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## **Eliminate Inappropriate Barriers to Use of Medications for Alcohol and Drug Addiction Treatment**

Research by the NIH's National Institute on Drug Abuse and National Institute on Alcohol Abuse and Alcoholism and other leading scientists has proven that alcohol and drug addiction is a disease that can be treated successfully, and has identified medications that are effective tools in addiction treatment. But these effective interventions are reaching very few of the more than 23 million Americans who suffer from substance use disorders. Both the public and private sectors inadequately fund addiction treatment and create barriers to providing medications and other successful treatments to those who need them.

Our nation must eliminate barriers to these medications and to other addiction treatments as well as expand our treatment capacity to reach the more than 21 million Americans in need of care. Doing so will save tens of thousands of lives and billions of dollars and will strengthen families and communities throughout the nation.

## Summary

### **Untreated Addiction Costs Society Thousands of Lives and Billions of Dollars Each Year**

- While the AMA and NIH have determined that addiction is a disease that can be successfully treated, nearly 21 million of the 23.2 million Americans with substance use disorders received no treatment in 2006.
- Alcohol consumption and illicit drug use cost nearly 100,000 lives and over \$360 billion dollars per year.

### **Alcohol and Drug Treatment and Prevention Save Lives and Money**

- Addiction treatment cuts alcohol and drug use in half, reduces crime by 80 percent and arrests by up to 64 percent. It also greatly diminishes incidences of HIV infection.
- Taxpayers save \$7 for every \$1 spent on treatment through both increased productivity and through reduced health care, criminal justice, and social service costs.

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## **Discovery of Effective Medications**

- In recent years a number of new medications to assist individuals in recovery from drug and alcohol addiction have appeared on the market, including Suboxone, Subutex, Naltrexone, and Vivitrol. Other medications such as Methadone have existed for many years but continue to be underutilized.
- Studies have repeatedly demonstrated the effectiveness of these new treatments. A 2007 study of extended-release naltrexone found that patients went significantly longer before drinking and significantly longer before their first heavy drinking event, decreased the number of drinking and heavy drinking days per month, and had a 21% higher rate of continued abstinence at the end of the study than individuals receiving a placebo. Two recent studies, one from 2003, another from 2008, have found that opioid-dependent patients who use buprenorphine as part of their treatment manage to stay in treatment for longer periods of time and test negative for illicit substances at least three quarters of the time. Numerous studies have demonstrated that patients who continue in methadone maintenance treatment have substantially reduced drug use, criminal activity, and HIV infections.
- In September 2007, in its “First Consensus Standards for the Treatment of Substance Abuse Conditions,” the National Quality Forum recommended that “[p]harmacotherapy ...be offered and available to all adult patients diagnosed with alcohol dependence and without medical contraindications.”

## **“Fail First” Policies and Other Barriers to Access to Effective Medications**

- Medicaid programs in several states do not cover some or all of the medications used to treat substance abuse. Even when states do cover the medication, they often create substantial, counterproductive barriers to patients’ access to these potentially lifesaving medications, including:
  - “Fail First” policies requiring that the patient fail on another, usually cheaper medication or treatment before approving use of particular medications, even if the prescribed medication is clearly more effective;
  - Covering medications only in certain settings;
  - Covering medications only as a medical, not a pharmacy, benefit;
  - Requiring prior Medicaid authorization before prescribing medications; and
  - Requiring that the program or provider pre-purchase the medication but only charge Medicaid following use, a policy which makes the medications unaffordable to most treatment programs which lack the cash flow for such expenditures.
- These barriers unfairly deprive patients of the medications they need, resulting in substantial untreated or improperly treated addiction that impairs the health of the patients and causes great damage to their families, communities, and our nation.
- Case study: Vivitrol. Although all State Medicaid programs that have made a decision have agreed to provide coverage for Vivitrol, most have imposed significant barriers to use. Approximately 9 states require that patients fail first on some other medication before allowing doctors to prescribe Vivitrol even when the physician believes that Vivitrol is the appropriate medication for the patient. Many others states have “Buy and

Bill” requirements, forcing providers to purchase the drug without knowing the demand or knowing that they will be covered for it, thereby creating potential cash flow problems for many treatment providers. Other states require prior authorization or impose other obstacles.

- Case study: Methadone and Suboxone. Although literally decades of studies have demonstrated the effectiveness of methadone maintenance treatment in reducing drug use, criminal activity, and other health and social ills, this effective medication remains underutilized due to myths and stereotypes which have led to discrimination against patients and lack of financial and other support for service providers. Suboxone is a more recent treatment for opiate addiction that studies have also repeatedly shown to be an effective treatment method. According to a recent study conducted by the Avisa Group, in collaboration with the National Conference of State Legislatures, 10 of the 46 states who provided information did not provide any Medicaid coverage for Methadone. 7 of 47 states did not place Suboxone on their Medicaid drug formulary or provide Medicaid coverage for it to be provided in either a physician’s office or a Narcotic Treatment Program.

### **Conclusion**

**Medicaid and other programs should remove “fail-first” and all other unnecessary obstacles that limit the access of individuals with alcohol and drug addiction to medications and other life-saving treatments that have proven safe and effective. Such obstacles cost states more over the long-term than any cost accrued by paying for the treatments. More important, failure to provide such treatment could cost the lives of those who could have benefited from such treatment.**

## Discussion

### Untreated Addiction Costs Society Thousands of Lives and Billions of Dollars Each Year

- **While the AMA and NIH have determined that addiction is a disease that can be successfully treated, nearly 21 million of the 23.2 million Americans with substance use disorders received no treatment in 2006.** [[http://www.ama-assn.org/ama1/pub/upload/mm/388/alcoholism\\_treatable.pdf](http://www.ama-assn.org/ama1/pub/upload/mm/388/alcoholism_treatable.pdf)], [“Drugs, Brains, and Behavior: The Science of Drug Addiction,” National Institute on Drug Abuse, April 2007, <http://www.drugabuse.gov/scienceofaddiction/sciofaddiction.pdf>] (These numbers were unchanged in Substance Abuse and Mental Health Services Administration (SAMHSA)’s most recent survey on drug use [“Results from the 2007 National Survey on Drug Use and Health: National Findings,” Substance Abuse and Mental Health Services Administration, September 2008, <http://www.oas.samhsa.gov/nsduhLatest.htm>]
- **Alcohol consumption and illicit drug use cost nearly 100,000 lives per year.** A 2004 study published in the Journal of the American Medical Association found that, in 2002, alcohol consumption was responsible for approximately 85,000 deaths (including 16,653 driving deaths) and illicit drug use approximately 17,000 deaths (from both direct and indirect causes). [*Actual Causes of Death in the United States, 2000*, <http://www.csdp.org/research/1238.pdf>]
- **Alcohol and drug abuse cost society over a third of trillion dollars per year.** A 2004 analysis by The Lewin Group found that drug abuse cost the US \$180.8 billion in 2002, through increased health care, criminal justice and social welfare costs as well as through decreased productivity. A similar study of the economic costs of alcohol-abuse estimated over \$184.6 billion in costs from lost earnings and productivity, crime and property damage, increased social welfare costs, and medical and treatment costs. [*The Economic Costs of Drug Abuse in the United States, 1992-2002, Office of National Drug Control Policy, 2004; Updating Estimates of the Economic Cost of Alcohol Abuse: Estimates, Updating Methods, and Data, 2000, Henrick Harwood, National Institute on Alcohol Abuse and Alcoholism*]
- **Alcohol costs American businesses an estimated \$134 billion in productivity losses.** According to George Washington University’s Ensuring Solutions to Alcohol Problems Project, 12.7 million full-time workers, 8.9% of all full-time workers, have drinking problems and alcohol costs \$134 billion in productivity losses, mostly due to missed work (65.3% due to alcohol-related illness, 27.2% due to premature death, and 7.5% due to crime) [<http://www.ensuringsolutions.org>]

### Alcohol and Drug Prevention and Treatment Save Both Lives and Money

- **Addiction treatment has been shown to cut alcohol and drug use in half, reduce crime by 80 percent and arrests by up to 64 percent, and has a demonstrated impact on HIV risk behaviors and incidences of HIV infection.** [*The National Treatment*

*Improvement Evaluation Study (NTIES). 1997. Office of Evaluation, Scientific Analysis and Synthesis, Center for Substance Abuse Treatment, Substance Abuse and Mental Health Services Administration. NIDA Research Report - HIV/AIDS: NIH Publication No. 06-5760, Printed March 2006,*  
<http://www.nida.nih.gov/ResearchReports/HIV/hiv.html> ]

- **Addiction treatment is sustainable; studies have found that, one year after program completion, addiction treatment is significantly associated with a 67% reduction in weekly cocaine use, a 65% reduction in weekly heroin use, a 52% decrease in heavy alcohol use, a 61% reduction in illegal activity, and a 46% decrease in suicidal ideation. Moreover, these outcomes are generally stable for the same clients five years post treatment.** [Hubbard, R.L. (1997). *Overview of 1-year Follow-up Outcomes in the Drug Abuse Treatment Outcome Study (DATOS). Psychology of Addictive Behaviors, 11*, 261-278. (2003) *Overview of 5-year Follow-up Outcomes in the Drug Abuse Treatment Outcomes Studies (DATOS). 263-70.*]
- **Taxpayers save \$7 for every \$1 spent on treatment and \$5.60 for every \$1 spent on prevention, as a result of both increased productivity and reduced health care, criminal justice, and social service costs. When adding the savings to healthcare, every \$1 dollar spent on addiction treatment saves society more than \$12.** [Principles of Drug Addiction Treatment: A Research Based Guide, National Institute on Drug Abuse, <http://www.nida.nih.gov/PODAT/PODAT6.html#FAQ11>]

### **Discovery of Effective Medications**

- **In the last 15 years, a number of new medications to assist individuals in recovery from drug and alcohol addiction have appeared on the market.** Among the many new treatments discovered in recent years are Suboxone, Subutex, Naltrexone, and Vivitrol. Other medications such as Methadone have existed for many years but continue to be underutilized.
- **The use of pharmacotherapy has become an increasingly accepted and important part of substance abuse treatment.** In September 2007, in its “First Consensus Standards for the Treatment of Substance Abuse Conditions,” the National Quality Forum recommended that “[p]harmacotherapy...be offered and available to all adult patients diagnosed with [opioid dependence, alcohol dependence and nicotine dependence] without medical contraindications. Pharmacotherapy, if prescribed, should be provided in addition to and directly linked with psychosocial treatment/support.” [National Quality Forum Issues First Consensus Standards for the Treatment of Substance Use Conditions, ]
- **Studies have repeatedly demonstrated the effectiveness of these new treatments.** A January 1999 literature review by the U.S. Department of Health and Human Services’ Agency for Healthcare Research and Quality found that “Pharmacotherapy is emerging as an important component of treatment for people with alcohol dependence. Two relatively new medications, naltrexone and acamprosate, show good evidence of being

superior to placebo in the treatment of alcoholism. Disulfiram is less clearly superior to placebo than are naltrexone or acamprosate, although positive effects are found. To date, serotonergic agents have not been demonstrated to show efficacy in treating alcohol-dependent patients who do not have depression or anxiety.” [West, S. et al (1999). *Pharmacotherapy for Alcohol Dependence. Agency for Healthcare Research and Quality Evidence Report/Technology Assessment, No. 3* <http://www.ahrq.gov/clinic/tp/alcotp.htm>]

A 2007 study of extended-release naltrexone found that individuals receiving a 380 mg dose went significantly longer before drinking (median of 41 days vs. 12 days) and significantly longer before their first heavy drinking event (>180 days vs. 20 days), decreased the number of drinking (0.7 vs. 7.2) and heavy drinking (0.2 vs. 2.9) days per month and had a 21% higher rate of continued abstinence at the end of the study than individuals receiving a placebo. [O’Malley, S.S. et al (2007). *Efficacy of Extended-Release Naltrexone in Alcohol-Dependent Patients Who Are Abstinent Before Treatment. Journal of Clinical Psychopharmacology, Vol. 27, No. 5, 507-512.*] (See also: Ciraulo, D.A. et al (2008). “Early Treatment Response in Alcohol Dependence with Extended-Release Naltrexone.” *Journal of Clinical Psychiatry, Vol. 69, No. 2, 190-195.*)

A recent study of Vivitrol (extended-release naltrexone) by the Florida Advancing Recovery Project, a part of the Substance Abuse Program at the Florida Department of Children and Families, tracked 72 clients over a two year period. Study participants reported a decrease in number of heavy drinking days per month from an average of 28.9 days at the beginning of the treatment to 1.7 days at the time of the second injection and 0.3 days at the time of the third injection. Some participants reported abstinence following the first injection, although some participants did not appear to benefit from the medication. Additionally, mean self-reported urge to drink decreased by two thirds on a scale of five; mean self-reported motivation to change increased from approximately 5.5 to above 8 on a scale of ten over the course of the treatment; program participants’ readmissions to treatment following discharge decreased by 66% in the year after receiving the medication compared with the year prior to treatment; and individuals who received at least 3 injections stayed in treatment for longer periods compared to those who did not use medication, had higher levels of employment at discharge, and had improved living situations at discharge. Furthermore, most of the improvement in client outcomes occurred by the time of the third injection. [Florida Advancing Recovery Project (2009). *Implementing Medication Assisted Treatment using Vivitrol, November 2006-October 2008, Preliminary DRAFT Results. Substance Abuse Program Office, Florida Department of Children and Families.*]

A 2001 meta-analysis of studies comparing naltrexone use to a placebo found that, on average, 14% fewer subjects taking naltrexone relapsed into heavy drinking than the subjects taking a placebo and 10% more naltrexone-users, on average, remained abstinent from alcohol consumption, than placebo. Additionally, naltrexone-treated subjects consumed alcohol on average 3% fewer days than placebo patients and drank 1.0 standard alcoholic drink less per drinking day than placebo- treated subjects. [Streeton C., Whelan G. (2001). *Naltrexone, a relapse prevention maintenance treatment of*

*alcohol dependence: a meta-analysis of randomized controlled trials. Alcohol Alcohol 36:544-552.] (See also Oslin, D.W. et al (2008). "A Placebo-Controlled Randomized Clinical Trial of Naltrexone in the Context of Different Levels of Psychosocial Intervention." Alcoholism: Clinical and Experimental Research, Vol. 32, No. 7, 1-10.)*

A 2008 study following 53 opioid-dependent patients using buprenorphine/naloxone as part of their treatment found that 53% remained in treatment for more than a year and 38% remained for at least two years. The patients provided 1106 urine specimens during the time they were followed (for up to five years). 91% showed no evidence of illicit opioids; 96% had no evidence of cocaine; and 98% had no evidence of benzodiazepines; and 99% had no evidence of methadone. [*Fiellin, D.A. et al (2008). Long-Term Treatment with Buprenorphine/Naloxone in Primary Care: Results at 2-5 Years. The American Journal on Addictions, Vol. 17, No. 2, 116-120.*]

A second study, from 2003, comparing retention rates of 20 opiate dependent individuals being treated with buprenorphine with 20 on placebo found that 75% of the group using buprenorphine remained in treatment after one year compared with 0% of those in the control group. Patients in the buprenorphine group underwent thrice-weekly supervised urine analyses. A mean of 74.8% of samples obtained were negative for the substances analyzed (including illicit opiates, central stimulants, cannabinoids, and benzodiazepines). [*Kakko, J. et al (2007). 1-Year Retention and Social Function after Buprenorphine-Assisted Relapse Prevention Treatment for Heroin Dependence in Sweden: a Randomised, Placebo-Controlled Trial. The Lancet, Vol. 361, No. 9358, 662-668.*]

A 1978 study by The New York Academy of Sciences found that, of heroin users who remained in continuous methadone treatment over a course of twelve years, 97% reported no further opiate use and 63% reported no forms of substance abuse or criminal activity, compared with 30% and 8% of those who discontinued treatment, respectively. [*Dole, V.P., Joseph, H.. Long-term Outcome of Patients Treated with Methadone Maintenance, Annals of the New York Academy of Sciences, 1978, Vol. 311:181-189*] Similarly, in a 1988 three-year meta-analysis of treatment programs in New York, Philadelphia, and Baltimore involving 388 patients, 71% of those who completed methadone treatment ceased to use IV drugs, compared with only 18% of those who left treatment. [*Ball, J.C. et al. Reducing the Risk of AIDS Through Methadone Treatment, Journal of Health and Human Behavior, 1988, Vol.2:214-226*]

### **Barriers to Access to Effective Medications**

- **Public funding provides the vast majority of substance abuse expenditures, increasing from 62 percent in 1991 to 76 percent in 2001. Private insurance represented only 13 percent of addiction treatment expenditures in 2001, even though it covered 36 percent of all health care expenditures.** [*National Expenditures for Mental Health Services and Substance Abuse Treatment 1991-2001, SAMHSA, 2005, <http://www.samhsa.gov/spendingestimates/SEPGenRpt013105v2BLX.pdf>*]

- **Medicaid programs in several states do not cover some or all of the medications used to treat substance abuse.** According to a recent study conducted by the Avisa Group, in collaboration with the National Conference of State Legislatures, 10 of the 46 states who provided information did not provide any Medicaid coverage for Methadone. 7 of 47 states did not place Suboxone on their Medicaid drug formulary or provide Medicaid coverage for it to be provided in either a physician's office or a Narcotic Treatment Program. 12 of the 47 states had similar policies in regards to Naltrexone. [Rinaldo, D. (April 2008). *50-State Table: Medicaid Financing of Medication-Assisted Treatment of Opiate Addiction*. <http://www.ncsl.org/programs/health/forum/matmedicaid.htm>.]
- **Even when states do cover the medication, they often create substantial, counterproductive barriers to patients' access to these potentially lifesaving medications.** State Medicaid programs have created a number of different barriers that significantly limit patients' access to these medications. Among the barriers that have been erected are: covering these medications only in certain settings; covering the medications only as a medical, not a pharmacy, benefit; requiring prior Medicaid authorization before prescribing the medication; requiring that the patient fail on another, usually cheaper medication or treatment before approving use of a more expensive medication (often referred to as fail-first); and/or requiring that the program or provider pre-purchase the medication but only charge Medicaid following use, a policy which makes the medications unaffordable to most treatment programs which lack the cash flow for such expenditures.

As an example, although all State Medicaid programs that have made a decision have agreed to provide coverage for Vivitrol, the vast majority have imposed significant barriers to use. Approximately 9 states require that patients fail first on some other medication before allowing doctors to prescribe Vivitrol. Many others states have "Buy and Bill" requirements, forcing providers to purchase the drug without knowing the demand or knowing that they will be covered for it, thereby creating potential cash flow problems for many treatment providers. Other states require prior authorization or impose other obstacles.

- **The policy of denying access to these treatments runs counter to a number of new federal and state initiatives aimed at increasing access to treatment and the routes through which treatment is made available.** Under SAMHSA's new Screening, Brief Intervention, and Referral to Treatment (SBIRT) initiative, screenings and referrals for alcohol and drug addiction will be taking place in a host of new medical settings, in particular general medical settings. It is important that these new screeners be aware of all existing forms of treatment and be able to prescribe medically appropriate treatment services, including medication, when they feel such treatment is the right care for a patient. Furthermore, offering such services will fit well with the goal of greater integration of behavioral health services into primary care settings and with SAMHSA/CSAT's goal of creating a model in which there is "no wrong door" for entering one's journey to recovery, a goal which aims to maximize the ways in which individuals are able to begin their recovery.

- **The policy also runs counter to the federal government’s own policy in funding some of these drugs.** For instance, the Veterans Administration’s (VA) policy on extended- release injectable naltrexone is to allow the prescriber to determine “the patient’s likely adherence with oral naltrexone” as well as the patient’s own willingness or ability to take oral naltrexone. The VA does not require that the individual fail first with oral naltrexone or other antialcoholic agents, nor does it require evidence of prior abstinence before prescription of injectable naltrexone.

### Fail First Policies

- **Among the most significant barriers to accessing treatment is the requirement that individuals fail on one of type of medication before accessing another, potentially more effective treatment medication. Such policies remove treatment decisions from the experts who are able to make individualized judgments about the needs of those seeking treatment. Furthermore, by forcing individuals to fail on one drug before they are eligible for another, these policies may result in losing individuals back to addiction and thus in a missed opportunity for tying these individuals into the treatment system (and all the benefits that would accrue from such a connection).** Two recent studies published in *Alcoholism: Clinical and Experimental Research* have found that individuals who fail to adhere to their medication have a significantly higher risk of relapse than those who remain on the drug. In one of these studies, individuals who were adherent to Naltrexone were abstinent on average 80.7% of days compared with 65.9% of days for those who stopped taking their prescription. [Zweben A. et al (2008). *Relationship between medication adherence and treatment outcomes: The COMBINE study. Alcoholism: Clinical and Experimental Research Vol. 32, No. 9, 1-9 (Sept 2008).*] A July study in the same magazine reported a significant association between medication adherence and time to day of first heavy drinking. [Oslin, D.W. et al, (2008) *A placebo-controlled randomized clinical trial of Naltrexone in the context of different levels of psychosocial intervention. Alcoholism: Clinical and Experimental Research Vol. 32, No. 7, 1299-1308 (July 2008).*] Additionally, a 1996 study of women who lost government funding for their Methadone Maintenance found that 62.5% returned to medium to high heroin use and illicit activities to support that use. [Knight, K.R. et al (1996), *Defunding the poor: the impact of lost access to subsidized methadone maintenance on women injection users. Journal of Drug Issues 26(4) 923-942 (Fall 1996).*]

### Conclusion

**Medicaid and other programs should remove all unnecessary obstacles that limit the access of individuals with alcohol and/or drug addiction to life-saving treatments that have proven safe and effective. Such obstacles may cost states more over the long-term than any cost accrued by paying for the treatments. More important, failure to provide such treatment could cost the lives of those who could have benefited from such treatment.** Patients who suffer from alcohol and drug dependence pose particular challenges for Medicaid and for treatment providers. There is often only one opportunity to provide these individuals with the

lifesaving treatments they need to overcome their addiction. Unnecessary obstacles to attaining such treatments may prevent the individual's successful retention in and completion of treatment. Such failure will likely cost states far more than it would have cost to provide appropriate care.

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