Methadone Today

The official newsletter of DONT **August/Sept 2004 Volume IX Number VI**

LAAM is No Longer Available in U.S.

LAAM is no longer a medication option for opiate addiction treatment—Roxanne, the pharmaceutical company that manufactured and distributed the medication ceased production of LAAM in 2003, and their remaining supply ran out earlier this year. Roxanne's decision was voluntary—that is, the federal government did not ask or require them to stop producing LAAM.

In fact, the drug was banned a couple of years ago in Europe, following the discovery that LAAM can cause cardiac arrhythmia—a potentially life threatening heart condition. But the U.S. Food and Drug Administration (FDA) did not ban the medication—they did however, add the adverse side effect to the warning label to notify doctors and patients of it. Nonetheless, many U.S. opioid treatment providers either ceased providing LAAM to patients (transferring patients on LAAM to methadone) or at least did not offer LAAM to new patients. But they would give patients already on LAAM the option to continue receiving the medication, rather than transfer to methadone.

There is no doubt that one of the main reasons behind Roxanne's decision to stop producing LAAM is the low demand for it. Since the revelation that the medication can cause cardiac problems, it simply was not profitable enough for them to make it anymore. Probably also playing into the decision is the fact that since most patients do as well or better on methadone than LAAM, Roxanne did not feel that pulling the plug on LAAM would hurt patients.

Because Roxanne still has the patent on LAAM, no other company can manufacture, market or distribute the medication. Though in theory, years from now when the patent runs out, other companies could begin manufacturing and distributing LAAM in the U.S., the reality is that LAAM will never again be available in the U.S.—or anywhere else for that matter, since it is banned in Europe and was never approved for use in other countries outside of Europe. It is probably safe to say that LAAM will not be approved or even trialed in any such countries given the risk of cardiac arrhythmia now associated with it.

(Cont p. 3)

Drug Treatment is Minor Issue in Election

Methadone Today recently received a letter from someone inquiring about the presidential election and candidates' attitudes and policy proposals regarding opiate agonist treatment (i.e., methadone treatment). In comparison to past presidential elections, candidates have devoted little time discussing drug policy and related issues. Candidates have instead spent much of their time on issues related to national security, Iraq, and the economy.

In the 2000 and 2004 presidential campaigns, there were candidates who had a clear record concerning drug treatment and methadone treatment in particular--but these candidates did not win their party's nominations, so they were not/will not be on the ballot in the general election. In 2000, Senator John McCain ran against Governor George W. Bush in the Republican Party primary. Senator McCain is an outspoken opponent of methadone treatment, having sponsored a bill that would have prevented medical providers that offer methadone maintenance treatment from receiving any government funding.

In the current presidential campaign (2004), one of the Democrats that ran in their primary had also been critical of methadone treatment. Former Vermont Governor Howard Dean was considered for a short period of time to be the frontrunner in the Democratic Primary. At the time Howard Dean became governor, Vermont was one of several states that still did not allow methadone treatment at all. Governor Dean was initially against allowing methadone treatment but later reversed himself and agreed to sign legislation--but only if the legislation had some very serious restrictions. Governor Dean later dropped out of the presidential race, and Senator John Kerry won the Democratic nomination.

The two major party candidates, Republican President George W. Bush and Democratic Senator John Kerry have not spoken out regarding opioid agonist treatment. The only major proposal of either candidate that is somewhat related to drug treatment is Senator Kerry's health care proposal. Assuming that Kerry's proposal, if passed, does indeed result in more Americans having health insurance, more opiate addicts, who were previously uninsured, would presumably have access to methadone treatment via their insurance. ***(Cont. p. 2)***

Dear Methadone Today,

I just read your March 2004 edition and wish to comment on the rights of inmates to have MMT. I explained before that their argument of it being a cost issue is wrong, as in my case, I ended up going cold turkey, 120 mg to zero, in jail where I had 10 codes which are lock down incidents due to me seizing up. The jail spent thousands of dollars treating me that first month, which included a trip to the suicide section as they transferred me from one jail to another where they spent overtime to transport me around, and in each new jail I had to go over a new complete set of rules and meds. I was also on Tegretol for seizures, and at one jail, I was denied this.

I had over 20 seizures and lost control of my bodily functions. I did not eat for ten days. Other inmates wanted to get rid of me, as I could not take care of myself, and I had to constantly use the bathroom. In a closed-in, two-man cell, that is a no-no which causes big problems. I was told that inmates wanted me out of their pod as I was causing them to lose recreation time, and all through this, my life choices were being made by AN UNQUALIFIED GUARD. In other words, whatever Corrections Officer was on duty at the time had to make choices of what to do with me. So this means I should be under at least a nurse's eye in my state of detoxing 120 mg cold turkey, yet I was not given any medical help--even during seizures. This is cruel and unusual punishment.

I came into jail with a list of my medications, as the sentencing judge put a note in my file, which requested that the jails take note of my many medical problems. But inside the jail walls, the medical staff used the judge's note for toilet paper and laughed. Now, I had a prescription for methadone as the footwork was done and the prescription was already written, but the jails refused to dose me. I also asked to pay for my own medication, and again I was laughed at! This really is cruel and unusual punishment, and I wish to help get some kind of assistance to guys in jail who are in the same predicament, but I do not know where to go, so could you point me in the right direction as I would love to help in any way I can to get MMT into men's jails! I live in the state of Connecticut.

I sit here today in constant fear as I am on MMT now, and I could get a simple parking ticket and end up in jail ***(Cont p. 3)***

Election (from p. 1).

As we have reported in previous issues of ***Methadone Today***, President Bush spent his first term promoting his "faith-based drug treatment initiative." Essentially, this initiative exempted "faith-based" organizations from the rules other drug addiction treatment providers have to follow in order to obtain government funding. In the case of treatment for opiate addiction, this initiative did little more than funnel government money away from effective treatments (i.e., methadone treatment) that are sorely underfunded as it is. The meager amount of government money should at least be used to fund treatments with a proven track record, rather than funding treatments based on whether faith happens to be a central tenet of the treatment program. As we said previously, there is nothing wrong with utilizing faith for support in recovery, but faith is not in itself a drug addiction treatment. Funding should go toward quality treatment programs with competent, well-trained staff who provide a treatment modality that has been proven to be effective. In the case of opiate addiction, the most effective treatment is opiate agonist treatment (i.e., methadone)--a treatment modality that few, if any, "faith-based" treatment providers utilize. Thus, if re-elected, President Bush will probably not do anything to improve the accessibility of effective opiate addiction treatment.

In addition, prospective voters who are interested in the candidates and their respective party's stand on drug treatment and drug policy generally may want to look at the party platforms. The platforms give a summary of the party's position on a wide variety of issues. Both the Democratic and Republican parties do discuss drug policy generally. While there is much overlap between the two parties' platforms regarding drug policy, there are some differences in the philosophy and rhetoric of the parties on this issue. The Democratic Party's platform seems to stress the need for a broad policy--that includes both law enforcement and drug treatment. The Republican Party's platform puts more emphasis on tough law enforcement.

Neither major party presidential candidate is likely to alter the status quo when it comes to methadone treatment and related issues. But hopefully the above information will help prospective voters who are concerned about issues related to opiate addiction and opiate agonist treatment determine which presidential candidate they prefer. **VOTE—It's important!**

Methadone Treatment and Pregnancy--Findings on Dose Adequacy, Split Dosing

Addiction Treatment Forum reported on a few studies regarding methadone maintenance treatment during pregnancy [*for citation information on these research studies, see this issue of Addiction Treatment Forum on the internet (www.atforum.com)*].* It has already been well established that: 1). Methadone maintenance is the best treatment for pregnant opiate addicts for the health of both mother and fetus. Methadone patients who are pregnant should continue maintaining on the medication, and opiate addicts who become pregnant should initiate methadone treatment; 2). During pregnancy, methadone patients should remain on an adequate dose--maintaining on relatively moderate to higher doses of methadone does not endanger the fetus or increase the likelihood of neo-natal withdrawal, while dose reductions may harm the fetus due to withdrawal or worse result in the patient's relapse to illicit short acting opiate abuse, which would seriously endanger the health of the fetus and the pregnant patient; and 3). Later in pregnancy, methadone patients may need an increase in methadone dose; at least up until recently, the reasons for this has not been entirely clear.

While experts were already aware that during pregnancy, methadone patients may need a dose increase, two studies also found that many pregnant methadone patients may do better on a split dose, ingesting a portion of the daily dose two or three times during the day, rather than taking the entire daily dose at once. The apparent reason for this was revealed in another study--methadone appears to be metabolized more rapidly in pregnant patients, so the half-life of methadone in these patients is shorter; that is, the effects of methadone don't last as long as in typical patients. In one study, pregnant methadone patients on a split dose were more physically active than pregnant methadone patients who dosed once a day. The second study revealed a more important benefit of split dosing in pregnant methadone patients--cocaine abuse was considerably less in pregnant methadone patients on a split dose. Addictionologists and obstetricians should pay particular attention to this study, since cocaine use during pregnancy endangers the developing fetus.

In conclusion, the prescription of an adequate methadone dose is of the utmost importance in the case of the pregnant methadone patient to promote the health of the patient and her developing fetus. It appears that a split dose may also be a good idea, particularly in patients prone to cocaine abuse. Opioid withdrawal in newborns sometimes occurs, but the likelihood of it occurring or the severity of the withdrawal symptoms is not related to the pregnant methadone patient's dose. If opioid withdrawal does occur in a newborn infant, the symptoms can and should be promptly relieved with non-opioid medication. Finally, babies born to methadone patients are as healthy as other babies--there are no long-term health consequences for the baby.

Editor's Note: Buprenorphine treatment is generally not recommended during pregnancy simply because there has not been sufficient experience or research treating pregnant opiate addicts with buprenorphine to establish that it is safe for pregnant women and their developing fetuses. So while buprenorphine treatment may turn out to be a safe option for treating opiate addiction during pregnancy, buprenorphine patients who become pregnant are urged to transfer to methadone treatment.

**Followup: MMT & Pregnancy," Addiction Treatment Forum, Vol. XIII, #1 (Winter 2004).*

Methadone Today would like to thank our Medical Advisory Board for their participation.

Our Medical Advisory Board includes:

Dr. Vincent Dole, Rockefeller University;
Dr. Marc Shinderman, Director/Owner of Center for Addictive Problems in Chicago;
Dr. Andrew Byrne from New South Wales, Australia, who has written two books about methadone and addiction;
Dr. Brian McCarroll, Director/Owner of Bio-Med in Clinton Township, MI;
Dr. Charles Schuster, Director of the University Psychiatric Center in Detroit, MI and former head of NIDA; and his associate
Dr. John Hopper, Medical Director of UPC.

LAAM No Longer Available (from p. 1).

For most current or future opiate agonist treatment patients, the fact that LAAM will no longer be available is not big news. Ever since cardiac arrhythmia was named as a potential LAAM side effect, it was only being used as a last resort. . . but even prior to this, there was not a great deal of interest in the medication. However, there is an argument to be made that LAAM is of value to a small percentage of patients.

In opiate agonist treatment, there are only a limited number of medication options. Not counting LAAM, the only opioid medications widely accepted for the treatment of opiate addiction are methadone, buprenorphine and codeine. Of course, methadone was the first medication used for this purpose and methadone treatment remains the gold standard in the treatment of opiate addiction. A few years ago, the FDA approved buprenorphine for the treatment of opiate addiction. Codeine cannot be prescribed for the treatment of opiate addiction in the United States. However, codeine has been widely used for this purpose in Germany with apparent success and is sometimes used for this purpose informally in countries like Canada, where low dose codeine preparations are available over-the-counter (codeine is not available OTC in the U.S.). Thus, in the U.S., methadone and buprenorphine are the only medications available for opiate agonist treatment.

While most patients do well on one or both of these medications, there are a few patients who do not. Buprenorphine is not a good option for some patients---at most, it is only equivalent to roughly 60 mg/d of methadone, so it is not likely to help patients in need of higher dose opiate agonist treatment and will actually cause withdrawal symptoms in patients with a high level of opiate dependency. With both medications, a small percentage of patients will find the side effects difficult to tolerate. In addition, a few patients metabolize methadone very rapidly, to the point that they have trouble stabilizing on the medication even when 'splitting' the dose. Oftentimes, such patients are not good candidates for buprenorphine, as they require higher dose opiate agonist treatment.

LAAM may help some of the patients who, for various reasons discussed above, do not do well on the two currently available opioid medications approved for the treatment of opiate addiction. Certainly, the risk of cardiac arrhythmia associated with LAAM should be taken seriously, but in some of these patients, this risk may be outweighed by the benefit of being able to stabilize on LAAM without intolerable side effects, a benefit that could not be achieved with methadone or buprenorphine. Other steps could be taken to reduce the risk of a cardiac problem occurring in LAAM patients. Patients with pre-existing cardiac conditions would be screened out, and periodic EKGs would be used to detect cardiac arrhythmia before a serious problem can occur. In patients taking LAAM, cardiac arrhythmia is a fairly rare side effect--which explains why the FDA did not ban LAAM. For this reason, LAAM should remain available in the U.S., and hopefully Roxanne will reconsider their decision to stop manufacturing it.

Dear Methadone Today (from p. 1).

without my medications and it scares me a lot! It is time to come out and truly treat humans as humans and not animals, as that is what happens to you when you detox 120 mg/d of methadone cold turkey, as you simply turn into an animal. I wish to thank you for providing a place to vent our views and for all the information you provide on MMT, and to the REAL DOCTORS who treat us as human beings. **-Charlie**

Dear Charlie,

It is appalling that inmates are treated in this manner in the United States. The courts have historically been very conservative in their interpretation of the Eighth Amendment of the U.S. Constitution, which is supposed to protect people from 'Cruel and unusual punishment'. The issue of medical care for inmates and their constitutional rights under the Eighth Amendment has been particularly dicey. The courts have established that the state has to provide inmates with some degree of medical care, but the standards they must reach are set very low.

Even under these low standards, it appears that this jail failed to meet their constitutional duty. When you were clearly in medical distress (even most lay people with no medical background would realize that an individual having seizures is in need of medical care), the guards needed to get you under medical supervision—a doctor or at bare minimum, a nurse—as soon as possible. You are also correct that you should have been placed under the supervision of a nurse while being withdrawn cold turkey from 120 mg/d of methadone, but courts would not likely consider that cruel and unusual punishment, at least in the case of an otherwise healthy individual. Jails and prisons have been able to get away with this because opioid withdrawal is seldom life-threatening. Hopefully, attitudes among jail and prison officials are changing, especially following a couple of cases in Florida where an inmate withdrawing from methadone cold turkey died and the families sued the jail and won large sum awards.

We could devote far more space to this issue, but we will hold off on discussion for a future article. If you want to help inmates in Connecticut having similar problems, you may want to contact George C. via e-mail at ARMMAT@aol.com. He has been very active on this issue, frequently meeting and corresponding with Connecticut prison officials, as well as following legislation related to this issue. George is a representative of **Advocates for Recovery through Medicine**.

The most common reason given by jail/prison officials for not providing methadone to inmates is that methadone may be diverted to other inmates. Illicit drug use is a problem in prison, so the reasoning is that methadone will just add to the supply of drugs there. Studies of Rikers Island, a New York prison that provides methadone to some of its inmates and prisons in countries where methadone treatment is provided clearly demonstrate that methadone can be dispensed in prison without problems with diversion and abuse.

Watch for another article on Medical Maintenance in the October 2004 issue of *Methadone Today*

Answers to Frequently Asked Questions about Hepatitis C

The following is a reprint of an American Liver Foundation Publication. This pamphlet comes with "The Home Access Hepatitis C Check", a home Hepatitis C test. We are printing this because a large percentage of methadone patients have hepatitis C, many of whom do not even realize they have the disease.*

What is hepatitis C?

Hepatitis C is a liver disease caused by the hepatitis C virus (HCV), which is found in an infected person's blood. Hepatitis C is a serious disease. Many people may carry the virus for the rest of their lives. Infected people can develop liver damage but do not necessarily feel sick. Even those who develop a persistent infection may not show symptoms until there is severe liver damage. In some cases, hepatitis C can cause cirrhosis (scarring) of the liver, liver failure and liver cancer over a period of 20 to 30 years.

Who is most likely to be infected with the hepatitis C virus?

Anyone can be infected with the hepatitis C virus. However, people most likely to be infected with the hepatitis C virus include individuals who: 1) had a blood transfusion and/or received an organ transplant such as kidney, lung or heart, before effective screening began in July 1992; 2) have been or are on long term kidney dialysis (hemodialysis); 3) received treatment with a clotting factor concentrate manufactured before 1987; 4) have ever injected illegal drugs, even once; 5) have had sexual contact with multiple individuals over the course of their lifetime; 6) have been health care workers with exposure to blood from a hepatitis C infected person, especially through accidental needle sticks; or 7) have ever had a sexually transmitted disease (STD).

What are the symptoms of hepatitis C?

The most common symptom of hepatitis C is fatigue; however, most infected people have no recognizable signs or symptoms for a long time, Some people do experience flu-like symptoms, such as loss of appetite, nausea and vomiting, fever, weakness, tiredness and mild abdominal pain. Less common symptoms are dark urine and jaundice of the skin and eyes. The only way to know if you are infected is through blood tests.

Is hepatitis C contagious?

Yes. Usually the hepatitis C virus is spread from one person to another by direct exposure to infected blood or blood products and contaminated needles or other sharp objects. Occasionally, the hepatitis C virus may be spread by: 1) an infected mother to her newborn; 2) infected household members; or 3) sexual contact. Sexual transmission typically occurs among people with multiple sexual partners or a history of sexually transmitted disease. HCV transmission is rare among long-term sexual partners who do not have other sexual contacts.

If you are infected, we recommend taking extra steps to avoid blood to blood contact with others to prevent any possibility of infecting other people close to you. Do not share items that may be contaminated with blood such as razors and toothbrushes. Consider using condoms, because sexual transmission, although rare, is possible.

What is the hepatitis C test?

The human body makes antibodies to fight off all kinds of infections. Your body creates antibodies to the hepatitis C virus if you are infected with it. This service* tests your blood for these antibodies.

Is this test accurate?

Yes. In a multi center clinical study this test service*, using blood from a finger stick obtained by non-medically trained participants, was proven to be greater than 99% accurate compared to a blood sample drawn by a medical professional and tested using current test methods.

It can take up to six months for your blood to develop antibodies to the hepatitis C virus. [The test] may not detect more recent infections. We recommend you take the test six months or more AFTER you have been exposed to the hepatitis C virus.

What does my test result mean?

There are 4 possible test results:

1) A "negative" test result means antibodies to the virus were not found in your test sample, and it is extremely unlikely that you have been infected. [Even] If you receive this test result, you should be evaluated by a physician of your choice if you become ill or if you remain concerned that you could be infected with the hepatitis C virus.

2) A "positive" test result means antibodies to the virus were found in your test sample and that you should consider yourself infected with the Hepatitis C virus. If you receive this test result, we recommend you consult a physician of your choice for medical advice and follow-up.

3) An "indeterminate" test result means that initial testing of your blood detected antibodies but further testing did not conclusively show that these were antibodies to the hepatitis C virus. If you receive this test result, we recommend you consult a physician of your choice and/or be re-tested.

4) A "result not available" test result means that the laboratory was unable to provide a result from your sample. This happens when your test card doesn't have enough blood on it or is wet, soiled, contaminated, or shipped incorrectly. [This only applies to home tests and can be avoided by following the test's directions carefully].

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DONT is a non-profit 501(c)3 organization dedicated to helping patients achieve quality methadone treatment, preserve patient dignity, provide greater public understanding, eliminate discrimination toward methadone patients, and promotion of harm reduction policies.

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