Earl Hightower's Remarks
2014 National Rx Drug Abuse Summit
Medication Assisted Treatment for Opiate Addiction

Thank you, Chairman Rogers, for holding this important Summit and helping to bring attention to solutions to the opioid abuse, addiction and overdose epidemic.

I advocate for a comprehensive approach that includes the latest evidence-based treatments to address the problem of opioid addiction, including the use appropriate use of medication; also known as Medically Assisted Treatment (MAT).

As you all know, there are three medications that have been approved by the U.S. Food and Drug Administration (FDA) for the treatment of opiate addiction: methadone, buprenorphine and naltrexone.

Long Acting Injectable naltrexone (Vivitrol®), unlike methadone and buprenorphine, is non-addictive and non-narcotic and, as such, is not scheduled by the DEA and is not associated with abuse or diversion for illicit use.

The DEA Schedule of Controlled Substances lists Methadone as a Schedule II drug because it has legitimate medical uses, but is also addictive and can have serious side effects including respiratory and cardiac suppression, which can lead to overdose and death. Methadone is currently administered to about 300,000 individuals daily in approximately 1,300 methadone clinics[i].

Buprenorphine/Naloxone (AKA Suboxone® and Zubsolv®) is a Schedule III controlled substance because it has "a potential for abuse less than substances in Schedules I or II and abuse may lead to moderate or low physical dependence or high psychological dependence" and is generally prescribed by a family physician once they have fulfilled the federally established eight-hour educational requirement.

In 2002, buprenorphine became available and present estimates indicate that about 1,000,000 people in the United States will be treated with buprenorphine this year.[ii] This represents more than a 7,000% increase over the past ten years, far outpacing the growth of all other opioids including methadone.

The two opioid maintenance treatments, methadone and buprenorphine/naloxone, are currently the primary medications used in America today to treat opioid dependence. The number of individuals treated with either methadone or buprenorphine/naloxone increased from approximately 230,000 people in 2003, to more than 1,300,000 individuals in 2014.

This five-fold increase is a dramatic development with significant public health implications. For many patients seriously addicted to opioids, these opioid maintenance therapies are appropriate adjuncts to treatment. However, it is critical to recognize that opioid maintenance therapy should not be the only treatment offered to opioid dependent individuals, as is the current case, and should never be provided absent a comprehensive treatment program that includes psychosocial counseling, drug testing and an exit strategy.

Please understand however that the most widely prescribed addiction medication, buprenorphine/naloxone is administered mainly absent any referral to addiction treatment, monitoring or with any thought to how to successfully taper patients off the medication. **The sad reality is that M.A.T. is no longer an acronym for Medication Assisted Treatment. Instead, as it relates to the manner in which buprenorphine/naloxone is prescribed, MAT now means Medicine as Treatment. That is a subtle but very dangerous shift in policy and practice!**

Advocates for Buprenorphine say, "why would you want to taper someone off such a successful and life-saving medication?" We don't force diabetics off insulin.

That's a good argument if it was true that Buprenorphine was as harmless and effective for treating addiction as insulin is at treating diabetes. However, the research does not bear that out.

In 2011, the first large and randomized controlled multisite trial of patients dependent on prescription opioids assessed the consequences of terminating treatment with buprenorphine-naloxone[1]. This study reported near universal relapse (92%) to opioids after a 12-week treatment. The finding of near universal relapse after treatment discontinuation is particularly important in light of the fact that almost all patients who are being treated with buprenorphine will discontinue the medication eventually. In fact, once a patient has been inducted on to buprenorphine, the actual duration of treatment obtained in a retrospective pharmacy claims analysis is just 68 days.[2] In other words, for the vast majority of opioid-dependent individuals, treatment with buprenorphine alone is merely kicking the can down the road.

Understandably, advocates purport that the Weiss et al. study is evidence that patients should stay on buprenorphine longer in order to achieve better benefits. However, only 7.2% of patients receiving buprenorphine-naloxone plus counseling and 6.1% of patients receiving buprenorphine-naloxone alone were abstinent from opiates (other than buprenorphine) during the full trial. The percentage of negative UDAs from alcohol or illicit drugs other than opiates was not reported. The best reported outcome in the Weiss study was that 49% of patients received a "successful outcome" while on buprenorphine in the first 12 weeks. "Successful outcome" was defined in the study as "no more than four days in a month with self-reported opioid use", plus "no more than one missing urine sample", plus "absence of two consecutive opioid-positive UDS". In phase two of the study, "successful outcome" was defined as "abstaining from opioids (other than buprenorphine) in week 12 and during at least two of the previous three weeks (weeks nine-eleven)" or "abstinence from opioids (other than buprenorphine) during week twenty-four and at least two of the past three weeks."

I know of no treatment program that would consider this a successful outcome.

1 Weiss, R. et al. (2011). Adjunctive Counseling During Brief and Extended Buprenorphine-Naloxone Treatment for Prescription Opioid Dependence. *Archives of General Psychiatry.* 68(12):1238-46

2 Baser O, Chalk M, Fiellin DA, Gastfriend DR. Cost and utilization outcomes of opioid-dependence treatments. Am J Manag Care 2011;17:S235-46.

In all published studies, buprenorphine, at best, was found to be better than placebo and equivalent to and in some instances better than methadone (60 mg) **in reducing opioid use**. Under research conditions, about half of all study subjects were retained for the duration of the trial (3-4 months).

The percent of urine drug screens (UDS) that were negative for opioids (other than buprenorphine) in the four studies that reported this outcome ranged from a low of approximately 7% to 53%. Put in other words, between 47% and 92% of UDS were positive for illicit opioids even though patients were currently receiving buprenorphine. Only two studies reported data on the concurrent abuse of cocaine while being treated with buprenorphine: 44%[3] and 52%[4] of UDS were positive for cocaine. No study to date reports to what extent alcohol or other drugs such as methamphetamine, marijuana, etc. were on board.

Since when did the bar for measuring treatment success become so low? Are we really going to settle for "less opioid use" as the gold standard of treatment over the goal of abstinence from all drugs? Parents, would you agree to such a treatment standard for your son or daughter?

I'll go a step further. Given the cognitive impairments that are clearly associated with buprenorphine/naloxone, is it possible that it's actually a hindrance to the real work that required in treatment to actually achieve abstinence and recovery?

Several studies now show that buprenorphine causes and/or extends cognitive impairment. One such study looked at cognitive performance amongst opioid maintenance patients, abstinent opioid users, and non-opioid users[5]. This study tested thirteen cognitive functions between these three groups. The study found that "significant differences in group cognitive performance" were seen in the opioid maintenance group, with this group "exhibiting the poorest profile". The opioid maintenance group showed the poorest performance in tests of "executive function, information processing speed, verbal and non-verbal learning". The authors tested both methadone and buprenorphine users and their study revealed that "no substantive difference" was seen in the performance of methadone users compared to buprenorphine users despite the "different pharmacological profiles of these drugs". The authors concluded that maintenance treatment providers should "be aware" that their patients demonstrate impairment across a range of cognitive tests, which in severe cases "may manifest in higher levels of disinhibition, risk-taking, poor problem solving skills and poor learning".

Another study focused on the neuropsychological functioning of patients on buprenorphine verses abstinent heroin abusers on naltrexone therapy[6]. This study found that the buprenorphine group performed "significantly poorer than controls on tests of visual perception/visual memory" and

3 Fudala, P. (2003). Office-Based Treatment of Opiate Addiction with a Sublingual-Tablet Formulation of Buprenorphine and Naloxone, *New England Journal of Medicine*, 349 (10); 949-958.

4 Johnson, R. et al. (2000). A controlled trial of levomethadyl acetate, buprenorphine, and methadone for opioid dependence. *New England Journal of Medicine*; 343: 1290-1297

5 Shane Darke, Skye McDonald, Sharlene Kaye, & Michelle Torok (2012). Comparative patterns of cognitive performance amongst opioid maintenance patients, abstinent opioid users and non-opioid users. *Drug and Alcohol Dependence*, 126: 309-315.

"encoding verbal information during immediate or working memory tasks" and had "significantly inferior performance to controls on delayed verbal memory".

Despite poor outcomes, federal law (DATA 2000) continues to allow general practitioner physicians to treat up to 100 opioid addicts with Suboxone® in an office-based setting with minimal training, and with no requirements to test for opiates, alcohol or other drugs. New regulations were just passed that lifted the 100 patient maximum and allows patients to go home with a 30-day dose with no additional medical supervision.

While some treatment programs and psychiatrists use buprenorphine/naloxone in clinical practice, they also provide a full range of treatment such as psychotherapy, psycho-social treatment and/or 12-Step-oriented care and recovery.

However, the vast majority of "Suboxone® doctors" are doing nothing more than writing a prescription for buprenorphine/naloxone with no referral to outside treatment for opioid-dependence and doing nothing to identify and treat each patient's alcohol and/or other non-opioid drug abuse/dependence or its underlying causes.

Hear me clearly, addiction has major neurological aspects, which for some people may be chronic or lifelong in duration. The more severe the brain dysfunction and the more protracted the course of recovery, the more likely it is the individual will need medications to achieve sustained sobriety. I'm not against MAT.

In fact, probably the best course of treatment for an opioid dependant person is to use medications, including buprenorphine to detox the individual and once fully detoxed, place them on Vivitrol, the long-acting, injectable naltrexone. Once stable, immerse them in a year or more of intensive psychosocial counseling, trauma and other mental health therapy, 12-step work, and close monitoring.

If you are still unconvinced that we should take a much closer look at the negative impact of our current approach to treating opioid dependence with replacement drugs like buprenorphine/naloxone and methadone, please take a look at this 10-year graph which depicts first the number of individuals on illicit opioids steadily increasing compared to the increase of methadone and the rapid increase in buprenorphine.

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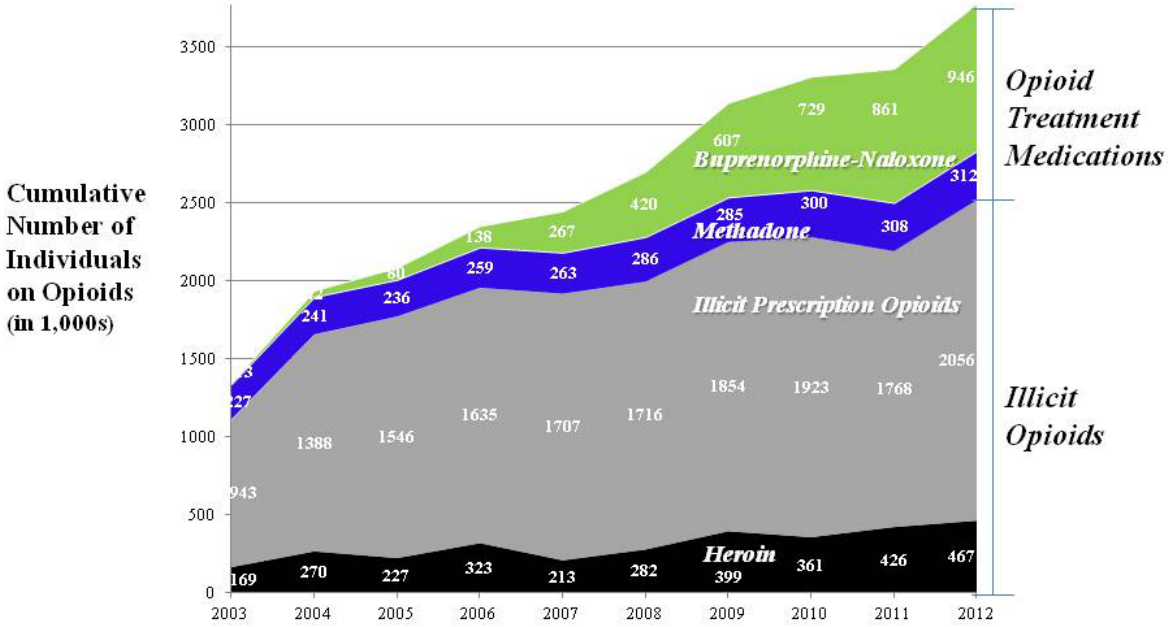
6 Lambros Messinis, Epameinondas Lyros, Virginia Andrian, Paraskevi Katsakiori, George Panagis, Vasileios Georgiou, & Panagiotis Papathanasopoulos (2009). Neuropsychological functioning in buprenorphine maintained patients verses abstinent heroin abusers on naltrexone hydrochloride therapy. *Human Psychopharmacology Clin Exp* 24: 524-531.



The fact is that the increased use of buprenorphine/naloxone and methadone has not been associated with decreased heroin or prescription opioids.

Given the extremely high relapse rates associated with buprenorphine/naloxone and the short amount of time addicts actually stay on the medication (68 days on average), and given the cognitive impairments and the lack of monitoring and referral to other types of treatment, one has to ask, what's actually driving the rates of heroin and prescription drug dependence and overdose to epidemic levels?

Abstinence, not harm-reduction, must be our aim if we are to seek a real solution to the opioid-dependence and overdose epidemic in America.

I hope you will join me at the Abstinence-Based Treatment Alliance as we seek to move away from the harm of a growing harm-reduction strategy and place abstinence as the gold-standard of treatment and recovery in America.

[i] Substance Abuse and Mental Health Services Administration. *Behavioral Health Barometer: United States, 2013*. HHS Publication No. SMA-13-4796. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2013. Accessed online March 19, 2014 at: http://www.samhsa.gov/data/StatesInBrief/2K14/National_BHBarometer.pdf

[ii] IMS: SDI's Total Patient Tracker (TPT), Projected Patient Count, Moving Annual Total 2003-2013. Note: The information for buprenorphine and naltrexone are estimates derived from the use of information under license from the following IMS Health information service. IMS expressly reserves all rights, including rights of copying, distribution and republication.