing drug-related disease and criminal recidivism. In a randomized clinical trial of methadone maintenance among 200 prisoners with pre-incarceration heroin dependence, those who received counseling plus methadone maintenance in prison with continued treatment in the community upon release were significantly less likely to be opioid- or cocaine-positive according to urine drug testing than those who received counseling only with passive referral or those who received counseling in prison with transfer to methadone upon release.[22] Other research points to buprenorphine treatment as a promising intervention for prisoners with heroin addiction histories and stresses that challenges related to dosing, administration, and regulation can be overcome via collaboration among treatment, research, and

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[20] Karberg JC, James DJ. *Substance Dependence, Abuse, and Treatment of Jail Inmates, 2002.* Washington, DC: Office of Justice Programs, Bureau of Justice Statistics; 2005. Dept of Justice publication NCJ 209588.

Mumola CJ, Karberg JC. *Drug Use and Dependence, State and Federal Prisoners, 2004.* Washington, DC: Office of Justice Programs, Bureau of Justice Statistics; 2006. Dept of Justice publication NCJ 213530

[21] Nunn A, Zaller N, Dickman S, Trimbur C, Nijhawan A, Rich JD. Methadone and buprenorphine prescribing and referral practices in U.S. prison systems: results from a nationwide survey. Drug and Alcohol Dependence 105:83-88, 2009.

[22] Kinlock TW, Gordon MS, Schwartz RP, Fitzgerald TT, O'Grady KE. A randomized clinical trial of methadone maintenance for prisoners: findings at 12 months post-release. JSAT 37:277-285, 2009.

correctional personnel, particularly important at the Federal Government level (e.g., Federal Bureau of Prisons).[23]

A lack of consistency in integrating effective treatments severely challenges our Nation's public health and safety agenda to reduce drug abuse and related crime. Therefore, we must provide community organizers, opinion leaders, and policy makers with the tools needed to, once and for all, neutralize the ideological practices that stigmatize substance use disorders, particularly as they affect criminal justice populations.

Conclusion

The combined neuroscientific discoveries of the last two decades give us an unprecedented and detailed view of the risks, processes, and consequences of addiction. From this vantage point, scientists stand ready to test and develop a whole new generation of diverse pharmacotherapeutic agents to combat the devastating effects of drug addiction in more individualized and effective ways. As a result, we find ourselves at the threshold of incredible public health opportunities.

But scientific discovery is not enough. The scope and cost of the effort required to bring any successful new medications to market hinges on the unique synergism that can be generated when public-private partnerships focus on a common goal. In addition, to guarantee the success of such partnerships, we also need to work diligently to optimize the delivery of integrated health care that is responsive to new knowledge and to the particular features that characterize the disease of addiction.

Thank you for this opportunity and I will be pleased to answer any questions you may have.

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[23] Kinlock TW, Gordon MS, Schwartz RP, Fitzgerald TT. Developing and implementing a new prison-based buprenorphine treatment program. Journal of Offender Rehabilitation 49:91-109, 2010.

Mr. KUCINICH. Thank you, Dr. Volkow.

We've been joined by Mr. Cummings of Maryland and Mr. Kennedy of Rhode Island. They will be participating in the questions of the witnesses.

And I am going to begin with the first round.

Dr. McLellan, if we did treat drug addiction with evidence-based treatment, including effective medicines, and did so on a widespread basis, what effect do you think that would have on the wide-scale problem of illicit drug use, drug trafficking and drug-related violence?

Mr. MCLELLAN. Well, one of the best examples, Congressman, is what's happening in AIDS. We find that aggressive treatment of AIDS not only is reducing the prevalence of AIDS, it is reducing the incidence of AIDS. That is, by reducing the number of people affected, you're reducing the number of people——

Mr. KUCINICH. Well, let me help focus this. Would it significantly cut our demand in the United States for illicit drugs if we had this evidence-based treatment?

Mr. MCLELLAN. Sorry, my hearing is not that good.

Mr. KUCINICH. Would it significantly cut demand in the United States for illicit drugs, for example?

Mr. MCLELLAN. Yes, I think it would cut demand.

Mr. KUCINICH. And would it reduce the desirability of the U.S. market for drug cartels and gangs?

Mr. MCLELLAN. I think that's a plausible conclusion, yes.

Mr. KUCINICH. So, based on your years of research, would you say that evidence-based treatment would make a demonstrable impact on society?

Mr. MCLELLAN. Yes, definitely.

Mr. KUCINICH. So, with so much drug addiction and related societal costs and with so many actual medical treatments available and promising compounds for new medications, it strikes me as being unfortunate that we are not fully invested in medication development and delivery on a broad scale.

Why is that? Why has that happened?

Mr. MCLELLAN. Yeah, that's—it seems like a simple issue. There are medications, let's go buy them, let's put them into play; it is a nice, simple solution. Unfortunately, this is a complicated issue. And, really, there are four issues that complicate it.

And the first is insurance. For too long, most of the people affected were not insured. Second, as Dr. Volkow said and as I said in my opening testimony, another part is the work force. We haven't had educated doctors, nurses, pharmacists. So that's been an important part. Third is stigma, the stigma of this illness. And combined, they do one thing and they do it profoundly: They affect the marketplace for pharmaceutical industries to get into this.

If you don't have coverage to pay for the medications that would be developed, if you don't have a work force that could prescribe it, and there's perceived stigma and problems, it is just not the kind of place that most pharmaceutical companies have ventured in.

Mr. KUCINICH. Well——

Mr. MCLELLAN. We think we can change that, and we have plans to.

Mr. KUCINICH. Dr. Volkow, it has been estimated that 70 to 80 percent U.S. demand for illicit drugs is exercised by 20 to 30 percent of users. Those are addicts and chronic users.

Are there currently medicines available to effectively treat those addicts and stop a significant proportion of them from using illicit drugs? And what scientific advances show promise for the near-term development of new, effective medications and vaccines that could be used to treat the drug-addicted population?

Dr. VOLKOW. Yes, there are very effective medications to treat heroin addiction. There are very effective medications to treat alcoholism. There are very effective medications to treat nicotine addiction. There are no medications approved for cocaine, marijuana, methamphetamine, inhalants.

What are the promising? In my view, one of the most promising findings has been the recognition that vaccines can work. There had been concerns that these vaccines could lead to increased use to overcome the effects of the antibodies. That did not materialize. And, currently, we will have results from the nicotine vaccine trial in the next 2 years.

Mr. KUCINICH. Do you have any concerns that this particular approach could be over-reliant on a behaviorist model?

Dr. VOLKOW. My perspective is that behavioral interventions are extraordinarily important, and we don't need to choose a vaccine versus a behavioral; you use both. Drug addiction is a very serious condition, substance abuse, and you have to deal with it aggressively. So, like with cancer, you do behavioral interventions and you do treatment, medical interventions.

Mr. KUCINICH. Thank you very much.

The chair recognizes Mr. Jordan.

Mr. JORDAN. I thank the chairman. And that was my question, or where I wanted to focus.

And let me start with you, Dr. McLellan. And pass along our best to Mr. Kerlikowske. He's been in front of the committee many times, and we appreciate his work and your work.

We have had this debate a little bit——

Mr. MCLELLAN. Sir, I am very sorry. Would you mind turning your mic? I can't hear. I am sorry.

Mr. JORDAN. It's usually the other way around that we have this problem.

Mr. MCLELLAN. Yeah.

Mr. JORDAN. This is the first time we've had it this way.

There has been this discussion in your agency about treatment versus law enforcement and that debate. And now we have, kind of, maybe even a step further, I guess you could say, in the question that the chairman just raised.

Do you think, in any way, this focus on using drugs to treat drug addiction, in any way, is diminishing the affected person taking personal responsibility, you know, the idea of individual choice, and some of the underlying concerns that may have prompted or—maybe "caused" is too strong a word—or contributed to the addiction in the first place?

I mean, I think that's a legitimate concern that I know I have and raised it in my opening statement and the chairman just referred to it.

Mr. MCLELLAN. Yes, I noticed that in your statement.

If you imagine that drug addiction is simply bad behavior, then you'd really be—you want to be very careful that you don't do anything that would reenforce that bad behavior or, for God's sake, get other people to initiate it.

But we know very clearly from a lot of research that this country has already paid for, much of it done by my colleague Dr. Volkow: Addiction is not just bad behavior.

Drug use is preventable behavior, and our strategy is very clear on wanting to prevent it because we can. But we don't know how but we know that, as use continues, a separate disease process takes over. It erodes the ability to control that use.

So we think the smart thing to do is prevent, is work very hard to reduce supply, work very hard to prevent drug use before it starts, get physicians to learn how to recognize and intervene early on the behaviors and on the consequences of early drug use. But, once addiction starts, you need medications, and it is important to add that.

Mr. JORDAN. A couple questions. How much money is our Government currently spending to deal with drug problems, in all the various agencies?

And then kind of a second question: How do your agency and NIDA, how do you—the two agencies in front of us here, in front of the committee, how do you interact and collaborate and work together?

Mr. MCLELLAN. I am happy to have her give her perspective.

I don't want to give you an exact figure on the amount that's spent. I can tell you that it is about $22 billion that's been——

Mr. JORDAN. Spread out over HHS and with your—I mean, where is it at? Give me the general——

Mr. MCLELLAN. I am most comfortable talking about the treatment of addiction. And it is, in round numbers, $22 billion, about 80 percent of that coming from the Federal Government, really.

In terms of how we interact, we are interacting in a really very collegial and collaborative manner. We are working with all of HHS to train new doctors, nurses, pharmacists. We are working, as part of the health care reform package, with HHS to get, for the first time, a benefit into health care reform that will enable doctors to get paid to recognize, intervene, and treat addiction before it gets to the point that it is out of control. And we are working very closely with NIDA to support new research which is necessary to develop even more tools.

Mr. JORDAN. Dr. Volkow, do you want to comment?

Dr. VOLKOW. Well, one of my perspectives as director of NIDA is that science that is not useful to improve the quality of life of individuals is not worth doing. So the partnership with the other agencies is crucial. And we have had, traditionally, a very close relationship with ONDCP, since ONDCP has the ability to integrate the actions of multiple agencies.

So when there is a priority area—for example, as cited in the plan for the ONDCP, the increases in psychotherapeutic abuse in this country—they come to us and say, "This is one of our priorities. What is it that you can do from the science perspective to help reverse it?" So, at the very basis of how we make decisions

of where we are going to fund research, we get information and the needs of ONDCP into account.

Our budget, since you were speaking about budgets, just for research is a billion dollars. And that relates to all of the drugs. As well, within that amount of money, $300 million set up for investment on HIV, since drug abuse contributes to it.

There is another institute at the NIH that is involved with another addiction, alcoholism. And the budget of that agency is close to half a billion dollars.

Mr. JORDAN. Thank you, Mr. Chairman.

Mr. KUCINICH. I thank the gentleman.

The chair recognizes Mr. Cummings for 5 minutes.

Mr. CUMMINGS. Thank you very much, Mr. Chairman. I want to thank you for holding this hearing.

Both of you, it is good to see you all.

Dr. Volkow, you say in your testimony that many pharmaceutical companies have traditionally shied away from medications development for illicit drug disorders because of a relatively small patient population who also tend to be in lower-income brackets, lack health insurance, or rely on the State for their care.

With the recent passage of the Patient Protection and Affordable Care Act, it is going to improve coverage and access to services for substance abuse disorders in the same primary care settings as now services all other illnesses.

What are we doing to incentivize pharmaceutical companies to experiment and produce new drugs?

Dr. VOLKOW. Thanks for that question. Actually, it is a very relevant one, and it is a question that we have posed ourselves in the health system 15 years ago, and the Institute of Medicine actually called in a committee to try to answer that question. How is sitting in the line of the urgency of developing medications, the opportunities and the lack of investment from pharmaceutical, that we can reverse that trend. The Institute of Medicine came up with very specific recommendations that would have unfortunately not been implemented.

What are some of those recommendations? Having to give, for example, a protected market for a given medication. So those recommendations still apply. I think that in the meantime, though, there are much greater opportunities that you just cited.

Many individuals who did not have a way of paying will now be able do so. And that's why, at this present moment, we have a unique opportunity to try to engage pharmaceutical companies into partnering in ways that will be beneficial for them and beneficial for the country.

Mr. MCLELLAN. If I may, I would like to add to that another part, and that is training for physicians.

Physicians and nurses don't get the training they need in this illness and, thus, are not comfortable prescribing any medication. So another opportunity, in addition to the ones Dr. Volkow talks about, is the work now going on to try to get physicians, and particularly primary care physicians, to become facile with these new medications and have a basic understanding of these diseases.

Mr. CUMMINGS. You know, there was just a recent article about how difficult it is, how many students, medical students, don't

want to go into primary care. And, of course, we have some things in that bill to try to incentivize.

But, you know, we've been dealing with these kinds of issues for a long time. And other than the things that you've just said, how do we guarantee ourselves the—rather than, say, going on a merry-go-round, where we seem to make little progress, how do we maximize the probability of actually being effective and efficient with regard to the things you're talking about?

Either one of you, or both.

Dr. VOLKOW. Well, there are two questions, one of them that relates to the need to build infrastructure in the health care system. So when patients that now have insurance come for health, for the treatment of drug addiction, there will be specialties that can actually take care of them. That's a crucial component.

The second one, which has been more complex, is involvement of the pharmaceutical industry. And, again, pharmaceutical, like any private industry, will be incentivized if there is success with a given medication.

So right now, with a new perspective with respect to vaccines development, that I predict we will be successful with nicotine vaccine—I predict that will incentivize other pharmaceuticals to go for treatments that are illicit substances.

For the illicit substances, we still have a very limited market that integrates the involvement of private companies. Currently, as we speak, the Institute of Medicine is holding a conference to try to figure out ways in which we can, sort of, contain or reverse the disengagement of pharmaceutical—not on substance abuse, because they have not been very much involved, but on development of medications for depression, for schizophrenia, for anxiety.

For mental illnesses, we've seen a decrease in the investments, and these will be catastrophic. And it is catastrophic for us because we take advantage of those medications that may be used for depression, in some instances are useful for addiction.

It is going to end, at the end of the day, by coming up with compromises on the way that we do things. The IOM already came about it. We need to incentivize the pharmaceutical industry if we want to have this medications development, just like we incentivize for other needs. If the country needs tanks to go to war, we need to incentivize the companies that do them. Otherwise, spontaneously, it is not going to happen.

This is urgent. Hundreds of thousands of people's lives are ruined because of drug addiction. It need not be like that. We have the science. We know how to develop it. We just don't have the resources to get it to the next level.

Mr. CUMMINGS. I see my time is up. Thank you, Mr. Chairman.

Mr. KUCINICH. The chair recognizes Mr. Kennedy.

Mr. KENNEDY. Welcome.

If you could address the point that I want to make, and that is that we don't have an addiction treatment system whatsoever in our country.

Personally, I've made a very close personal analysis of treatment centers. I've gone to the best in the country, myself: Mayo, Ashley, Sierra Tucson, others. It's all based upon treating based upon your weaknesses instead of treating based upon your strengths. And it

is outside where you live, so it doesn't help you in the course of your life.

And our reimbursement system doesn't—forget the specialties. All you really need if you're trying to stay on the wagon is to have someone in your life on a consistent basis help you.

And I am wondering, to what extent have you allowed in the regulations that are now being done to implement parity, to allow those with neurological disorders—and this is a neurological disorder because it is a chemical imbalance that people try to self-medicate to address; hence, the reason we are talking about pharmaceuticals to help address.

Are we doing something to allow insurance policies to pay for nonmedical services, like having someone stay on top of you and making sure that you don't have this, "90 and 90, there you go, you're off on your own," as opposed to someone has to have only acute episodic care because that's the only thing that we have reimbursable under our current insurance system.

And it is so costly, and yet it is so ineffective. And why are we paying for it in this country? And it's the best that we have out there, it's the gold standard, and, yet, it's awful.

Mr. MCLELLAN. Something that is painfully obvious to you is not clear to the rest of America, and that is that addiction is a disease and it is a chronic disease. Unfortunately, for a very long time, we've been thinking about this as bad behavior that needs an acute, rapid lesson in life. Well, if we treated diabetes or hypertension or asthma that way, we'd have terrible results.

So, two answers to your question. I think the very recognition that we've been thinking about this in the wrong way and segregating a treatment system away from the rest of medicine has not served us well. So we are off of that, and we are on to, I think, the right thinking and the right model.

Mr. KENNEDY. Now, tell me, what are we going to do to certify treatment providers so people don't end up continuing to waste all their money on everything out there that's so bad and not getting any results?

Mr. MCLELLAN. I want to say—and I am sorry Representative Cummings isn't here. I do not feel the kind of skepticism and worry that is apparent so much in the questioning. This is a very good time. I think we've got it right and we are making real progress now.

And to that question, we have the attention of all the primary care medical societies. They have recognition that they need the kind of training that's necessary to properly certify them. We are working with the National Board of Medical Examiners to, at a fundamental level, test kids coming out of medical schools and other schools on these issues. We are including benefits that will——

Mr. KENNEDY. I love what you're doing on that. I just have to get all this stuff on the record.

Mr. MCLELLAN. Yeah.

Mr. KENNEDY. Why don't we have an NCQA, an agency for health care research, certifying these mental health providers and not certifying them because they are not doing what they are supposed to do? Or shutting them down.

Mr. MCLELLAN. That is a very good idea.

Mr. KENNEDY [continuing]. So they are not wasting people's money anymore and pretending like they are giving people treatment when they are not.

And having people, instead, when they are spending their 30-grand a month, spending it over the course of a year to have someone in their lives that helps them in their own community. Why aren't we telling the insurers, "This is the model?" And why aren't we doing it in the VA, so that's what they look for as the model?

Mr. MCLELLAN. I think we are on the right track, Congressman. And I think you're going to see progress very shortly in just that area.

Mr. KENNEDY. Well, we have an opportunity in the implementation of these regs on parity to actually reimburse for this model of care that's nonmedical, which is actually most productive for dealing with chronic illnesses of a neurological nature. And this helps people with autism, Alzheimer's, Parkinson's, you know, everybody. So our fight is the fight for everybody.

And I would make that point with respect to the IOM report on drugs. We don't need to incentivize pharmaceuticals. All we need to do is get everyone to double down on research of the brain, and we will find out that there are great answers for pharmaceuticals to go into treatment for depression and addiction too. But it will come when everyone else is fighting for just basic research in neuroscience.

You know, forget the silo of trying to get them to incentivize for drug addiction, because you don't have popular will to do that. I mean, I know Nora knows stigma well enough to know that's not being to happen.

Mr. KUCINICH. I thank the gentleman.

I just want to say that we in the Congress are proud of Representative Kennedy's courage and his advocacy, and it is important for the Nation.

Thank you, Mr. Kennedy.

The chair recognizes the distinguished Congresswoman from California, Ms. Watson.

Ms. WATSON. Thank you so much, Mr. Chairman.

I can't think of a subject any more needed for attention than the one that we are addressing today. Because I think of some decades in the past—and I represent Los Angeles, and our bus drivers were driving buses and the buses were turning over on the freeway without accidents. My nephew was a bus driver, so I said to him, "What's going on out there?" He said, "Most of the bus drivers are using crack cocaine."

So I went to the supervisor, and I said to him, "You know what you need to do? You need to test. Because the lives of all of your employees and the lives of our citizens are at stake. And the people who are driving these buses are buying homes, have children in school, and we just cannot throw them away."

So they started to do random testing, but I put a bill in, so that we could have neighborhood—and I am addressing this to my colleague, Mr. Kennedy, for some of the remarks he made—so we could have neighborhood treatment centers where people could

walk in and get treatment. It got all the way up to the Governor, and he said that it was too expensive and vetoed the bill.

Ever since then, we have the largest prison population in the country. And 50 percent of those incarcerated were addicted to drugs, and they get very little treatment or not the right kind of treatment in these institutions.

It has been a concern of mine forever. I chaired the Health and Human Services Committee in the Senate in California for 17 years. Every year we would put a bill in, and we couldn't get it funded. Now the State is broke, so I doubt if we will ever have a program.

So, what is the Office of National Drug Control's strategy for providing those who are incarcerated with the treatment they need to reduce reincarceration, relapse, and overdose rates? And what role should drug addiction medications play in this treatment?

And this is to the two of you.

Mr. MCLELLAN. I can think of no more important question. It's one of the key parts of our Drug Control Strategy, partly because of the volume of the problem, the numbers of people affected and the importance.

It also is a question that illustrates something that I think I would like to make as a general comment. I'd be very careful about thinking of pitting one strategy, medication, versus supply reduction versus behavioral treatment. We don't want to do that. We want it all.

Ms. WATSON. Comprehensive?

Mr. MCLELLAN. Comprehensive, and particularly for those populations where there is a combination of risk to the community as well as a public health risk.

The good news is, we can. There are effective things that can be done, have been shown. And we've put money in the 2011 budget to incentivize just those things through the National Institute of Justice. Like what? Well, drug courts are an excellent example. The principals of drug courts—swift, certain sanctions, but modest—combined with evidence-based treatment and prevention strategies give you the very best opportunity to fight with both hands, to use all the tools that you have.

We want to apply those principles in reentry. We want to apply those principles particularly in community-oriented corrections, because there are so many—there are approximately—we use the same data you do, and we think about 2½ million people are in the community under corrections with a substance abuse problem. If it is not addressed, it's going to lead to re-addiction, re-offense, reincarceration, and a huge expense.

Again, the good news is there are models out there that have been shown to work that reduce all of those things: keep communities safe, reduce the drug use, save a lot of money.

Dr. VOLKOW. And just to make a point about medications in the criminal justice system, that's in an area where the evidence is so strong, that, in fact, we don't need more evidence. Treating with medications while in the criminal justice system and maintaining that treatment once the prisoner is released is not just significantly beneficial for the person, vis-a-vis their drug use, but it dramatically reduces their rate of reincarceration.

So it is a win-win with respect to the drug use behavior and with respect to the criminal behavior. So it is not just cost-effective, it is actually cost-saving.

Ms. WATSON. If I may, just 1 second more, Mr. Chairman.

I represent an area in Los Angeles called Hollywood, and there's not a time when you read the newspapers, turn on your TV or your radio to see some young celebrity involved with drugs. It is rampant in that community.

And the reason why I said, Dr. McLellan, that we needed to look at a comprehensive approach, because these people are dealing with psychological, emotional problems leading to their drug use—too much too soon too fast, too much fame and so on. And so we have to have the right combination.

And as my colleague Mr. Kennedy said, it needs to be close to home, where we can deal with all the factors that impact on people in a community like this, let alone the poor, poverty-stricken communities and their use just to get away from their real lives. So we have to have that comprehensive approach that treats the whole person and the entire community at the same time.

Thank you so very much.

Thank you for the time, Mr. Chairman.

Mr. KUCINICH. I thank the gentlelady.

We are going to begin a second round of questioning of the witnesses. We are going to begin with Mr. Kennedy for 5 minutes.

You may proceed.

Mr. KENNEDY. Thank you.

I can't emphasize enough the feeling of outrage I have about this treatment. Because you can think about this stuff until you're blue in the face, you can learn about it until the end of the world, you can get all the emotional and psychological treatment until the end of the earth, and it is not going to change your behavior.

And we don't have any behavioral changes going on in these treatment facilities, no behavioral modification. If you don't change your behavior, your thinking won't change. It's the key.

So you fill everybody up with a head full of AA and program and treatment, and it's not going to do them a bit of good because you send them out, they are thinking a different thing but they are still acting the way they were when they went in.

It is so basic, and yet we are doing it everywhere. And the problem with all of this is that we have this stigma, and it is just being perpetuated right now, because all we are doing is talking about, understandably, the symptoms and people incarcerated and people on crack driving buses and blah, blah, blah.

The bottom line is, the biggest challenge going forward is narcotic analgesics are the biggest-prescribed drugs in this country. And our veterans are being prescribed this at record rates to deal with the symptoms of the signature wound on this war: TBI and PTSD.

We shouldn't at all in this hearing be talking about criminal justice, you know, all of these stigmatized drugs. We should be talking about people self-medicating. And we should be focusing on the people that everybody understands are self-medicating because of their service to our country. Because that destigmatizes it and people get it.

And it is a huge problem; it is going to get bigger. And our fight should by the fight for our veterans. And if we can't even get it right in the VA, which is clearly—they don't even have metrics for this—I am wondering, what are we doing? I mean, even VISN to VISN has different approaches. They are just writing. It's just—where are we?

And if we can't get it right with these regs that we are trying to put in place now for this health bill, 72 percent of all vets are never going to see a VA. They are going to get their health care through this private insurance plan. That health care bill was a veterans bill. Of the remaining 28 percent, 67 percent of them are also going to get supplemental private health insurance coverage.

What are we doing to make sure those private health plans are sensitive to veterans' needs and dealing with wrap-around services for their brain trauma so they are not self-medicating because of the trauma and the brain damage?

If we address that, if we do research on neuroscience for the veteran, believe me, pharma is going to come to the table on all of the other things, because we are going to get all the extra money we need to deal with brain issues. And, in the process, we are going to find out about treating depression, treating addiction, treating everything else.

If we go out at this way that we are talking about now, trying to deal with the return, the recidivism for convictions, all of that, yeah, it makes sense for us on a budget, it makes sense for us on a human level, but it just doesn't make sense politically. And we are fooling ourselves if we are going to spend any time talking about it and thinking we are going to go anywhere, especially in this environment of austere budgets.

So what I want to know is, why aren't we getting our act together with the VA? And why aren't we getting our act together with implementing regs that actually do supportive living, supportive employment, and supportive education, so people can live with the chronic illness over life as opposed to paying hundreds and hundreds of millions, billions of dollars in these no-win treatment settings that are gold-plated losers in terms of helping people perpetuate their thinking they are getting treatment when they are not?

I mean, we are sitting here—I mean, no offense. We are talking—you just said—that's a very good question, but it doesn't address the big picture. This is the big picture. We are not getting it right, the implementation of the regs, and we are not doing it at the VA, which is where all of the insurers take their lesson from.

How are we going get anywhere if we don't do it right in those two places?

Dr. VOLKOW. Well, one of the things that I was thinking is that we are going to be faced with the veterans returning from this war with problems that, in medicine, we have not really addressed in the past. The level of trauma that they are surviving will very undoubtedly lead to many more cases of severe chronic pain, No. 1. No. 2, you mentioned TBI, which is also something that, in many ways, this war has exposed us to.

So we don't even have sufficient knowledge on how to treat these conditions. For chronic pain, we use opiate analgesics, and we treat it as if it were acute pain times so many months.

Dr. VOLKOW. We have thought in the past that will prevent these individuals from getting addicted to their pain medication. We're finding otherwise.

So one of the areas that we are investing in at the Institute is to develop medications and knowledge regarding the treatment and management of chronic pain to minimize the likelihood that those individuals become addicted to their medication and that they can control their pain. But we do not at this point have sufficient knowledge.

Mr. KENNEDY. Well, Dr. Steinberg at Stanford University, head of neuroscience, says he does. He says he can interrupt the neuropathways to block pain. I said, why aren't you introducing it? He said, I'm about to at the VA system at Stanford, and hopefully they can take it nationwide.

The neuroscience that is going on in this country is breakthrough. The notion that we can't start to cut the pathways to pain and treat it without doing these narcotic analgesics and hook a whole generation of vets is shameful on us as a country, that we're about to addict all these people and then send them off to do other illicit drugs, like heroin and the rest, when they're not getting enough narcotics from their docs. I mean, to me, we're missing the big picture again.

Dr. VOLKOW. I agree, and it is a priority area for our Institute.

Mr. KENNEDY. If you want to talk about addiction, let's talk about what we're doing to addict a whole generation of American heroes. We're leaving them prisoners in our country, stranded behind the enemy lines of their signature wound on the war. They are being held hostage right now by this disease, because we're not treating it right.

This has nothing to do with crack addicts in California driving buses or prisoners in prison. This is about our American heroes. Let's keep it that way. Because, if we do, we can move forward on this. If we start talking about everything else, we're losing it.

Our fight is neuroscience. It's those with Alzheimer's, autism, epilepsy, Parkinson's. Because it's all the same brain. Once we do research on that, we're going to get pharma to come to the table. We need to do neuroscience research, and they'll all see the great discoveries, and they're going to want to be at the table. Because they're going to realize there are going to be answers to all of these other neurological disorders.

And if we do the implementation for treatment right for addiction, guess what? Then it's right for those with Alzheimer's, right for those with Parkinson's, right for those with autism. Why aren't we getting this in the regs now and just segmenting it for neurological disorders in this parity reg?

Dr. VOLKOW. Patrick, I'm going to answer you. Because this is exactly—and I really admire your passion.

While I'm sitting down and listening that Pfizer Wyatt got rid of 1,000 neuroscientists, and Glaxo basically closed their psychotherapeutic development program. I'm seeing that Merck is also downsizing. I'm also hearing that Lilly is also downsizing, despite

all of the advances in neuroscience; and it is because they have not been very successful of bringing medications into the clinic.

Many factors account for it. One of them is cost. What it is, they have not been very successful at all. There are other areas where medications—they have been able to get investments back, like cardiovascular disease. But psychotherapeutics has been an area that many of the pharma are starting to cut. And that's why I brought it up, because I think that we, as a country, are going to lose enormously if that continues to happen if we don't contain it.

Mr. KENNEDY. My point would be you get Office of Management and Budget and they look at this bill, they see we're on the hook for everybody with neurological disorders. The cost for Alzheimer's is going to skyrocket. We're all paying for it. Autism, skyrocket. Parkinson's, epilepsy, and now the veterans population with TBI and PTSD. We're on the hook as Uncle Sam big time. We had better invest or else we're going to be paying through the back end.

So it's going to pay for us as a government to step up and do the down payment on research, on neuroscience or else we're going to be paying though the back end. And this is where we need the IOM to say to the Federal Government, here's a way out. If we're going to have cost-effective, comparative effectiveness in this bill, here's where it counts. Comparative effectiveness analysis shows if we research this stuff here, we're going to get interventions that are going to make a huge difference in just putting off the onset of Alzheimer's, mitigating the impact of autism, you know, mitigating the impact of schizophrenia, allowing these vets, which we're all ready to do, to repair spinal cords so they can get out of their wheelchairs and get into society.

And I mean for us to think—for us not to think big and think that the addiction field is there with Alzheimer's, autism, and all of the rest, think as one mind with the brain and not think big pharma is going to come if we get one picture on this in the vision. I think so.

I mean, I think if you define it that a neuroscientist gave me one more year with my dad. Neuroscience is going to give a family with Alzheimer's, bring the memory back for their loved one. A neuroscientist is going to help a family with a kid with autism or Parkinson's or schizophrenia to not have to worry as much while that child grows up about being marginalized.

They're our first responders in this war on the biggest burden of illness which is neurological disorders. They're going to set us free. These neuroscientists are going to go in there and they're going to set us free, first and foremost our veterans. If we can't get that message across, we don't deserve to be in our business. I mean, this is it. This is going to save people's lives in huge ways. We're in the weeds here. We're in the weeds right now.

Dr. VOLKOW. I agree, and that's one of the reasons why I'm very grateful to be here and being able to present the obstacles that we are facing.

And I will definitively—since the meeting isn't going right now at the IOM—highlight your point and your request that the IOM come up with very specific points and that can be used to guide how to revert these changes that we're seeing in the pharmaceutical companies.

And I will also for the record be willing to provide the committee with the information regarding this investment, the decreasing investments from pharmaceutical industry for psychotherapeutics. I think we need to be aware of this.

Mr. KENNEDY. I would like to get that answer on functional reimbursement for neurological disorders in this parity bill. You all at ONDCP, at NIH, the experts in the field, have to weigh in with HHS. This comment period is still open.

If we don't reimburse for continued support for chronic illnesses—addiction is one of them, but all of the other ones that I just mentioned are also—we're missing the change from sick care to health care. We're missing a big opportunity.

Mr. MCLELLAN. I would just add that, historically, you've got a terrific precedent on your side, as I was around when the first addiction treatment system was developed. And it was developed to treat the then opiate problems of returning veterans from a foreign war. If that hadn't happened, there would have been no political will to create that system. Well, we need to advance beyond that, as you have said.

The science is there. I agree with you. Absolutely, veterans need to have the same kind of care for their neurological behavioral problems that they have for their cardiovascular problems. Now they don't. If we follow our strategy, if we vigorously defend parity and vigorously implement the health care reform, they'll have that chance.

Mr. KUCINICH. I think one of the things that the gentleman's question brings up is where are we with respect to nonnarcotic, nonaddictive pain relief.

I thank the gentleman for his questions.

I'm going to recognize Ms. Watson, if she would like to.

Ms. WATSON. I yield back.

Mr. KUCINICH. I'll take my 5 minutes right now. Dr. McLellan, we heard from Dr. Volkow that it's cost effective to treat prisoners with medications while in prison and before release to prevent relapse and recidivism. Does the administration have plans to expand access to medications in the criminal justice system?

Mr. MCLELLAN. Yes. We have plans to expand that access in prisons but also in communities for individuals who jointly have criminal justice problems that are associated with their addiction as well as the addiction itself.

So we don't just want to do it in jails or prisons. We want to do it for people who are under parole and probation. We want to do it for people who are reentering. And, yes, there are provisions through the National Institute of Justice and building upon the evidence-based behavioral interventions but also the medications that Dr. Valkow spoke of.

Mr. KUCINICH. Thank you.

Dr. Volkow, in terms of neuroresearch, once pathways are developed through addiction and a person kicks their habit, do those pathways still exist in a way that can inform other types of repetitive behaviors that are not necessarily—that are, in effect, a side effect, notwithstanding their kicking their drug habit?

Dr. VOLKOW. That's actually a very important question. Many investigators have tried to address the consequence how long do the

brain changes last after you stop taking the drug; and if they do not revert back to normal, what are the consequences on behavior, which is one of I think your very specific question.

What research shows is that there is significant variability in terms of the ability of the human brain to recover. In some cases, you see almost complete biochemical recovery of the abnormalities and in others you don't. And when you don't see the recovery, what you do see is derangement and increased reactivity to stress on people that have been addicted to drug addiction, even after years they stopped taking them. And this, of course, puts them at much greater risk to relapse. Because if they encounter an adverse situation like losing their job or losing someone they love, that is a period of great risk for relapse because of that enhanced sensitivity to stress that was developed from the chronic use of drugs.

Mr. KUCINICH. In the case of alcohol abuse, someone who's a long term alcoholic can develop what's known as an encephalopathy that is really an organic change in the brain. What does the research show about parallel organic brain syndromes with respect to drug addiction and the ability of the human brain to recover?

Dr. VOLKOW. Well, there are—I mean, there are differences among the drugs. Some of the drugs are more toxic than others. Among the most toxic drugs, we have methamphetamine. Methamphetamine, with repeated use, can produce damage of cells like the dopamine cells that are very important in your ability to perceive pleasure and excitement. So the repeated use of these drugs can lead individuals, even years after they've stopped taking the drug, with a lot of excitement, with what we call in psychiatry, anatonia, the ability to perceive pleasure with a lack of motivation.

Mr. KUCINICH. What about cocaine addiction? What's the physiology in terms of cocaine addiction and what damage is done?

Dr. VOLKOW. The damage from cocaine comes from an effect of cocaine on blood vessels. It is a vasoconstrictor, and that means it decreases the flow to your heart. It decreases the flow to the brain. And that's why we started to see myocardial infarction in young people when they were taking cocaine. But that also happens in your brain.

Mr. KUCINICH. Long-term effect?

Dr. VOLKOW. When you have damage from lack of blood into your brain, that can be long-lasting; and if the cells are dead, there is no way that you can actually bring them back.

What you can do—

Mr. KUCINICH. What about behavioral effects long term?

Dr. VOLKOW. With cocaine, if you have a stroke within the motor areas of the brain, that will leave you paralyzed and you will not necessarily recover your full motion. If you have it in the back of your head where you see vision, that could leave you blind. If you have it in an area that's involved in more silent types of behavior like thinking, that will lead to destruction in thinking.

So it is a matter almost like a roulette. Where do you have the stroke in your brain that's produced from the effect of cocaine. That will lead to the symptoms.

There is recovery, though. We know that the adult brain can recover even from strokes, and what happens is the rest of the brain can take over. The younger you are, the better your prognosis, be-

cause your brain is more plastic. But the addict's brain can still recover by engaging other areas of the brain to take that activity.

So even with strokes from drug use, we expect recovery in those patients if they receive proper treatment.

Mr. MCLELLAN. I would like to add something that's less perceived but as insidious. People wonder why after long periods of time, let's say an incarceration, a person would use a drug. Haven't they learned their lesson? Don't they realize that drugs are bad? Don't tell me it's brain changes that do that. And the answer is, yes, it is brain changes.

We know that cues that have been associated with drug use—people, places, things—have the ability not to just to remind somebody about drug use, they have the ability to elicit the same changes as the drugs themselves in the brain. They light up—Dr. Volkow's work has shown they light up the same structures of the brain. They produce powerful craving even when they haven't used.

Mr. KUCINICH. What do you mean "they?"

Mr. MCLELLAN. "They" is any stimulus that has been associated with drug use.

I've come out of jail. I haven't used cocaine for a long time. I run into Joey and Billy, the guys I used to use cocaine with. Not only do I know, because my mother told me so, these are not the guys to hang around with, that elicits powerful craving that you can show in an MRI. And that is part of the reason relapse rates are as high as they are. There are behavioral changes brought about through learned associations.

Mr. KUCINICH. We've heard of research where women who are pregnant who are drug addicted that has an effect on the fetus, the child; is that correct?

Dr. VOLKOW. That is correct.

Mr. KUCINICH. So would then pharmaceutical-related treatments block those receptors in the fetus or newborn as well?

Dr. VOLKOW. Incredibly important question.

Drugs of abuse enter the fetus brain, and psychotherapeutics will also enter the fetus brain. What we do not know sufficiently is the extent to which some of these psychotherapeutics could also be potentially harmful for the fetus.

Take an example. Nicotine replacement therapy for smoking cessation on a woman that is pregnant, nicotine is in utero damage. It produces damage to the brain of the infant. If you give a nicotine replacement therapy, the nicotine will go into the fetus and affect it.

So the handling of the substance abuser that's pregnant with medication is an area that requires specific research on any one given medication to ensure that we will not do damage.

Mr. KUCINICH. Let me conclude this panel with one question. It's kind of an obvious question. It may not get asked because it is so obvious, but I would like to hear an answer from both of you. Why do we have this tremendous number of people who are on drugs? What's happened in our society? Why? I mean, you must ask yourself even as you're trying to deal with the mechanics of treatment, why? What do you think—why do we have this kind of wide-spread drug abuse?

Mr. MCLELLAN. You are talking to the wrong guy. I've devoted my whole life to this, and my family is riddled with it, and I'm worried every moment of every day about my grandsons.

Here is my answer. I'll tell you what I know, and I'll tell you what I think.

What I know is drug use is different than drug addiction. Drug use is a function of availability, access, ease of availability, like any other attractive commodity. You make more candy bars available, more people use candy bars. That is a fact. Second, another thing I know is that abuse and addiction is partially a function of genetics. We don't know how much, but we know that it contributes about the same amount of expression of illness as genetics contribute to the expression of diabetes, hypertension, and asthma. So when you have an extremely wealthy country that has an abundance of access to drugs of different types of different varieties, you have more opportunities to use and more people who are using. Once that happens, the disease process—you know, the disease of addiction as well as the side effects of drunk driving and accidents and all of the other sequelae of just simple use take effect.

That's why as a guy who does treatment research my whole life I don't want to just see treatment be the only answer to the drug problem. We need supply reduction as well as many more medications and much better prevention.

That's everything that I know. That's what I tell my grandkids right there.

Mr. KUCINICH. Dr. Volkow.

Dr. VOLKOW. I think that there are many reasons why we have people end up taking drugs and becoming addicted. The issue of availability is a crucial factor. The more a substance is available, the more probability that the kids will start using it; and the younger they start using drugs, they raise the risk to become addicted. That's No. 1.

No. 2, we also, of course, recognize the issue of genetics. So if you come from a family where there is a history of addiction—which I also have in my family—they are more vulnerable to being addicted.

Three, there is another factor that we know that contributes, and that is almost any type of mental disorder will increase your vulnerability to taking drugs; and that can be depression, anxiety, schizophrenia, attention deficit disorder. Why? Because you may then use the medication not just to get high but to feel better.

And in fact in this country, for example, those that remain as smokers, there is a great overrepresentation of individuals with mental illness. So a mental disorder will put you at greater risk.

So those are three factors that are biological that will increase your vulnerability. Now, why is it if it is genetic—and this is a more basic question. Why is it that those genes remain if they are adverse and have these negative consequences? And, of course, that is a very fascinating question with respect to why is it that some people become compulsive users and cannot stop it. That plays to basic understanding about how the brain creates memories, how some people can learn faster than others. Well, that may come to a certain price.

So this plasticity of the brain is one of the factors that contributes to that vulnerability of the addiction, but that plasticity is also extraordinary important in allowing us to learn.

Mr. KUCINICH. You know, this has been a very important discussion, and I saw Mr. Cummings came back, and Ms. Watson has not asked questions this round. Before we dismiss this panel, do you, Madam, have any questions?

Ms. WATSON. If you will yield for just a moment.

Mr. KUCINICH. I will, and also Mr. Cummings. Because I guess there are questions that are very deep here, and I just want to make sure that the Members of Congress who are present have a chance. We're about to dismiss this panel, but, before we do, do you have a final question?

Ms. WATSON. Coincidentally, I have an appointment at 2:30 today with Erika Christensen. She is an actress, and she's in my district in Hollywood now, and her mission on the Hill today is to promote the importance of substance abuse education and to talk about it as a crime preventative tool and the importance of treatment in front in diversion as a way to reduce the recidivism rates of offenders who are already in the criminal justice system.

I just asked my staff to see if we could locate her in the building now. She will be here today and tomorrow and see if she can come at the end of the second panel.

Mr. KUCINICH. Without objection, that would be fine. Mr. Cummings, do you have any questions?

Mr. CUMMINGS. Yes, I do. I want to pick up where you left off. I live in the inner city of Baltimore, inner city. I have been there all my life, and I see a lot of young people who I have known since they were toddlers. Some of them sadly have grown up to be drug addicted. Others have gone on to college and done well. And I'm always curious as to how they got into it.

And when I talk and, Dr. Volkow, when I was listening to what you were just saying a moment ago, you talked about the mental illness part. I know there is something called clinical depression; and I assume there are other kinds of depression, too.

I notice that a lot of these young people don't have a sense of hope. I'm just telling you. They don't—it's hard for them to see a future. A lot of young women tell me that they got involved in drug addiction because of some young man, trying to impress somebody, some guy. He talks them into it. Oh, just only take one time. You'll be fine. And the next thing you know, she's in pretty bad shape. There are—and the thing that I guess that really gets me is how drug addiction can change a person drastically from a person who may have been honest to someone who lies all the time; from someone who has never stolen anything to someone who will steal; from someone who never thought about harming another person to someone who will kill someone.

I tell people quite often, while I love my neighborhood, quite often most of the time I sleep better outside of my neighborhood than in my neighborhood. Because I realize a lot of the very young people that I watched grow up with that will say, Mr. Cummings, how are you doing, show a lot of respect. Having been a criminal lawyer, I can tell you I know that in certain circumstances they could harm me. As a matter of fact, my predecessor, Parren Mitch-

ell, who was well respected, was robbed at least three or four times. And we lived literally in the same neighborhood. And, by the way, by the same young people that had a phenomenal amount of respect for him.

I guess my question goes to is there—I mean, you know, you talk about mental illness. We see people who spend thousands upon thousands of dollars every year to address mental illness. So we've got—but yet and still it seems like not a lot with regard to mental illness is addressed when we give somebody medication or whatever. Are we balancing that or has our society come to even accept the fact that drug addiction is usually accompanied by some type of mental problem?

And the reason why I started off the way I started off this question is because a lot of times people may have a problem, but it may not be classified as mental illness. Because I believe you can be—I believe you can be so depressed over your circumstances that you don't even know you may have a mental problem. So I'm just wondering. I just want your reaction to that, and then I'm finished.

Dr. VOLKOW. Yes, and I think that is absolutely correct. And I think one of the recommendations that we need as an agency is to start with, for example, young people that end up in the criminal justice system with a problem with drugs that they be evaluated for the possibility that they may have a psychiatric disorder that has not been recognized. And, indeed, on the recognition of mental illness in adolescents, where it is not full-blown, as you see it in adults, it is not an easy thing to do. So many kids go around feeling depressed, with a learning disorder and taking drugs without realizing why they are doing it. So that is something that we can address. Then your second question, because that is a problem that we have in the country that should be taken care of, which is we basically separated, divorced, the treatment of drug abuse from the treatment of mental illness. I'm a psychiatrist. I was trained at New York University. I was not trained to deal with the substance abuse problems of mentally ill patients, even though 85 percent of them suffers from some type of addiction behavior. So we've separated that care of substance abuse from that of mental illness, rather than integrating. Because—guess what—it comes together in both directions. So if you take drugs, that may increase your vulnerability for a mental illness. If you have another mental illness like depression, that increases your vulnerability for substance abuse disorder. This is something that we need to change the way that we are providing for the education of psychiatry and the treatment of individuals with mental illness and/or substance use and/or other conditions.

Mr. MCLELLAN. If I could just contribute. I want to answer as a scientist, and I want to answer as another guy who's in the middle of a city, Philadelphia, and I don't want to leave the hearing with this kind of bleak idea that there is nothing that we can do. Just the opposite.

But I'll tell you. If you're really asking, as I ask myself so often, how come I can't tell who's going to get this? How come I couldn't stop it? How come I couldn't help one of these young people that you're talking about? And I think science tells us something there. You have a role as a neighbor. You have a role as a parent. You

have a role as a schoolteacher. You have a role as a policeman, a health care provider. None of those parts can do it by themselves, and that's what we've been trying to do for too long. One of the things we've seen in science and one of the ways we're trying to correct it is we want to stop quite literally buying prevention and treatment things that are just pieces of the real piece, of the real effective element. We want to bring prevention-prepared communities together, Baltimore, Philadelphia, everywhere, where all of the parts are working together, all of the parts are able to see these kids, not just when they start to use but as other problems start to emerge. And we can do that, and it's time that we do it. The last thing I want to leave you with is another thing that is more hopeful and something we haven't talked about. Yes, these illnesses are devastating. They're terribly costly. They ruin lives. They ruin communities. But there's hope. There are 20 million people now that label themselves as being in stable recovery. So it is possible; and, in fact, we think it's expectable. Treatment ought to lead to recovery, and it can.

One of the reasons we're talking about medications and brain science and bringing those things together is that, with those new tools, we will make that number 40 million and ultimately 60 million.

So I don't want to leave the hearing with kind of, oh, my God, there is nothing we can do. We can do things, and this is the time to do them.

Mr. KENNEDY. I want to thank both of you for the great work you do. My enthusiasm in questioning you is to get my point across. And I can't thank you enough, Dr. McLellan, in trying to get these State boards changed so we get more people in the health care field knowledgeable so they can diagnose and treat these illnesses.

And, Dr. Volkow, your, you know, great work over the years in research has been so instrumental in moving it forward. I look forward to continuing to work with you.

Thank you so much for your work, both of you.

Mr. KUCINICH. Thank you very much, Mr. Kennedy and members of the panel, for participating in this discussion and hearing from our expert witnesses. This hearing is necessarily focused on what kinds of medication might be available based on years on research in neuroscience which would help to—that would help people deal with their addictions. But I'm fully aware that there are other ways and other therapies that could be adjunctive and complementary. We have not really spent much time discussing them today, although our witnesses have acknowledged that they're looking at a broad spectrum approach toward addiction and not advocating just one approach. Because just one approach, if we're talking about drug therapy, would immediately be a behaviorist approach which would be mechanistic. If we're talking only about genetics, it tends to be mechanistic. We get into stimulus response psychology. We get into more of a behavior of psychology then opposed to humanistic psychology. We get into a neuropsychiatric model as opposed to something that maybe Menninger would have done years ago looking at the bridge between science and religion, between physics and metaphysics, into looking at the potential of the human spirit for transformation.

Because there's another element here that we really haven't probed at all and that gets out of the psychology of victimization. That goes to what happens when someone does take responsibility and maybe connects with spiritual principles in their own life that helps them to transcend their dilemma. We didn't get into that today, but, given this discussion, I think at some point I think this subcommittee will.

I want to thank the witnesses, and we'll now move to the next panel. I'm going to make the introductions right now. Mr. Mike Mavromatis is a 48-year-old American who lives in Columbus, OH. He owns a family restaurant in Columbus. He is a husband, father of three, grandfather to two. He's an addiction survivor, having recovered from an addiction to Vicodin, a prescription pain medication. He serves on the board of trustees at Central Ohio's oldest and largest sober club, which hosts 20 12-step peer support meetings per week. He's also a member of the National Alliance of Advocates for Buprenorphine Treatment.

Welcome, and we appreciate your presence here.

Dr. Jeffrey Samet is a professor of medicine and public health at Boston University School of Medicine and Public Health. He's also vice chair for public health there. Additionally, he's chief of the section of general internal medicine at the Boston School of Medicine and Boston Medical Center and medical director of the Substance Abuse Prevention and Treatment Services for Boston Public Health Commission. He's the director and president-elect of the American Board of Addiction Medicine. His research addresses substance abuse in HIV infection from health services behavior and epidemiological perspectives.

Mr. Greg Warren is the President and CEO of Baltimore Substance Abuse Systems. His organization directs the prevention, treatment, and strategic planning for drug and alcohol treatment of Baltimore City. The organization has received awards and has been recognized nationally for its innovative work in changing the way substance abuse is delivered and financed in Baltimore City. Previous to BSA, he was the director of Substance Abuse Treatment Services for the Department of Public Safety and Correction Services for the State of Maryland. In this role, he expanded substance abuse treatment for incarcerated offenders.

Mr. Orman Hall, MA, has been the director of the Alcohol, Drug Addiction, and Mental Health Services Board since 1989. This board is responsible for planning, funding, and monitoring all public behavior health services in Fairfield County. Previously, Mr. Hall was a research and evaluation director for the Tri-County Medical Health Board in Ohio and President of the Ohio Association of Alcohol, Drug Addiction, and Mental Health Services Boards.

Mr. Charles O'Keeffe is a professor in the Institute on Drug and Alcohol Studies and the Departments of Preventive Medicine and Community Health, and Pharmacology and Toxicology at Virginia Commonwealth University. Previously, he was President and CEO of Reckitt Benckiser Pharmaceuticals Inc., served in the White House for three Presidents as adviser, special assistant for international health, and deputy director for International Affairs in the Office of Drug Abuse Policy. He served on U.S. delegations to the

World Health Assembly and U.S. Health Commission on Narcotic Drugs, was instrumental in helping Congress reach consensus on the Drug Addiction Treatment Act of 2000. Finally, Mr. Richard Pops, Chairman, President, Chief Executive Officer of Alkermes; and he's previously served as its Chief Executive Officer from 1991 through 2007. Under his leadership, Alkermes has grown from a privately held company with 25 employees to a publicly traded pharmaceutical company with more than 500 employees and two commercial products. Mr. Pops currently serves on several boards of directors, including Biotechnology Industry Organization, the Pharmaceutical Research and Manufacturers of America, and the Harvard Medical School Board of Fellows. This is also a very distinguished panel and much appreciated to have all of you be here for your testimony.

It's the policy of our Committee on Oversight and Government Reform to swear in all witnesses before they testify. I would ask that you rise, raise your right hands.

[Witnesses sworn.]

Mr. KUCINICH. Let the record reflect that each of the witnesses answered in the affirmative. As with panel one, I would ask that each witness give an oral summary of your testimony. Please keep the summary under 5 minutes in duration, up to 5 minutes. Your complete testimony will be included in the record of the hearing, and what you don't get a chance to recite in your testimony, I assume that during the question and answer period you'll be able to cover some of the points you want to make.

So I would ask that we start with Mr. Mavromatis. You may proceed.

STATEMENTS OF MIKE MAVROMATIS, MEMBER, ADDICTIONSURVIVORS.ORG; JEFFREY SAMET, MD, MA, MPH, PROFESSOR OF MEDICINE, BOSTON UNIVERSITY SCHOOL OF MEDICINE; GREGORY C. WARREN, MA, MBA, PRESIDENT AND CEO, BALTIMORE SUBSTANCE ABUSE SYSTEMS, INC.; ORMAN HALL, EXECUTIVE DIRECTOR, FAIRFIELD COUNTY OHIO ALCOHOL DRUG ABUSE MENTAL HEALTH BOARD; CHARLES O'KEEFFE, PROFESSOR, DEPARTMENTS OF PHARMACOLOGY & TOXICOLOGY/EPIDEMIOLOGY & COMMUNITY HEALTH, INSTITUTE FOR DRUG AND ALCOHOL STUDIES, VCU SCHOOL OF MEDICINE; AND RICHARD F. POPS, CHAIRMAN, PRESIDENT, AND CHIEF EXECUTIVE OFFICER, ALKERMES, INC.

STATEMENT OF MIKE MAVROMATIS

Mr. MAVROMATIS. Chairman Kucinich and committee members, thank you for inviting me to give testimony at this hearing. It's obviously something that's very near and dear to my heart and my family's.

I'm a father, a husband, a grandfather, small business owner from Columbus, OH. Over the years, prior to 1999, I served on many community boards, business associations, coached sports, and so on. In 1999, while remodeling our family restaurant, I sustained an injury. Didn't think much of it. Couple months later, it didn't get much better. Visited the family doctor. The family doctor pro-

ceeded to treat me with Vicodin, starting with two tablets a day, one in the morning, one in the afternoon. Over a 4-year period, that treatment increased to basically 120 tablets every 12 days.

During my time with my doctor, I was always honest. I never asked for more medication and relayed to him how I felt honestly and earnestly.

How that changed my life. I became very withdrawn from my family, business, life in general. My social life is gone. I was no longer an active husband or parent, and I was caught in a downward spiral. So, as with anybody, I tried to find out what was wrong, what changed in my life. Obviously, it wasn't old age only that was setting in or anything else. My weight was increasing. So I went through the process of elimination, and what it came down to was my chronic pain issues and how I was being treated for it.

So I decided to stop the Vicodin, stop taking the Vicodin 1 day. And when I did that, within 5, 6 hours, I was in severe withdrawal and the reality of my situation became very clear. That transpired into a situation where I was trapped in a deep, dark place by fear, guilt, and shame. I no longer had the ability to freely choose.

Instead of being able to do the logical thing and seek help, I tried to self-medicate. I went to 12-step groups. I tried to detox myself from Vicodin. I tried to wean myself from Vicodin. Each time I tried, I failed. My daily use increased with each failure. And by the time I entered treatment in February 2006, my use had increased from 120 Vicodin every 12 days to 100 or more every day; and I was spending up to $130,000 a year to support that daily use. In 2006, when I started treatment, my weight had increased from 1999 to 2006 to 305 pounds. I was passing blood in my urine; and, worst of all, I was no longer a husband or a father. I was just a shell of the person I used to be. To try and find solutions, because I finally reached a point where this disease had brought me to my knees, and I had to either find real solutions or just give up and die, I started online, and online I found information about Suboxone on a site, NAABT.org. Not only did I find the vital medical facts I needed and overall educational material about the disease of addiction, to which I was actually naive to prior to this, they offered a doctor-patient matching system; and through that system I was able to get in contact and begin treatment with a local addiction specialist. This offered me the opportunity to be treated with dignity and to continue my life without needing to go away for 60, 90 days or whatever it would take.

When I started the Suboxone, the induction process was interesting, because after about 90 minutes, I felt as though I had never had Vicodin before in my life. I felt no high or euphoria sensations from Suboxone and honestly felt normal for the first time in years. From there, through good instruction and education and incorporating Suboxone into an overall recovery program, a very encompassing recovery program——

[Bells sound.]

Mr. KUCINICH. For those of you who are new to this Hill, that means the House is about to enter into votes. So what I will do is I'll hear testimony from Mr. Mavromatis and Dr. Samet, and then we will take a break of about 30 minutes for votes, and we'll come

back and pick up where we left off. So as soon as those buzzers stop ringing, you can proceed.

Mr. MAVROMATIS. Through taking Suboxone and implementing it with a full and encompassing recovery program based on education, understanding, and peer support, I was able to put my life back together.

Now it has been 4 years and 4 months later, and I've had no relapse, no desire. I'm back to being an active father, husband, grandfather, and small business person in my community. There are some that choose to debate whether the addiction is truly a disease or simply a choice of action. I ask them to look at the facts of what I have experienced. My brain has been biologically altered. It may or may not totally return to a pre-contraction state. Though I'm healed from this disease in terms of putting it into remission, I will always be susceptible to it. I will always have to live my life differently with certain limitations and a more attentive health regime. I will have to do this just as a person who suffers from heart disease would, just as a person who suffers from cancer or diabetes would. Over the past 4 years, I've had the opportunity to work with other people like myself who have experienced the same on a daily basis. Many of them are veterans through our local VA and many online and in person. Of those who have taken Suboxone and worked at the program earnestly—and when I say that I mean within the confines of a full and encompassing recovery program—the success has been really, really well.

[The prepared statement of Mr. Mavromatis follows:]

Mike Mavromatis
Member, Addictionsurvivors.org

Domestic Policy Subcommittee
Of the
Oversight and Government Reform Committee

Wednesday, June 23, 2010
2154 Rayburn HOB
10:00 a.m.

"Treating Addiction as a Disease: The Promise of Medication Assisted Recovery."

Rep. Kucinich and committee members, thank you for inviting me here today, to share my story and to hopefully shed some insight deep into how this disease affects everyday Americans!

This is an important issue and this disease does not discriminate, most of all along political lines! This is an American Society issue and I am very thankful Rep. Kucinich that you are holding this hearing.

As you read my experience, my very personal story, I believe you will come to understand why I am convinced of two things.

First, this is certainly a disease and not simply an infliction caused by personal choice.

Second, why we must embrace and take full advantage of the gains in Medical Science. Be it current medications like Suboxone and the development of new medications along that same Medical Breakthrough.

My name is Mike Mavromatis; I am a 48 year old American who lives in Columbus, Ohio. I am a husband, a father of three and a grandfather to two. Our family owns a restaurant in Columbus which has been in business since 1948. I am an active and proactive member of my community and over my years I have served in business associations, school panels and the Kiwanis. I have spent time coaching sports at the Jr. High School level; I have been heavily involved in charity events and the support thereof. I am a typical hard working middle class family member. I am your neighbor, I am your child's coach, I own the favorite place you like to dine, I am the person you come to for employment or for a donation, I am your best friend, I am your sibling, I am your loved one, I am "you" and I suffer from the disease of addiction!

If you remove my last comment, that I suffer from the Disease of addiction, this was my life prior to 1999. In the fall of 1999 we were remolding our now 62 year old family restaurant. I strained myself in the process and at the time did not think much of it. After several months of not healing and increased pain, I visited my family doctor. After an

examination and pictures, he shared with me that I had damaged the L5 in my back and that I had a rather pronounced curve to my spin, due to this damage and possibly other prior damage. I was informed that over time as I aged my complications might very well increase. He began to treat me with two opiate pain killers per day to help regulate the pain, one to be taken in the morning and one prior to bedtime, as these were my more sever times.

This worked just fine and other than getting the pain relief desired, I felt no other sensations from this medication, vicodin. I knew what it meant to feel high from my younger days prior to being a father, I felt no such sensations. I followed my doctor's orders and always took my medication as directed.

From this time near the end of 1999 to a period in the fall of fall of 2003 and winter of 2004 my life changed dramatically. I saw my doctor every three months so I could get my blood pressure monitored and that prescription refilled, as well as the vicodin for my back. Each time I visited my doctor through this time I was completely honest with him on how I felt and as my pain would return and increase, I shared that with him. My doctor would adjust my pain medication as he felt necessary and I continued to take it as directed.

However, also through this time, I began to change as a person. I went from being a very active and proactive man, to one in slow decline and one becoming detached from everything important to him. My family, my business and my community. Further, my physical health was in decline as well. This was a very slow and unsuspecting process. By the time the fall of 2003 had arrived, I was miserable. Emotionally I was faking life everyday, if that makes sense. I would go through the motions and I wasn't doing a very good job of that. My weight grew from my normal 235 pounds to around 260 pounds. I was always finding excuses to not be involved with my family and to leave my business early.

At this time, my vicodin prescription had grown from the two tablets per day in 1999 to 120 tablets every 12 days! Please note, I took my medications as directed, I was always honest with my doctor and I never requested an increase in my vicodin dose.

However, this was all soon to change!

As I felt terrible physically and emotionally, I set out to figure out why! I began to eliminate what changes had taken place in my life from a personal aspect to a business aspect, both physical and emotional. In hopes of finding what might be causing this. The end result was the medication vicodon and of course my chronic pain issues which it was meant to treat.

For me the solution was simple, stop taking the vicodin. Well I did, I stopped taking it and six to eight hours later I was as sick as I had ever been, experiencing things I had never felt before, both physically and emotionally. I was literally doubled over defecating

from both ends, I had muscle spasms, chills and this very strange and terrible sensation that my insides were trying to crawl out of my skin.

Emotionally I was hit with harsh anxiety, fear, guilt and shame all at once! I was yelling out due to the physical withdrawal symptoms and crying due to shame and guilt at the same time.

So the logical question is simple, Mike why did you not seek medical help? Honestly, to this day I can offer a simple black or white reasoning for that, as it is what I would expect myself to do and that is exactly what I would expect anyone to do! The best way for me to describe this is to tell you that my rational ability to choose had been stripped from me and it was being controlled by the disease of addiction. Everything I had been as a man, as a person, was no longer there.

All of this came to happen in a matter of hours and it was clear to me what I was dealing with, I was addicted to drugs! That is when the guilt and shame hit the hardest. How could I let this happen? How could I fail my family like this? How could I become what I had spent so many years shielding my children from? And how could I let my wife down like this? How could I fail the person who I shared the most with?

Instead of taking the logical steps, I hid, I fell backwards into a deep dark place which I use to only read about others doing! My shame, guilt and fear sent me down a path of trying to fix this myself, while hiding it from my family and from the world. I tried various ways to detox myself and various ways to taper off of the vicodin. I would sneak out to AA meetings far from my home, searching for help and each time I tried, I failed. It got so bad that I would hide in the middle of the night from my family, as they slept I would try to detox myself, withering in pain in a lower level bathroom or in the basement! Other than the family dog, my secret was shared with no one.

Each time I would try to solve this problem myself, I would fail and my daily vicodin use would increase. Between the changes of the year from 2003 to 2004 until February 2006 when I sought out Suboxone therapy, my use grew from 120 vicodin tablets every 12 days, to nearly that, every single day!

Yes, that is right; I was taking up to and beyond more than 100 pain killers per day and doing unthinkable things to obtain them! As if that was not enough destruction, I was spending up to 130,000.00 per year to support my life in active addiction!

By 2/06 my weight had increase up to 305 pounds! My liver and kidneys were shot and I was passing blood in my urine. Worst of all, I was hiding something from my wife, the person most close to me in life, the person whom I always had total honesty with, no matter the issue, no matter the problem! Looking into her loving eyes and knowing this was my bottom, my breaking point.

I finally decided to tell me wife what was taking place and how bad of shape I was in. Many have asked, how did she not know? It is amazing how easy it is to hide this disease, specifically opiate addiction when one finds the need to.

I could not tell my wife the truth however until I had found a clear cut and decisive way to deal with this disease. Not only did I have to bring the truth to her, but, also a real solution, I owed her no less! So I began to research various types of treatment, beyond the traditional self help peer support I had been trying and my constant failure at self medicating.

I learned about Suboxone therapy by doing online searches and I found a very educational site called naabt.org. Not only did NAABT offer very informative and factual medical information, but through that site I found addictionsurvivors.org a peer support forum which offered a wealth of information and understanding, I desperately needed.

Through the doctor / patient matching system at NAABT I was able to find a local addiction specialist who offered Suboxone therapy. I set a consultation appointment and that went very well. After this appointment, I sat my wife down to expose my fear, guilt and shame to her, to share my disease with her. She embraced me and assured me that together, as we have always done, we will get through this and though not pleased with me hiding this, it was going to be OK and side by side, we would learn and heal from this.

I placed myself into moderate withdrawal prior to going into my doctor's office. Unlike normal procedure I opted to do inpatient induction onto Suboxone which is very rare, but, it was a personal choice my wife and I made. The induction process however is the same. After arriving the induction process began and within 90 minutes I actually felt as though I had never taken a vicodin in my life. When I looked back at that period between the winter of 03/04 and what took place to this point, I was more than astonished at how effective this medication was.

From this point on I had to begin to learn about Suboxone and about this disease. I had to learn that as effective as Suboxone was, it was not recovery, nor was it a cure. That true recovery would come from within me. However, finally that terrible cycle of trying to detox, trying to find a way out only to relapse had been bridged. I could now think clearly and decisively. I could begin to address all of the mental, emotional and physical chains holding me in this terrible state.

Since February 2006 my life has changed dramatically. Though I still suffer from chronic pain due to back and hip problems, today I am learning new ways to deal with them and to improve them. Today I am back to being a productive and proactive, an engaged husband, father, grandfather and community leader. Not only have I not suffered a relapse, honestly I have not had any desire for vicodin.

Since 2/06 I have shared with and worked daily with others who suffer from this disease. I sit on the board of trustees of Central Ohio's oldest and largest Sober Club

(organization) which hosts twenty 12 Step peer support meetings per week. Along with that, we have been able to begin to educate and share how advances in medicine can now offer opportunities and help to those who have gone through the detox / relapse cycle for years!

There are other very important values of Suboxone therapy. It helps to remove the stigma created by this disease, which so many hide from and which prevents them from seeking quality treatment. You see the fear of what society thinks is real, as it can affect ones job or social standing. Suboxone Therapy removes that by permitting the patient the dignity of the privacy of their doctors' office and they do not have to miss work, as they enter recovery and begin to heal. Please believe me, this in it's self is a real open door to helping so many!

That is my story, my experience. The story of a productive American who was able to enjoy the American dream and who was blessed to have a loving family! A man who went from that, to taking more than 100 pain killers per day, nearly killing himself and destroying his family, without trying to, without wanting to and without going looking for it! To a man who once again not only has hope, but, who has his life back!

From my experience I would like to share two very important things.

First, prior to contracting this disease I use to think that people "chose" to be addicts. That they chose to throw their lives away and always live for the high or to always live running from something. Today I know better. Today I know better because I have lived it! I did not choose this. I did not going looking for it and when I contracted it; my ability of free choice had been if not totally stripped from me, to at the very least being totally controlled by this disease.

Some choose to debate if this really is a disease or not. I ask them to look at the facts of what I have experienced. My brain has been biologically altered. It may or may not totally return to a pre-contraction state! Though I am healed from this disease, though my disease has been put into remission I will always be susceptible to it. I will always have to live my life differently with certain limitations and with a more attentive health regime. I will have to do this, just as the person who suffers from Heart Disease will, just as the person who suffers from Cancer or Diabetes will.

Please make no mistake; I understand that there are many who fall prey to this disease due to personal choice, by using substances for recreational use! However, the fact still remains they cross that threshold where their ability to choose, is removed. The bottom-line is, the end result is the same!

Also please let me share this, the number of people developing this disease as I did is not only on a very frightening rise, but, will soon become the majority of suffers!

Finally on this; "is it really a disease" debate. Even if one choose to not accept the medical science supporting that it is, isn't the bottom-line issue here that we have an

enormous problem which is tearing at the fabric of our nation. A problem which grows daily destroying people and families? A problem which takes from our resources and from our economic stability, making productive people, unproductive? A problem which has nothing to do with politics, but instead a problem which speaks to the overall health and productivity of our nation?

Second I would like to comment on the value of Medicated Assisted Treatment. I interact daily with people who for 5, 10 and even 20 years or more have been in the constant cycle of detox / relapse! I deal daily with trying to help those who cannot find a way to clear the path for productive and proactive recovery!

Daily I share my story, my experience with this disease in hopes of let others know, that Medical Science now offers new proactive and progressive help.

Medical science has finally offered us medication which fosters and lends it's self to recovery and healing. Suboxone as it has proven to me through my experience is specifically formulated to not build a tolerance in patients, to not permit it's self to be abused, unlike older medications it works best at the lowest possible dose and it is a step down program. Suboxone bridges that raging river of harsh detox and the longer term post acute detox symptoms which can last for months or even past a year, always preventing or trying to prevent the patient from focusing on healing themselves and from working productive and proactive recovery.

Today medical science has finally caught up with this disease, now it is up to us, lawmakers, medical professionals and people like me, to take advantage of it. If we don't, not only will it be an injustice to those currently suffering, but, we will fall even more behind this disease creating an impossible situation!

In closing please let me share these thoughts. We beat this disease by staying ahead of it, not chasing it. We beat it through education, medical science, traditional therapy and peer support all combined. Recovery is about living life again. It is about enjoying life again!

It is not about living under constant struggle and fear of relapse!

Also please let me add, being a fiscal conservative and a small business owner, I spend each day finding ways to be more productive for less. I fight daily wasteful spending and honestly, I am one of the first to yell foul when I see tax dollars being wasted. If I were not convinced, if it had not been proven to me through my own personal experience and the experience of hundreds whom I have worked with over the past four plus years, I would not be here today to support this and to give witness to the benefits and the need for the proactive and productive benefits of medications like Suboxone.

Further, please take the facts of my story when you consider the fiscal responsibilities of helping others with this breakthrough medication and hopefully more to come like it. I was spending 130,000.00 per year to support my life in active addiction. Those were wasted funding, which were serving society in no positive fashion!

Today, living in active recovery, not only do I not waste 130,000.00 per year, but, I am productive again and contributing to society! As a business person this is pretty simple math to me. Our society cannot not afford either morally, health wise or fiscally to not take advantage of the new medical science now available.

Thank you, Rep. Kucinich for holding a hearing on such an important issue – if medications were more widely available to treat more addictions, we could save millions of lives, as my story demonstrates. Thank you again for permitting me this opportunity.

Rep. Souder, thank you for sponsoring H.R. 3634 the Drug Addiction Treatment Expansion Act of 2003. Mr. Kennedy, Mr. Cummings and Mr. Burton, thank each of you for cosponsoring this. I wish I could take each of you by the hand and show you how important that was and how much good was done in helping American's change their lives, (save their lives) by raising the Suboxone Therapy patient limit for doctors. It was very proactive. Now, if you could find a path to eliminate this restriction completely, maybe not only can we help the rest of those American's suffering, but, it would be a large step in lowering the treatment cost, across the board!

Rep. Kennedy, a very personal and heart felt congratulations to you on your recovery, life triumphs and for being a voice for so many!

Mr. KUCINICH. Thank you, sir; and thank you for your courage in coming before a congressional subcommittee to testify.

Mr. MAVROMATIS. I'm a little bit out of my water.

Mr. KUCINICH. Your presence here is quite meaningful, and your family and your community should be very proud of you being here at this moment. So I thank you, sir. Dr. Samet, you may proceed.

STATEMENT OF JEFFREY SAMET

Dr. SAMET. Mr. Chairman and members of the committee, on behalf of the American Society of Addiction Medicine [ASAM], I welcome the opportunity to testify on pharmacotherapies for substance use disorders.

ASAM is a national medical specialty society of more than 3,000 physicians. ASAM's mission is to increase access to and improve the quality of addiction medicine and treatment. I am a general internist with expertise in addiction medicine and a professor at Boston University School of Medicine. I have followed patients in primary care at Boston Medical Center since the 1980's. In our urban primary care clinic, 400 patients with opioid dependence receive buprenorphine. In my other role as medical director of the Boston Public Health Commission's Substance Abuse Services, I oversee physicians who work in the opioid treatment program and provide care to approximately 400 patients who receive the medication methadone. These medications enable patients to change their lives for the better. These two medications are among a limited number of pharmacotherapies available for the treatment of addiction.

As physicians who care for patients with addictions, my colleagues and I understand how critical effective treatments, including medications, are for individuals with substance use dependence. Addiction is a treatable chronic illness, as you've heard; and treatment yields benefits, as you've also heard, for individuals, families, and society.

Like other chronic diseases that I treat in primary care such as diabetes and hypertension, medical management of addiction may include medicines that are taken for prolonged periods. These treatments we know improve patients' overall survival, decrease drug use, decrease transmission of HIV, decrease criminal activity, increase social functioning, including employment and housing.

I provide direct patient care for approximately 50 patients with opioid dependence. I have found biuprenorphine to be a highly effective medication. Most patients, as you've also heard, have found it to be transformative and transformative in a good direction. We also manage the State hotline for those looking for buprenorphine treatment and get calls, about 8 to 10 a day, from individuals across the State. Readily accessible treatment for this condition is critical, as we are losing about two people a day to opioid overdose in Massachusetts.

Buprenorphine and methadone are opioid agonists. Because of their pharmacology, neither of these medications cause euphoria in patients who are opioid dependent.

I realize that stories can sometimes convey the value of our actions. One brief one, in 2003, a 20-year-old woman was referred to one of my colleagues by her mom. Mom described the daughter who had a heroin addiction, had experienced multiple overdoses al-

ready, and had undergone multiple detoxifications. The daughter was evaluated and begun on buprenorphine. She started using with the assistance of the medication, attended self-help meetings, and 7 years later has remained clean and sober. In treatment, on treatment, graduated college with honors and works full time in New York City now.

In September 2003, we started a collaborative care program to provide buprenorphine treatment with our primary care clinic to accommodate the large demand. Our model resulted in feasible initiation and maintenance of buprenorphine for the majority of our patients.

With this model and the support of the State to expand treatment, buprenorphine is now provided in 14 community health centers; and another 1,500 patients receive this truly life-saving medication.

One challenge I have encountered with pharmacotherapy is insurance discrimination. Some insurers simply refuse to pay for addiction medications. We hope that once the Wellstone-Domenici parity law is fully in effect this inequity will be remedied. We also ask that Congress use its oversight authority to see this law is enforced and individuals can access their benefits promised to them under the law.

Unfortunately, there are fewer pharmacotherapies to treat addiction today than there are for other chronic illnesses. For my HIV-infected patients, compared to 1990 when we had one medication, there are now more than 20. In 1990, there were three medications to treat addictive disorders. Today, there are five. That is an improvement but nowhere comparable to the need. If we had more medications for addictive disorders, we would be able to put them to good use.

In closing, thank you again for the opportunity to testify today. Millions of Americans are living productive lives in recovery, and you heard that before. We see it in our clinic. ASAM remains committed to working with policymakers to ensure that all Americans who need treatment are able to access it, high-quality treatment services. Access to new pharmacotherapies would be of great value in enabling us to do just that.

[The prepared statement of Dr. Samet follows:]

Testimony

Of

Dr. Jeffrey Samet, MD, MA, MPH

Professor of Medicine
Boston University School of Medicine

On behalf of
The American Society of Addiction Medicine

Before the
Committee on Oversight and Government Reform
Domestic Policy Subcommittee
United States House of Representatives

June 23, 2010

Mr. Chairman, Ranking Member Jordan and Members of the Committee, on behalf of the American Society of Addiction Medicine (ASAM), I applaud you for holding this important hearing today on "Treating Addiction as a Disease: The Promise of Medication Assisted Recovery." I welcome the opportunity to testify on pharmacotherapies for substance use disorders.

As physicians who care for patients with addictions, my colleagues and I understand how critical effective treatments, including medications, are for individuals with substance use dependence. Addiction is a treatable chronic illness and treatment yields benefits for individuals, families and society.

In my primary care practice, I see firsthand both the benefits of pharmacotherapies to treat addiction and hear the stories of the pervasive barriers that prevent individuals from accessing effective medication assisted treatment. During my testimony, I will outline the benefits of these medications, particularly in a primary care setting. I will make recommendations to overcome policy barriers that prevent widespread adoption of medication assisted treatment. Finally, I will make the case for the need for an even wider array of new medicines to treat addictive disorders.

BACKGROUND

ASAM is a national medical specialty society of more than 3,000 physicians. ASAM's mission is to increase access to and improve the quality of addiction treatment. ASAM seeks to educate physicians, medical and osteopathic students and other health care providers about addiction and addiction medicine.

I am a primary care physician trained as a general internist with expertise in Addiction medicine. I am a Professor of Medicine at Boston University School of Medicine and Chief of General Internal Medicine. I have followed patients in primary care at Boston Medical Center since the 1980s and have been funded by the National Institute on Drug Abuse and the National Institute on Alcohol Abuse and Alcoholism for the past 15 years, in part to examine the delivery of addiction care in the primary care setting. In our urban primary care clinic at Boston Medical Center we care for approximately 400 patients with opioid dependence who receive treatment with the medication buprenorphine. In my other role as Medical Director of the Boston Public Health Commission's Substance Abuse Services Division, I oversee physicians who work in the Opioid Treatment Program and provide care to approximately 400 patients with opioid dependence who receive treatment with the medication methadone. These medications enable patients to change their lives for the better.

MEDICAL UTILITY OF USING PHARMACOTHERAPIES TO TREAT ADDICTION & CURRENT MEDICATIONS THAT ARE PROVEN EFFECTIVE AT TREATING ADDICTION

Today, these two medications, buprenorphine and methadone, are among a limited number of effective pharmacotherapies that are available for the treatment of addiction.

Like other chronic diseases that I treat in primary care, such as diabetes and hypertension, medical management of addiction may include medicines that are taken for prolonged periods, "maintenance therapies." The National Quality Forum (NQF) has issued guidelines recommending the combination of medications and psychosocial support as part of an integrated treatment program.[1] When medications and psychosocial support are used for addiction treatment they:

- Improve the patient's overall survival

[1] National Quality Forum Report, National Standards for the Treatment of Substance Use Conditions, 2007.

- Improve patient retention in treatment
- Decrease heroin, alcohol and other drug use
- Decrease the transmission of HIV
- Decrease criminal activity
- Increase social functioning including employment and housing[2]
- Improve birth outcomes[3]

TREATING ADDICTION IN PRIMARY CARE

In my primary care practice, I am one of eight physicians that can prescribe buprenorphine and I provide direct patient care to approximately 50 of the 400 patients with opioid dependence. I have found buprenorphine to be a highly effective medication for the treatment of heroin and prescription opioid addiction. Many, in fact, most patients have found it transformative.

We also manage the State hotline for those looking for buprenorphine treatment and get 8-10 calls a day from individuals across the state. People are desperate for treatment as they know this is an effective tool and yet some cannot access it as readily as we would like. Readily accessible treatment for this condition is critical as we are losing two people a day to an overdose in Massachusetts.

Buprenorphine and methadone are opioid agonists that, when taken daily, have been shown to be highly effective in treating heroin and prescription opioid dependence. When taken in adequate doses these medications: 1) alleviate acute opioid withdrawal symptoms, 2) prevent opioid craving and urges, and 3) cause "narcotic blockade" thus blocking any reward or euphoria if the patient relapses. Because of their pharmacology, neither of these medications cause euphoria in patients who are opioid dependent. Buprenorphine, a relatively new medication for treating opioid dependence, has been available in the US since 2002 and can be prescribed in primary care settings by qualified physicians. On the other hand, methadone, which has been used to treat opioid dependence for over 45 years, is dispensed in highly structured federally and state regulated opioid treatment programs.

Other medications for addiction on the market include oral naltrexone, injectable naltrexone, acamprosate and disulfiram for alcohol dependence. Oral naltrexone although effective, has proven less transformative than buprenorphine to date as evidenced by the lack of patient demand for this pharmacotherapy. Adherence, or taking one's medication, can also be a substantial issue for the alcoholism oral medications, hence the development of the injectable formulation of naltrexone.

I realize that stories can sometimes convey the value of our actions. I will describe two of our patients.

In 2003, when buprenorphine initially became available, a 20 year old woman was referred to one of my colleagues by her mother. In mom's desperate call for help, she described her daughter who had a heroin addiction, had experienced multiple overdoses and had undergone multiple detoxifications. The daughter was evaluated and begun on buprenorphine. She stopped using with the assistance of this medication, attended self-help meetings and 7 years later has

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[2] Alford DP, LaBelle C, Richardson JM, O'Connell JJ, Hohl CA, Cheng DM, Samet JH. Treating homeless opioid dependent patients with buprenorphine in an office-based setting. J Gen Intern Med. 2007; 22:171-176.

[3] Strain EC, Stitzer ML. Methadone Treatment for Opioid Dependence. 1999.

remained clean and sober on treatment, graduated college with honors and now works fulltime in New York City.

My own patient, a 19 year old woman, previously a high school cheerleader, was brought in by her father, a local prominent town official. We initially started her on buprenorphine but it was not sufficient to treat her addiction. Her father ended up pursuing court mandated addiction treatment. This led to her entering into a methadone program and with this structure and the benefits of that medication, she has now been in recovery for 4 years. She is currently receiving 28–day "take-homes" of methadone in our primary care clinic. Today she is working full-time while in college, has a boyfriend and recently took out a car loan. As a physician, having options when one good medication is not effective makes a big difference.

SUCCESSES AND CHALLENGES OF TREATING ADDICTION

Primary care is an effective environment for the delivery of addiction treatment and primary care treatment improves outcomes. A 2005 study found that receipt of two or more primary care visits lowered the odds of drug use or alcohol intoxication and decreased alcohol and drug use severity.[4]

Additionally, in the Kaiser Permanente system in California, one analysis found that for patients with substance use disorder-related medical conditions, integrating medical and substance use disorder treatment services results in decreases in hospital rates, fewer days of inpatient treatment, and fewer emergency department visits. Total medical costs per patient per month were halved, from $431 to $200.[5]

Primary care teams comprised of physicians, nurses and case managers, are ideally positioned to support patients in and seeking recovery as they are able to:

- Establish a supportive relationship with regular follow up
- Facilitate involvement in 12-step groups
- Help patients recognize and cope with relapse precipitants and craving
- Manage depression, anxiety and other co-occurring conditions
- Consider optimal use of pharmacotherapy
- Collaborate with addiction and mental health professionals[6,7]

Coordinating care between addiction treatment services and primary care services can yield benefits. From the patient's perspective, the benefits associated with linking medical care and substance use disorder services include:

- Facilitated access to substance use disorder treatment and primary care services
- Decreased severity of substance use disorder and medical problems
- Increased patient satisfaction with health care[8]

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[4] Saitz R, Horton NJ, Larson MJ, Winter M, Samet JH. Addiction. 2005; 100:70-78.
[5] Parthasarathy, S., Mertens, J., Moore, C., & Weisner, C. (2003). Utilization and cost impact of integrating substance abuse treatment and primary care. *Medical Care*, 41(3), 357-367.
[6] Friedmann PD, Saitz R, Samet JH. JAMA. 1998;279:1227-1231.
[7] Friedmann PD, Rose J, Hayaki J, et al. J Gen Intern Med. 2006;21:1229-1275.
[8] Samet JH, Friedmann P, Saitz R. Arch Intern Med. 2001; 161: 85-91.

From a societal or public health perspective, the potential benefits of linking the two include:

- Reduced health care costs
- Diminished duplication of services
- Improved health outcomes

In September 2003, we started a collaborative care program to provide buprenorphine treatment for our patients within our primary care clinic to accommodate the large public demand for opioid dependence treatment. Our collaborative care model included nurse care managers and primary care physicians and resulted in feasible initiation and maintenance of buprenorphine for the majority of our patients. With this model and the support of the state to expand treatment, buprenorphine is now provided in 14 community health centers and another 1,500 patients receive this life saving medication.

Insurance Discrimination
One of the challenges my colleagues and I have encountered to treating patients with pharmacotherapies is insurance discrimination – some insurers simply refuse to pay for addiction medications.

We hope that once the Wellstone Domenici parity law is fully in effect, this inequity will be remedied as the law requires plans to treat substance use disorders on par with medical/surgical conditions. We believe it is a violation of the statute for plans to refuse to cover addiction pharmacotherapies if they cover pharmacotherapies to treat other medical/surgical conditions.

We are hopeful that the relevant federal agencies will ensure parity is implemented according to Congressional intent and fully enforced with penalties for plans that violate the law. The parity regulations are scheduled to go into effect July 1, but several insurers have filed a lawsuit to stop the regulations. We ask that Congress use its oversight authority to see that this law is enforced and individuals can access their benefits promised to them under the law.

Lack of Pharmacotherapies in the Market
Unfortunately, because of a combination of factors including insurance discrimination, stigma and lack of a stable market for addiction pharmacotherapies, there are fewer available medications to treat addiction today than there are for other chronic illnesses we see in primary care. For example, today, 235 new medications are currently in development to treat diabetes and related conditions. For my HIV infected patients, compared to 1990 when we had one medication, there are now more than 20. In 1990 there were 3 medications to treat addictive disorders, today there are five. That is an improvement but the rate of improvement is nowhere comparable to the need! I can say that if we had more medications for addictive disorders, we would be able to put them to good use caring for patients. That process does not happen instantaneously, but that would be a wonderful challenge that I and many medical colleagues would love to be able to tackle.

CONCLUSION

In closing, thank you again for the opportunity to testify here today.

Millions of Americans are living productive lives in recovery. However, 23 million Americans are in need of treatment. ASAM remains committed to working with policymakers to erase the treatment gap by ensuring that all Americans who need treatment are able to access, high quality addiction treatment services. Access to new pharmacotherapies would be of great value in enabling us to do just that.

Mr. KUCINICH. I thank the gentleman for his testimony.

We are going to recess here until approximately 12:30, at which time we will resume with testimony from the rest of the witnesses, and then we'll go to questions.

We will be in recess until 12:30.

[Recess.]

Mr. KUCINICH. The committee will come to order.

Thank you for your patience while we conducted a series of votes on the floor of the House of Representatives.

We're going to pick up where we left off and hear testimony from Mr. Warren. You may proceed. Thank you.

STATEMENT OF GREGORY C. WARREN

Mr. WARREN. Thank you, Mr. Chairman and members of the committee, on behalf of Baltimore Substance Abuse Systems, which is the funding, strategic planning entity that funds over 60 drug treatment programs in Baltimore City, treats 21,000 people, I appreciate sharing the story of what we've been able to accomplish with medicated-assisted treatment, which is one aspect of my talk.

The second is describe some of the experiences I had as director of substance abuse treatment services for the State prison system and how we can use medication-assisted treatment to better link people into care upon release.

I was struck very much by the quality of the debate that happened prior to the break, and there are some several key philosophical approaches that I use in my work that I've learned over the years of counseling people suffering from addiction. And that is it is very, very important to take advantage of that what I call motivational moment that an individual has that says I have a problem and substance abuse may be one of the root causes of it. That's the first piece.

The second is that recovery takes a long time. That phrase "it takes a village" is very, very true. What we've decided to do in Baltimore is begin to change the way we even describe treatment. We prefer a language that says continuity of care. When someone comes into an emergency room because they have liver pain, they then get into one type of substance abuse care, transition to another type of substance abuse care, and then transition to another type of substance abuse care. The end result may be recovery coaches that aren't sponsors, aren't counselors but really help that person better integrate into society.

We think medication-assisted treatment is a significant lever to helping improve the outcomes of the patients that we see.

So just to back up for a minute, let me describe briefly what is going on in Baltimore.

Baltimore is a population just up the street, 650,000 people, of which 12 percent suffer from substance abuse. We have the unfortunate luxury of having heroin dominate the admissions into treatment. So 67 percent of all admissions, heroin is cited as the primary drug of choice. That has given us the ability to develop unique intervention targeted to one drug, one illicit drug, rather than being concerned about evidence-based practices across a wider range of drugs.

In 2006—I was with the State prison system at the time, but Dr. Josh Sharfstein, who is currently the Deputy Director of the FDA, really thought of buprenorphine as a potential to really make a difference in Baltimore City. So what was decided to have create—and during my tenure we have expanded a great deal—was to set up a public health response to an individual disease.

So let me tell what you that means. It means that whether you go into an outpatient program, into an ER, or into a detention center, that you should have the option of medication. The benefit of buprenorphine for us, which is different than methadone, which we're a big supporter of, is that we fund the substance abuse treatment for that individual for the first 35 days. We stabilize that person in treatment on average of 155 days.

At that point, the person has health entitlement benefits and their urines are free—drug free—and they have begun to really achieve some substantial milestones in terms of their recovery. They then are transitioned to a continuing care doctor.

So because of the comprehensive system of helping people get insurance, stabilizing them in care, and then moving to continuing care doctors, we're freeing up our financing and we're also freeing up space within our treatment programs.

To illustrate this, when I took over the BSAS, we had 112 buprenorphine slots—spaces. We currently have 506. Now through those slots we have transitioned over 3,000 people to continuing care doctors who are getting their medications, you know, and being treated for their other medical issues and mental health issues in federally qualified health center and primary care physician offices.

The best news of all is that 94 percent of those people, those stable people that we've transitioned to continuing care doctors, still remain in care after 6 months. So they now have health insurance, they're stable, they are in active recovery, and they continue to be in what we call a medical home, that primary care physician that's going to help look after all of their needs.

Some of the stories, particularly from the panelists to my right, there are a great number of medical complications that frequently are related to addiction; and to be able to get someone placed in a place where all of those things can be taken care of comprehensively is just such a significant advantage.

We believe that the way we're incentivizing care today has to fundamentally change. We currently fund episodic acute care. What we're interested in doing is creating new funding mechanisms that reward the referral, in other words, the emergency room, the detention center, or the drug treatment program to refer somebody to another type of substance abuse care; and they should be financially incentivized as well. So instead of just funding one place with four walls and a roof, we want to fund the entire system and have the funding follow the patient. That is our buprenorphine initiative in a nutshell.

Let me switch very quickly to my work in corrections.

Prior to my starting at public safety in 2005, people regularly died in our detention center and prison of overdose. The single biggest period of overdose deaths is after someone leaves an institution and they go back and try to use the same dose of heroin that

they did prior to their incarceration or when they leave hospital stays. This is a significant challenge in filling—sorry, significant challenge in causing stress with correctional officers, institutions; and it is a public safety issue within detention centers and prisons, which is illicit drug use.

So, for us, what happened was in our detention center we processed within Baltimore City about 85,000 people. We now assess every single one of those people. Over 70 percent readily self-report that they have an addiction problem. We believe it is higher than that, but just that they would self-report it is—that's a substantial benefit.

We now induce people on methadone and detox them with methadone inside the detention center, and in the calendar year before I left we detoxed 5,400 people using methadone and other drugs. People who get arrested on methadone were historically thrown off of their dose. We now maintain those individuals on methadone while they're incarcerated so that if they do get probation, if they are released on their own recognizance or can make bail, they can return to the program without having to go through withdrawal. This has saved lives in Baltimore City.

What we now plan to do in our next phase, which is one of the reasons why we have to come on board in charge of Baltimore City, is I need to increase the infrastructure to absorb heroin addicts who come in because of a drug-related offense. We want to induce them, start them on buprenorphine or methadone, and have them leave the institution the same day, get medicated upon release, which then takes the significant pressure of withdrawal and the need to commit new criminal acts away from them. We think in doing this we'll make a substantial impact on the murder rate, crime, spread of HIV, and other things.

By the end of this fall——

Mr. KUCINICH. Could you wrap up your testimony?

Mr. WARREN. This fall, we'll have some research coming out that will help us determine if we've saved money with health care expenses deferred, recidivism rates, and otherwise. Because we think we potentially have a story to tell. We just need outside researchers to come in and help us tell our story, rather than us trying to tell our own story.

Thank you for the opportunity to share.

[The prepared statement of Mr. Warren follows:]

Greg Warren, MA, MBA
President and CEO
Baltimore Substance Abuse Systems, Inc.

Domestic Policy Subcommittee Of the
Oversight and Government Reform Committee

Wednesday, June 23, 2010
2154 Rayburn HOB
10:00 a.m.

"Treating Addiction as a Disease: The Promise of Medication Assisted Recovery."

Organization

Baltimore Substance Abuse Systems, Inc., Baltimore HealthCare Access, Inc., and the Baltimore City Health Department

The Baltimore Buprenorphine Initiative

Overview

Baltimore City has one of the most severe heroin addiction problems in the United States. This is evidenced by the number of admissions to substance abuse programs, emergency department visits and deaths from heroin overdoses. Long term dependence on opiates also contributes to the worsening of other chronic conditions such as diabetes, hypertension and asthma. Further consequences of untreated opioid dependence are premature death, increased crime and destroyed families.

Despite increased substance abuse treatment in Baltimore over the last decade, the availability of treatment remains inadequate to meet the increasing need for substance abuse treatment in the city. To respond the significant treatment gap and to address Baltimore's high rate of overdose deaths, the Baltimore Buprenorphine Initiative (BBI) was implemented in October 2006 by the Baltimore City Health Department (BCHD) and Baltimore Substance Abuse Systems, Inc. (BSAS), the city's local treatment authority for addiction, in partnership with Baltimore HealthCare Access, Inc. (BHCA).

Buprenorphine is a medication used to treat opioid addiction that can be prescribed in physician offices and other settings. Given the significant number of medical doctors in Baltimore and the demand for more treatment, the three city agencies developed a new model of treatment using buprenorphine that capitalized on the medical system resource available in the city. The BBI has the following goals:

1. Increase access to buprenorphine treatment for opiate addicted individuals in Baltimore City
2. Develop a system of care for uninsured opioid addicted patients that provides a continuum of care starting in the publicly funded drug treatment system and continues to medical management in the community.
3. Expand the number of publicly funded outpatient substance abuse treatment slots that provide counseling and buprenorphine treatment.
4. Expand the number of certified physicians able to prescribe buprenorphine treatment.
5. Provide a model for public financing of substance abuse treatment
6. Create a system that creates a "medical home" for the uninsured

Implementation

The Baltimore Buprenorphine Initiative (BBI) is a joint project of the Baltimore City Health Department, Baltimore Substance Abuse Systems, Inc., and Baltimore HealthCare Access, Inc. and promotes individualized, patient-centered buprenorphine therapy in conjunction with behavioral treatment with a goal of recovery from opioid addiction. The model promotes a continuum of care that includes an outpatient treatment regimen, medication induction, as well as maintenance and stabilization in the medical care system

There are three major components of the BBI, which are also shown in the diagram below:

- **Patients start buprenorphine in a substance abuse treatment center.** The BBI provides patients with buprenorphine as well as other therapeutic services including, but not limited to, individual and group therapy. Patients initiate services in one of the designated BSAS-funded outpatient treatment centers. Patients may also start treatment in a physician's office or a residential treatment center. Buprenorphine induction takes place through on-site physicians at each treatment center and are seen by the on-site physician and nursing staff on a regular basis as they are maintained on buprenorphine while receiving ongoing individual and group counseling services. Patients are provided with the services of an advocate from Baltimore HealthCare Access, Inc. (BHCA) to help obtain health insurance so that the cost of the buprenorphine can be covered and that patients can obtain ongoing treatment by a buprenorphine -certified continuing care physician once stable.

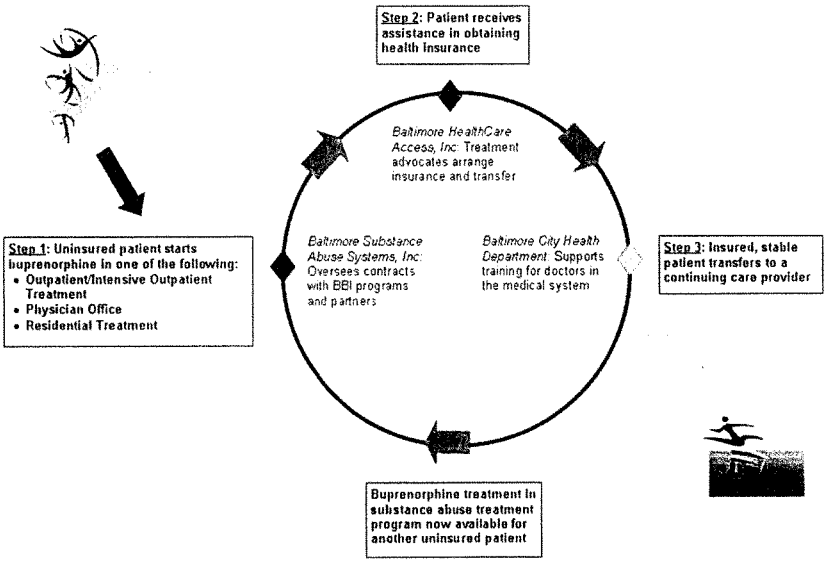
- **Patient transitions to the medical system for buprenorphine stabilization and medical care.** The BHCA advocate works with the treatment center clinical team to identify patients who meet the criteria for transfer to the medical or mental health system for continuing care. The BHCA advocate facilitates the transfer process by sending designated clinical and other information to the assigned physician and then continues to support the patient and the physician for an additional six months following transfer.

- **Patient continues to receive substance abuse counseling.** If interested or clinically recommended, the patient continues to receive at least three additional months of counseling at the original substance abuse center

after transfer to the assigned physician.

Once a patient transfers to a continuing care physician in the community, a space is opened up for another uninsured patient to receive buprenorphine treatment, thus expanding access to care.

The Baltimore Buprenorphine Initiative



The total annual cost to operate the BBI for fiscal year 2009 was $2,847,000. These costs include funding for medication, outpatient counseling, physician and nursing staff and support to BHCA for treatment advocate staff. Funding streams include the Single State Agency funds from block grants, Baltimore City General funds and a grant from the Robert Wood Johnson Foundation.

Outcomes

The BBI has been extremely effective in expanding access to opioid addiction treatment in Baltimore City and promoting recovery for individuals suffering from opioid addiction. Since the inception of the program, the BBI has treated over 3,000 patients. Length of stay in treatment is a strong predictor of long term recovery and treatment effectiveness. For FY 2009, 58 % of patients were retained in treatment for 90 days or longer across the participating BBI treatment programs. A major objective of the BBI is to stabilize and transfer patients to continuing care physicians and to date we have reduced the period of stabilizing patients and transferring BBI patients out of substance

abuse programs to primary care physicians from 281 days at its inception to 155 days today. We are also pleased that 94% of patients continue to receive medical care six months after transitioning a continuing care physician for the substance abuse needs. An external evaluation of the BBI is being conducted currently investigating the savings in emergency room visits, hospitalizations and criminal recidivism and will be available in September, 2010.

In addition to the above outcome measures, the BBI published clinical guidelines in March, 2009 to promote adherence to a set of standards based on current evidence of effective practice. A set of standardized documentation materials were included as part of the guidelines and training of all medical, nursing, counseling and other BBI staff was conducted to promote understanding and compliance with the new protocols. A quality improvement effort is currently underway to assure ongoing monitoring and promotion of quality across BBI programs. Since 2009 BBI has received three national awards for its clinical practices, integration of public health city, state and private agencies and financing system.

How the Program has been sustained

BCHD and BSAS have been extremely effective in advocating for increased funding to support expanded buprenorphine treatment. Since October, 2006, the BBI has tripled its funding from the state of Maryland, demonstrating the strong support from the state legislature and Governor. The BBI's unique system of care that facilitates patients obtaining health insurance and moving to the medical care system where care is reimbursed supports long term sustainability. In January, 2010, Maryland included buprenorphine treatment in outpatient programs as a covered benefit by the Primary Adult Care Program, the insurance program most utilized by BBI patients. This expanded third party reimbursement will significantly reduce the number of uninsured patients requiring BSAS support and will allow BBI to treat additional patients and sustain the program long term.

Corrections to Community

Heroin addiction is a significant driver of criminal activity in Baltimore City.

Baltimore has a pressing need for expanded drug addiction treatment capacity. An estimated 74,000 people in Baltimore City or 12% of its population suffer from substance abuse (Maryland State ADAA 2008a; US Census Bureau 2006). However, BSAS is only able to fund approximately 7,500 treatment slots per year, which treat about 22,000 people (BSAS 2008a; Maryland State ADAA 2008b). Treatment slots for heroin addiction are particularly in short supply: Baltimore has long had one of the nation's highest rates of heroin addiction (NIDA 2007, p. 21; DEA 2003), and its publicly funded methadone programs report a 100% utilization rate of treatment slots (BSAS 2008b).

In 2007 there were 85,000 individuals arrested in Baltimore. While 60% of individuals arrested are released within 24 hours, an estimated 53,000 processed individuals are addicted to heroin (Warren GC 2008). The city has been reported to have the highest rate

of heroin positive tests for new arrestees in the U.S. (Gray TA and Wish ED 1998). In addition, there are an estimated 5,600 inmates with addiction diagnoses returning to Baltimore City each year upon the completion of their sentences in state correctional facilities (Warren GC 2008).

This large number of re-entering inmates addicted to heroin and the shortage of drug treatment capacity leaves Baltimore hard-pressed to adequately treat the city's addicted population. For example, in March 2008 there were 330 men and 70 women who underwent opioid detoxification in the DPDS (Warren GC 2008). The lack of treatment capacity for these individuals fuels the city's high crime, HIV infection, and overdose death rates. Up to 75% of thefts, robberies, and murders are linked to substance abuse. Injection drug use associated with heroin use in Baltimore is the leading cause of HIV infection as well as the leading cause of AIDS, which is primarily responsible for the deaths of city residents between the ages of 25 and 44 (Drug Strategies 2000). The city also has one of the highest drug overdose rates in the country (Baltimore City Health Department 2007).

The attached spreadsheet describes the intervention that I implemented while at the Department of Public Safety and Correctional Services in Maryland. In response to a Department of Justice lawsuit we rectified long standing issues surrounding poor clinical care of detainees suffering from heroin addiction. Its goals were to:

1. Maintain methadone clients on their dose, if they were in a methadone program in the community, at the time of their arrest during their pre-trial detention.
2. Provide appropriate detoxification services to heroin addicts, to include the use of methadone if deemed appropriate
3. Coordinate the transfer back to the community methadone program if the patient is released from pre-trial detention.

Since its inception during the calendar year 2008 over 1,000 individuals annually have been maintained on their medications. In addition over 5,200 detainees received humane medical treatment for their withdrawal needs annually as well. Our plan is to induce heroin addicts (who wish to) onto buprenorphine or methadone and enable them to directly enter a substance abuse program upon their release. We believe this will reduce crime and the quality of life for the individuals involved as well as Baltimore City.

For More Information

Please see the BSAS website at www.bsasinc.org and/or contact Greg Warren at 410-637-1900 ext. 211 or at gwarren@bsasinc.org

Mr. KUCINICH. Thank you, Mr. Warren.
Mr. Hall.

STATEMENT OF ORMAN HALL

Mr. HALL. Thank you, Chairman Kucinich.

I am basically Mr. Warren's equivalent in Fairfield County, OH, which is a mixed rural suburban community that is adjacent to Columbus. To be completely honest, I'm rather amazed at how common all of the themes are in terms of what people are talking about here.

What I would like to discuss briefly is the scope of what I believe may be the most profound public health problem that's ever confronted our State and what I think are some potential solutions to that problem.

First of all, in terms of the scope of the problem, in 2002, approximately 4 percent of those persons in treatment for addiction disorders in Fairfield County were there for opiate and heroin addiction problems. By 2008, we experienced a pretty significant uptick. We were at 31 percent. Thirty-one percent of those persons in treatment for addiction disorders in our county were there because they had heroin or opiate addiction problems. Last month—as of last month, almost 70 percent of those persons in treatment for addiction disorders in Fairfield County in rural suburban Fairfield County were there because they were opiate or heroin addicted. In terms of criminal justice statistics, 85 percent of our drug participants are either addicted to heroin or opiates.

Last year, in 2009, we completed a jail utilization study in conjunction with the sheriff's office that covered 2 years, 2003, which was at the beginning of the heroin and opiate epidemic in our community, and 2008, which was toward the end. In 2003, we estimated that the Fairfield County commissioner spent about $350,000 incarcerating opiate addicts. By 2008, 52 percent of all jail days were accounted for by opiate addicts; and the total cost was $2½ million. We also found that more than 90 percent of those persons who were incarcerated for opiate addiction problems were repeat offenders who had been in jail on an average of 5 previous times.

Now how could this have happened in Fairfield County, OH? Obviously, we have illicit pills coming up from Florida and Kentucky, which is a serious problem. We also have heroin coming down from Columbus. But one staggering statistic that I've just recently been able to come up with I think potentially explains most of our problem.

The Ohio Pharmacy Board reports that for the four-county area of Fairfield, Athens, Hocking, and Perry Counties, a region of 269,000 people, there were 13.9 million doses of oxycodone and hydrocodone dispensed legally across all of those residents. If every one of those 269,000 people received an average dose, that would be 52 OxyContins, Percocets, and Vicodins for every man, woman, and child that lives in Fairfield, Athens, Hawking, and Vinton Counties.

If you include propoxyphene and tramadol among those drugs, the numbers raise to 20.1 million, or 75 doses for every person that lives in our area. Unbelievable.

What works. For those people who have crossed the line and are now involved in our criminal justice system, we have found that four things work: a combination of drug court, intensive treatment, frequent random urine screens, and medication-assisted therapy using Suboxone. Suboxone is incredibly important from my perspective. It relieves craving without euphoria, and it displaces other opiates from the receptors.

Now what has been our experience? In the first 2 years of our drug court program that included all four of those elements we were able to suspend 14,000 jail days at a savings of $910,000 to our County. And, again, a combination of all of those four things.

In closing, we are being overwhelmed in central and southern Ohio. The number of opiate and heroin addicts is staggering. We need more drug court capacity, we need more treatment, and we need more Suboxone.

Thank you, sir.

[The prepared statement of Mr. Hall follows:]

TESTIMONY OF
ORMAN HALL
EXECUTIVE DIRECTOR, FAIRFIELD COUNTY ALCOHOL, DRUG ADDICTION AND MENTAL HEALTH SERVICES BOARD, LANCASTER, OHIO

DOMESTIC POLICY SUBCOMMITTEE
OF THE OVERSIGHT AND GOVERNMENT REFORM COMMITTEE
JUNE 23, 2010

Chairman Kucinich, Congressman Jordan, and distinguished members of the Committee, my name is Orman Hall and I am the Executive Director of the Fairfield County Alcohol, Drug Addiction and Mental Health Services Board in Lancaster, Ohio. Previously, I served as the Director of Planning and Evaluation at the Tri-County Board of Recovery and Mental Health Services in Troy, Ohio. These boards are responsible for planning, funding and monitoring mental health and substance abuse treatment services.

During my twenty year tenure with the Fairfield County ADAMH Board, I have had the opportunity to assess community needs and track behavioral health treatment patterns in a number of Ohio communities. I am here today to discuss what may be the most profound public health crisis to ever confront our state and to offer what I believe are practical, cost effective suggestions that could save lives and mitigate the terrible consequences many families suffer in my county and throughout Ohio. The public health crisis that I speak of is the alarming increase in Heroin and prescription opiate abuse among adolescents and young adults.

Fairfield County's opiate problem became apparent in January of 2005. During that month the community of Lancaster mourned the loss of five of its residents to accidental overdose. These preventable deaths foreshadowed a problem which has since grown exponentially.

In 2002, opiate addicts accounted for 4% of those persons in treatment for substance abuse disorders. As of May 2010, opiate and heroin addicts account for 67% of all persons in treatment. Our municipal court reports that 80% of drug court participants are addicted to heroin and other opiates (T. Bartek, personal communication, May 19, 2010) Additionally we have seen the cost of incarcerating opiate and Heroin addicts in our county jail soar from an estimated $350,000 in 2003 to $2.5 million in 2008. Among opiate addicted persons incarcerated in 2008, more than ninety percent were repeat offenders. (Phalen &

Hall, 2009)

This problem is not confined to Fairfield County. According to the Ohio Department of Health there was a 304 percent increase in accidental overdose deaths attributable to prescription opiates between 1997 and 2007. Opiate overdoses now exceed motor vehicle deaths and constitute the single largest cause of accidental death in our state. (Ohio Department of Health, 2009)

This epidemic has devastated our community. Every week the Recovery Center must inform parents of addicted young people that we are unable to provide intensive treatment and medication assisted therapy to their family member. Many of these young adults will end up in prison or will overdose and die.

How could a problem of this magnitude have occurred in the predominantly rural farm communities of Central and Southeastern Ohio? Bill Winsley, Director of the Ohio Pharmacy Board reports there were 14 million doses of Oxycodone and Hydrocodone legally dispensed to the 269,694 residents of Fairfield, Athens, Hocking, and Perry Counties in 2009. (W. Winsley, personal communication, June 2, 2010) That is the equivalent of 52 pain pills for every man, woman and child living in these four rural counties.

Dr. Robert Masone, an anesthesiologist and pain management specialist in Lancaster has collected urine screens and checked the Ohio Pharmacy Board's narcotic database for his patients receiving pain killers. He estimates that 20% of prescribed pain killers are diverted for illegal purposes. (R. Masone, personal communication, June 14, 2010)

Dr. Phillip Prior, a physician specializing in addiction medicine at the Chillicothe VA Hospital asserts that opiates are not effective for chronic pain. Opiate dependence can occur within less than a month of first treatment. Tolerance for opiates increases rapidly requiring escalating dose levels to maintain the desired therapeutic effect. Eventually opiate dependent patients must be detoxed and will experience heightened sensitivity to pain accompanied by severe depression. Seeking relief from symptoms, many of these now addicted patients are driven to habitual use even when the drug is no longer needed. (P. Prior, personal communication, May 14, 2010)

Opiates are a class of drug commonly used in pain management. These drugs produce an intense euphoria which renders them highly addictive. Included

among the opiates are pain medications such as Oxycontin, Percoset, Vicodin, Demerol, Morphine, and the illegal drug, heroin. (Gay, & Hall, 2010)

Regardless of whether you are addicted to heroin or prescription opiates, overcoming opiate addiction is excruciating and most people fail. One national study reports that relapse rates for opiate addiction may range between eighty to ninety-five percent. Treatment failure of this magnitude is unacceptable given the growth of opiate addiction and the newly exposed segments of our population. (Mintzer, Eisenberg, Terra, MacVane, & Himmelstein, 2007)

In early 2006, a year after the tragic deaths of five of our residents in a single month, the Fairfield County ADAMH realized it was time for a change in our approach to opiate addiction. During initial discussions between the Board and Recovery Center it became clear that residential treatment, the most commonly used method would not be viable. With costs approaching $20,000 per episode it was simply too expensive. Also, clinical staff at the Recovery Center voiced concerns about the frequent relapses they were seeing among clients returning from residential programs.

Next we looked at Methadone, a long standing option that has been successful in the stabilization of opiate addicts. Unfortunately, this option was also cost prohibitive because no Methadone clinic exists in our county.

Another option was Suboxone, a drug recently approved by the FDA for the treatment of opiate addiction. This drug has several unique clinical properties that make it useful in the treatment of opiate addiction. Firstly, Suboxone patients are unable to abuse other opiates. According to Recovery Center Physician Sara McIntosh "It blocks the receptors like a plug in an outlet. So if another opiate like heroin is added, Suboxone kicks it off." (S. McIntosh, personal communication, February 24, 2010) Secondly, Suboxone has a ceiling effect at about 16 mg. If an addict attempts to take more medication than prescribed the user will experience no additional effect. Finally, because of the way it acts on the brain Suboxone doesn't produce the euphoria opiate addicts seek. Instead it relieves symptoms of withdrawal leaving recovering addicts with the presence of mind needed to change their lives.

In January of 2007, Suboxone was implemented along with intensive outpatient therapy as a part of a federally funded adult drug court program. The evaluation of that program suggests that Suboxone can effect meaningful change for a cohort of chronic criminal offenders addicted to opiates. (Hall, Myers, & Hall,

2009.)

Participants in adult drug court differed from the general population in important ways. The cohort was typified by low levels of education. Thirty-one percent (31%) of the participants had not completed high school and none were college graduates. Lower levels of educational achievement were paralleled by correspondingly low levels of relational commitment with eighty-five percent (85%) single or divorced. Whatever socioeconomic or personal deficits account for these deviations may also have negatively impacted treatment outcomes.

In spite of these disadvantages, sixty-three percent (63%) of the participants who were addicted to opiates and no other drugs and were treated with Suboxone, successfully completed the program. (Hall, Myers, and Hall, 2009) In my estimation, Suboxone was critically important to the effectiveness of the adult drug court. Further, while we have not yet completed a formal evaluation of Suboxone outside of the criminal justice system, it is my belief, that Suboxone will prove equally effective for the treatment of non-criminal opiate addicts.

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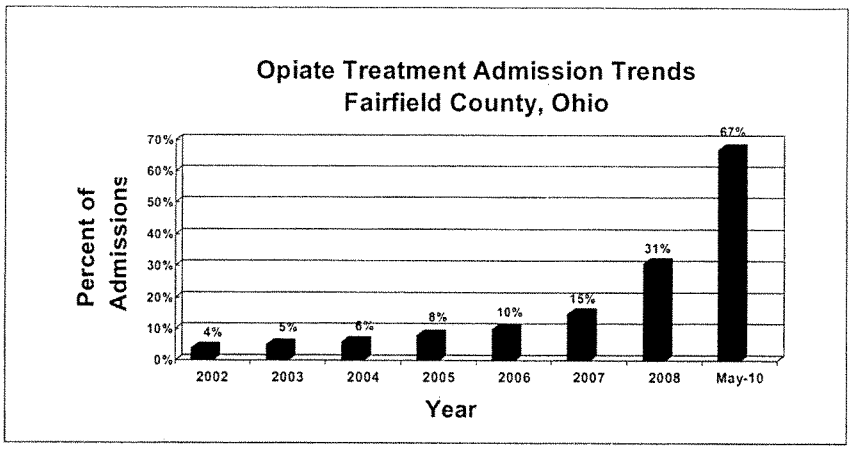
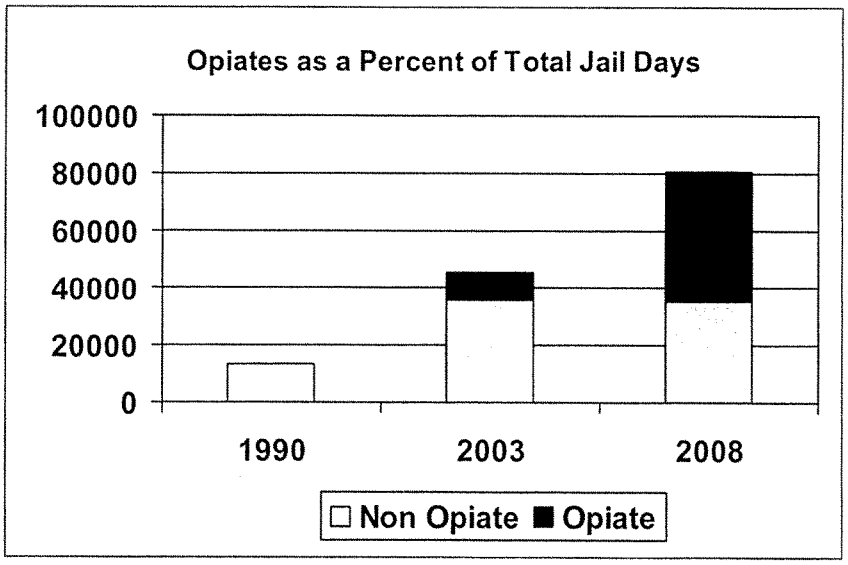

Opiate Treatment Admission Trends
Fairfield County, Ohio
Percent of Admissions
70%
60%
50%
40%
30%
20%
10%
0%
4%
5%
6%
8%
10%
15%
31%
67%
2002
2003
2004
2005
2006
2007
2008
May-10
Year


Opiates as a Percent of Total Jail Days
100000
80000
60000
40000
20000
0
1990
2003
2008
Non Opiate
Opiate

Mr. KUCINICH. Thank you, Mr. Hall.
Mr. O'Keeffe.

STATEMENT OF CHARLES O'KEEFFE

Mr. O'KEEFFE. Thank you, Mr. Chairman.

I will summarize my testimony here and request that my full testimony be inserted in the record.

I had the privilege of working with the National Institute on Drug Abuse in the Cooperative Research and Development Agreement which resulted in the ultimate FDA approval of buprenorphine or Suboxone for opiate dependence. This successful industry-government collaboration has resulted in the treatment of over 2 million people who might never have been treated for opiate dependence without the successful confluence of several factors.

In the late 1990's, under the leadership of then-Senator Biden, Senators Levin and Hatch, then-Chairmen Bliley and Hyde and Mr. Dingell, the Drug Addiction Treatment Act of 2000 was enacted. This act, for the first time in nearly a century, allowed effective agonist-based treatment for opiate dependence in patients in the privacy of the offices and clinics of qualified physicians.

These congressional leaders recognized the significant inadequacies of the highly regulated closed-system addiction treatment programs which had grown out of temporary regulations, temporary fixes begun during the Nixon administration and regularly expanded, often at the behest and to the delight of many of the closed-system treatment providers since that time.

These congressional leaders understood the stigma associated with addiction. They recognized that, unlike cancer, AIDS, diabetes, hypertension, there were no patient advocacy groups to encourage better treatment. They recognized that, despite the fact that nearly every one of us knows or is aware of a family member or friend devastated by this disease, seldom will we talk about it, much less advocate for better research on its causes and treatments.

These congressional leaders recognized that the pharmaceutical industry had little interest in spending scarce research budgets for products for disease whose patients were often unemployed or underemployed, often had no insurance and no other medical coverage or ability to purchase these products.

These leaders recognized that many rejected or failed to fully comprehend the increasingly validated findings of the scientific community related to this disease. They understood that many believed that an addiction was simply irresponsible behavior which should be punished. They recognized that some of these same attitudes also permeated into the structures of medicine, academia, and government. Yet, despite these barriers, the leadership provided by the Biden, Levin, Hatch, Bliley, Hyde, Dingell consortium insisted on better treatment.

Despite the reluctance, sometimes intransigence, of the Food and Drug Administration, despite the expressed concerns of the DEA, and despite the objections of entrenched commercial interests, despite the clear lack of enthusiasm of ONDCP, the 106th Congress passed the Drug Addiction Treatment Act unanimously in the Senate and 412 to 1 in the House. Thus began a paradigm shift in the

treatment of opiate dependence in the United States, and we all relaxed, and that was a mistake.

The barriers to development of products to treat addiction are still in place. Medications for addiction treatment are of little interest to the pharmaceutical industry because there is no incentive to commit scarce R&D funds to development of products unlikely to provide a significant return on that investment. The insufficiency of contract funds available to the National Institute on Drug Abuse limits their ability to engage in development activities suitable for FDA submissions.

The failure of FDA to take a position on what constitutes efficacy in clinical trials for addiction is a major deterrent to investment and research on these products. The stigma of addiction and the fear of DEA leaves many physicians to avoid treating this disease, despite the fact that many of their patients suffer from it. Medical schools are providing inadequate training and treatment for this disease. Stigma prevents patients who suffer from it from seeking treatment.

Additional, and perhaps safer, medications for the treatment of opiate dependence could probably be put in the hands of qualified providers within a year, except for the expressed lack of interest of the Food and Drug Administration and the less-than-helpful interpretations of the Controlled Substances Act by the DEA.

For the benefit of millions of patients who need addiction treatment, I suggest that now is an appropriate time for the Congress to consider options which might encourage the commercial pharmaceutical industry to invest in research for safe and effective treatment of an addictive disease. Among those options which seem to me worthy of consideration by the Congress are the following:

Some modification of the Orphan Drug Act to provide exclusivity for products approved by FDA for this indication without regard to patient numbers.

Perhaps a modification of section 524 of the Food, Drug and Cosmetic Act, which was created last year by the FDA amendments 2 years ago of 2007, by authorizing the FDA to issue a priority review voucher for addictive diseases or an exclusivity voucher similar to one proposed by then-Senator Biden allowing a sponsor of an approved addiction treatment product to transfer a period of exclusivity to another marketed product.

And, finally, perhaps a modification of section 48D of the Internal Revenue Code which would allow qualifying companies to claim a tax credit or receive a grant for qualifying therapeutic addiction treatment discovery projects.

Thank you, Mr. Chairman.

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

Testimony of Charles O'Keeffe
Professor
Institute for Drug and Alcohol Studies,
Departments of Preventative Medicine and Community Health,
Pharmacology and Toxicology
School of Medicine
Virginia Commonwealth University

Before the
Committee on Oversight and Government Reform
Subcommittee on Domestic Policy

June 23, 2010

Mr. Chairman, members of the committee, it's a privilege to be here this morning. My name is Charles O'Keeffe. I'm a professor in the Institute on Drug and Alcohol Studies and the Departments of Preventive Medicine and Community Health, and Pharmacology and Toxicology at the Virginia Commonwealth University School of Medicine, and a Fellow of the College on Problems of Drug Dependence.

Prior to retiring and taking these academic appointments I served as President and Chief Executive Officer of Reckitt Benckiser Pharmaceuticals the successor to Reckitt & Colman Pharmaceuticals. It was in that role that I had the privilege of working with the National Institute on Drug Abuse in the Cooperative Research and Development Agreement which developed buprenorphine for the treatment of opiate dependence. This successful government/industry collaboration has resulted in the treatment of over two million patients who might never have been treated for opiate dependence without the successful confluence of several factors.

The first, and perhaps most important, factor which enabled these patients to be treated was the recognition by several key members of the Congress that our treatment system for patients with this disease was both antiquated and dysfunctional, to the point of preventing patients from being treated by highly qualified physicians.

The second factor was the competence and tenacity of the leadership and scientists at the National Institute of Drug Abuse and those scientists whose research NIDA supports. NIDA leadership, backed by solid scientific findings convinced the Board of Directors of Reckitt & Colman that the company had a social responsibility to cooperate in this development despite the expectation that they were unlikely to recover their development costs.

The third factor was the willingness of the Food and Drug Administration to engage in dialogue with the Congress, NIDA, and the sponsor and their ultimate designation of orphan Drug status for buprenorphine for this disease.

Nevertheless, despite these positive congruent factors, there were considerable hurdles and significant opposition to these changes from vested commercial and philosophic interests.

In the end, science, good medical practice and improvements in public policy prevailed; some barriers were temporarily overcome, and care for a significant number of patients has become available or has improved.

Unfortunately, progress since the enactment of DATA has slowed significantly, and without prodding from this Congress I can envision a deterioration of patient care despite major advances in science.

In the late 1990's, under the strong leadership of then-Senator Biden, Senators Levin and Hatch, then-Chairmen Bliley and Hyde and Mr. Dingell, the Drug Addiction Treatment Act of 2000 was enacted. This act, for the first time in nearly a century, allowed effective

agonist-based treatment of opiate dependence for patients in the privacy of the offices and clinics of qualified physicians.

These congressional leaders recognized the significant inadequacies of the highly regulated closed-system addiction treatment programs which had grown out of "temporary" regulatory fixes begun during the Nixon Administration and regularly expanded, often at the behest and to the delight of many of the closed-system treatment providers since that time.

These congressional leaders understood the stigma associated with addiction. They recognized that unlike cancer, AIDS, diabetes and hypertension, there were no patient advocacy groups to encourage better treatment. They recognized that despite the fact that nearly every one of us knows or is aware of a family member or friend devastated by this disease, seldom will we talk about it, much less advocate for better research on its causes and treatments.

These congressional leaders recognized that the pharmaceutical industry had little interest in spending scarce research budgets for products for a disease whose patients were often unemployed or underemployed and often had no insurance or other medical coverage or ability to purchase these products.

These leaders recognized that many rejected or failed to fully comprehend the increasingly validated findings of the scientific community related to this disease.

They understood that many believed that addiction was simply irresponsible behavior which should be punished. They recognized that some of these same attitudes also permeated into the structures of medicine, academia, and government.

Yet despite these barriers the leadership provided by the Biden, Levin, Hatch, Bliley, Hyde, Dingell consortium insisted on better treatment.

Despite the reluctance, sometimes intransigence, of the FDA – despite the expressed concerns of the DEA – despite the objections of entrenched commercial interests – despite the clear lack of enthusiasm of the ONDCP, the 106th Congress passed the Drug Addiction Treatment Act unanimously in the Senate, and 412 – 1 in the House.

Thus began a paradigm shift in the treatment of opiate dependence in the United States.

And we all relaxed – and that was a mistake.

The barriers to development of products to treat addiction are still in place. Medications for addiction treatment are of little interest to the pharmaceutical industry because there is no incentive to commit scarce R&D funds to development of products unlikely to provide a significant return on that investment. The insufficiency of contract funds available at the National Institute on Drug Abuse limits their ability to engage in development activities suitable for FDA submissions. The failure of FDA to take a position on what

constitutes efficacy in clinical trials for addiction is a major deterrent to investment in research on these products. The stigma of addiction and fear of DEA leads many physicians to avoid treating this disease despite the fact that many of their patients suffer from it. Medical schools are providing inadequate training in treatment for this disease. Stigma prevents patients who suffer from it from seeking treatment.

Additional, and perhaps safer, medications for the treatment of opiate dependence could probably be put in the hands of qualified providers within a year, except for the expressed lack of interest of the FDA and the less than helpful interpretations of the Controlled Substances Act by the DEA.

Regarding FDA's lack of interest; a petition necessary in order for an approved and needed medication (LAAM) to be made available to patients who fail to respond to currently-marketed products was submitted in October 2007. It was acknowledged by FDA on November 1, 2007. On April 28, 2008 the FDA responded to the petition with a "Don't call us – we'll call you" letter saying that they were too busy to bother with it. In December 2008, a follow-up letter was sent to the FDA noting the passage of more than a year and asking that the petition be reprioritized. In January 2009 the American Academy of Addiction Psychiatry sent a letter to FDA asking that the petition be reviewed expeditiously. In February 2009 the American Osteopathic Academy of Addiction Medicine sent a request to FDA urging review and a positive determination of the petition. In March 2009 the American Psychiatric Association strongly urged the FDA to review the petition at the earliest possible time. It's now June, 2010 – 2 years and 8 months after the initial petition, over two years since the FDA said they were too busy to deal with it. There has been no response to any of the follow-up letters.

Copies of that correspondence have been attached to my testimony.

For the reasons stated above, and for the benefit of the millions of patients who need addiction treatment I suggest that now is an appropriate time for the Congress to consider options which might encourage the commercial pharmaceutical industry to invest in research for safe and effective treatment of addictive disease. Among those options which seem to me worthy of consideration by the Congress are the following;

1. Modification of the Orphan Drug Act to provide exclusivity for products approved by FDA for this indication without regard to patient numbers,
2. Modification of Section 524 of the Food Drug & Cosmetic Act which was created by the FDA Amendments Act of 2007 by authorizing the FDA to issue a "Priority Review Voucher" for addictive diseases,
3. An "Exclusivity Voucher" similar to one proposed by then-Senator Biden allowing a sponsor of an approved addiction treatment product to transfer a period of exclusivity to another marketed product.
4. A modification of Section 48D of the Internal Revenue Code which would allow qualifying companies to claim a tax credit or receive a grant for a qualifying therapeutic addiction treatment discovery project.

Appendix

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Medical Center
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Department of Epidemiology and Community Health

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October 31, 2007

Division of Dockets Management
Food and Drug Administration (HFA-305)
Department of Health and Human Services
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Citizen Petition

This petition is submitted in quadruplicate pursuant to 21 CFR 10.25(a) and 10.30 , and in accordance with 21 CFR 314.161, requesting the Commissioner of the Food and Drug Administration to make a determination whether a listed drug has been voluntarily withdrawn for safety or effectiveness reasons, as outlined below.

A. Action Requested

The petitioner requests that the Commissioner of the Food and Drug Administration determine whether levomethadyl acetate HCl (Orlaam®) NDA 20-315 currently held by Roxane Laboratories Inc. has been voluntarily withdrawn or withheld from sale for safety or efficacy reasons. In addition, we request the Commissioner to confirm the eligibility of Orlaam® (levomethadyl acetate HCl) oral solution as a Reference Listed Drug such that it will be allowed to form the basis of an ANDA.

B. Statement of Grounds

The Electronic *Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluation* (Electronic Orange Book) identifies drug products approved on the basis of safety and effectiveness by the Food and Drug Administration (FDA) under the Food, Drug, and Cosmetic Act. The main criterion for inclusion of any product is that the product is the subject of an application with an effective approval that has not been withdrawn for safety or efficacy reasons.

On July 9, 1993 the original NDA 20-315 was approved. On August 23, 2003 Roxane Laboratories notified physicians that it would discontinue the product following depletion of then-existing stocks, expected to occur during the 1st quarter of 2004.

Thereafter, Orlaam® (levomethadyl acetate HCl) oral solution was moved to the Discontinued Drug Products section of the *Electronic Orange Book* (Attachment 1).

Roxane's Orlaam® product is the only levomethadyl acetate HCl product listed in the *Electronic Orange Book.*

Enclosed please find (Attachment 2) the package insert revised in May 2001. Since approval of this most recent configuration in 2001, no specific MedWatch notices or other labeling updates have been posted for this product.

C. Environmental Impact

The petitioner claims a categorical exclusion under 21 CFR 25.31.

D. Economic Impact

The petitioner does not believe that this is applicable in this case, but will agree to provide such an analysis, if requested by the Agency.

E. Certification

The undersigned certifies that to his best knowledge and belief, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner, which are unfavorable to the petition.

Sincerely,

Charles O'Keeffe
Professor
Epidemiology and Community Health
VCU School of Medicine
MCV Campus – Leigh House
1000 East Clay Street
PO Box 980212
Richmond, VA 23298-0212
Tel. 804 828-6246

Attachments:

1. Approved Drug Products with Therapeutic Equivalence Evaluations, Electronic Orange Book listing (OB_Disc) accessed October 31, 2007
2. Approved labeling (May 2001) for the Discontinued Drug Product. ORLAAM® (levomethadyl acetate HCl) 10mg/ml oral solution (concentrate)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

November 1, 2007

Charles O'Keeffe
Epidemiology and Community Health
VCU School of Medicine
1000 East Clay Street
P.O Box , Virginia 23298-0212

Dear O'Keeffe:

Your petition requesting the Food and Drug Administration determine whether levomethadyl acetate HCl (Orlaam) NDA-20-315, has been voluntarily withdrawn from sale for safety or efficacy reasons, was received by this office on 11/01/2007. It was assigned docket number 2007P-0431/CP1 and it was filed on 11/01/2007. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Carolyn Kachovec

Carolyn Kachovec, Director
Division of Dockets Management
Office of Management Programs
Office of Management

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

APR 28 2008

Charles O'Keeffe
Virginia Commonwealth University
School of Medicine
Leigh House
1000 East Clay Street
P.O. Box 980212
Richmond, VA 23298-0212

Re: Docket No. FDA-2007-P-0347

Dear Dr. O'Keeffe:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet made a determination regarding the issue raised in your citizen petition dated October 31, 2007.[1] Your petition requests that we determine whether Orlaam (levomethadyl acetate HCl) oral solution was voluntarily withdrawn from sale for reasons of safety or efficacy.

We have been unable to reach a decision on your petition due to the need to address other Agency priorities. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as possible given the numerous demands on the Agency's resources.

Sincerely,

Jane A. Axelrad

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

[1] This citizen petition was originally assigned docket number 2007P-0431/CP1. The number was changed to FDA-2007-P-0347 as a result of FDA's transition to its new docketing system (Regulations.gov) in January 2008.

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December 2, 2008

Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research
Food and Drug Administration
Rockville, MD 20857

Re: Docket No. FDA-2007-P-0347

Dear Ms. Axelrad,

This letter acknowledges your interim response letter of April 28, 2008 notifying me that FDA has not yet made a determination regarding my petition dated October 31, 2007 requesting a determination whether Orlaam (levomethadyl acetate HCl) was withdrawn from sale for reasons of safety or efficacy.

You indicated that the Agency has been unable to reach a decision due to the need to address other priorities.

The purpose of this letter is to remind the Agency of the petition and express my concern that patients may be dying as a result of inaction on this matter. This petition, in conjunction with another which requests the agency to allow a tablet dosage form is but the first step in a process which I hope will make LAAM available to treat those patients who are not able to participate in methadone treatment programs and have not responded adequately to treatment with buprenorphine, the only two approved treatments for opiate dependence.

Several steps and decisions, both regulatory and legislative, will be necessary before LAAM could be used in this manner, but none of those steps can proceed until a decision is reached on this petition; and I am quite confident that all of the information necessary to make the decision is readily available to the Agency. I am fully aware of the circumstances surrounding the withdrawal of Orlaam, and I am confident that most experts in addiction medicine a well as the Agency are aware of those circumstances. We are all fully aware that Orlaam was not withdrawn for reasons of safety or efficacy. I would be pleased to provide any information the Agency believes it doesn't have at its fingertips in order to make this decision.

an equal opportunity/affirmative action university

As a result of the passage of the Drug Addiction Treatment Act (DATA) of 2000, and FDA approval of two buprenorphine products the following year, physicians for the first time in over eighty years became able to treat opiate dependence in the mainstream practice of medicine (a goal of the medical community and recommendation of the Institute of Medicine for at least twenty years). Since that time more than one million patients have been brought into this treatment by qualified physicians. Most of these patients have responded adequately. Unfortunately, when patients do not respond adequately to this treatment physicians have no other pharmaceutical treatment to offer. They must consequently refer these patients to either methadone treatment programs or drug-free twelve-step programs. Many patients who find themselves in this position reject those referrals either because they've tried drug-free programs without success or refuse to enroll in methadone programs because of either the stigma associated with these clinics or their location. The result is return to illicit narcotic use with the consequent enhanced risk of HIV/AIDS, hepatitis, and overdose death. The limited availability of LAAM to this select group of patients who have failed other treatments, under adequate treatment protocols is likely to offer hope to those physicians and patients who reach this difficult position, and in all probability result in lives saved.

I fully understand the burden under which the Agency operates and am sympathetic to the need to prioritize resources. But I genuinely believe that this decision can be made with a minimum diversion of scarce resources and the consequent decision would allow a process to begin which has the potential of saving many lives.

I would urge you to reprioritize this petition to allow this process to begin.

Sincerely,

Charles O'Keeffe
Professor

AAAP American Academy of Addiction Psychiatry

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Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research
Food and Drug Administration
10903 New Hampshire Avenue
Building 51, Room 6140
Silver Spring, MD 20993

January 13, 2009

Re: Docket #s FDA-2007-P-0347 and 2007-P-0175

Dear Dr. Axelrad,

The American Academy of Addiction Psychiatry is one of the primary professional organizations representing psychiatrists practicing in the medical subspecialty of addiction psychiatry. We have over 800 members nationwide and advocate on national issues related to best practices for the treatment of addiction and mental disorders. We are aware that petitions asking the agency to determine that ORLAAM (levomethadyl acetate HCl) was not withdrawn from sale for safety or efficacy reasons, and to allow the filing of an ANDA for levomethadyl acetate HCl (LAAM) tablets have been submitted to FDA. We are writing to urge you to undertake this determination immediately.

It is our understanding that ORLAAM was withdrawn by the manufacturer after a labeling change which required a black box warning regarding the potential for cardiac arrhythmias causing a reduction in its use. It is our understanding that the approval of buprenorphine products further negatively impacted ORLAAM sales resulting in the manufacturer's decision to no longer market this drug in the United States. This decision was a burden for many patients who were being successfully treated with the medication, and for their treating physicians who had to modify therapy.

While many (most) patients can be treated with the other two approved medications for the treatment of opiate dependence (buprenorphine and methadone), treatment of some patients remains problematic and sometimes unsuccessful. As was observed in the past, when ORLAAM was available, many of these patients could be successfully treated with that medication. At the moment, without this treatment option, it is likely that many of these patients have reverted to illicit opiate addiction and are exposed to the life-threatening consequences of this disease. The return of LAAM to our treatment armamentarium would be likely to bring a significant number of these patients back into treatment and to help them to return to a productive life. A positive action by FDA would make it possible for this medication to again be made available to those patients who have failed to respond to other pharmacologic treatment for opiate dependence, and to patients for whom this medication is necessary because of their employment schedules or distance from treatment programs.

The benefits of LAAM treatment are clear. It is also possible to monitor clinically for adverse effects that might occur with LAAM as recommended by FDA. Further, these requirements no longer confer a clinical disadvantage to LAAM since methadone has been shown to have potential for adverse cardiac effects similar to LAAM and the standard of care for methadone maintenance treatment will soon require monitoring as would be necessary for LAAM.

We strongly urge you to review and make determinations on these petitions at the earliest possible time, so that physicians have all of the pharmacological tools available to treat those with opioid addiction. If you need additional information or advice we stand ready to assist the agency in any appropriate way.

Sincerely,

Elinore F. McCance-Katz, MD, PhD
President

American Osteopathic Academy of Addiction Medicine

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February 5, 2009

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research
Food and Drug Administration
10903 New Hampshire Avenue
Building 51, Room 6140
Silver Spring, MD 20993

Re: Docket #s FDA-2007-P-0347 and 2007-P-0175

Dear Dr. Axelrad,

The American Osteopathic Association is a member association representing more than 64,000 osteopathic physicians (D.O.s). The AOA serves as the primary certifying body for D.O.s, and is the accrediting agency for all osteopathic medical colleges and health care facilities. The American Osteopathic Academy of Addiction Medicine is the specialty organization within AOA which is committed to the access of quality and competent multidisciplinary services to those afflicted with the disorders of substance abuse and addiction. We are committed to the highest level of education for professionals and the community in the field of addiction medicine.

The purpose of this letter is to encourage the FDA to make a decision on petitions which request the agency to determine that ORLAAM (levomethadyl acetate HCl) was not withdrawn from the US market for safety or efficacy reasons, and to allow the filing of an Abbreviated New Drug Application for levomethadyl acetate HCl (LAAM) tablets. These petitions were submitted to the agency more than 15 months ago. We are writing to urge you to undertake this determination immediately.

We are aware that ORLAAM was withdrawn by the manufacturer after a labeling change which required a black box warning regarding the potential for cardiac arrhythmias causing a reduction in its use; and the subsequent approval of buprenorphine products further negatively impacted ORLAAM sales resulting in the manufacturer's decision discontinue marketing this drug in the United States. This decision had a negative impact on the treatment of many patients who were being successfully treated with LAAM. The decision also required treating physicians to modify therapy and resulted in a return to illicit opiate use for some patients for whom methadone or buprenorphine treatment was not possible.

Patients can be treated with the other two approved medications buprenorphine and methadone, but some patients remains problematic, and treatment with these medications is sometimes unsuccessful. LAAM has been shown to be efficacious in many patients who were not appropriate for methadone therapy. Its removal from the market resulted in many of these patients reverting to illicit opiate addiction and exposure to the life-threatening consequences of this disease. A positive action by FDA on these petitions would make it possible for this medication to again be made available to those patients who have failed to respond to other pharmacologic treatment for opiate dependence, and to patients for whom this medication is necessary because of their employment schedules or distance from treatment programs.

The benefits of LAAM treatment are clear. Clinical monitoring for adverse effects that might occur with LAAM is well within the capability of trained clinicians and such monitoring no longer confers a clinical disadvantage to LAAM since methadone has been shown to have potential for adverse cardiac effects similar to LAAM and the standard of care for methadone maintenance treatment will soon include monitoring not unlike that required for LAAM.

We strongly urge you to review and make positive determinations on these petitions at the earliest possible time, so that physicians have all of the pharmacological tools available to treat those with opioid addiction. If you need additional information or advice we stand ready to assist the agency in any appropriate way.

Sincerely,

R Gregory Lande, DO

R. Gregory Lande, DO, FACN
President

Anthony Dekker, DO, FAOAAM
Past President's Council Chairman

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March 30, 2009

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research
Food and Drug Administration
10903 New Hampshire Avenue
Building 51, Room 6140
Silver Spring, MD 20993

RE: Docket Nos. FDA-2007-P-0347 and FDA-2007-P-0175

Dear Ms. Axelrad:

The American Psychiatric Association (APA), the national medical specialty society representing more than 38,000 psychiatric physicians, appreciates the opportunity to submit these comments concerning the Food and Drug Administration's (FDA or the Agency) regulation of ORLAAM (levomethadyl acetate HCl). We are aware that there are two citizen's petitions pending before the Agency asking for a determination that ORLAAM was not withdrawn from sale for safety or efficacy reasons, and to allow the filing of an abbreviated new drug application (ANDA) for levomethadyl acetate HCl (LAAM) tablets have been submitted to FDA. We are writing to urge you to swiftly render a determination on these petitions.

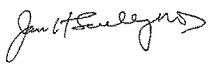
While many, indeed most, patients can be treated with the other three approved medications for the treatment of opiate dependence (buprenorphine, methadone, and naltrexone), treatment of some patients remains problematic and sometimes unsuccessful. In the past, ORLAAM was a viable treatment for the few patients who could not be treated with either buprenorphine or methadone.

It is APA's understanding that ORLAAM was voluntarily withdrawn by the manufacturer after there was a reduction in use of the drug following a labeling change which required a black box warning regarding the potential for cardiac arrhythmias. That labeling change, combined with the approval of buprenorphine products, further negatively impacted ORLAAM sales resulting in the manufacturer's decision to no longer market this drug in the United States. This decision was a burden for many patients who were

being successfully treated with the medication, and for their treating physicians who had to modify therapy. Based on the continual need for physicians to have as many treatment options for opioid addiction available, APA strongly urges you to review and make determinations on these petitions at the earliest possible time.

Thank you for your consideration of these comments. We look forward to working with you in the future on these issues. If you have any further questions, please contact Jennifer Tassler, Deputy Director, Regulatory Affairs, at jtassler@psych.org or at (703) 907-7842.

Sincerely,



Mr. KUCINICH. Thank you.
Mr. Pops, you may proceed.

STATEMENT OF RICHARD F. POPS

Mr. POPS. Thank you, Mr. Chairman, distinguished Members. Thanks for inviting me here today.

I am the CEO of a biotech company called Alkermes, with about 600 employees, 300 of which are the Boston area and 300 of which are in Ohio. We as a biotech company are engaged in the act of typically focusing on treatment of diseases that the large pharmaceutical companies shy away from. In our case, this includes the treatment of addiction. So it is really our real-world experience as one of the few companies working to develop medications in this area that brings me here today.

With original seed funding from NIDA, our scientists created a drug called Vivitrol. Vivitrol is a once-a-month medication. It is a nonaddictive medicine, administered by injection once a month, which relieves the patient of the need to take one or more pills one or more times a day. And, as you may know, taking daily medication for patients with addictive disorders is extremely difficult.

Vivitrol was approved by the FDA for the treatment of alcohol dependence in 2006, and with that approval in hand then we set out on a research program to demonstrate Vivitrol's potential of utility and treatment of opiate dependence as well. That was very successful from a clinical standpoint, and we're hoping for FDA approval in this indication later this year.

We began our work at the molecular level by trying to understand the neuroscience behind addiction. With our successes in the lab and in the clinic, we end up here in Washington with you with a deep interest in advancing the public policy so that our innovations actually get to patients.

You're aware of the statistics. I won't repeat many of them, but they are staggering. Millions of Americans with addiction are unserved or untreated and don't have access to important treatment options.

If you compare the use of medicine for the treatment of depression to that of alcohol dependence, it is instructive. The rate of medication prescribed per covered life for depression is almost 1 in 10 for antidepressants, and that compares to alcoholism to less than 1 in 5,000.

The system in the U.S. bearing the largest economic and public safety brunt of alcohol addiction is criminal justice, where 40 percent of all violent crimes involve alcohol; and, despite this prevalence, over 80 percent of addicted offenders fail to receive treatment for their disease.

So in addition to this being bad medicine, it is bad economics. These untreated patients are costing the system billions of dollars, as you know. That might have been understandable 30 years ago when the scientific understanding of the addicted brain was at its infancy. But today, knowing what we know about the neuroscience of addiction, failure to use medicines is inexcusable.

With the FDA now having approved medications based on rigorous demonstration of their safety and their efficacy and with the NIH and the Institute of Medicine calling for their use in combina-

tion with counseling, it is now time for society to begin to treat substance abuse as the disease that it is.

This work at Alkermes has become very real to us. We receive letters and stories from patients who have benefited from the use of Vivitrol as part of their treatment program. They are incredibly moving, and they are a driving motivation within our organization. But we are definitely the minority. The treatment of addiction is not a mainstream pharmaceutical market, as you've heard. None of the largest pharmaceutical companies sell products for the treatment of addiction, but I believe this can and will change.

Government can help. In fact, I believe the government policy changes are likely necessary to solidify the development of new medications for alcohol and drug addiction.

We have specific recommendations that we summarize in the written testimony, but, in a brief nutshell, there are simple and powerful things that can be done:

First, simply implementing established treatment standards like those of the National Quality Forum and making them a condition to participating in public and private programs would be a huge step forward. These standards exist.

No. 2, providing grants and incentives for States to assist them with establishing addiction pharmacology programs.

Third, simply using performance-based metrics like you hear about in Baltimore and Ohio to fund programs that work and accredit providers who use those that work.

And then, finally, an even more aggressive idea similar to what you did with vaccines is to jump-start the market with guaranteed minimum purchase orders for a limited period of time.

These kinds of initiatives represent ways that government leadership can help patients gain access to effective medications, create incentives for companies to invest in R&D, and avoid the huge costs of nontreatment of these patients.

So I'll finish there. We really do believe that State and Federal Government can play a role here and begin to bring the promise of the modern pharmaceutical research that we do in our company and other companies, bring that to the treatment of addiction.

Thank you again.

[The prepared statement of Mr. Pops follows:]

Testimony

of

Richard Pops

President and Chief Executive Officer
Alkermes, Inc.

Before the
Committee on Oversight and Government Reform
Domestic Policy Subcommittee
United States House of Representatives

June 23, 2010

Mr. Chairman, Ranking Member Jordan and distinguished Members of the Committee, thank you for inviting me to testify here today. I serve as CEO of Alkermes, Inc., a biotechnology company based in Waltham, Massachusetts with manufacturing facilities in Wilmington, Ohio. I have been CEO of Alkermes for nearly 20 years and during this time, Alkermes has grown from a privately held company with 25 employees to a publicly traded biotechnology company with approximately 600 employees. In addition to my role at Alkermes, I serve on the Board of Directors of several biotechnology companies, as well as the Biotechnology Industry Organization (BIO); the Pharmaceutical Research and Manufacturers of America (PhRMA) and the Harvard Medical School Board of Fellows.

Alkermes' products, which combine novel molecules and innovative drug delivery technologies, target widespread diseases including central nervous system (CNS) disorders, addiction and diabetes. We approach the drug development process from a patient-centric perspective, with patient needs and behaviors in mind and with the goal of improving patient adherence to medications to help ensure long-term treatment success.

We currently manufacture two commercial products. RISPERDAL® CONSTA®, a long-acting formulation of risperidone, is the first and only long-acting, atypical antipsychotic approved by the U.S. Food and Drug Administration (FDA) for the treatment of schizophrenia and bipolar I disorder and is marketed by our partner Johnson and Johnson. RISPERDAL CONSTA uses our proprietary Medisorb® injectable extended-release technology to deliver and maintain therapeutic medication levels in the body through just one injection every two weeks. Using this same proprietary technology, we developed a once-monthly injectable version of naltrexone for the treatment of alcohol and opioid dependence, commercially known as VIVITROL®. It is our experience as one of the few companies working to develop and commercialize medications for addiction that brings me here today to discuss the importance of pharmacotherapies for the treatment of substance use disorders.

We understand how critical effective treatments for addiction are for both individuals with drug and alcohol dependence and their families. Left untreated, addiction exacts a toll on individuals, their families and the medical system at large. Moreover, the societal consequences are catastrophic – in terms of lost employment, failed interpersonal relationships, multigenerational neglect and trauma, healthcare costs, death and the unaffordable burden on the criminal justice system.[1]

Development of Medication Assisted Treatment for Addiction

Addiction is a biological brain disease but it has generally not been treated as such. Despite a preponderance of scientific evidence demonstrating that there are underlying biological bases for addiction, there remain widespread misperceptions that view

[1] Principles of Drug Addiction Treatment: A Research-Based Guide. Second Edition. National Institute on Drug Abuse National Institutes of Health U.S. Department of Health and Human Services, Rockville MD, NIH Publication No. 09-4180, 2009.

addiction as a failure of will.[2] Just as we treat prevalent diseases such as diabetes with a combination of behavior modification and medication, we must treat addiction with both counseling and medication. But for the vast majority of patients, we do not treat addiction with medication and the pace of medication development and adoption in this disease area is the slowest of any major public health problem in America.[3]

How long does it take after a National Institutes of Health (NIH) request to industry for a needed medication to become available? Back in 1976, the recognition of addiction as a medical disease prompted the National Institute on Drug Abuse (NIDA) to broadcast the need for a long-acting antagonist medication for substance use disorders. NIDA realized that patients with addiction couldn't reliably take oral medications each day to treat their disease.

While Alkermes had developed long-acting drugs in partnership with pharmaceutical partners in the past, we had never developed a drug on our own. Alkermes was aware that developing drugs in the addiction space was not for the faint of heart as evidenced by the fact that no substantial development work had been done in the space in years. Challenges included the difficulties of conducting clinical trials in this particular patient population, the lack of infrastructure to deliver evidence-based treatment and the continued misperception that addiction is a failure of will rather than a medical diagnosis.

In addition, there was no clear commercial opportunity. The large pharmaceutical companies were not selling branded pharmaceutical products in the addiction market. In fact, the feedback we received from pharmaceutical companies at the time was that such a market was unlikely ever to develop. We were not persuaded by that argument. We reasoned that if we could develop truly innovative, safe and efficacious medicine for the benefit of patients, we would find a way to make the economics work.

In April 2006, after more than 10 years of development work and nearly $200 million in investment (a substantial sum of money for a small biotechnology company), the FDA approved VIVITROL, a 30-day sustained-release, injectable form of naltrexone for the treatment of alcohol dependence.[4] VIVITROL, designed to address many of the adherence issues posed by existing oral medications, is the first and only antagonist, non-addictive, non-aversive, once-monthly injection for the treatment of alcohol dependence.

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[2] Principles of Drug Addiction Treatment: A Research-Based Guide, Second Edition. National Institute on Drug Abuse National Institutes of Health U.S. Department of Health and Human Services, Rockville MD, NIH Publication No. 09-4180, 2009.

[3] McGlynn EA, Asch SM, Adams J, Keesey J, Hicks J, DeCristofaro A, Kerr EA The quality of health care delivered to adults in the United States. NEJM 2003 Jun 26;348(26):2635-45.

[4] Accessed from http://vivitrol.com/pdf_docs/prescribing_info.pdf June 17, 2010.

Alkermes' investment in the development of VIVITROL was supported by nearly $200,000 in early development stage funding from the NIH and National Institute on Alcohol Abuse and Alcoholism (NIAAA). Recently, after completing an additional clinical study for VIVITROL in the treatment of opioid dependence, Alkermes filed a supplemental New Drug Application with the FDA for the approval of VIVITROL for the treatment of opioid dependence.[5] The FDA assigned the application priority review status and an October 12, 2010 action date.[6]

Challenges to the Adoption and Development of Addiction Pharmacotherapies

Unlike for other diseases that pose serious public health concerns, there are few medications available to treat drug and alcohol dependence. There are four FDA-approved medications to treat alcohol dependence. In contrast to VIVITROL, the three other FDA-approved medications require daily oral dosing. There are three medications approved to treat opioid dependence, all of which require daily oral dosing and two of which are opioid-based therapies. However, as described below, only a small fraction of individuals with addiction ever receive medication assisted therapy in the U.S. today.

Despite the rapidly increasing population that is using, abusing and becoming dependent upon illicit drugs and alcohol and the relative paucity of therapeutic options, pharmaceutical companies continue to shy away from the development of medications for substance use disorders. What discourages companies from entering the addiction market and what could address these factors and incentivize new entrants into the field?

Factors that Discourage Companies from Developing Medications to Treat Substance Use Disorders

Pharmaceutical companies are reluctant to develop medications for the treatment of substance use disorders because they do not perceive there to be a viable market for such products. Our commercial experience to date with VIVITROL supports this view. Even with a FDA-approved safe and effective product that addresses real patient needs, policy and other barriers are preventing patients from access to effective medications.

Although medication-assisted treatment for addiction is well recognized and endorsed by many governmental and non-governmental organizations, this support has not translated

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[5] The sNDA was submitted after completion of a six-month, multi-center, randomized phase 3 clinical trial for VIVITROL for opioid dependence which met its primary efficacy endpoint and all secondary efficacy endpoints. Data from the analysis showed that patients treated once-monthly with VIVITROL demonstrated statistically significant higher rates of opioid-free urine screens, compared to patients treated with placebo ($p<0.0002$). Furthermore, the median patient taking VIVITROL had 90% opioid-free urine screens during the evaluation phase of the study and patients treated with VIVITROL demonstrated a significant reduction in opioid craving compared to patients treated with placebo.

[6] On May 25, 2010, the supplemental New Drug Application (sNDA) for VIVITROL for opioid dependence was designated for priority review by the FDA. The designation is assigned to drugs that offer major advances in treatment, or provide a treatment where no adequate therapy exists and accelerates the FDA's target review timeline from ten to six months. The FDA's decision to grant priority review for VIVITROL for opioid dependence further supports the existence of a high unmet need for alternative therapies for patients with addiction.

to adoption of medication-assisted treatment or increased access to medications for patients. For example, the following organizations have issued clinical protocols or policy recommendations supporting the use of medication-assisted treatment for addiction:

- National Quality Forum (NQF)
- National Institute on Alcohol Abuse and Alcholism (NIAAA)
- National Institute on Drug Abuse (NIDA)
- U.S. Department of Veterans Affairs (VA)
- Department of Defense (DoD)
- Center for Substance Abuse Treatment (CSAT)
- American Medical Association (AMA)
- American Psychiatric Association (APA)
- American Society of Addiction Medicine (ASAM)
- National Association for Alcoholism and Drug Abuse Counselors (NAADAC)
- National Association of Drug Court Professional (NADCP)

Despite this support for medication-assisted treatment, the adoption of pharmacotherapy is remarkably low. For example, compare the use of pharmacotherapies for the treatment of depression to that of alcohol dependence. The rate of medication prescribed per covered lives for depression is almost 1 in 10 for antidepressants, but for alcoholism it is less than 1 in 5,000.[7] In 2006, a national study found that over 90% of U.S. public treatment programs did not use naltrexone.[8] In 2001, substance use disorder medications comprised less than 1% of all substance use disorder treatment costs[9] and in 2004, substance use disorder specific pharmacotherapy was offered in fewer than 25% of public and private specialty programs.[10] Furthermore, the largest system in the U.S. bearing the economic and public safety brunt of alcohol addiction is the criminal justice system, where 40% of all violent crimes involve alcohol.[11] Yet over 80% of addicted offenders fail to receive treatment for their addiction and there is even less use of evidence-based medication treatment.[12] Why?

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[7] Mark TL. Are Medications for Alcoholism Underutilized? An Analysis of Private-Sector and Medicaid Claims. Drug Benefit Trends 16(3):154-158, 2004.

[8] Ducharme, L. J., Knudsen, H. K., & Roman, P. M. (2006a). Trends in the adoption of medications for alcohol dependence. Journal of Clinical Psychopharmacology, 26, S13–S19 (PMID: 17114950).

[9] Mark TL, Coffey RM, McKusick D, Harwood H, King E, Bouchery E, et al. National Expenditures for Mental Health Services and Substance Abuse Treatment 1991–2001 (No. SMA 05-3999). Rockville, MD: Substance Abuse and Mental Health Services Administration; 2005.

[10] Knudsen HK, Ducharme LJ, Roman PM. The adoption of medications in substance abuse treatment: associations with organizational characteristics and technology clusters. Drug & Alcohol Dependence. 2007 Mar 16;87(2-3):164-74. Epub 2006 Sep 12.

[11] Greenfield LA, Henneberg M. Victim and Offender Self-Reports of Alcohol Involvement in Crime. Alc Res Health 2001;25:20-31.

[12] Chandler RK, Fletcher BW, Volkow ND. Treating Drug Abuse and Addiction in the Criminal Justice System: Improving Public Health and Safety. JAMA 2009; 301(2):183-190.

Lack of Implementation of Treatment Guidelines. In some cases, the low adoption of pharmacotherapy is due to the lack of implementation of issued guidelines. For example, the availability and consideration of FDA-approved pharmacological treatments for substance use disorder is mandated for all facilities of the Veterans Health Administration (VHA). In its recently revised practice guidelines, VHA clearly supports the availability and active consideration of these pharmacological treatments. For example, the VA/DoD guidelines say, "Established pharmacologic treatments, notably disulfiram and naltrexone, combined with addiction-focused counseling may reduce the amount of drinking, the risk of relapse, the number of days of drinking, and craving in some alcohol-dependent individuals."[13] But despite this support for medication-assisted therapy, the use of substance use disorder pharmacotherapy in the VHA system is still limited.[14] In 2007, only three percent of veterans diagnosed with an alcohol use disorder received any pharmacotherapy.[15]

Lack of Infrastructure to Support Pharmacotherapy Use. In other cases, low adoption of pharmacotherapy may be due to the lack of infrastructure to support the use of medication in those facilities charged with managing addiction, such as the lack of adequate personnel to prescribe, administer and monitor medications and frequently, lack of adequate payment or insurance coverage for medications.

Failure to Shift Treatment Paradigm. For 75 years, the dominant treatment model for alcohol dependence has consisted of talk therapy or counseling. Before the advent of effective medication, this was understandable; however, in the current era of addiction science, this is not modern treatment. With the FDA approving these agents based on their safety and efficacy, and the NIH and Institute of Medicine calling for their use in combination with counseling, it is time for the medical disorder of alcohol dependence to be treated like one.

Lack of Tools to Encourage Use of Evidence-Based Treatment Approaches and to Reward Success. The largest source of funding for addiction treatment in the public sector comes from the Substance Abuse and Mental Health Services Administration (SAMHSA) Substance Abuse Prevention and Treatment (SAPT) block grants to states. States have a great deal of discretion in determining the services to be covered by block grant funds and the type of treatment to be delivered. In addition, CSAT makes available a variety of targeted capacity expansion grant programs to eligible applicants to support the treatment of substance use disorders in the criminal justice setting and other treatment settings. In each instance, the federal government has not made the allocation of funding contingent upon the use of medication-assisted treatment and has not utilized performance-based metrics to allocate treatment dollars and drive programmatic changes to accelerate the adoption of medication.

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[13] Clinical Practice Guideline For Management of Substance Abuse Disorder, Veterans Affairs/Department of Defense. Module P; pp. 44. Accessed from: http://www.healthquality.va.gov/sud/sud_sum_v2_0.pdf on June 17, 2010.

[14] GAO Report, VA Faces Challenges in Providing Substance Use Disorder Services and Is Taking Steps to Improve These Services for Veterans, March 2010.

[15] Harris AHS, Kivlahan DR, Bowe T, Humphreys KN. Pharmacotherapy of Alcohol Use Disorders in the Veterans Health Administration. Psychiatric Services 61:392–398, 2010

Without such federal guidelines and incentives around the use of pharmacotherapy, only a few states have developed their own programs to promote the use of pharmacotherapy for the treatment of substance use disorders. For example, the state of Missouri recently enacted an effective model with the following elements:

1. System-wide training of all treatment providers about evidence-based medications,
2. Discrete pharmacotherapy funding to supply programs with all approved medications,
3. Coordination with Medicaid and criminal justice systems to serve a broad range of patients in need,
4. Contracting with new medically oriented providers as needed to assure accessibility to all approved pharmacotherapies, and
5. Mandating access to all FDA-approved pharmacotherapies for patients with programs that fail to comply losing eligibility for state and SAMHSA block-grant funded contracts.

Missouri discovered that it is within the authority of the Director of the State Division of Alcohol and Drug Abuse to establish such a mandate. Missouri also determined that it was essential to secure discrete funding for addiction pharmacotherapy from the state budget in order to overcome a key obstacle to evidence-based treatment.

Failure to effectively integrate evidence-based substance use disorder treatment in the primary care setting. Prior to the era of effective pharmacotherapies, there was little generalist physicians could do to treat alcohol or drug dependence in their practices, therefore few screened and fewer made efforts to intervene. For 25 years, however, the federal government has sought to engage primary care in screening, brief intervention, referral and treatment (SBIRT) initiatives; however, primary care providers still fail to adequately address substance use disorder. The establishment of new SBIRT billing codes in the past two years has begun to incentivize improvements but progress is slow. Linkage between primary care providers and specialty treatment providers is poor with a majority of cases failing to be diagnosed and the few patients who are diagnosed often not referred to or engaged in treatment. In this manner, a medical condition remains stigmatized in the mind of medical professionals.

Recommendations for Policy Changes to Solidify Addiction Pharmacotherapy Development

Even for diseases for which there is a huge unmet medical need like addiction, manufacturers will only research, develop and ultimately make available to patients products for which there is a market receptive to new agents and demand for their use. Since the fields of addiction treatment and primary care medicine are proving unreceptive to the agents that have been developed, industry will efficiently invest its research and development capital elsewhere, to the great detriment of the public health.

This is a unique field, one that behaves unlike others when it comes to new medications. Initiatives are needed to address this problem that is specific to addiction and consistent across relevant governmental agencies. Alkermes therefore recommends the following policy changes to support the use of evidence-based addiction pharmacotherapy treatment and incentivize new entrants to this important market:

- Require provider and plan compliance with National Quality Forum standards relating to the use of medication assisted treatment for substance use disorder as a condition to participate in federal programs and receipt of federal and state funding for substance use disorder treatment.
- Develop and implement comprehensive data collection tools and related performance-based metrics for use by all publicly-funded treatment programs.
- Utilize performance-based metrics to promote cost-effective and evidence-based practices by, among other things:
    - allocating precious federal and state treatment dollars to those programs that have utilized evidence-based practices and demonstrated success in the treatment of substance use disorders.
    - incorporating a discrete allocation for approved addiction pharmacotherapies within the SAMHSA Block Grant, the targeted capacity expansion grants and similar programs.
    - incorporating performance measurement into treatment provider accreditation activities.
- Provide grants to states to assist with establishing addiction pharmacotherapy programs and incentivize states for rapid deployment of such programs.
- Increase funding for demonstration projects utilizing pharmacotherapy in federal systems like the VA, DoD, Indian Health Service (IHS) and DOJ/Federal Bureau of Prisons (FBOP) and, within such systems mandate the collection, analysis and dissemination of any such treatment experiences broadly within these organizations.
- Provide increased government oversight around the implementation of published federal agency treatment guidelines.
- Direct NIDA, NIAAA, SAMHSA/CSAT and other government agencies to develop and launch educational training and technical assistance to a broad spectrum of providers (i.e., addiction, criminal justice, infectious disease, hepatology/GI, primary care, employee health) around the evidence-based and cost-effective treatment of substance use disorders, including tools for screening, diagnosis and medically-based treatment.
- Solidify the market for a limited period by guaranteeing purchase orders for minimum volumes of medication (similar to what was done by government to include development of new vaccines). By purchase orders or other such methods, the federal government could ensure a substantial market for addiction

pharmacotherapies. Doing so would address the barrier of limited and uncertain payments for addiction pharmacotherapies by guaranteeing a market.

Active government support of evidence-based pharmacotherapy is critical to creating incentives for future research and development efforts. Similar to the ongoing debate over hurdles to the development of much needed new antibiotic therapies, government incentives will be the deciding factor in whether private companies will allocate their increasingly rare research dollars to the development of drugs in the critical field of addiction versus other more established markets.

CONCLUSION

In closing, thank you again for the opportunity to testify here today about Alkermes' experience in the addiction marketplace. We have dedicated a substantial portion of our company's resources over the last decade to the treatment of substance use disorders, but we are still struggling to get our innovations to patients. Our experience leads us to believe that effective treatment of substance use disorder in America will not be possible until state and federal governments assume the pivotal role in shifting the treatment paradigm towards evidence-based practices. The American public has begun to embrace the notion that addiction is a disease and scientific advisory bodies have endorsed the concept of evidence-based practice. But the treatment system, the primary health care system and the criminal justice system are rooted in profound and persistent inertia. The public health need is obvious but the enormous capital and brainpower resources of private industry keep flowing elsewhere. We believe that federal and state leadership are in a position to translate guidelines encouraging the use of pharmacotherapy in substance use disorder into real treatment options. We believe that if the government exerts such leadership then the promise of medication development will finally deliver for the millions of individuals and families affected by addiction.

Mr. KUCINICH. Thank you.

We're going to move on now to questions of second panel. I would like to begin with Dr. Samet.

Some in the substance abuse treatment field reject the use of addiction medications as substituting one drug for another. What is your medical opinion about this?

Dr. SAMET. Medications for addiction can be of the type that are agonists to the receptors, where the term of substituting the drug or not, often antagonists, the evidence is that both types of medications are effective. But that's the data. To say otherwise I would say is the entering of stigma into the evidence for treatment.

Mr. KUCINICH. And so how do we destigmatize addiction and bring it into mainstream medicine? How can we do this in a way that gets the benefit of medications in the way other chronic diseases are able to do that?

Dr. SAMET. I think we can do it by pushing the concept of evidence-based medicine. I think that's happening. I think when I began on faculty of the medical school 20 years ago, it seemed like a distant goal. I think it's happening right now. So what you're saying needs to happen is happening. It just has to be accelerated. It's very possible. We have seen it.

Mr. KUCINICH. Now, Mr. Warren, you testified that the total annual cost to operate the Baltimore Buprenorphine Initiative for 2009, including funding for medications, outpatient counseling, physician, nursing, treatment advocate staff, that total was $2.8 million. It seems like a lot of money. You testified that with the use of buprenorphine you have reduced the period of stabilizing patients and transferring them to outpatient programs from 281 days to 155 days, enabling you to treat more patients. So is this program cost effective?

Mr. WARREN. We have found it to be hugely, hugely cost effective. For us to maintain that particular person on their medication and in treatment forever and ever and ever would be mind-numbing financially. What we're able to do, though, is realize what is out there now in the health care system, utilize a block grant to fund people who are truly uninsured, help them get insurance. And then once they get medical assistance they then move to that pool of funding, which the State of Maryland then brings in $0.61 for every $1. So, for us, we're able to treat three to four times as many people than historically we would simply because we're trying to optimize the public health system to the fullest.

Mr. KUCINICH. Now, Mr. Hall, has Fairfield County, OH, found it cost effective to pay for these medications as part of a drug court program? And have you been able to reduce the incarceration costs that skyrocketed in your county as a result of the opiate addiction epidemic?

Mr. HALL. Chairman Kucinich, we've been hit by a tidal wave of opiate addiction in central and southern Ohio.

The initial——

Mr. KUCINICH. Let me just stop you there. Why? I mean, besides from the obvious, why?

Mr. HALL. I can speculate. I think it really goes back to three things. We have a tremendous number of opiates coming up from Florida and Kentucky and Portsmouth, OH. We have heroin from

Mexico coming in from Columbus. But, from my perspective, the big problem is an unsuspecting health care community that is just inundating our part of the State with unnecessary and inappropriate levels of prescription painkillers. Again, 13.9 million doses of oxycodone and hydrocodone products across a population of 269,000 people. That's 52 doses for every man, woman, and child that lives in those four counties. It is staggering. I think it is the tip of the sword.

Mr. KUCINICH. And who's consuming these.

Mr. HALL. I'm sorry.

Mr. KUCINICH. Who's consuming these?

Mr. HALL. I think we probably have—I think we could have——

Mr. KUCINICH. It is not every man, woman, and child. So who's consuming them?

Mr. HALL. I think we have probably several thousand people in our area in Fairfield County maybe that are opiate addicted that still aren't known to our system.

Mr. KUCINICH. So somebody who is opiate addicted, how many of those might one addict take in a day?

Mr. HALL. Well, you know, that's a good question; and probably clinical experts could answer that better than me. But what I do know from discussions with a good friend of mine, Dr. Philip Pryor, an addictionologist, said that as human beings we have an almost unlimited ability or capacity to tolerate opiates.

If you look at the tolerance levels for alcohol, the ratio is about four to one. An early stage alcoholic can drink about a six-pack a day and get what they need. A late stage alcoholic may drink a case.

But if you look at opiate addiction, an early stage opiate addict may use 60 milligrams a day, but a late stage opiate heroin addict may be using the equivalent of 1 to 2,000 milligrams of heroin. That's a 70–to–1 ratio.

Mr. KUCINICH. Mr. Mavromatis, can your personal experience shed some light on this in terms of volume of a particular drug?

Mr. MAVROMATIS. If you look at the shorter-acting opiates that are pharmaceutical like Vicodin, Percodan, Percocet, things like that, the range is pretty broad. But it can be anywhere from 20, 25 tablets per day to what I was consuming, you know, up to 100 or more.

Mr. KUCINICH. Twenty-five tablets of what dose?

Mr. MAVROMATIS. Five milligram to ten milligram.

Mr. KUCINICH. When you were moving into this addiction, were you aware that you were doing that?

Mr. MAVROMATIS. No. Nope. You know, it was a slow and unsuspecting process. I went to the doctor. I did everything the doctor asked me to do. I was always honest with the doctor. And my decline in life, I guess my personal life, my emotional life was slow, too. I would slowly become—I was slowly becoming detached from my business, from my family, from my community, from things that I always did, things that I loved to do.

And what I didn't realize at the time is my body's building a tolerance. So when the doctor asked me, Mike, how do you feel? Well, Doc, I feel pretty good, but the sciatic nerve is starting to act up again. And there went the process, until I realized I had a problem.

Mr. KUCINICH. During that period, you said you put on weight. So you ate more. It increased your appetite. Is that right? Or did you just put——

Mr. MAVROMATIS. I don't think it was so much Mike likes to eat, and being in the restaurant and being Greek, obviously. But I don't think it was that. I think it was being detached, you know. Slowing down. Instead of spending 14 hours in the business 6 days a week, you know—what I mean it was a slow decline. Instead of coaching three junior high school sports, all of a sudden you're coaching one.

Mr. KUCINICH. So it was withdrawal from work.

Mr. MAVROMATIS. Exactly. A withdrawal—a withdrawal from normalcy I guess is a good way to describe it. And by the winter of 2003, 2004, when I decided, you know, you have a problem and you need to start figuring out what it is, so I started the process of elimination, what has changed, you know, my weight increased up to somewhere between 255, 265, something like that. And that's when I decided, you know, it has to be the medications you're taking, so stop taking them. And that's when reality hit me in the face.

Mr. KUCINICH. Back to Mr. Hall, tell me more about the extraordinary level of consumption of these opiates that is going on. Talk to me more about that.

Mr. HALL. To be completely honest, Mr. Chairman, the data that we have is still unfolding. I don't know that we can estimate within any clear sense how many people there are in our county that are affected, given the tolerance ratios. We fear there could be several thousand people in Fairfield County alone. We know that there are many counties to the south of us that have even worse problems than we——

Mr. KUCINICH. Are you laying the groundwork for epidemiological studies or for longitudinal studies that would try to see any other markers or indices that would reflect upon on this staggering amount of drug use?

Mr. HALL. Yes, sir. We desperately need that kind of work. We conducted some opinion surveys in our county that are also quite disturbing. A survey of 350 Fairfield County adults indicated that around 78 percent of the people that responded were aware of someone in their immediate family or among their friends that had received an opiate prescription within the past year. Twenty-two percent were aware of someone that was using an opiate painkiller without a prescription. So it appears to me that the problem is fairly widespread in our area, and those counties immediately to the south of us appear to have a bigger problem than we do.

Mr. KUCINICH. And these are prescriptions, as opposed to black market?

Mr. HALL. I think it is a mix. It's hard to discern the degree to which they are prescription prescribed as opposed to coming in illicitly.

What we do know, there is an anesthesiologist in our community that's beginning to do some research about diversion; and he believes that among those patients in his practice that are receiving opiate prescription that maybe as much as 20 percent of those prescriptions are being diverted for illicit use.

Mr. KUCINICH. Let me ask Mr. Mavromatis again. As you were sliding into this addiction, what kind of feeling did you get? What did these opiates do for you?

Mr. MAVROMATIS. That's what was deceiving. I was taking—prescribed Vicodin for pain, and I took it. And other than helping me with the pain, I didn't have any other sensation. I didn't have a high sensation.

You know, when I was young, fresh out of high school and you'd go out and have a few drinks and have a good time or whatever you might partake in, I knew what feeling high was.

Mr. KUCINICH. So for you this wasn't about getting high. It was about what? Pain relief?

Mr. MAVROMATIS. Oh, absolutely. I had injured myself remodeling our restaurant, and I had done damage to the L5 disk in my back, and that's been a slow progression.

Mr. KUCINICH. So if you took the drug, you didn't have pain. But you kept taking it, and you got addicted.

Mr. MAVROMATIS. Right. And as I would—time would go on. Evidently, the tolerance to the medication would build, so the pain would start to creep back in. The doctor says, Mike, how are you feeling? I'd tell him honestly either I was great or, Doc, the pain—the sciatic nerve is starting to act up again, or I'm having trouble with getting up with muscle spasms or aches in the middle of the night or whatever. So up the dose.

Mr. KUCINICH. This discussion—in a previous panel, we got into this, too, with Mr. Kennedy. So getting into the area of effective pain management, nonnarcotic approaches, if they can be effective, nonnarcotic, nonaddictive approaches. Pain management is a whole area of medicine that I suppose needs to be mindful of the kind of discussion we're having today.

Someone had his hand up. Mr. Warren, do you want to enter into this discussion?

Mr. WARREN. This issue of what's driving the drug trade. Prescription drugs was sort of the interchange that I wanted to respond to. We have a very large market—it's well-known—Lexington Market in Baltimore City, and it is an area of our city that numerous high-profile individuals want to redevelop. And so the theory was that, well, there are methadone clients, buprenorphine clients that are going there and selling their drugs and that's why you have an open air drug market around that market.

Well, what we did was, for 6 months, we monitored who was arrested at that market and at the same time looked at who showed up at the detention center. And so what we found was that a minuscule 2, 3 percent of people being arrested were in drug treatment. They were not there selling their methadone or selling their buprenorphine.

What were there was people were selling prescription, full-agonist drugs, the Percocet, Percodan, Vicodin. And where they got those prescriptions is up to conjecture. My hunch is they were taking from the grandmother, their parents, their relatives' medicine cabinets and going down and selling some of that prescription drugs that people take for legitimate pain medication.

And there needs to be a significant position awareness campaign that they need to improve their monitoring of the prescriptions that

they are giving to individuals, because that is what was driving the drug trade in this particular area of Baltimore City.

Mr. KUCINICH. Mr. O'Keefe and Mr. Pops, how critical was the NIH funding in support to both your companies' development of Suboxone and Vivitrol? Is there a strong case for continued Federal funding and research on medications' development to create progress in this area? Mr. O'Keefe.

Mr. O'KEEFFE. It was absolutely critical for Suboxone. It would not have happened without research from NIDA. A series of things had to happen. There had to be some exclusivity, there had to be approval by the FDA, and there had to be funding from NIDA.

Mr. KUCINICH. Before we go to Mr. Pops, I just want to ask you as a followup, you stated that the failure of the FDA to take a position on what constitutes efficacy in clinical trials for addiction is a major deterrent to investment and research on these products.

Mr. O'KEEFFE. It is a major deterrent. FDA has not decided yet how they want to measure the efficacy of drugs.

For example, if a pharmaceutical company had a new product for the treatment of opiate dependence—well, opiate dependence may be a different story. Let's look at something for which there is no treatment, like methamphetamine.

The FDA cannot yet decide whether a reduction in use of methamphetamine is a measure of efficacy or whether total abstention from methamphetamine is the mark that they would put on the chart for efficacy. And until that happens no pharmaceutical company is going to spend a great deal of money if they don't know what the end is for them to research.

So that's one of the major problems of deterrence to development to interest the pharmaceutical companies.

Mr. KUCINICH. Mr. Pops.

Mr. POPS. So, similarly, the NIDA funding was important. NIDA had been calling for literally 30 years for the development of a long-acting injectable from of an opiate receptor antagonist. And it really took until our technology became available for us to make that happen.

So the seed funding was important, but it is important to recognize the bigger question. We probably had to come up with another couple hundred million dollars on top of that to develop the drug. And I would say that, today, NIDA's voice amplifying and underscoring the importance of the data that resulted from clinical trials is extremely important at this moment. So it wasn't just at the beginning. It was throughout the entire process based on the quality of the data being researched.

Mr. KUCINICH. Thank you.

Dr. Samet, our subcommittee has found and Mr. O'Keefe testified that one of the reasons doctors are hesitant to treat patients who are addicted to drugs with medications is because of the scrutiny it brings from the Drug Enforcement Agency, which regulates opiate-based medications. Have you found this to be true in your work, in your involvement with the American Society of Addiction Medicine?

Dr. SAMET. Actually, I'm probably one of the few docs who had the DEA come by and say, we want to check what you're doing. I think it's likely more perception than reality. Docs are concerned

because DEA can make your life difficult. But docs who are using Suboxone and fairly established, agreed-upon approaches with patients, in truth don't have a lot to worry about, would be the way I'd put it.

I can speak from my one situation where what they asked for we gave them. They said good work. But there's that perception.

Mr. KUCINICH. Is there any—I just want to go down the line here, starting with Mr. Mavromatis. Is there anything that you'd like to say to the subcommittee for the record with respect to the direction that you think we should be taking and looking at for the purposes of having a more effective national drug policy, Mr. Mavromatis?

And then we'll go right down the line. It will just take a minute.

Mr. MAVROMATIS. Thank you.

I view Suboxone as the example, because that's what I know. With Suboxone, unlike the older recovery medications, you actual have a medication that is proactive and productive and fosters and lends itself to recovery. Yet it has restrictions on it that are counterproductive.

So when I go to help people or my peers, so to speak, find doctors and find help, it's not there. You know, a doctor prescribing Suboxone can only prescribe to 100 patients. And then when I look at it in what people are paying—in our area, in Columbus, we're blessed to have a lot of doctors prescribing. In other parts of Ohio, for instance, where there aren't any, the expense is night and day. Competition brings the price down. I think there is like, overall, maybe 1 percent doctors willing to prescribe.

So I think my feeling, from my point of view, is if—whatever you do, use the gains we now have, and we're going to have more, with medical science to be more productive and more proactive and take that education and group it, blend it with the education of old, the peer support, the spiritual, and all that, so we're moving forward. Instead of doing little things that with each step we take forward we're backing up a step or half step, so——

Mr. KUCINICH. Thank you.

Dr. Samet.

Dr. SAMET. Thank you for the opportunity to reflect on that. I think that, with more medications available to treat addictions, more patients will be treated. A few medications can treat a sizable number. The more you have, the more options to include those patients who don't succeed the first time around.

But that will also require training physicians and nurses to know how to treat patients for these problems, to understand these problems. It hasn't been traditionally part of the curriculum, but it is becoming, and that needs to be encouraged.

Finally, because, as you heard from Dr. McLellan, the substance use treatment system began independent of the medical system, more coordinating care between that system and the medical system is critical, both communication at every level—and, really, the time has come to make the treatment of addiction a mainstream medical issue, in part so that we help people with those problems and in part so that we can treat everything else that's going on. Because if we don't, that's not possible.

Mr. KUCINICH. Thank you.

Mr. Warren.

Mr. WARREN. Thank you for the opportunity to share in this important point.

I would say three things. First, buprenorphine has enabled us to establish relationships with other parts of the health care system that heretofore we've had no contact with, FQHCs, hospitals, primary care physicians. It creates, I believe, the foundation of learning that we'll need when national health care reform hits in 2014 and beyond.

The second thing that I think really needs to be stressed about Suboxone is Suboxone doesn't cure anybody. It simply provides the opportunity to help. It provides us the leverage to make amends for bankrupt educational systems, social support networks, and so forth that need to be created for these individuals that have never had this support before; and it gives us the time to develop it. That's the important thing.

The second piece is if we want to make a difference in crime in this country, we have to realize that drug addiction drives crime. If we can offer an intervention that allows—in the conversation I had with our police commissioner the other day, he said, the two biggest things you could give a police officer would be here is a card you can give somebody to get a job and here is a card to give somebody to get help for their drug treatment. The people who cause us the most angst in the communities in which we live are the people suffering from addiction. Creative uses of drug court, detention centers in the prison system to help people I think would make a big difference.

I started a therapeutic community in one institution. I went to graduation. This gentleman came up to me and said, hey, the last 6 months have been great. I've learned so much. But, listen, I know I'm about to be released in about a week. I need medication-assisted treatment or else I will go right back.

They need that support to reinvigorate their lives. So medication isn't just a treatment. It is a good opportunity for a whole variety of reasons.

Mr. KUCINICH. Thank you.

Mr. Hall.

Mr. HALL. Yes, Mr. Chairman. I believe what is going on in central and southern Ohio is a signal for a national emergency. I think that opiates are probably the most addictive substance known to man and that without a multilayered approach we're going to have hundreds of thousands of people in prison unnecessarily and dying way too early.

Again, I think we need to take a multilayered approach to this problem that includes things like drug court, intensive outpatient therapy, and medication-assisted therapy. I'm personally familiar with Suboxone. I think it has made a profound difference in our community. We need more of those things to combat this problem.

Mr. KUCINICH. Mr. O'Keefe.

Mr. O'KEEFFE. Mr. Chairman, we've heard a great deal about the success and the advantages of Suboxone in treatment for patients. I mentioned in my testimony the concerns about the Drug Enforcement Administration and the fear of the Drug Enforcement Administration.

As an example, back in July of last year, the Drug Enforcement Administration sent a letter to all physicians who were qualified to use buprenorphine for the treatment of opiate dependence. Now they simply said, to accurately plan for and properly allocate resources effectively and efficiently, we are attempting to discern whether or not the data-waived physician portion of your medical practice will need to be inspected. The letter was viewed to be fairly threatening by many physicians, and physicians objected to it.

It in fact also included a request for information and a form which was never approved by OMB. And after objections by physicians, the DEA—and the ONDCP—the DEA agreed that they would send out a letter clarifying.

That clarifying letter said, speaking of the earlier letter, that letter was not intended to discourage or limit treatment services or imply that inspections were somehow the result of targeting for individual activity. If a practitioner chooses to return their DEA-waived registration to DEA due to inactivity, DEA would simply remove that practitioner from our regulatory inspection program. Such action would prevent unnecessary onsite visits and enable DEA to employ its resources more efficiently.

Most physicians took that is an invitation to turn in their right to prescribe Suboxone. As a result of that, of the 18,000 physicians in the United States who were at that time able to prescribe buprenorphine, 676 of them voluntarily returned their registrations to the Drug Enforcement Administration, resulting in 67,000 patients who were denied treatment. Because each of those could prescribe for 100 patients.

These are exactly the kind of physicians that we're trying to recruit into the program. We want the physician who is treating only one or two patients to be able to treat that patient. But so long as they are threatened by the DEA they have no intention of opening themselves to an inspection by a gun-toting DEA agent for the treatment of one or two patients. So I think it is a real deterrent. The DEA is a deterrent, significant deterrent.

Mr. KUCINICH. Thank you.

Mr. Pops, proceed.

Mr. POPS. First of all, hearings like this one today are very important. So thank you very much for your leadership on this.

I was moved personally by Congressman Kennedy's remarks. This idea that we tolerate suboptimal outcomes in the treatment of this disease while patients go to treatment facilities, quote, unquote, and receive suboptimal care is a travesty.

So, as I said in my earlier comments, simply collecting data on the outcomes that one gets with Suboxone or Vivitrol and publishing that data and disseminating it and holding people to these standards would be a really important role the government can play.

And then I also would amplify the comment about returning servicemen and women and veterans. Biotechnology drugs in general are often not on the VA formulary; and so the benefit of all of this modern research, which we really are the leaders in the world here in the United States, is often is not translated into the people who protect us, and I think it is a mistake.

Mr. KUCINICH. I want to thank each and every one of the panelists.

This has been a hearing that will lead us into the next series of hearings that we're going to have on national drug policy. This subcommittee is charged with responsibility for oversight over national drug policy and for making recommendations. So I want to thank you for the role that you're playing in helping the veterans form, the members of this committee, the subcommittee, and the Members of Congress as to the directions that we might take that would be more effective for the individual who is struggling with an addiction and for the society at large.

I'm Dennis Kucinich, chairman of the Domestic Policy Subcommittee of the Oversight and Government Reform Committee. The title and topic of today's hearing has been Treating Addiction As a Disease: The Promise of Medication Assisted Recovery. This subcommittee will continue to work in this area and look at a variety of treatments and to support those that are working to try to meet the challenge and discourage addictions.

Thank you, gentlemen. There being no further business before this subcommittee, stand adjourned.

[Whereupon, at 1:41 p.m., the subcommittee was adjourned.]

[The prepared statement of Hon. Diane E. Watson and additional information submitted for the hearing record follow:]

Opening Statement

Congresswoman Diane E. Watson

"Treating Addiction as a Disease: The Promise of Medication Assisted Recovery"

Subcommittee on Domestic Policy
Oversight and Government Reform Committee

Wednesday, June 23, 2010
2154 Rayburn HOB
10:00 A.M.

Thank you Mr. Chairman for holding today's important hearing on the development and use of medications to treat the disease of drug addiction. According to the National Institute on Drug Abuse, the Department of Health and Human Services, multiple federal and international organizations, medical researchers, and treatment providers, drug addiction medications paired with behavioral treatments can effectively treat this disease. Unfortunately, more than

90 percent of the 23 million Americans who suffer from substance abuse disorders do not receive effective treatment for a variety of personal and structural reasons.

As we analyze the nation's approach to reducing the availability and abuse of drugs it is important to emphasize both the individual and group costs of addiction. Domestically, the disease of addiction has devastating consequences for individuals, families, communities, and our judicial and health care systems; while on an international scale, as stated by Secretary of State Clinton while in Mexico, "our insatiable demand for illegal drugs fuels the drug trade." It is imperative that we define and demolish the barriers to treatment

for the millions of Americans struggling to regain themselves from the depths of addiction.

If we can prevent Americans from ever using drugs, and provide effective treatment for those who do, we can save lives and foster healthier communities at home and abroad.

Thank you again Mr. Chairman for your leadership on this issue, and thank you to each of today's witnesses for testifying before us today. I yield back the remainder of my time.

JUN-21-2010 14:09 1 212 523 8433 1 212 523 8433 P.01

Robert G. Newman, M.D.
Continuum Health Partners, Inc.
555 West 57th Street
New York, NY 10019

Phone: (212) 523-8390
Fax: (212) 523-8433

06-24-10
Submitted for the record
by Dr. Robert G. Newman, MD
of Continuum Health Partners, Inc.

CONTINUUM HEALTH PARTNERS, INC.

Dennis J. Kucinich, Chairman
Domestic Policy Subcommittee
Of the
Oversight and Government Reform Committee

2154 Rayburn House Office Building
Wednesday, June 23, 2010
10:00 a.m.

"Treating Addiction as a Disease: The Promise of Medication Assisted Recovery"

Fax

To: MS. CLAIRE COLEMAN

From: HINDY BERNSTEIN FOR ROBERT G. NEWMAN, MD

Date: JUNE 21, 2010

Pages: 4 (INCLUDING COVER PAGE)

● Comments:

THANK YOU FOR YOUR PHONE CALLS. AS DISCUSSED, THIS MORNING WE FAXED THE ATTACHED TO THE MAJORITY MEMBERS OF THE DOMESTIC POLICY SUBCOMMITTEE.

ANY QUESTIONS, PLEASE DON'T HESITATE TO CONTACT US.
SINCERELY,

HINDY BERNSTEIN

ASSISTANT TO ROBERT G. NEWMAN, MD

NOTICE OF CONFIDENTIALITY

The information contained in this transmission is confidential and may be privileged and/or contain confidential health information that is legally protected by state and federal law, including the Health Insurance Portability and Accountability Act of 1996 and related regulations. This information is intended only for the use of the individual or organization to whom it is addressed. If it is not meant for you please notify the sender immediately by telephone so arrangements may be made to return the documents or destroy them. Use, disclosure, distribution or copying of documents transmitted to you in error is strictly prohibited. Thank you.

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Robert G. Newman, M.D.
Director
The Baron Edmond de Rothschild
Chemical Dependency Institute of
Beth Israel Medical Center

DOMESTIC POLICY SUBCOMMITTEE OF HOUSE OVERSIGHT AND GOVERNMENT REFORM COMMITTEE

"Treating Addiction as a Disease: The Promise of Medication Assisted Recovery"
Hearing 23 June 2010, Washington DC

Submitted by Robert Newman, MD, MPH, Director,
Baron Edmond de Rothschild Chemical Dependency Institute of
Beth Israel Medical Center, New York

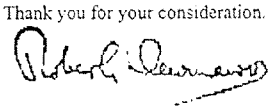
Responding optimally to the complex problem of addiction clearly requires the broadest possible array of approaches, and I applaud the Subcommittee for exploring the promise of medication assisted treatments in particular.

The Subcommittee should take note of the failure, to date, to utilize fully the extremely effective medications already available. I refer to maintenance with methadone and, more recently, buprenorphine in treating dependence on heroin and a variety of prescription analgesics. These medications are being provided to well over 250,000 patients in the US and to over one million world-wide. They have been the subject of more research evaluation than any medicines in history, and the results have consistently shown great efficacy and, when used appropriately, safety. They have been endorsed for decades by such prestigious bodies as the National Institute on Drug Abuse, the Institute of Medicine and the World Health Organization, and US taxpayer dollars (under the past as well as present administration) have financed major expansion of maintenance treatment overseas, for instance in Viet Nam.

And yet, TRICARE (Department of Defense) and CHAMPVA (Department of Veterans Affairs), which provide health insurance coverage to former military, dependents and survivors of those who gave their lives on behalf of our freedom, exclude maintenance treatment.* It is difficult to comprehend why our nation's heroes and their loved ones are denied a life-and-death treatment that is heralded almost universally as "the gold standard" of care of opiate dependence. Furthermore, it is my understanding that this outrage can be corrected almost instantaneously by administrative *fiat*, without requiring any legislative action.

I ask you to seek the opinion on this matter of some of the witnesses who will appear before you – for example, the Director of the National Institute on Drug Abuse, Dr. Nora Volkow, and the Deputy Director of the Office of National Drug Control Policy. I am confident they will agree that a change is long overdue, and that they too will urge you to use your influence to see that the change is made promptly.

Thank you for your consideration.



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*DoD: 32CFR199.4(e)(11)(ii);
VA: http://www4.va.gov/hac/factsheets/medsbymail/01-24pharmacybenefits.pdf).

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Robert G. Newman, M.D.
Director
The Baron Edmond de Rothschild
Chemical Dependency Institute of
Beth Israel Medical Center

June 21, 2010

Domestic Policy Subcommittee

Congressman Dennis Kucinich - Chairman
Congressman Elijah Cummings
Congressman John Tierney
Congresswoman Diane Watson
Congressman Jim Cooper
Congressman Patrick Kennedy
Congressman Peter Welch
Congressman Bill Foster
Congresswoman Marcy Kaptur

Re: Domestic Policy Subcommittee Hearing – June 23, 2010
Treating Addiction as a Disease: The Promise of Medication Assisted Recovery

I hope you will consider the attached comments regarding your June 23rd Subcommittee Hearing.

Sincere thanks,

Robert G. Newman, MD, MPH

Attachment

06-24-10 Submitted for the Record by Charles O'Keeffe KU School of Medicine

U. S. Department of Justice
Drug Enforcement Administration
Miami Field Division
2100 North Commerce Parkway
Weston, Florida 33326

www.dea.gov

July 24, 2009

Dennis J. Kucinich, Chairman
Domestic Policy Subcommittee
Of the
Oversight and Government Reform Committee

2154 Rayburn House Office Building
Washington, June 24, 2010
10:00 a.m.

"Treating Addiction as a Disease: The Promise of Medication Assisted Recovery"

Dear Registrant:

On October 17, 2000, Congress passed the Drug Addiction Treatment Act (DATA) which permits qualified practitioners to administer or dispense (including prescribe) any Schedule III, IV, or V narcotic drug approved by the Food and Drug Administration specifically for use in maintenance or detoxification treatment to a narcotic dependent person. At this time, the only two drugs approved for such treatment are Subutex® and Suboxone®.

The legislation waives the requirement for a qualified practitioner to obtain a separate DEA registration as a Narcotic Treatment Program (NTP). Although a DATA-Waived practitioner is waived from the requirement, he or she is subject to inspection by the Drug Enforcement Administration. Under the authority of the Controlled Substances Act (CSA) (21 U.S.C. 822(f)), DEA is authorized to conduct periodic inspections of registrants to ensure compliance with the CSA and its implementing regulations.

The Drug Enforcement Administration's Miami Field Division is in the process of preparing its Fiscal Year 2010 Regulatory Work Plan (which begins October 1, 2009) to include inspections of DATA-Waived practitioners. To accurately plan for and properly allocate resources effectively and efficiently, we are attempting to discern whether the DATA-Waived portion of your medical practice will need to be inspected.

Our records indicate that your DEA registration currently includes a unique identifier which designates you as a DATA-Waived practitioner (also referred to as an "X number"). DEA believes that in some cases practitioners were simply seeking continuing education credits, and were not aware that the training would result in the issuance of a modified DEA Registration. In many instances these practitioners are not operating as a DATA-Waived practitioner and simply do not need a modified registration for their practice.

If you do not now or in the future plan to treat opioid dependant patients, you are not required to maintain a modified registration. Should you choose to, you may request removal of the unique identifier by simply filling out the attached form and returning it to the DEA. Once DEA receives and processes your request, we can remove your name from the list of those medical practices scheduled for inspection.

Please be assured that this will not affect your ability to legitimately prescribe or dispense controlled substances (other than Subutex® and Suboxone®) under your DEA registration number. If, at a later date, you elect to treat opioid dependant patients, the unique identifier ("X number") can be reinstated upon your written request.

If you are prescribing and/or dispensing buprenorphine for the treatment of opioid addiction, please complete the attached questionnaire and return it to the DEA by facsimile at (954) 306-5352 or by mail no later than September 15, 2009:

DEA Diversion Program
Attn: Yanira Rodriguez
2100 North Commerce Parkway
Weston, Florida 33326

The DEA appreciates your effort to remain in compliance with the CSA. You can obtain an Informational Document entitled, DEA Requirements for DATA-Waived Physicians Who Treat Narcotic Addiction Using Buprenorphine at www.DEAdiversion.usdoj.gov to assist in your preparation for a DEA inspection. If you have any further questions, please contact Yanira Rodriguez at 954-306-4652.

Sincerely,

Barbara A. McGrath
Diversion Program Manager
Miami Field Division

To: DEA Diversion Program
Attn: Yanira Rodriguez
2100 North Commerce Parkway
Weston, FL 33326

From: _____
Physician's Name

_____
DEA Registration Number

_____
Address 1

_____
Address 2

_____
City, State, Zip Code

I currently hold a modified DEA registration as a DATA-waived physician. I do not treat narcotic dependence with controlled substances. I request that the modification to my DEA registration (the "X number") be removed and that my regular DEA registration be restored to an unmodified status. I understand that DEA will notify the Substance Abuse & Mental Health Services Administration Center for Substance Abuse Treatment (SAMHSA/CSAT) of my request.

I am aware that, should I decide in the future to tread opioid dependant patients with buprenorphine, I may request reinstatement of the modification at any time.

I understand that a new DEA Registration Certificate reflecting my original, unmodified registration number will be issued after my request is processed.

_____
Physician's Signature

_____
Physician's Name (please print clearly)

_____ _____
Date

To: DEA Diversion Program
Attn: Yanira Rodriguez
2100 North Commerce Parkway
Weston, FL 33326

From: _____
Physician's Name

_____
DEA Registration Number

_____
Address 1

_____
Address 2

_____
City, State, Zip Code

1. Are you currently practicing as a DATA-Waived physician? _____

2. How many opioid dependant patients do you treat? _____

3. Do you dispense buprenorphine (Suboxone® or Subutex®), prescribe buprenorphine, or do you do both?

   a. I dispense _____
   b. I prescribe _____
   c. I dispense and prescribe _____

_____
Physician's Signature

_____
Physician's Name (please print clearly)

_____
Date

Please provide information pertaining to the DATA WAVIER Program & email the information. As to the documents required, please have on hand for the visit.

REQUIRED	COMMENT
Copy of State License and CSAT Certification & waiver letter	
Registrant Background (Curriculum Vitae)	
Incorporated Business, Sole Proprietor or Partnership?	
Hours and Days of Operation	
Number of Employees (Full/Part Time)	
Maintenance & Detoxification Treatment procedures	
Intake Protocol – How do you receive new patients	
Patient Demographics	
Number of Patients currently on program	
Patient eligibility criteria (ie…Questionnaire, exam, lab screening)	
Type of drug prescribed (Suboxone or Subutex)	
Are drugs stocked at the office	
Monitoring Procedures (ie., Urine specimens - Random or Scheduled, counseling)	
Office building description (square footage…etc.)	
Type of security system if applicable	
Provide copies of forms used to document patient addiction treatment.	
If applicable:	
Copies of DEA 222 Order Forms	
Drug Inventory	
DEA 106 – Theft and Loss of Controlled Substances Reports	
DEA 41 – Disposal/Destruction Reports	

U.S. Department of Justice
Drug Enforcement Administration
Office of Diversion Control
8701 Morrissette Drive
Springfield, VA 22152

www.dea.gov

October 2, 2009

Dear Practitioner:

This letter serves to clarify a recent letter you may have received regarding inspections by the Drug Enforcement Administration (DEA) of practitioners who are registered with DEA pursuant to the Drug Abuse Treatment Act of 2000 (DATA). DATA established criteria to permit qualified practitioners to utilize Subutex® and Suboxone® in the treatment of individuals with narcotic addiction.

Routine inspections of certain types of registrants (e.g. manufacturers, distributors, narcotic treatment programs, and others) have been conducted since passage of the Controlled Substances Act (CSA) in 1971. These unannounced, on-site inspections are intended to verify a registrant's compliance with recordkeeping, security, and other CSA requirements. DATA-Waived practitioners were included in this nation-wide regulatory program due to specific recordkeeping requirements and patient limits established by DATA legislation and its implementing regulations. Since that time, DEA has conducted numerous inspections of DATA-Waived practitioners as well as other categories of registrants.

In order to better utilize its resources, and to prevent any disruption to those medical practices that are not conducting DATA-Waived treatment activities, DEA sent its initial letter to individual practitioners registered as DATA-Waived practitioners. That letter was not intended to discourage or limit treatment services or imply that the inspections were somehow the result of "targeting" for illegal activity. If a practitioner chose to return their DATA-Waived registration to DEA due to inactivity, DEA would simply remove that practitioner from our regulatory inspection program. Such action would prevent unnecessary on-site visits and enable DEA to deploy its resources more efficiently.

In addition, any attachment consisting of a "check-list" of questions or a request for specific information you may have received with the initial letters should be disregarded. These attachments were sent by an individual employee to a limited number of practitioners without official authorization and should not have been included with the letter. DEA field components have been instructed to discontinue issuing any such attachments in future correspondence.

Addiction treatment is an essential part of an effective strategy in addressing the problem of drug abuse in the United States. DEA is committed to help qualified practitioners obtain the necessary registration needed when conducting DATA-Waived services.

Additional information regarding this issue and other matters relating to the DEA Office of Diversion Control may be found at www.DEAdiversion.usdoj.gov. An informational document concerning DEA inspections of DATA-Waived practitioners entitled *DEA Requirements for DATA-Waived Physicians Who Treat Narcotic Addiction Using Buprenorphine* is also available at www.DEAdiversion.usdoj.gov under "Resources", click on "Publications," then on "Informational Documents".

Sincerely,

Joseph T. Rannazzisi
Deputy Assistant Administrator
Office of Diversion Control

06-29-10 Submitted For the Record
by Dr. Nora D. Volkow, MD of the National Institute on Drug Abuse

CNS SPECTRUMS The International Journal of Neuropsychiatric Medicine

Donald A. Kindelski, Chairman
Domestic Policy Subcommittee
Of the
Oversight and Government Reform Committee

2154 Rayburn House Office Building
Wednesday, June 23, 2010
10:00 a.m.

"Treating Addiction as a Disease: The Promise of Medication Assisted Recovery"

The Perfect Storm: CNS Drug Development in Trouble

Andrew A. Nierenberg, MD

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"For every complex problem there is an answer that is clear, simple, and wrong".

H.L. Menken

The high cost and high risk of central nervous system (CNS) drug development coupled with decreased opportunities for pharmaceutical companies to recoup their investments and make profits to further reinvest in research and development

(R&D) is now reaching its logical conclusion: companies will curtail making new medications for CNS diseases. As Tom Insel reports in his National Institute of Mental Health (NIMH) Director's Blog,[1] GlaxoSmithKline (GSK) and AstraZeneca (AZ) will no longer develop psychiatric medications. In the past, GSK took the risk of studying the anticonvulsant lamotrigine (LTG) for bipolar depression using an unorthodox drug development program.[2] LTG was subsequently approved for preventing mood episodes in bipolar disorder.[3] AZ developed quetiapine (QTP) as an antipsychotic and subsequently found that QTP worked as an antimanic and antidepressant for bipolar disorder.[4-6] LTG and QTP are now among the most widely prescribed medications in psychiatry. The loss of GSK's and AZ's programs is a major blow to the psychiatric community. Dr. Insel optimistically writes that the NIMH may play a role in further R&D by finding a few key discoveries and help develop a new pipeline. But he is also cautious about replicating or replacing pharma, and realistically notes that the limited budget of the NIMH will not account for the cost of bringing even one new medication to market. He also states that "Conducting clinical research more efficiently may free up some resources required to make a major investment. But limits in the NIMH's funding clearly indicate that, as we set priorities, hard choices will need to be made between investing in new medications and attempting to optimize the use of existing ones".[1]

Pharma's retreat from CNS drug development, coupled with woefully inadequate funding of the NIMH, does not bode well for the future of psychiatric medication development. With the exception of lithium, I am not aware of a single medication brought to market from sources other than from pharma in the past 35 years (if anyone knows of any, please let me know). Assuming an inflation-adjusted estimate of an NIMH budget of $35 billion over 35 years, no new treatments after $35 billion is quite impressive. Dr. Insel's dilemma about what to invest in with a limited (and perhaps flat or shrinking) budget presents a formidable problem for the field. If the NIMH invests in new medications at the expense of funding clinical effectiveness research (that provides data for clinicians to make better decisions about prescribing existing treatments) then the changes in treatment will not occur for many years. Today's clinicians need better guidance for today's patients and if the dream of the new health care reform is to be realized, we need those answers for this generation and cannot wait for the next generation. On the other hand, if the NIMH invests in clinical effectiveness research at the expense of developing new medications, then drug development will be further imperiled.

One solution proposed by Dr. Insel is to conduct "clinical research more efficiently". I worry that this solution may not be so easy to achieve. Clinical research is currently quite costly because it requires many people to conduct it properly, with precision and integrity, while maintaining the safety of the participants. Clinical research requires a substantial infrastructure and many sites to complete studies that include a sufficient number of participants to answer the study questions. Coordination of sites, researchers, research assistants, data flow, database management, statistical support, and the generation of manuscripts takes time and expertise. Following the Sequenced Treatment Alternatives to Relieve Depression (STAR*D), the Depression Trials Network (DTN) was formed and subsequently conducted several studies that have examined the emergence of suicidal ideation during selective serotonin reuptake inhibitor treatment, effectiveness of combinations of antidepressants and combinations of antidepressants and antipsychotics, and Combining Medications to Enhanced Depression Outcomes, a study of combinations of antidepressants versus monotherapy. All of these effectiveness trials used the infrastructure that NIMH had invested in to conduct STAR*D. The studies were started quickly, used expert sites, were coordinated with fidelity to the protocols, used an efficient tablet-based paperless data management system, recruited close to 100% of the planned number of participants, had an excellent continuous performance improvement system, and were conducted on time and within budget.

For complex reasons, the DTN finished the term of its NIMH contract and was dismantled. By all definitions and performance metrics, the DTN conducted the clinical effectiveness research as efficiently as possible and is unlikely to be recreated (or refunded) anytime soon. It is unclear how the DTN could have been more efficient. If the NIMH decides to get out of the clinical trial business, then no other agency is likely to study how to "optimize existing" psychiatric treatments. If available treatments are not optimized, then the diminishing number of studies from pharma will continue to focus on efficacy (differences of active drugs from placebo) and will fail to inform clinical practice. With pharma retreating from drug development, fewer new drugs will make it to market, and those that do will not have the data about how clinicians should optimally use them.

One could easily be discouraged given the withdrawal of pharma from CNS drug development and limited funding from NIMH. The hope is on page 1,617 of the 2010 HealthCare Reform act that establishes a Patient-Centered Outcomes Research Institute for comparative effectiveness research to be funded at $500 million/year. It will be essential that psychiatric disorders are included in this important endeavor. Only then will we and our patients survive this perfect storm. *CNS*

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AstraZeneca shuffles, eliminates Del. R&D jobs

AstraZeneca says restructuring will affect 3,500 R&D jobs, with 1,800 to be cut

Associated Press

Companies: AstraZeneca plc

[illegible] AP Business Writer On Tuesday, March 2, 2010 4:26 pm EST

DOVER, Del. (AP) -- Pharmaceutical company AstraZeneca PLC said Tuesday that it is reorganizing its global research and development operations and eliminating about 1,800 R&D jobs as part of a previously announced cost-cutting plan.

About 550 jobs will be eliminated at AstraZeneca's U.S. headquarters in Delaware as it moves primary research and development elsewhere, the London-based company said.

AstraZeneca also said it will close research sites in the United Kingdom and Sweden, and that about 3,500 R&D jobs will be affected as part of a plan announced in January to cut 8,000 jobs, or 12 percent of its work force, by 2014.

The termination of psychiatric laboratory research in Delaware represents about one-third of the company's R&D work force in the state, where future R&D efforts will focus on shepherding drugs through clinical trials and regulatory approval.

AstraZeneca said its facilities in Boston will see some growth as employees transfer from other sites.

"[illegible]en that the company is closing entire facilities around the world, we are thankful that AstraZeneca remains one of our state's largest employers," said Delaware Gov. Jack Markell. "Their commitment to making Delaware their North American center for clinical excellence is a bright spot here. I am encouraged and hopeful that this new focus on making Delaware a clinical hub for their products will put people back to work."

Shares of AstraZeneca rose 37 cents to close at $44.36 Tuesday.

AstraZeneca currently has 17 principal R&D sites in eight countries.

While continuing research on cancer and infection drugs and therapies for cardiovascular, gastrointestinal, respiratory, inflammatory and neurological conditions, AstraZeneca said it will **cease disease-specific research on drugs** to treat thrombosis, acid reflux disease, ovarian and bladder cancers, systemic scleroderma, **schizophrenia, bipolar disorder, depression, anxiety**, and hepatitis C. It also said it end vaccine research other than for influenza and respiratory syncytial virus.

The changes will result in the closure of the Charnwood research site in Leicestershire, England, and a smaller facility in Cambridge. Employment at Alderley Park, the company's largest R&D site in the U.K., will increase as employees transfer from elsewhere, the company said.

AstraZeneca said it also is looking to sell its London-based Arrow Therapeutics business, and that pharmaceutical development work at its Avlon facility near Bristol will cease, with some roles transferring to other sites in the U.K.

In Sweden, AstraZeneca will close its research site in Lund and boost the work force at its Molndal facility to accommodate activities to be transferred from the Lund and Charnwood sites.

"[illegible] have made real strides in improving our efficiency in recent years, but there is a continuing need to adapt our organization in [illegible]ation of future challenges," Executive Vice President of Development Anders Ekblom said in a prepared statement.

"I am also acutely aware that these proposed changes will have a significant impact on our people, and we are committed to providing support to them," he added.

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Drug Company Cost Cuts: Careful What You Wish For

http://www.fool.com/investing/general/2010/02/26/drug-company-cost-cuts-careful-what-you-wish-for.aspx

Brian Orelli, Ph.D.
February 26, 2010

Drug companies, perhaps more than those in any other industry, have a hard time catering to both short-term and long-term investors at the same time. Because of the long development leeway, investments in research and development (R&D) don't bear fruit for many years down the line. But if drug companies cater to short-term investors now and cut R&D, they put the future of the company in jeopardy.

The patent cliff may be coming, but so far most major drug companies have kept research and development expenses fairly constant, with a few notable increases due to acquisitions.

Company	2007 R&D Expense Relative to 2006	2008 R&D Expense Relative to 2006	2009 R&D Expense Relative to 2006
Abbott Labs	112%	121%	123%
AstraZeneca	128%	125%	112%
Bristol-Myers uibb (NYSE: IY)	108%	119%	124%
Eli Lilly (NYSE: LLY)	111%	123%	138%
GlaxoSmithKline (NYSE: GSK)	95%	74%	90%
Johnson & Johnson (NYSE: JNJ)	108%	106%	98%
Merck (NYSE: MRK)	115%	118%	142%
Novartis (NYSE: NVS)	121%	131%	140%
Pfizer (NYSE: PFE)	102%	101%	105%
sanofi-aventis	113%	109%	112%

Source: Capital IQ, a division of Standard & Poor's.

That's about to change.

More with less?
During their end-of-the-year conference calls, Pfizer, Glaxo, and AstraZeneca said they plan to scale back R&D expenses.

^ ^er the acquisition of Wyeth, it makes sense for Pfizer to spend less than the combined panies would have individually. This year, it is budgeting between $9.1 billion and $9.6 billion esearch and development, which is down sharply from the $11 billion that Pfizer and Wyeth spent when they were separate companies. Some savings might come from redundant support

staff and auxiliary equipment, but most of the savings will probably come from killing duplicate programs. There's little reason to develop two drugs that go after the same target, after all, and picking the better of the two should only make Pfizer stronger.

A bigger worry is what Pfizer plans to do once Wyeth is fully integrated. In 2012, Pfizer expects that it will reduce research and development spending to between $8 billion and $8.5 billion. You can understand why Pfizer would want to decrease costs in its post-Lipitor era, but it's still worrisome for investors who plan to hold well beyond the transition period.

Glaxo plans to focus on fewer therapeutic areas and cut development of drugs for certain indications like depression and pain. The company plans to save $750 million per year by 2012 from cuts to R&D, sales, and administrative expense. Depending on how the cuts break down, R&D might not be hurt so badly; the company says it'll plow 30% of the cuts back into the company, with the other 70% trickling down into the profit line.

AstraZeneca's plan is to consolidate its research sites to save money. Not having to pay for extra heating and cafeterias might be a good idea, but it also plans to reduce the research staff by 1,800 positions. That's a lot fewer bodies looking for the next blockbuster.

In-licensing is the new centrifuge

OK, maybe that last play on words didn't work out so well. What I mean is that while drug companies may be decreasing their research workforce, they're likely to continue spending on the development side of things. One analyst estimates that in-licensing drugs from small drugmakers can yield returns three times higher than developing them in-house.

That estimated savings may be a bit high, but it's clear that pharmaceuticals can reduce their risk of failure by licensing the drugs after some risk has passed -- for instance, after the safety checks out in a phase 1 trial, or proof of concept in phase 2. They're also able to avoid some of the later development risk on the original developer by tying milestone payments to the clinical and commercial success of the drug.

Investors really shouldn't care whether the drugs are developed in-house or not. All they need to worry about is whether drug companies are spending money *somewhere* today in order to have revenue for tomorrow.

Chuck Saletta has five companies for you that are set to dominate the competition.

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