

Mr. Chairman and Members of the Insurance Committee. My name is Dr. Gregory Brigham; I am a Licensed and Board Certified Clinical Psychologist. My wife, children and, grandchildren live, work and, attend school here in Central Ohio.

I am a graduate of The Ohio State University. I have specialized in the treatment of drug dependence for over 25 years. My areas of expertise involve both behavioral and pharmacological interventions for drug dependence. I am the Chief Research Officer at Maryhaven, Central Ohio's oldest and most comprehensive provider of behavioral health services with a specialization in addiction recovery. My full time efforts are focused on conducting NIH sponsored randomized clinical trials, for the development and evaluation of drug dependence treatments.

I am here as a proponent of HB 384-Comprehensive Mental Health Parity.

If a medical condition can be reliably diagnosed, successfully treated with medication and behavioral procedures and, the treatment has a favorable cost to benefit ratio; there is no legitimate reason to exclude that condition from healthcare coverage. My testimony will provide examples of scientific evidence that drug and alcohol dependence meets these criteria.

The majority of my prepared remarks will be taken from a literature review entitled "Drug Dependence, a Chronic Medical Illness; Implications for Treatment, Insurance, and Outcomes." This scholarly article was vetted via peer review and published in one of the world's premier medical journals; *The Journal of the American Medical Association* (McLellan, Lewis, O'Brien & Kleber, 2000).

Drug dependence costs the United States approximately \$67 billion annually in crime, lost work productivity, foster care, and other social problems. Perhaps these extreme social costs contribute to the continuing stigma and prejudice that allows substance use disorders to go largely untreated and discriminated against by health insurers?

The difficulty in treating these disorders may further the arguments against supporting treatment; studies show that 40% to 60% of patients treated for alcohol or other drug dependence relapse to some substance use within 6 months to one year.

Is this high or low? What is the standard to which these outcomes should be compared? Drug dependence is largely accepted in the treatment and scientific community as a chronic illness. So how does it compare to other chronic medical conditions?

I will compare drug dependence with two well-accepted and extensively studied chronic medical conditions: hypertension and asthma.

Diagnosis

Who has drug dependence?

There is no laboratory test of drug dependence it is operationally defined in the Diagnostic and Statistical Manual of the American Psychiatric Association and studies have repeatedly show these diagnostic criteria to be valid and reliable.

Two of the diagnostic criteria, tolerance and withdrawal, indicate neurologic cellular adaptation or physiologic dependence. However, this cellular neuro-pathology alone is neither necessary nor sufficient for a diagnosis of substance dependence. Those receiving a dependence diagnosis are required to show a “compulsive desire for and use of the drug(s) despite serious adverse consequences” such as “use instead of or while performing important responsibilities.”

Genetic Heritability

Is it genetic?

An established method of estimating the level of genetic contribution to an illness is to compare the rates of a disorder in dizygotic and monozygotic twins.

Heritability estimates from twin studies of hypertension range from 0.25 to 0.50, depending on the sample and the diagnostic criteria used.

Twin studies of adult-onset asthma produce heritability estimates, from 0.36 to 0.70.

Numerous twin studies have been published in the substance dependence field, all showing significantly higher rates of dependence among twins than among non-twin siblings and higher rates among monozygotic than dizygotic twins.

Published heritability estimates include:

- 0.34 for males dependent on heroin,
- 0.55 for males dependent on alcohol,
- 0.52 for females dependent on marijuana, and
- 0.61 for cigarette-dependent twins of both sexes.

	Drug Dependence	Hypertension	Asthma
Twin Studies Heritability Estimates	0.34 to 0.61	0.25 to 0.50	0.36 to 0.70

Personal Responsibility

What is the role of personal responsibility?

The initial use of drugs or alcohol is a voluntary behavior and therefore the role of personal responsibility is a legitimate consideration. The majority of individuals who use drugs do not become dependent; some interaction between vulnerability and behavior is required. How does this compare with other chronic illness?

Salt sensitivity is a genetically transmitted risk factor for the eventual development of a form of hypertension. Not all of those who inherit salt sensitivity develop hypertension. This is partly because, the use of salt, is determined by a combination of familial salt use patterns and individual choice. Risk factors such as obesity, stress level, and inactivity are products of familial, cultural, and personal choice factors. Therefore, among those with a demonstrated genetic risk, a significant part of the total risk for developing hypertension can be linked to individual behaviors.

Just how voluntary these initial behaviors are is not completely known. Consider the choice to try a drug, which appears voluntary however, the effects of the drug can be influenced profoundly by genetic factors. Those whose initial, involuntary physiologic responses to alcohol or other drugs are extremely pleasurable will be more likely to repeat the drug taking than those whose reaction is neutral or negative.

Research has shown that sons of alcohol-dependent fathers inherit more tolerance to alcohol's effects and are less likely to experience hangovers than sons of non-alcohol dependent fathers.

In contrast, the inherited presence of an aldehyde dehydrogenase genotype (associated with alcohol metabolism) causes an involuntary skin "flushing" response to alcohol. Individuals who have a strong genotype (homozygous for the allele) of this characteristic (approximately 35% of the Chinese population, and 20% of Jewish males in Israel) have an especially unpleasant initial reaction to voluntary alcohol use and there are virtually no alcoholics found with this genotype.

Treatment Response

Two important questions in the comparison of drug dependence and other chronic illnesses is first, will the problem decrease without treatment (is it truly chronic?) and second, will it improve with treatment by medications and behavioral therapies? There is a large body of research on drug dependence treatment outcomes, I will provide one example to address each of these questions.

Metzger measured drug use, needle-sharing practices, and human immunodeficiency virus (HIV) infection rates of 2 large samples of opiate dependent persons in

Philadelphia. An *in-treatment* group of 152 patients were randomly selected at admission to a methadone maintenance program. An *Out-of-treatment group* 103 individuals who were also heroin-dependent and matched to the treatment group by age, race, sex, neighborhood, and other relevant background factors.

Both groups were interviewed and tested for HIV status every 6 months for 7 years. At the initial assessment, 13% of the in-treatment sample and 21% of the out-of-treatment sample were HIV positive. By 7 years, 21 % of the in-treatment and 51% of the out-of-treatment group tested HIV positive (8% versus 30% conversion to HIV positive).

Svikis studied a group of pregnant women who applied for prenatal care and tested positive for cocaine use in a routine drug screen. These women were provided 1 week of residential drug treatment followed by twice-weekly outpatient counseling in the context of their scheduled prenatal visits. These women were then compared with 46 pregnant, demographically matched women who tested positive for cocaine use and received standard prenatal care during the year before.

At delivery, 37% of the treated patients tested positive for cocaine use compared with 63% of the untreated women.

Infants of the treated women averaged higher birth weights (2934 vs. 2539 g) and longer gestational periods (39 vs. 34 weeks).

Following delivery, 10% of infants in the treated group required care in the neonatal intensive care unit (mean, 7 days). In comparison, 26% of infants in the untreated group required intensive care (mean, 39 days). The average cost of this care was \$14,500 for the treated group and \$46,700 for the comparison group.

Medications

Rightly so or not, many consider the presence of efficacious medications as an indication as to whether or not a condition is indeed an “illness.”

Under Food and Drug Administration guidelines, which require randomized clinical trials, numerous medications have reached the market for treatment of dependence on nicotine, opiates, and alcohol. Here I will provide examples of opioid medications. There are three types of medications for the treatment of opiate dependence; agonist, partial agonist and antagonist all acting directly on opioid receptors, particularly the μ -receptors.

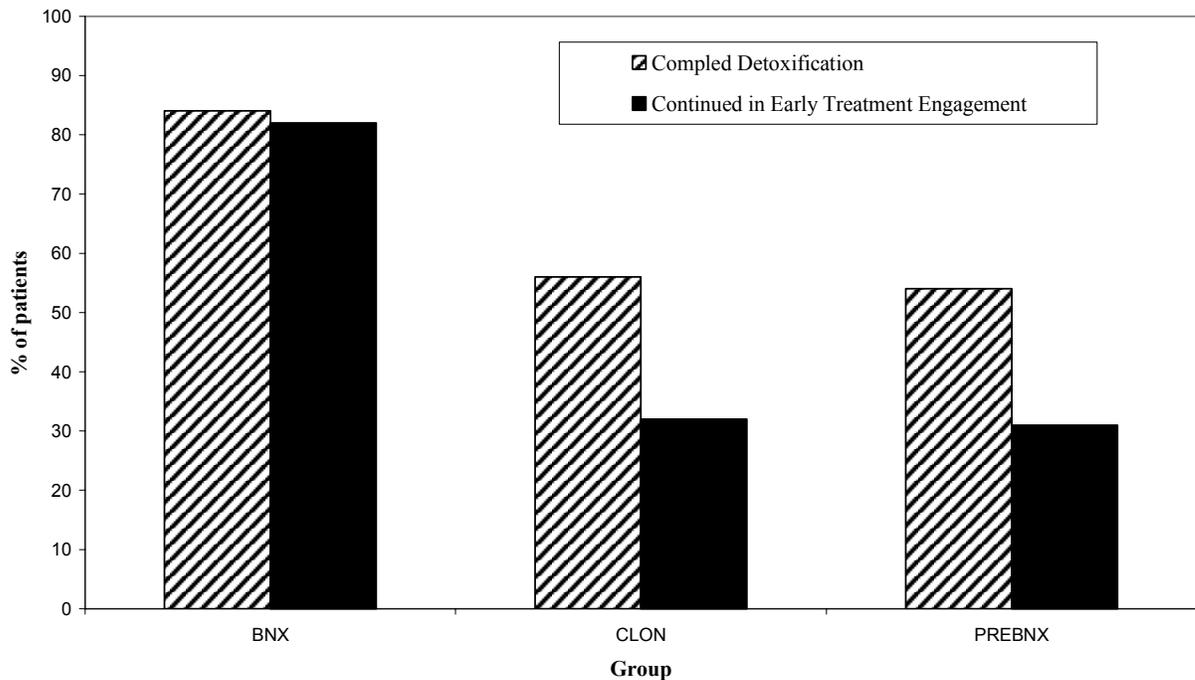
Agonist medications, such as methadone hydrochloride, are prescribed in the short-term as part of an opioid detoxification protocol or in the long term as a maintenance regimen. Double-blind, placebo-controlled trials have shown methadone to be effective in both inpatient and outpatient detoxification, however detoxification without ongoing treatment simply does not work. As a maintenance medication, methadone’s oral route of administration, slow onset of action, and long half-life have been effective in reducing

opiate use, crime, and the spread of infectious diseases, as was recently validated by a National Institutes of Health Consensus Conference.

The partial agonist buprenorphine hydrochloride (marketed as Subutex or in combination with naloxone as Suboxone) is administered sublingually and is active for approximately 24 to 36 hours. Large double-blind, placebo-controlled trials of buprenorphine have shown reductions in opiate use comparable with methadone but with fewer withdrawal symptoms on discontinuation.

At Maryhaven we found that by switching to Buprenorphine from clonidine we were able to increase detoxification completion rates from 50% to 80% and even more important increase treatment engagement rates from 30% to 80% (Brigham et al., 2007).

Figure 1



Opioid antagonists such as naltrexone block the actions of heroin through competitive binding for 48 to 72 hours, producing neither euphoria nor dysphoria in abstinent patients. (Compliance is a particular problem with oral formulations of this medication however long acting injectable formulations are now available and approved for the treatment of alcoholism.)

Naltrexone in combination with social or criminal justice sanctions is routinely used with good success in the monitored treatment of physicians, nurses, and other professionals.

In a controlled trial, Cornish and colleagues found that naltrexone added to standard federal probation produced 70% less opiate use and 50% less re-incarceration than standard probation alone.

There are numerous effective medications for alcohol and nicotine dependence and very promising medications are on the horizon for other disorders such as vaccines for cocaine dependence.

Comparison of Treatment for Drug Dependence with other Chronic Diseases

Drug dependence can be well managed with a combination of medication and behavioral intervention.

Patients who receive these treatments have favorable outcomes during treatment and for 6 to 12 months following treatment.

Favorable outcomes typically continue for patients who remain in long term treatment (agonist medication programs) or in programs like Alcoholics Anonymous, however, because of insurance restrictions, many patients receive only acute stabilization (detoxification and short-term treatment).

Practice guidelines from the National Institutes of Health indicate that 90 days of treatment is the minimum threshold for effective treatment (National Institute on Drug Abuse, 1999).

One year follow-up studies show only 40% to 60% of discharged patients are continuously abstinent (perfect adherence), although an additional 15% to 30% have not resumed dependent use (good adherence) during this period. Problems of low socioeconomic status, co-morbid psychiatric conditions, and lack of family and social supports are among the most important predictors of poor adherence during addiction treatment and of relapse following treatment.

Hypertension and asthma are also chronic disorders, requiring continuing care throughout a patient's life. Treatments for these illnesses are effective but heavily dependent on adherence to the medical regimen for that effectiveness.

Studies have shown that:

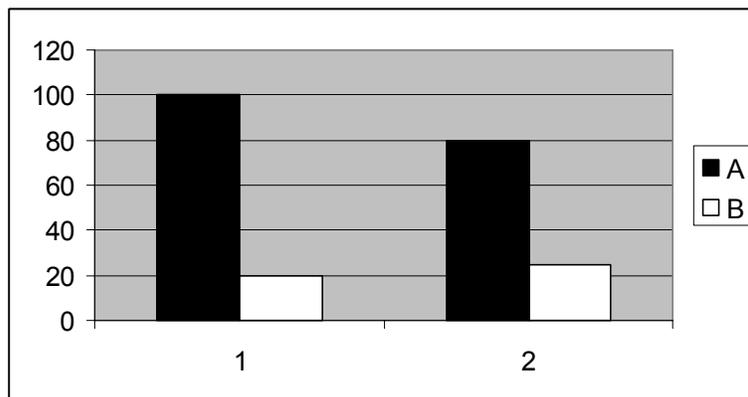
- Less than 40% of patients with hypertension or asthma adhere fully to their medication regimens.
- The problem is even worse for the behavioral and diet changes that are so important for the maintenance of gains in these chronic illnesses. Again, studies indicate that less than 30% of patients with adult-onset asthma or hypertension adhere to prescribed diet and/or behavioral changes that are designed to increase functional status and to reduce risk factors for recurrence of the disorders.

- Across all 3 of these chronic medical illnesses, adherence and ultimately outcome are poorest among patients with low socioeconomic status, lack of family and social supports, or significant psychiatric co-morbidity.
- Perhaps because of the similarity in treatment adherence, there are also similar relapse rates across these disorders. Outcome studies indicate that approximately 50% to 70% of adult patients with hypertension or asthma experience recurrence of symptoms each year to the point where they require additional medical care to reestablish symptom remission.

	Drug Dependence	Hypertension	Asthma
Medication Adherence	<80%*	<40%	<40%
Behavioral Adherence		<30%	<30%
Relapse Rates	40% to 60%	50% to 70%	50% to 70%

(*Kakko et al., 2007)

Evaluations of drug abuse treatment are often conducted following cessation of the treatment. When symptoms return the treatment is considered a failure. Return of symptoms following cessation of treatment is considered evidence of effectiveness in the treatment of other chronic illnesses.



Cost Effectiveness

In a benefit to cost study of substance abuse treatment in California, Ettner, examined 43 substance abuse treatment programs, in 13 counties, representing 2567 patients. Findings were, on average, substance abuse treatment costs \$1,583 and is associated with monetary benefits to society of \$11,487 representing a greater than 7:1 ratio of benefits to cost (Ettner et al., 2006).

In an effort to improve insurance coverage for mental health and substance abuse services the Federal Employee Health Benefits Program (FEHB) offered these services on par with general medical benefits beginning 1/01/2001. Goldman conducted an evaluation of 7 FEHB plans from 1999 to 2002 with a matched set of health plans that did not include parity for mental health and substance abuse services. They concluded that implementation of parity in insurance benefits, coupled with management of care, can improve insurance protection without increasing total costs (Goldman et al., 2006).

Summary

Few persons who try drugs will become dependent.

There is a predictable pathogenesis to dependence, which is marked by persistent changes in brain chemistry and function.

It is not yet possible to explain the physiological and psychological processes that transform voluntary drug use into involuntary drug dependence.

Twin studies indicate a definite genetic heritability.

Personal choice and environmental factors are clearly involved. The vulnerability, onset, and course of drug dependence are similar to that of other chronic illnesses such as hypertension, and asthma.

A review of 100 randomized clinical trials of drug abuse treatment indicates significant reductions in drug use, improved personal health, and reduced social pathology during and following treatment (McLellan et al., 2000).

Costs to benefits ratios for mental health and substance abuse parity or very favorable.

Like other chronic illnesses, the effects of drug dependence treatment are optimized when patients remain in continuing care and monitoring without limits or restrictions on the number of days or visits covered.

Effective pharmacological and behavioral drug abuse treatments are available. The best treatment response has been seen in those who receive an adequate and ongoing dose of treatment.

References:

Brigham, G. S., Amass, L., Winhusen, T., Harrer, J. M., & Pelt, A. (2007). Using buprenorphine short-term taper to facilitate early treatment engagement. *Journal of Substance Abuse Treatment, 32*, 349-356.

Ettner, S. L., Huang, D., Evans, E., Ash, D. R., Hardy, M., & Yih-Ing, H. (2006). Erratum: Correction to "Benefit-cost in the California Treatment Outcome Project: Does substance abuse treatment 'pay for itself'?" *Health Services Research, 41*, 613.

Goldman, H. H., Frank, R. G., Burnam, M. A., Huskamp, H. A., Ridgely, M. S., Normand, S. T., Young, A. S., Barry, C. L., Azzone, V., Busch, A. B., Azrin, S. T., Moran, G., Lichtenstein, C., & Blasinsky, M. (2006). Behavioral Health Insurance Parity for Federal Employees. *New England Journal of Medicine, 354*, 1378-1386.

Kakko, J., Grönbladh, L., Svanborg, K. D., von Wachenfeldt, J., Rück, C., Rawlings, B., Nilsson, L., & Heilig, M. (2007). A stepped care strategy using buprenorphine and methadone versus conventional methadone maintenance in heroin dependence: A randomized controlled trial. *American Journal of Psychiatry, 164*, 797-803.

McLellan, A. T., O'Brien, C. P., Lewis, D. L. & Kleber, H. D. (2000). Drug addiction as a chronic medical illness: implications for treatment, insurance and evaluation. *JAMA, 284*, 1689-1695.

National Institute on Drug Abuse. *Principles of Drug Addiction Treatment: A Research Based Guide*. Bethesda, MD: National Institutes of Health; 1999. NIH publication 99-4180.