

WARNING!
Buprenorphine
(Subutex /Suboxone)



The NaltrexZone™

Antagonist Assisted Abstinence with Naltrexone Pellets

(U.S. Patent No. 6,203,813)

Naltrexone Maintenance Therapy

We provide an amazingly simple program for addicts to stay clean from drug use. Our patented pellets slowly release a low dose of naltrexone into the blood stream. Studies have shown that low naltrexone blood levels will stop self-administration of opiates. We provide this naltrexone maintenance therapy along with cognitive behavior therapy (CBT) which will lead to a program of long term abstinence. Best yet, when your 12-Step Program has taken you to the point that you are ready to get off the Maintenance Therapy, you can just stop using the pellets without any withdrawal or detoxification.

[Read more >](#)

Detoxification with Buprenorphine (Suboxone, Subutex)

Patients need to be detoxified before starting the Naltrexone Maintenance Therapy. At the NaltrexZone, all of our physicians are licensed to provide this treatment with Suboxone and Subutex as specified by the Drug Abuse Treatment Act of 2000 (DATA 2000). Suboxone is readily available at the NaltrexZone. While all detoxifications involve some degree of discomfort, we have found that our program limits withdrawal symptoms to a very low and very tolerable level.

[Read more >](#)

Naltrexone and the Criminal Justice System

Judges and others in the criminal justice system dislike methadone because it is addictive. Naltrexone works very well because it's neither addictive nor pleasurable. Using our naltrexone pellets helps addicts comply with the therapy. And, it is a medically proven fact that addicts undergoing Naltrexone therapy have been proven to be at significantly less risk of reincarceration. This is really a win-win situation for the addict and for society.

[Read more >](#)

Video Testimonial

See what one of Dr. Goberman's patients has to say about the [naltrexone pellet and naltrexone injection](#), in his own words.

[Click below to learn more:](#)

Lance Goberman, MD, JD
John Wilson, MD
Specializing in Addiction Medicine
Addiction Medicine Practice

I want to learn more about:

Detoxification from

- [Methadone](#)
- [Suboxone](#)
- [Short-acting opiates](#)

Temporary Suboxone Maintenance

[Alcohol Detoxification & Anticraving Therapy](#)

We are now treating patients for cocaine abuse - call to find out more, or to schedule an appointment

DETOX WITH BUPRENORPHINE, STAY CLEAN WITH NALTREXONE

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in
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FOUNDED BY LANCE GOOBERMAN, M.D., J.D., F.A.S.A.M.

Website developed by **CyberGnarus**

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Naltrexone Pellet Treatment Program

We offer detoxification (if necessary) followed by maintenance therapy with a patented pellet formulation.

What to Expect When You Come In

Maintenance and Detoxification Programs

- [From Methadone](#)
- [From Suboxone](#)
- [From Short-acting opiates](#)

Naltrexone Pellet Injection Program

Naltrexone Pellet Maintenance Therapy

WARNING! Patients who have used buprenorphine in any form for more than 4 days may experience a delayed withdrawal following pellet insertion. A challenge test with naloxone or naltrexone does not work immediately in buprenorphine dependent patients as it does in patients dependent upon methadone, heroin, Oxycontin, Percocet, etc. There may be a delay of two to twelve hours before the withdrawal is precipitated, alerting the practitioner that the patient has a buprenorphine dependency.

If it is suspected that the patient has a buprenorphine dependency, more than 4 days on buprenorphine, then the patient needs to be off the buprenorphine for a longer period of time before receiving a pellet. It should be recommended that these patients receive oral naltrexone prior to receiving a pellet. A capsule is also available that contains naltrexone and will indicate to the doctor, through a urine sample, that the patient has taken the capsule and is ready to receive a naltrexone pellet, eliminating the need for a challenge test.

TREATMENT OF ADDICTION TO OPIATES

There are many approaches to the treatment of addiction to opiates. Some of those involve maintenance for opioid replacement therapy which typically utilizes methadone or buprenorphine. Buprenorphine has also been used for many years for detoxification prior to abstinence therapy.(Alan W. Graham,

Naltrexone is effective against opiates and opioids including:

Pharmaceuticals:
buprenorphine
dilaudid
methadone
morphine
demerol
codeine
oxycodone
hydrocodone

Brand names:
Oxycontin
Percodan
Percocet
Vicodan
Tylenol #3
Tylenol #4
Darvon
Darvocet
Stadol
Nubaine
Ultram
Meperidol

Street drugs:
smack
horse
H
percs
oxys
dope

MD, FACP, FASAM, et al, Principals of Addiction Medicine, 3rd Edition, Pgs. 658-663)

Abstinence therapy is usually based in cognitive behavior therapy i.e., counseling, self-help groups, group therapy. More recently CBT is used in combination with medical therapy with an opiate antagonists such as naltrexone.

Abstinence therapy is usually preceded by detoxification from opiates. A variety of methods of detoxification both inpatient and outpatient are utilized by various practitioners. Many different modalities of detoxification are accepted in the field of addiction medicine. It is up to the clinician, based upon his evaluation of the patient and his training and experience as to which modality is indicated in a given situation.

Patients frequently self select for therapy and try many different kinds of therapy. They learn about therapies through word of mouth, the internet and other forms of advertising. Patients therefore present whether to a methadone clinic, hospital, or outpatient addiction treatment center with prior knowledge of the modalities that are used at that location and they are there because they prefer to try that modality at that particular time.

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Maintenance and Detoxification Program

This program is simple. It may not be easy, but it is simple.

INSTRUCTIONS

You have found that you are unable to just stop using heroin, oxys, percs or other opiates. We can TRY to make it tolerable, not fun or comfortable, but better than just bearable. This is done with oral medications for the first twenty four hours followed by three days of buprenorphine maintenance therapy and then oral sedatives and other medications for the symptoms of a lesser withdrawal.

The way this is done involves taking buprenorphine daily for three days and then other oral medications for three days. If you use the buprenorphine too early it may cause or worsen withdrawal symptoms. It is important that you start the buprenorphine only after you are definitely in withdrawal. Wait 24 hours after you stop using opiates.

For additional medication, you MUST return to the office. Other medications are available but you must return to the office for another visit (no additional charge for this follow up visit). DO NOT CALL FOR PRESCRIPTIONS.

DETOXIFICATION STEPS

1. Stop using opiates (Heroin, Percs, Oxys, etc.)
2. Wait at least 24 hours. You should be experiencing withdrawal at this time. You can take the baclofen and the clonidine to get through the 24 hours. These pills can lessen the severity of withdrawal.
 - Baclofen for muscle discomfort and sleep.
 - Clonidine for sweating, anxiety, and sleep.
 - Diphenhydramine for sleep
3. After at least 24 hours, start the buprenorphine. It should make you feel better IF you waited the 24 hours since your last dose of opiates. Otherwise, you may go into withdrawal and there is nothing to be done except the use of the medicines prescribed, baclofen and clonidine, and

wait for the discomfort to subside. Do not take more buprenorphine or opiates until another 24 hours has elapsed.

4. Repeat the dose every 24 hours. Take the buprenorphine once a day (every 24 hours) for three days. The whole amount prescribed. Do not divide the dose.
5. After the THREE days of buprenorphine are completed, you can use the baclofen and clonidine again. They may also cause drowsiness and dry mouth.
6. RETURN TO THE OFFICE for any problems that you have after the buprenorphine is finished. There is no charge for this visit. You will receive additional medications depending on what symptoms or problems that you are having. We have medications for:
 - Diarrhea
 - Belly pain and cramps
 - Nausea
 - Anxiety
 - Difficulty sleeping
 - Restless legs
 - Craving
7. On the 7th day clean, since you last used any opiates, take the naltrexone capsule. It is to be taken at home at least four hours prior to coming into the office to begin naltrexone maintenance therapy, including the injection of a naltrexone pellet.
8. The capsule will change the color of your urine To ORANGE. A urine sample will be checked before a pellet will be injected.

WARNING

You MUST be clean before you take naltrexone or you will get VERY sick. The withdrawal is WORSE than any you have ever experienced. It is recommended that you be clean for 7-10 days to prevent this from happening.

An injection of naloxone, a short acting type of naltrexone, will be administered to patients prior to receiving a pellet. If you are clean 7-10 days or if you are taking naltrexone there will be no effect from this injection. If NOT, in about 10 minutes you will start getting sick. It will wear off in about an hour but we will not put in a pellet.

We require that you take a naltrexone capsule at home before coming in for a pellet.

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Methadone Detoxification

It is generally not recommended that stable methadone patients transfer to Suboxone or Subutex. However, patients may request to transfer from methadone to Suboxone or Subutex for many different reasons.

For example, individual responses to methadone are variable, including the occurrence of side effects and drug interactions. Some patients are reluctant to be on effective methadone doses and may prefer to be maintained on Suboxone in a private office setting. A limiting factor for many patients considering maintenance treatment is the problem of dependence of the maintenance opioid. The pharmacological properties of Suboxone or Subutex, including slow dissociation from mu-opioid receptors and apparent mild withdrawal syndrome, may be perceived as a benefit by the patient. It is recommended that the physician review the risks/benefits of transferring from methadone to Suboxone or Subutex with the patient well in advance of the transition and provide the patient with realistic expectations during the transition.

Normal Transfer (from methadone-equivalent dose \leq 30 mg):
At least 48 - 60 hours should elapse after the last long-acting opioid dose. The initial dose of Suboxone or Subutex should be administered when moderate signs of withdrawal are evident.

High-Dose Transfer (from methadone-equivalent doses ranging from 30 - 60 mg):

- No Suboxone or Subutex should be given after the last methadone or long-acting opioid dose until the patient experiences maximal withdrawal discomfort (at least 48 - 96 hours after the last dose). Earlier dosing with Suboxone or Subutex is highly likely to precipitate withdrawal.
- Be prepared to administer limited amounts of withdrawal medication (eg, clonidine, loperamide, sleep aid, NSAID, etc) for symptomatic relief.
- High-dose transfer patients need careful monitoring and dose titration according to the response of the patient. If withdrawal symptoms have not worsened or have improved within 2 - 4 hours after the first dose of Suboxone or Subutex, an additional 4-my dose of Suboxone or Subutex is recommended. Clinicians have reported prescribing a

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third dose (2 - 4 mg) to be taken later in the evening if needed for withdrawal symptoms.

Dose Reduction Schedule

Days	Dose Schedule
1 - 7 days	8 mg buprenorphine
8 - 14 days	4 mg buprenorphine
15 - 21 days	2 mg buprenorphine
22 - 30 days	1 mg buprenorphine
31 - 37 days	Non-narcotic medication
~ 38 - 44 days	Start Naltrexone

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Suboxone Detoxification

- Significant withdrawal symptoms are unusual during gradual Suboxone or Subutex dose taper.
- The rate of dose reduction should be determined in collaboration with the patient.
- Patient may have possible feelings of less energy, lower appetite, irritability, difficulty in sleeping, etc. However, these effects are transitory and should only last a few days.
- Realistic goals for reduction should be established.
- Generally, the more gradual the reduction, the better the outcome.
- Patients should expect to experience some withdrawal discomfort once they reach low doses or stop taking Suboxone or Subutex completely.
- Slow down or stop the dose reductions if:
 - The patient starts to reuse opioid
 - The patient's physical, psychological, or social well-being begins to deteriorate
- Examples of dose reduction rates and schedules are shown on the following chart.

Dose Reduction Schedule

Days	Dose Schedule
1 - 4 days	8 mg buprenorphine
5 - 8 days	4 mg buprenorphine
9 - 12 days	2 mg buprenorphine
13 - 16 days	1 mg buprenorphine
17 - 30 days	Non-narcotic medication
~ 23 - 30 days	Start Naltrexone

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Alcohol Detoxification

Highlights of 36th Annual ASAM

Symposium #11

Implementing Pharmacotherapy for Alcohol Use Disorders

Organizer: Mark L. Willenbring, MD (NIAAA)

Speakers: David R. Gastfriend, MD; Barbara Mason, PhD; Helen Pettinati, PhD; and Robert Swift, MD

This symposium focused on the application of available evidence concerning pharmacotherapy of alcohol use disorders in clinical settings.

The second speaker, Dr. Pettinati, spoke on the effective use of disulfiram (Antabuse). The drug, which has been used for the treatment of alcoholism since 1948, is currently being investigated as a treatment for cocaine dependence, because of anecdotal reports that those taking disulfiram who also used cocaine had less craving for cocaine and therefore lower levels of use. When this was studied, it was found that disulfiram works even in non-alcohol-using cocaine users. The severity of the alcohol-disulfiram reaction is related to the dose of disulfiram and the amount of alcohol ingested. This reaction also varies from person to person, depending on the allelic form of aldehyde dehydrogenase, the enzyme that is blocked by disulfiram. The pivotal study of disulfiram was in 605 alcohol-dependent VA patients in 1986.[2] This study showed that the results were mostly related to the level of compliance in taking the medication. In other words, nonadherence to taking the drug is the most common reason for nonresponse to pharmacotherapy. Therefore, increasing compliance by monitoring medication administration or through the threat of serious consequences (eg, loss of medical license, etc.) increased the benefit of pharmacotherapy. The combination of disulfiram and naltrexone may be useful in treating patients with co-occurring cocaine and alcohol addictions.

Source: Medscape Psychiatry & Mental Health. 2005;10(1) ©2005 Medscape

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About Us

We provide a medically supervised, abstinence based program that utilizes the principles of Twelve Step recovery. This program was founded by Lance Goberman, M.D., and relies on his patented Naltrexone Pellets to assist the patient in remaining clean from drugs.

Our patients may originate from rehab, jail (probation/parole), out-patient detoxes, or post cold turkey. The patients must be verified as clean by passing a naloxone challenge test before they can participate in the program. If the patient is not clean he must be detoxified.

Naltrexone is recognized as an alternative to incarceration. The NaltrexZone method has been used for many years to help opiate dependent patients. About 20,000 pellets have been inserted in some very happy recovering people. None of them are cured but many are in remission and they learn to call their doctor when the need arises. Just like other patients with chronic diseases.

[What IS a NaltrexZone?](#)

[US Patent No. 6,203,813](#) -
Pharmaceutical delivery device and method of preparation therefor

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Directions

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Massachusetts The NaltrexZone of Boston

Rahim Shafa, M.D.

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Milford, Massachusetts 01757
508-478-6868

[Click for Mapquest map](#)

67 Union Street
#107
Natick, Massachusetts 01760
508-903-1500 ~ 617-285-8599

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<http://naltrexzone.rs/>

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[Statement of Jeffrey N. Gibbs, Esq.](#)

[Dr. Goberman's New Drug Application](#)

Slideshow

The following is a slideshow from a presentation given by Dr. Lance L. Goberman. Some of the slides are graphic in nature. Individuals who might be disturbed by such images should not view the tutorial.

Treating opiate addiction

From Harvard Health Publications, Harvard Medical School:

[Part I: Detoxification and maintenance](#)

[Part II: Alternatives to maintenance](#)

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Publications

- [Rapid Opiate Detoxification and Naltrexone Induction under General Anesthesia and Assisted Ventilation: Experience with 510 Patients in Four Countries](#)
In Press acta Psychiatrica Belgica, 1996, Colin Brewer, MRC Psycho., Mary Laban, M.R.C.A., Charles Schmulian, F.F.A., Lance Gooberman, M.D., Yiannis Kasvikis, M.R.C. Psych., Nabil Abdel Maksoud, M.D.
- [Rapid Opiate Detoxification](#)
American Journal of Drug and Alcohol Abuse, In Press, 1996, Lance L. Gooberman, M.D., Thaddeus Bartter, M.D.
- [Pellets vs. Oral Therapy 30 day Relapse Rates](#)
Lance L. Gooberman MD, David W. Bradway MD, Thaddeus Bartter MD
- [Fentanyl Challenges](#)
Lance L. Gooberman, MD, Thaddeus Bartter, MD, FCCP
- [Blood Levels](#)

Recommended Links

You may find additional information at these sites:

- [Pellet Technologies LLC](#)
Home of the patented Naltrexone Pellet
- [Dr. Lance L. Gooberman](#)
Inventor of the Naltrexone pellet
- [Midwest Rapid Opiate Detoxification Specialists](#)
Rapid detox centers and drug detoxification programs located in Chicago.
- [Canada Detox Centre](#)
- [Eleventh Step Books](#)
Providing resources and merchandise related to recovery, self help and personal growth

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Addiction in the News

Study Finds Alcohol-Abuse Drug Helps Curb Problem Gambling

Fox News, June 2008 - Naltrexone, a drug used to treat alcohol and opioid dependence also appears to help those addicted to gambling, according to a study in the May issue of the Journal of Clinical Psychiatry.

For the full text of this story, [click here](#).

Drug-related hospital morbidity following heroin dependence treatment with methadone or naltrexone implantation

Archives of General Psychiatry, April 2008 - Following naltrexone implant treatment, opioid-related risk decreased for overdose and nonoverdose conditions at 3 years.

For the full text of this story, [click here](#).

An Anti-Addiction Pill?

The New York Times Magazine, June 25, 2006 - While many in the treatment field have long called addiction a "disease," they've used the word in vague and metaphorical ways, meaning everything from a disease of the mind to a disease of the spirit. Many assumed that an addict suffers from a brain-chemistry problem, but scientists had not been able to peer into our heads to begin to prove it.

For the full text of this story, [click here](#).

Some Afghan Farmers Trade Poppy for Wheat

SURKH ROD, Afghanistan (AP) - The top U.N. drug official is heading to Afghanistan to check out reports that farmers are heeding government calls for a "holy war" on the rampant drug trade by slashing opium cultivation....

For the full text of this story, [click here](#).

Heroin-Related Deaths Rise in Austin

AUSTIN, Texas (AP) - Tracey Crossett graduated high school early, had a new car, a new boyfriend and planned to study music

in college.

For the full text of this story, [click here](#).

Drug Smugglers Blamed in Afghan Attack

KABUL, Afghanistan (AP) - The Afghan government on Thursday blamed drug smugglers - not Taliban or al-Qaida fighters - for a bomb attack on interim leader Hamid Karzai's vice presidential running mate, saying the country's landmark elections are a threat to their business....

For the full text of this story, [click here](#).

Major hope for addicts: Leonard Morse Hospital is on cutting edge with pellet implants

HOLLISTON -- Withdrawing from heroin was never easy for Charlie, an addict for two years. "Whenever I tried to stop, I would feel like s--- for about two weeks," he said. "I'd go through the most insane depression and anxiety. I wanted to rip my insides out..."

For the full text of this story, [click here](#).

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What to Expect When You Come In

NaltrexZone™ treats patients for addiction. This is made clear in all marketing materials. Marketing consists primarily of word of mouth, the internet and occasionally specific ads. No other treatment is offered as the NaltrexZones™ are addiction treatment centers and referred to as such invariably. Therefore, patients presenting to the NaltrexZones™ for treatment come for treatment of their addiction. They are essentially self referred after self diagnosis.

The term addiction is used as it is the common vernacular. More specific terminology is avoided in order to enhance communications. Specifically, DSMIVR criteria, which are most useful when physicians communicate either for research purposes or with insurance companies, is not utilized since NaltrexZones™ are not engaged in research and insurance companies are not billed.

When patients present to a NaltrexZone™, they are presenting for what they understand is their addiction. Therefore, the chief complaint (CC) is addiction. Patients are self selected for this problem and it is noted on the chart.

A brief and directed history is obtained. This history is brief and directed on the first visit due to the fact that these patients of necessity present somewhere along the spectrum of withdrawal to intoxication. Their attention spans are limited.

Facts necessary for detoxification are ascertained. Specifically the duration of the present use, pertinent use of interactive drugs, type and amount being used and mode of administration.

Additionally, a brief history of exposure to the most important treatment modalities, continuing self-help or 12 step recovery groups, is obtained. This subject is touched on repeatedly during the first and subsequent visits despite the intoxication-withdrawal spectrum problem. This is due to the fact that it has been shown that such brief interventions are beneficial. This has been shown by Drs. Judith and Edward Bernstein, and published as Brief Encounters Can Provide Motivation To Stop Drug Abuse, published in Drug and Alcohol Dependence, January, 2005.

A directed physical is performed. The physical is directed toward those signs, the medically objective findings, indicative of where the individual is along the spectrum of withdrawal through

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intoxication.

It is ascertained whether the patient is awake, alert, and oriented in the three spheres of person, place and time. This is done with the understanding that the patient is in some way influenced by the uncontrollable propensity to use mood altering drugs continuously. The skin is observed for jaundice as this may indicate that detoxification alone at this time may not be appropriate. The skin is also routinely observed for diaphoresis, piloerection, and lesions due to excoriation from histamine release. Pupils are observed primarily as a gauge of whether the patient is in withdrawal, dilated, or intoxicated, constriction and ptosis. Regularity of the heart rhythm is ascertained due to the fact that some concomitant drug use may produce arrhythmias. Specifically, "speed balling", or concurrent use of cocaine and heroin. The lungs may be affected by the mode of administration and concomitant drug use also.

When patients have received naltrexone administration by naltrexone pellet implantation the site is examined for signs of infection or rejection.

The above information results in an assessment or diagnoses where a determination is arrived at regarding where the patient is along the spectrum of withdrawal through intoxication.

The treatment plan will initially consist of medications to alleviate withdrawal symptoms as much as possible. There is NO comfortable detoxification. All detoxifications come with some degree of discomfort.

The basis of detoxification is withdrawal of the opiate agonist and stabilization for a short period of time on a partial agonist. This will lead to decrease in severity of withdrawal symptoms. The partial agonist drug of choice for this purpose is Buprenorphine.

The Buprenorphine is permitted under the Drug Abuse and Treatment Act 2000 (DATA 2000). Buprenorphine may be provided by physicians who have completed the required course, passed an examination, and been granted a waiver by the Drug Enforcement Administration (DEA) as indicated on their DEA licenses.

Following detoxification is the maintenance of an abstinence state and continuation of the recovery process.

The recovery process may involve continuation of anti-craving antagonis therapy as well as cognitive behavior therapy (CBT). NaltrexZones™ utilize naltrexone compounded into a pellet form and Twelve Step programs for these purposes.

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NALTREXONE PELLETT INJECTION PROGRAM

First implant on seventh day clean after a naltrexone tablet and/or a negative naloxone challenge.

Second pellet before 60 days (no naloxone challenge necessary)

Criteria to stop pellet injections:

1. 90 days clean
2. Regular attendance at Twelve Step meetings
3. A sponsor
4. A job or school (basically a life)
5. Trust reestablished in family and friends
6. You trust yourself (you can always go back on a pellet at any time)

Pellet therapy is replaced with oral therapy for a short time. A tablet is carried at all times and taken for urges or any positive thoughts regarding mood-altering substances. If tablets are needed daily or major life situations, i.e. weddings or funerals, occur pellet therapy is reconsidered.

Meeting attendance continues with office visits periodically and whenever necessary.

[Injection Procedure](#)

[Discharge Instructions](#)

[Consent Form](#)

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[Naltrexone Pellet and the FDA](#)

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NALTREXONE PELLETT MAINTENANCE THERAPY

A pure narcotic antagonist (naltrexone) is inserted under the skin of the patient. Detoxification and naltrexone maintenance therapy is not a cure for addiction. Naltrexone maintenance therapy is a crutch to be used in early recovery. The maintenance of abstinence is best achieved through participation in a 12-step recovery program. Studies have shown that the best indicator of long-term recovery is continued participation in a 12-step recovery program. The period of abstinence during which naltrexone is used leads to a loss of tolerance to the effects of opiates. A patient utilizing naltrexone needs to be aware that when the naltrexone pellet wears off and there is a return to using the same dose of opiates that he had previously used, the patient may kill himself.

After an area is anesthetized with 2% Lidocaine with epinephrine, it is prepared and draped in the usual manner. An incision is made with a #15 blade, approximately one-half inch in length. A pocket is created in the area adjacent to the incision by blunt dissection with blunt curved Metzenbaum scissors. A 1-gram naltrexone pellet is inserted into the pocket and the wound is closed with 2 simple interrupted sutures of #3-0 Vicryl and the wound is dressed.

Should the patient be injured after the procedure and require analgesia (pain medications), he must inform the doctor that he is on naltrexone maintenance therapy so that the proper medications may be prescribed. Because the patient may be involved in an accident or some other occurrence that renders him unable to inform the doctor that he is on the medication, it is recommended that he wear a Medic-Alert tag which advises the doctor that the patient is receiving naltrexone maintenance therapy. Patients are provided with such a tag (either a bracelet or a necklace) which have on it the name of the medication and the prescribing physicians name and phone number.

The patient must be aware that following implantation of the pellet, the following symptoms might signify wound infection: Tenderness, redness, swelling and warmth at the site of the insertion of the naltrexone. If the patient notices the development of these changes, contact the physician's office so that a prescription for an antibiotic may be called in to the pharmacist.

[How does Naltrexone Work?](#)

[Who can take Naltrexone?](#)

[What about Revia's Black Box Warning regarding liver toxicity?](#)

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What IS a NaltrexZone?

A NaltrexZone is an addiction treatment center. Patients dependent on opiates such as heroin, Oxycontin, methadone, Percocet, Vicodin, and other prescription pain killers receive treatment at NaltrexZones that are opening across the country. Naltrexone, a non-narcotic opiate blocker, is the mainstay of the treatment.

After the patient is detoxified the naltrexone maintenance therapy program begins. The program involves injection of our patented naltrexone pellet just under the skin of the upper arm. Once in place, the pellet will last 2-4 months.

Repeat pellets ensure abstinence until the patient builds a foundation in Twelve Step recovery or drops out of treatment and relapses. The procedure is repeated when the patient returns. The relapse periods get shorter and shorter over time as the patient builds his foundation in Twelve Step recovery and learns that he has a disease that can be addressed medically. Patients start to anticipate relapse and return at a point before detoxification is necessary. Eventually, during the increasing periods of abstinence, they realize they prefer to be clean and what it takes for them to maintain abstinence one day at a time.

Patients are directed to Twelve Step recovery but it sometimes takes a while for them to get there. Naltrexone alone is never enough and they eventually learn this.

The key to the success of this program seems to be in keeping them clean in their own environment, and in a non judgmental manner, helping them understand their disease as the disease it is. They are told that an asthmatic doesn't have to wait until he's blue to go to his doctor, a heart attack victim doesn't wait long before calling 911. Drug addicts are no different from these patients and they need to access medical help as soon as they can. The sooner they get to a NaltrexZone, the less they'll lose and the easier it will be to retain what they've accomplished during their abstinence. They learn that effective medical assistance is readily available at NaltrexZones.

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Directions

FROM NEW YORK AND NORTH

1. Follow New Jersey Turnpike (Interstate 95) South to Exit 4 from New York.
2. From Exit 4 of NJ Turnpike go North on Route 73 to Route 38.
3. Take Route 38 West two miles. (You will pass the Cherry Hill Mall on the right hand side of Route 38.)
4. After you pass the Cherry Hill Mall, turn right at the first traffic light onto Chapel Avenue (North).
5. Proceed approximately 1.5 miles on Chapel Avenue until you come to a small circle. Do not turn around on the circle, but bear to the right through the circle. This becomes Centre Street.
6. Proceed on Centre Street through two traffic lights.
7. We are located at the end of the block (after the second traffic light) at ONE SOUTH CENTRE STREET on the right. There is a pharmacy on the opposite side of the street - Rite Aid.
8. Turn right into the parking lot. We are on the third floor.

FROM BALTIMORE AND SOUTH

1. Follow Interstate 95 North to the Betsy Ross Bridge.
2. Cross over the bridge into New Jersey.
3. Follow the overhead signs to "Cherry Hill/Haddonfield" Rt. 644.
4. Take that exit. You will be on Haddonfield Road.
5. Continue to the 2nd traffic light - Park Avenue.
6. Turn left on Park Avenue.
7. Continue to the 3rd traffic light - Centre Street.
8. Turn Right on Centre Street.
9. Go down 1/2 block.
10. We are located at the end of the block (after the second traffic light) at ONE SOUTH CENTRE STREET on the right. There is a pharmacy on the opposite side of the street - Rite Aid.
11. Turn right into the parking lot. We are on the third floor.

FROM PHILADELPHIA AND WEST

1. From Western Pennsylvania follow Pennsylvania Turnpike to Valley Forge Exit via Interstate 76 to

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- Interstate 676 to Philadelphia.
2. Follow Interstate 676 (Schuylkill Expressway) to exit for Benjamin Franklin Bridge..
 3. After crossing the Benjamin Franklin Bridge, follow Route 30 East to Route 130 North.
 4. Continue on Route 130 North for one mile. Watch for the signs for Maple Avenue. The Sign will say Merchantville via Federal Street. Then it will say Maple Avenue.
 5. Turn right onto Maple Avenue. Go three traffic lights.
 6. Turn Left onto Centre Street. Proceed one and one-half blocks. Our office is on the right side of the street next to the Midlantic Bank at ONE SOUTH CENTRE STREET on the right..
 7. Turn right into the parking lot. We are on the third floor.

1.800.978.0808 :: 1.856.663.4447 :: 1.856.488.6380 (fax)

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CURRICULUM VITAE

NAME: Rahim Shafa
DATE OF BIRTH: May 9, 1957
PLACE OF BIRTH: Iran
CURRENT POSITION: Scientific Director, Metro West & Greater Boston CRC
Metro West & Greater Boston CNS Research Center
 215 West Street, P.O. Box, 298 Milford, MA 01757
PRIVATE PRACTICE: Director, Novel Clinical Psychopharmacology Care
 67 Union Street, MOB-S107 Natick, MA 01760
EDUCATION:
 1982 M.D. National University of Iran, Tehran, Iran
 1997 B.C. American Board of Adult Psychiatry & Neurology
 2003 W.C. American Academy of Addiction Psychiatry
 Buprenorphine outpatient maintenance program
POSTDOCTORAL TRAINING:
Internship and Residencies:
 1990-1991 Psychiatric Intern (Wilmington Hospital, Delaware State Hospital), Jefferson University, Wilmington, DE.
 1991 Psychodynamic Training; Child & Adolescent Development & Disorders; Conflict Between Men and Women; Eating Disorders, Philadelphia Psychiatric Institute (evening courses); Philadelphia, PA.
 1991-1992 PGYII, Inpatient Psychiatry, (Solomon Carter Fuller Mental Health Center, University Hospital), Boston University, Boston, MA.
 1992-1993 PGYIII, Outpatient Psychiatry (Psychosomatic Clinic, Boston City Hospital, VA Bedford) Boston University, Boston, MA.
 1993-1994 Chief Resident, Consultation Liaison, Boston City Hospital Medical Psychiatry, Boston University Medical Center, Boston, MA.
Fellowships:
 1994-1998 Research Fellow, Commonwealth Research Center, Massachusetts Mental Health Center, Harvard Medical School, Boston, MA.
 1995-1998 VA Special Fellow in Clinical Pharmacology, Brockton VA Medical Center, Harvard South Shore Psychiatry Residency Program, Harvard Medical School, Brockton, MA.
 March 2000 BCT Certificate, Columbia School of Physicians and Surgeons, NY.
 January 2003 Buprenorphine Management of Opioid Dependence, American Academy of Addiction Psychiatry.
LICENSURE AND CERTIFICATION:
 1982 Iran Board of Registration in Medicine
 1985 Licensed General Practitioner, British General Council
 1992 Massachusetts Board of Registration in Medicine

- 1993 California Board of Medical Quality Assurance
- 1997 Board Certified in adult Psychiatry & Neurology
- 1997 Instructor, Intensive Diagnostic Interview, Oral Review Board Exam Preparatory Course, Massachusetts Mental Health, Harvard Medical School
- 1998 Certified in Clinical Pharmacology Research Harvard Medical School
- 2000 Certified in ECT, Columbia School of Physicians and Surgeons, New York, NY
- 2003 Waiver Certificate, Buprenorphine Outpatient Maintenance Program, American Academy of Addiction Psychiatry

ACADEMIC APPOINTMENTS:

- 1985-1987 Director of Continuing Medical Education, National Iran Oil Co., (NIOC), Tehran, Iran
- 1991-1993 Psychiatry Resident, Boston University School of medicine, Boston, MA.
- 1993-1994 Chief Resident in Psychiatry, Boston University Medical Center, Medical Psychiatry Unit at The University Hospital & Chief Resident in Consultation Liaison Services at Boston City Hospital, Boston, MA.
- 1994-1998 Research Fellow Psychopharmacology, Harvard Medical School, Boston, MA.
- 1996-1998 Senior Fellow, Clinical Research in Psychiatry, Harvard Medical School, Commonwealth Research Center, Clinical Research and Evaluation Unit (CREU), Massachusetts Mental Health Center, Boston, MA.
- 1998-1999 Clinical Instructor in psychiatry, Staff Psychiatrist Geri/Med-Psych. Unit, Cambridge Health Alliance, Somerville Hospital, Harvard Medical School, Somerville, MA.
- 1998-2001 Consultant in Clinical Research; Implementation of Clinical Trials, Subject Recruitment, Subject Retainment & Follow-up, Harvard Medical School, Commonwealth Research Center, Massachusetts Mental Health Center, Boston, MA.
- 1998-2001 Clinical Investigator & Clinical Instructor in Psychiatry, Harvard Medical School, Commonwealth Research Center, Massachusetts Mental Health Center, Boston, MA.
- 2001-Present Scientific Director, Metro West CNS Research Center, 57 Union Street, MOB-S 107, Natick, MA.

HOSPITAL APPOINTMENTS:

- 1982-1984 Medical Director, Lieutenant Commander, Dept. of Health & Medical Education, Jen d'Armory of Iran, Chabahar, Iran.
- 1984-1986 Medical Director, Industrial Medicine & Director, Emergency Medicine, Industrial Island Hospital, National Iran Offshore Oil Company, Iran.
- 1986-1987 Vice President & Deputy Medical Director, Iraj (the Head Quarter) General Hospital, National Iran Oil Co., Tehran, Iran.
- 1994-1998 Research Fellow, Commonwealth Research Center, Massachusetts Mental Health Center, Boston, MA.
- 1998-1999 Teaching Faculty & Staff Psychiatrist, Cambridge Health Alliance, Somerville Hospital.
- 1998-2001 Consultant in Clinical Research, Commonwealth Research Center, Massachusetts Mental Health Center, Boston, MA.
- 1999-2001 Medical Director, (Community Psychiatry) at Wayside Youth & Family Support Network, 118 Lincoln Street, Framingham, MA.

- 1997-Present Staff Psychiatrist, Metro West Medical Center, Leonard Morse Hospital, Natick MA.
- 2000-Present Principal Investigator in Psychiatric Research & Clinical Psychopharmacology, Dept. of Psychiatry, Tenet Metro West Medical Center, Leonard Morse Hospital, Natick MA.

OTHER PROFESSIONAL POSITIONS AND MAJOR VISITING APPOINTMENTS

- 1984-1986 Associate Director, Dept., of Industrial Medicine & Public Health, Central & five Satellite Offshore Clinics, National Iran Offshore Oil Company, Iran.
- 1986-1987 Associate Director, Dept. of Industrial & Public Health, Iran General Hospital, National Iran Oil Company, Iran.
- 1987-1990 Instructor in Basic Medical Sciences, Stanley H. Kaplan Educational Center, San Diego, CA
- 1988-1990 Medical Examiner, Equifax Services, Inc., San Diego, CA
- 1997-Present Consultant Clinical Psychopharmacology, General Psychiatry, questions in regard to use of Alternative Medicine in Psychiatry, Dept. of Psychiatry Tenet Metro West Medical Center, Leonard Morse Hospital, Natick, MA.
- 2003-Present Psychiatric Research Staff, Walden Behavioral Care, the second Research Site for Metro West & Greater Boston CNS Research Center, Waltham, MA.

AWARDS AND HONORS:

- 1982 Top 1% class of 1982, National University of Iran.
- 1984 Recognition Award, for implementation of Cutaneous Leishmaniosis Vaccine, Iran.
- 1994 Clinical Research Fellowship in Psychopharmacology, Commonwealth Research Center, Massachusetts Mental Health Center, Harvard Medical School, Boston, MA.
- (1995) VA Grant Award Repeated Three Successive Years; 1995-
(1996) 1996, 1996-1997 & 1997-1998, Grant Awarded in Research
(1997) Fellowship in Clinical Pharmacology, Brockton VA Medical Center, Harvard Medical School, Harvard South Shore Psychiatry Residency Training Program, Brockton, MA.
- 2000 "Who is Who", Strathmore's Honors for Leadership and Achievement in Medicine. (2000-2001)
- 2002 "America's Top Psychiatrist", in (Psychopharmacology of Anxiety and Mood Disorder) recognized by "Consumers Research Council of America", an independent report in Recognition of Individual Professionals Accomplishments in field of Psychiatry. (2002-2003)

MEMBERSHIPS IN PROFESSIONAL SOCIETIES:

- American Medical Association
- American Psychiatric Association
- American Society of Clinical Psychopharmacology
- American Academy of Addiction Psychiatry
- American Association for The Advancement of Science
- Massachusetts Medical Society
- Massachusetts Psychiatric Society
- NAMI (National Association for Mentally Ill)
- New York Academy of Science
- IAMA (Iranian American Medical Associations)
- Iran Medical Council

British General Council

SELF REPORT OF TEACHING:

- 1993 Chief Resident, supervised psychiatry residents, Consultation & Liaison Psychiatry, Boston City Hospital, Boston, MA.
- 1994 Chief Resident, provided tutoring and supervised medical students and residents in psychiatry, Medical Psychiatry Unit, University Hospital, Boston University, Boston, MA.
- 1997-2001 Instructor, Intensive Diagnostic Interview, a preparatory Course for the Oral Review Board Exam in Psychiatry, Mass. Mental Health Center, Harvard Medical School, Boston, MA.

ADVISORY RESPONSIBILITIES:

- Member of advisory panel and speakers bureau, Astra Zenaca.
- Member of advisory panel and speakers bureau, Janssen.
- Member of advisory panel and speakers bureau, Bristol-Myers-Squibb.
- Member of advisory panel and speakers bureau, GlaxoSmithKline.
- Member of advisory panel and speakers bureau, Eli Lilly and Company.

ACCOUNT OF LEADERSHIP:

- 1980-1983 Doctors for Free Medical Care (Doctors Without Borders), prepared groups of medical professionals (mainly from the medical school faculty), arranged trips, and provided free medical service to the most deprived communities, Iran.
- 1981-1982 Medical Student Volunteer: Community Services, Instructor for CPR courses for the public, Taleghani Hospital, Eveen, Iran.
- 1982-1984 Devised, Supervised & Implemented Training Curriculum for paramedics in military, (Accredited by Iran's Ministry of Health to issue certificate), Jen d'Armory, Army of Iran, Chabahar, Iran.
- 1982-1984 Designed & Taught Algorithms for diagnosis & treatment of endemic diseases and emergency care for military paramedics, Chabahar, Iran.
- 1982-1984 Designed CME workshops and training courses for Medical Personnel in the Military, (especially the paramedics) Army of Iran, Chabahar, Iran.
- 1984-1987 Devised, Supervised & Implemented In-Service & CME Training courses for paramedics, physician assistants, nurses and nurse practitioners, National Iran Oil Company, Tehran, Iran.
- 1987 Director of CME courses for physicians, NIOC, Tehran, Iran (The department consisted of 17 general hospitals and 25 satellite clinics).
- 1988-1990 Designed Basic Science Lecture Series, (preparatory courses for FMGEMS, FLEX & NMB Examinations) and taught peer physician, Stanley H. Kaplan, San Diego, CA.
- 1993-1994 Chief Resident, Boston City Hospital, University Hospital, Boston University, Boston, MA.
- 1994-2000 Clinical Investigator / Lead Recruiter investigation of novel Antipsychotics, clinical psychopharmacology, Mass. Mental Health Center, Harvard Medical School, Boston, MA.
- 2001-present Principal Investigator and President of Metro West and Greater Boston Research Center, 215, West Street, Milford, MA.

CLINICAL RESEARCH EXPERIENCE:

- 1994-present CLINICAL INVESTIGATOR:

- Phase II Study, Safety and Efficacy of OPC 14597, an Inpatient antipsychotic trial.
- Phase II Study, Safety and Efficacy of Ziprasidone, an Inpatient antipsychotic trial.
- Phase III Study, dose range and Safety and Efficacy of OPC-14597, inpatient trial.
- Phase III Study, Ziprasidone, Outpatient Antipsychotic Trial.
- Phase I Study, Pharmacokinetics Study of IM Ziprasidone, Inpatient Trial.
- Phase III Study, Clinical Outcome & Service Utilization, an Outpatient trial of Quetiapine.
- Phase II Study and Efficacy of MDL100,907 an inpatient antipsychotic trial.
- Phase III Study, comparing Efficacy of Aripiprazole vs. Risperidone, inpatient trial.
- Phase III Study, Dose Range and Efficacy Study of MDL 100,907 inpatient study.
- Clozapine Response & Biogenic Amines in the Treatment of Refractory Schizophrenia, inpatient study.
- Clozapine Response & Biogenic Amines in the Treatment of Refractory Schizophrenia, inpatient study.
- Clozapine Response in treatment of First Episode Schizophrenia, inpatient & outpatient study.
- Clinical Efficacy of Olanzapine in treatment of First Episode Schizophrenia, an inpatient stabilization and outpatient follow up study.
- Quality of Life and Clinical Utilization Outcome of Treatment with Clozapine comparing to Olanzapine an outpatient trial.
- Study of Prolactin changes in response to treatment with Clozapine in First Episode Schizophrenia.
- "INTERSEPT" International study of Suicide & Y Schizophrenia in response to Clozapine, a double blind randomized, open label comparison outpatient trial of Clozapine vs. Olanzapine.
- Norepinephrine changes in Response to Clozapine treatment in First Episode Schizophrenia.
- Cognitive changes in response to treatment with Clozapine in refractory schizophrenia.
- An inpatient with outpatient follow up, single blind, active control study of efficacy of xxxxxx (comparing two atypical antipsychotics) in treatment and prevention of suicide in schizophrenia, 1997-2002.
- Several numbers of other (Phase II and/or/Phase III) protocols; inpatient/outpatient double blind, placebo controlled, study of safety, tolerability and efficacy of xxxxxx or xxxxxx (variety of novel antipsychotics) in treatment of chronic schizophrenia, 1994-1999.

1999-present PRINCIPAL INVESTIGATOR

- An inpatient double blind placebo control fix dose study of safety and efficacy of xxxxxx (a novel antipsychotic) in treatment of acute Bipolar Mania, 1999-2001.
- An outpatient double blind placebo control dose ranging study of efficacy of xxxxx (a novel antipsychotic) in stabilization, maintenance and relapse prevention of Bipolar Mania, 1999-2002.
- An outpatient double blind placebo control dose ranging study of safety, tolerability and efficacy of xxxxx (an antidepressant) in treatment of adolescents with major depression, 1999-2001.
- An outpatient blindly randomized open label Phase IV study of long-term safety and morbidity of xxxxx (a novel antipsychotic vs two other novel antipsychotics) in treatment of schizophrenia, 2001-2002
- An inpatient double blind, placebo control study of safety, tolerability and efficacy of xxxxx (an antiepileptic) in treatment of acute Bipolar Mania, 1999-2001).
- An outpatient double blind study of mono-therapy vs. two arms of combination therapy xxxxxx & xxxxxx (an antidepressant combined with

- an antipsychotic), in treatment of Bipolar Depression, 1999-2001).
- A Phase III, randomized, placebo-controlled, double-dummy study evaluating the safety and efficacy of oral xxxxxx (novel antipsychotic) vs. xxxxx (a conventional antipsychotic) and placebo in inpatients with an acute manic episode, 2001-2003.
- Comparison fasting triglyceride levels in cohort with schizophrenia and related disorders treated chronically with xxxxx,xxxxxx (novel antipsychotics and typical antipsychotics) 2001.
- The assessment of xxxxxx (a stimulant) for treatment of xxxxxx (novel antipsychotic) associated weight gain inpatients with schizophrenia, related disorders and Bipolar Disorder, 2001-2003.
- The xxxxx (a novel antipsychotic) observational study of cardiac outcome, simple large trial, an open label blindly randomized multinational study, 2002-Present.
- A case control investigation exploring the relationship between gene variants (xxx markers) and agranulocytosis or granulocytopenia in adult patients treated with xxxxxx (an atypical antipsychotic), 2002-Present.
- A Phase I Study of "Comparison of Steady-State Pharmacokinetics of xxxxx (Novel Antipsychotic) after Extended-Release xxx xxxxx (Novel Antipsychotic) xx mg and Immediate-Release Oral xxxxx (an Existing Novel Antipsychotic xx mg. b.i.d. in Subjects with Schizophrenia or Schizoaffective Disorder", 2003-2004.

MAJOR RESEARCH INTERESTS

Endo-Neuropsychopharmacology & Immunology

Pharmacogenomics & Chronic Mental Illness

Biology of Psychosis & Disturbance of Cognition

Biology of Reward System & Dual Diagnosis

Treatment Outcome Studies

PUBLICATIONS:

Shafa, R. Management of Burn Victims. NIOC Medical Letter 85:40-44, 984.

Shafa, R. Safety Points in Air Transportation of Wounded Victims. NIOC Medical Letter 101:11-15, 1986.

Shafa, R. Means of Stress Reduction. NIOC Medical Letter 120:12-18, 1587.

Shafa, R. Role of Stress in Provoking Complications in Wound Healing. NIOC Medical Letter 120:34-36, 1987.

Patel, JK., Shafa, R., Danzler, A., Salzman, C. Drug Metabolism Cytochrome P-450 Enzymes, in preparation.

Patel, JK., Shafa, R., Canuso, C., Kalinowski, AG., Schildkrout, JJ., Green, AI. Effects of Risperidone and Clozapine on Hyperprolactinemia and Prolactinoma in Chronic Psychosis, in preparation.

Shafa, R., Patel, JK., Green, AI. Re-challenge with Clozapine After Prior Long-term Use: Cardiovascular Symptoms, in preparation.

Patel, JK., Shafa, R., Khan, A. Cytochrome P450, Ethnicity and Drug Metabolism in preparation.

PRESENTATIONS:

Patel, JK., Shafa, R., Khan, A. Cytochrome P-40 Ethnicity and Drug Metabolism Mass DMH Symposium, Multicultural Advisory Committee for Professionals of Color, October, 1995.

Shafa, R., Patel, JK., Kalinowski, A., Schildkrout, JJ., Green, AI. "Pituitary Microadenoma, Risperidone and Clozapine". Poster presented at American Psychiatric Association Annual Meeting, May, 1996.

Dooley, P., Patel, JK., Kalinowski, AG., Shafa, R., Canuso, C., Green, AI. Recruitment for Psychopharmacological Studies in Schizophrenia: Gender Differences. Poster presented at the American Psychiatric Association, Annual Meeting, May 1996.

Stone, WS., Seidman, LJ., Kalinowski, AG., Shagrín, B., Patel, JK., Shafa, R.,

Canuso, C., Schildkraut, JJ., Green, AI. "Effect of Clozapine on Cognitive Functions in Treatment- Refractory Schizophrenia". Poster submitted to V. International Congress on Schizophrenia Research, 1997.

Shafa, R., Patel, JK., Kalinowski, AG., Green, AI. "Re-challenge with Clozapine: Cardiovascular Symptoms". Poster submitted for American Psychiatric Association, Annual Meeting, May 1997.

Shafa, R., Powsner, R., Fischman, AJ., Verna, S. "Brain Imaging and Positive Symptoms During a First Episode of Schizophrenia". Poster presented in Harvard Research Day, March 1997.

OTHER WRITTEN MATERIAL:

Shafa, R. Platonic Love: A Discussion of the Implications of Platonic Love on One's Mental Health. University Press, Tehran, Iran, 1977 (National University of Iran Medical Library).

Shafa, R. Dissertation: Hysteria (Dissociative and Conversion Disorders) an Overview of Etiology, Clinical Manifestations and Treatment, 1982. (National University of Iran Medical Library).

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Streaming Video Help Format and Requirements

The NaltrexZone uses Windows Media Format (wmv) to encode and deliver streaming video on the Internet. To view and listen to this video you need a sound card, Windows Media Player, and one of the following Internet connections: dialup modem (minimum 28K), DSL, cable modem, or faster (T1, T3, etc.) You can download Windows Media Player free from Microsoft, for both Windows and Mac operating systems.



Broadband vs. Dialup

Broadband versions are for visitors with DSL, Cable Modem, T1 or T3 Connections; dialup versions are optimized for access via dialup modems.

For a satisfactory viewing experience, a broadband connection is recommended. You may find that for training purposes, the dialup connection is not adequate.

Heavy Internet traffic may cause interruptions of video display due to periods of re-buffering. Potential problems include:

- Traffic jams. Streaming requires an Internet connection that's free of bottlenecks or "traffic jams." But the Internet isn't a direct pipeline from the source to you. Streamed content passes through many other computers on its way to your computer via your ISP. If any one of them is carrying too much other traffic, the streamed content may be interrupted and pause. Streamed content is "buffered" to help avoid this, but sometimes it's unavoidable. Usually the delay only lasts a few seconds, and the audio picks up where it stopped. Video is more sensitive to such interruptions.
- A slow computer. Even with a fast computer, if you have too many applications open, it could slow down your media streaming. If you notice things are sluggish, close all unnecessary applications and windows running on your computer. Just keep your Web browser and your media player open. (If you're just listening or watching, you can even close your browser.) In any case, speedy computers are better.
- Noisy phone lines. If you have a phone line that isn't

free of noise (humming, crackling), that's not good for streaming (or Web browsing). Disconnect any phones that cause a buzz or hum. Have your phone company check your line to get rid of humming or other line noise. Of course, a cable modem or DSL connection is best for streaming media.

Additional Resources for Troubleshooting

If you need more information or have trouble with downloading, installation or operation of the Windows Media Player there is a [troubleshooting guide](#) available at Microsoft Product Support Services.

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Regarding Compounding

Statement

Of

Jeffrey N. Gibbs, Esq.
Hyman, Phelps & McNamara, P.C.
Washington, D.C.
Regulatory Counsel to Lance Gooberman, M.D.

Before The

New Jersey State Board of Medical Examiners
Special Committee Investigatory Hearing

January 17, 2000

This statement is provided on behalf of Dr. Lance Gooberman, M.D. It describes the legal and regulatory status of the practice of pharmacy compounding. It is offered to demonstrate that the practice of pharmacy compounding is legal under both federal law and New Jersey state law, that the regulatory requirements for ensuring the safety and effectiveness of compounded drugs differ significantly from the requirements for manufactured drug products, and that Dr. Gooberman's practice of compounding naltrexone pellets for subcutaneous implantation in patients undergoing opiate detoxification is consistent with those requirements.

Introduction

Compounding is an integral part of the practice of pharmacy. It is legal in all fifty states. Tens of thousands of compounded dosage forms are dispensed each day in the United States.¹

In New Jersey, compounding is defined as "the act of preparing pharmaceutical components into medications, pursuant to an authorized prescriber's medication order, including, but not limited to prescription compounding, and intravenous admixture preparation."² Like other states, New Jersey state law imposes specific requirements on the practice of compounding. For example, specific New Jersey Statutes require compounded prescriptions to be filled in the amount and with the drugs as prescribed by the practitioners.³ limit who may compound drugs and under what conditions,⁴ and establish training,⁵ documentation,⁶ and handling and delivery requirements for

compounded prescriptions.⁷

However, nothing in New Jersey law says that a pharmacist must have a specified amount of data before compounding a drug, or that a physician must have a specified amount of data before prescribing a Compound drug. And, in fact, requiring a specified amount of data in advance is entirely incompatible with compounding. Physicians often prescribe a compounded drug to meet the unique needs of a single patient. Obviously, there can be no prior clinical experience in that situation.

The practice of pharmacy compounding is distinctly different from the process of drug manufacturing. The U.S. Pharmacopoeia (USP), an authoritative reference for establishing drug standards, describes the characteristics that differentiate compounding from manufacturing. They include: "the existence of specific practitioner-pharmacist-patient relationships; the quantity of medication prepared in anticipation of receiving a prescription or a prescription order; and the conditions of sale, which are limited to specific prescription orders."⁸

The USP has established a monograph that describes the standards for pharmacy compounding. USP took this action in express recognition of the importance of compounding. Significantly, although USP sets our detailed standards for compounding, it does not require that there be test done before a drug is compounded.

Similarly; the National Association of Boards of Pharmacy (NABP), to which most state boards of pharmacies belong, has created detailed standards for drug compounding, NABP's standards have been widely adopted by the states. However, the NABP's standards do not require that a pharmacist or physician possess any clinical data before compounding.

Compounding is most frequently necessary when the patient requires a drug that is not available commercially. Because approval of a new drug application is a time consuming and expensive process, manufacturers generally only develop drugs in the strengths and dosage forms that are most likely to ensure a return on their investment. If a particular patient needs a drug in a different strength or dosage form, compounding is the means by which the physician can provide the drug to that patient. Compounding is also useful for medications that are not stable and which must be prepared in small quantities, or when the patient is allergic to something (e.g. a dye) in the commercially available form of the drug.

In 1938, Congress passed the first statute regulating the distribution of drugs. As subsequently amended, federal law requires that before the drug may be marketed, the drug company must demonstrate that the drug is safe and effective for its intended use. As a result, drug companies must undertake one or more clinical studies of sufficient size to demonstrate the safety

and effectiveness of the product. By contrast, a compounded drug is not intended for general use. Thus, the regulatory scheme for ensuring the safety and effectiveness of compounded drugs is necessarily different than that for manufactured drug products.

In 1997, Congress established the regulatory scheme that now governs the practice of pharmacy compounding. The strategies selected by Congress to ensure the safety and effectiveness of compounded drugs clearly reflect the characteristic differences between compounded and manufactured drug products. The federal regulatory scheme focuses on controlling the process of compounding. It does not require a statistically significant assessment of the safety and effectiveness of the final drug product, as that assessment would be irrelevant to the needs of the patient for whom the compounded prescription was prescribed.

Pharmacy Compounding: The Federal Regulatory Requirements

Prior to 1997, the Food and Drug Administration (FDA) had taken the position that pharmacies that compounded were subject to the new drug approval (NDA) and good manufacturing practice (GMP) requirements of the Federal Food, Drug, and Cosmetic Act (FDC Act). According to the FDA, every time a pharmacy compounded a drug, it needed to comply with the GMP and NDA provisions of the FDC Act. While FDA said that in the exercise of its enforcement discretion, it would normally not require pharmacies to comply with the GMP and NDA requirements, the agency also said that it had the power to compel compliance. Under those standards, compounded drugs were - in theory - subject to the same standards for safety and efficacy as drugs manufactured for use in the general population. Congress disagreed with that approach.

In 1997, Congress amended the FDC Act by adding Section 503A which governs the practice of pharmacy compounding. Section 503A exempts compounded drugs from the new drug approval and good manufacturing practice requirements of the FDC Act, provided that the drugs are compounded in accordance with specified criteria.

These criteria include limiting compounding to licensed pharmacists and physicians, and restricting the type and quality of the materials that may be used. It is through adherence to these criteria that the safety and efficacy of compounded drug products is achieved. Therefore, a pharmacist who compounds a drug in accordance with these criteria is exempt from the NDA, GMP and labeling provisions that govern the development of drug products manufactured for use in a broader population of patients.¹⁰ Thus, there are no requirements for evaluating the safety or efficacy of the final compounded drug in animal or human trials. The statute does not require test data even if a compounded drug is widely prescribed and dispensed to thousands of patients.

In enacting the pharmacy legislation, Congress was well aware of the fact that new drugs generally require controlled clinical trials. Nevertheless, Congress exempted compounded drugs from the need to meet this standard. Congress recognized that compounding, by its very nature, should not have to meet the safety and efficacy standards that apply to manufactured drugs.

Compounding of Depo-Naltrexone Pellets

Dr. Gooberman's practice of compounding depo-naltrexone in pellet form for subcutaneous implantation in patients undergoing opiate detoxification is consistent with the criteria established by Congress for pharmacy compounding in Section 503A. Section 503A provides that compounding may only be performed by a licensed pharmacist or licensed physician subject to receipt of a valid prescription for an identified Patient. Dr. Gooberman complies with this requirement because he, as a licensed physician, prescribes compounded depo-naltrexone in pellet form for subcutaneous implantation in individually identified patients.

Section 503A also places limits on the type of drugs that may be used in compounding. According to Section 503A(b), a licensed pharmacist may compound a drug product using bulk drug substances that comply with the applicable USP or National Formulary (NF) monograph, when a monograph exists, as well as the USP chapter on pharmacy compounding. Naltrexone is covered by a USP monograph.

Any drug withdrawn from the market because it was found to be unsafe or not effective, or any drug which presents "demonstrable difficulties" for compounding that reasonably demonstrate an adverse effect on the safety or effectiveness of that drug product, may not be used in compounding.¹¹ Naltrexone is an FDA approved drug that has not been withdrawn from the market for reasons concerning its safety or effectiveness, nor has it been identified by FDA as a drug which presents "demonstrable difficulties" for compounding. Therefore, it meets these criteria.

Section 503A also places limits on the quantity of drug that may be compounded. This includes a prohibition on "regular" compounding, or compounding in "inordinate" amounts, of drug products which are essentially copies of commercially available drugs.¹²

Naltrexone is not commercially available in the pellet form prescribed by Dr. Gooberman. Orally administered forms of the drug are commercially available and are currently used as adjunctive therapy during the detoxification process for the purpose of blocking the pharmacological effects of exogenously administered opioids. The utility of orally administered naltrexone is limited, however, as dosing is dependent upon patient compliance. Because the drug is prescribed for patients whose lifestyles may make compliance extraordinarily difficult, the rate of

relapse is high. Depo-naltrexone in the pellet form is considered significantly different from oral naltrexone. Thus, compounding of the drug in this form is not considered compounding of a drug that is otherwise commercially available, and this limitation therefore does not apply to the pellets compounded by Dr. Gooberman.

While compounding may be limited to a single formulation for a single patient, that is not necessarily the case. Under Section 503A, a pharmacist can compound larger quantities of a drug, such as depo-naltrexone, for multiple patients and still not need FDA approval. Accordingly, Dr. Gooberman's prescription of depo-naltrexone for multiple patients is not inconsistent with Section 503A.

The law also intends there to be limits on the quantity of compounded drugs that may be shipped across state lines by individual pharmacists or pharmacies. Specifically, Section 503A seeks to limit the interstate distribution of "inordinate amount" in this context is to be established by FDA with each state through a Memorandum of Understanding (MOU). FDA has said that it will not enforce this provision until an MOU is adopted. FDA has not yet adopted an MOU.

Thus, Dr. Gooberman's prescriptions for compounded depo-naltrexone comply with FDA's requirements. He therefore does not need to have clinical data to prescribe this compounded medication.

-
1. International Academy of Compounding Pharmacists, The Art and Skill of Compounding, http://iacprx.org/about_compounding.htm.
 2. N.J.A.C. § 13:39-1.2(1999).
 3. N.J.A.C. § 45:14-16(1999).
 4. N.J.A.C. § 13:39-9.8(1999).
 5. N.J.A.C. § 13:39-11.7(1999).
 6. N.J.A.C. § 13:39-11.10(1999).
 7. N.J.A.C. § 13:39-11.13(1999).
 8. United States Pharmacopeia, Pharmacy Compounding Practices, USP 24-NF 19,2118.
 9. 21 U.S.C. § 355(d)
 10. 21 U.S.C. § 353a.
 11. 21 U.S.C. § 503A(b)(1)(D).
 12. 21 U.S.C. § 503A(b)(1)(D)

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Dr. Gooberman's New Drug Application

On May 26, 1999, Dr. Gooberman met with staff from the Division of Anesthetic, Critical Care and Addiction Products at the FDA. The purpose of this meeting was to explore the toxicological and clinical requirements necessary to obtain marketing approval for the use of depo-naltrexone in pellet form for subcutaneous implantation in patients undergoing opiate detoxification. In that meeting, Dr. Cynthia McCormick, the Chief of the Division of Anesthetic, Critical Care and Addiction Products, referred to the enactment of Section 503A in 1997. She specifically advised Dr. Gooberman that current law allows him to prescribe compounded product for his own patients and that approval of an NDA is required only for commercial marketing of a drug. Thus, Dr. Gooberman's decision to pursue FDA approval was entirely voluntary. Nonetheless, Dr. Gooberman has initiated the process for clinical evaluation of the naltrexone pellets for the purpose of seeking a NDA for this indication.

FDA advised Dr. Gooberman that he should conduct some animal studies to support his marketing application. This is a standard requirement for NDAs, and does not indicate that FDA believes animal testing was necessary before prescribing compounded naltrexone. Dr. Gooberman has retained an expert to help him prepare the protocols for these animal tests.

During the meeting, FDA also asked that Dr. Gooberman use a CMP-compliant manufacturing facility to make the naltrexone for the animal studies. Dr. Gooberman has identified two potential manufacturers. He has been in negotiations with them to reach an agreement under which they would supply the materials for these preclinical tests. It must be emphasized that Dr. Gooberman is not undertaking these steps -- preclinical testing and reaching an agreement with a supplier of preclinical trial materials -- solely to support the FDA approval process. They are not necessary to compound under the FDC Act or New Jersey law.

Dr. Gooberman has begun pursuing an NDA based on the interest of colleagues and his own conviction that the drug represents a public health benefit. The NDA process is time-consuming and expensive. While he hopes to interest a commercial partner in bringing the product to market, the initiation of this process demonstrates and extraordinary personal and financial commitment to expand the availability of this medication on the part of Dr. Gooberman, one that goes far beyond what

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physicians customarily do.

Conclusion

In conclusion, pharmacy compounding is legal under both Federal and New Jersey State law. Federal law provides that compounded drugs are exempt for the NDA, GMP and certain labeling requirements if they are compounded for individually identified patients in accordance with specific criteria that are designed to ensure the safety and effectiveness of compounded drugs. A drug compounded in accordance with those restrictions is exempt from the NDA, GMP, and labeling requirements that govern drug manufacturers, and does not need to be supported by clinical data.

Dr. Gooberman's practice of prescribing compounded depo-naltrexone in pellet form for use in individual patients for opiate detoxification is consistent with the safety and efficacy criteria established by Congress for compounded medications. Therefore, he is exempt from any obligation under federal law to conduct clinical trials to further assess the safety and efficacy of the compounded drug. His voluntary efforts to seek NDA approval for the drug demonstrates his commitment to ensuring that the drug is made available to a broader population of patients, and his willingness to meet a more demanding standard.

Compounding is likely to grow in clinical importance in the near future.

Requiring that physicians possess clinical data before compounding would mean that residents of New Jersey would be deprived of the significant medical benefits offered by pharmacy compounding.

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- [Rapid Opiate Detoxification](#)
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Home of the patented Naltrexone Pellet
- [Dr. Lance L. Gooberman](#)
Inventor of the Naltrexone pellet
- [Midwest Rapid Opiate Detoxification Specialists](#)
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Naltrexone Pellet Injection Procedure

1. Naloxone Challenge - 1 mg IV and observe for signs of withdrawal
2. Administer prophylactic antibiotic
3. Local Anesthesia
 - a. Wash hands with antimicrobial soap
 - b. Apply antimicrobial handcream
 - c. Apply non-sterile gloves
 - d. Cleanse skin with antimicrobial wipe
 - e. Cleanse skin with isopropyl alcohol
 - f. Inject area with 2% lidocaine with epinephrine and bicarbonate buffer in 5cc syringe with a 25g x ½" needle under ~ 1" of skin
4. Pellet insertion
 - a. Apply antimicrobial handcream
 - b. Apply non-sterile gloves
 - c. Open packet of sterile supplies
 - d. Prepare Area with 3 sterile betadine swabs
 - e. Apply sterile gloves
 - f. Apply sterile drapes
 - g. Make ~1cm incision with sterile #15 scalpel
 - h. Inject 5cc of 2% lidocaine with epinephrine and bicarbonate buffer in 5cc syringe with a 18g x 1 ½" needle through the wound in a medial direction anesthetizing a tract through which to insert the pellet insertion device.
 - i. Insert sterile pellet within sterile insertion device pellet
 - j. Close wound with staples from disposable stapler
5. Clean and dress wound
6. Provide wound care instruction sheet to patient

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Implantation Discharge Instructions

NaltrexZone (TM)

1. Wash hands before touching site.
2. Keep clear dressing over pellet site for 24 hours.
3. Pull dressing off after 24 hours.
4. Clean with soap and water as usual in shower every day.
5. Make sure stitches stay dry - pat dry after shower.
6. Pour peroxide over stitches after shower.
7. About 10-14 days stitches will dry up and crack off. If stitches are hanging, pull out with tweezers.

-
- For redness or swelling in first 24 hours use ice. May use over the counter pain relievers such as Tylenol, Ibuprofen, Naproxen Sodium.
 - Bruising may occur on abdomen secondary to numbing medication administration.
 - If pellet site bleeds, hold pressure over site. Ice will also help stop bleeding at site.
 - If pellet site irritated during working hours - cover with band-aid during day - keep site open to air at night (No band-aid).
 - Notify office if fever develops, redness or swelling occur, or any discharge occurs.
-

Patient may experience withdrawal symptoms within 30 minutes of receiving pellet if not opiate free.

Withdrawal symptoms include:

1. Muscle aches & twitching
2. Restlessness
3. Nausea/vomiting

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4. Diarrhea and/or crampy belly pain
5. Insomnia
6. Anxiety

The worst will be over within 6 hours of onset. They may last anywhere from 24 - 48 hours.

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CONSENT FOR NALTREXONE MAINTENANCE THERAPY WITH Pellet Injection

The NaltrexZone

This document confirms our conversations concerning your medical problems. The following are some of the items discussed with you. This list is not inclusive of all items or factors discussed or related to your medical problem including the procedure to be performed.

PATIENT: _____ AGE: _____ DATE: _____

1. HOW NALTREXONE WORKS

I hereby authorized The NaltrexZone as designated to perform a procedure known as naltrexone maintenance therapy (therapy) including the implantation of the depot-naltrexone pellet (pellet).

By signing this form, I agree to have a pellet injected in my body. Naltrexone blocks the effects of opiates, such as heroin. Naltrexone is not a cure for my addiction. If you have used opiates within the last week, you will go into withdrawal from the pellet.

If you use opiates while on naltrexone, nothing will happen unless the naltrexone wears off. Of course, for your treatment for addiction to be effective, you will need to go to support meetings such as a 12-Step Recovery Program.

During the therapy, a pellet which contains naltrexone will be inserted under the skin. The naltrexone is expected to be released from the pellet over time. This will prolong the opiate blocking condition. The effect of the pellet lasts approximately 60 days. I agree that the pellet should not be removed from my body by myself. If I experience any problems with the pellet I have been advised to contact The NaltrexZone. The NaltrexZone is not required to remove the pellet unless it is medically indicated.

Naltrexone is a medically accepted Food and Drug Administration (FDA) approved drug for the treatment of drug addiction and alcoholism. Furthermore, the implantation method is a medically accepted method of

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administering many drugs. However, implanting naltrexone under the skin is a new way to deliver naltrexone.

Naltrexone has not been approved by the FDA for use in pellets. The naltrexone used in the pellet will be compounded by a pharmacy. It will not come from a drug manufacturer.

The alternative to this method of treatment is to take naltrexone orally. Naltrexone has been approved by the FDA for this use and has been widely used for this purpose. This involves taking one pill each day.

The benefit of the pellet is that it will release the naltrexone over a long period of time. This means that you will not need to take naltrexone orally each day while the implant is active (which may be up to 60 days or more).

If I use opiates while on naltrexone, I will experience no euphoria unless the naltrexone wears off. If I start using heroin again, I understand I could die if I took my usual dose of heroin right away.

2. PELLET INJECTION

The implant will be inserted under the skin. An antiseptic will be applied first to clean the area. Then, a local anesthetic (Xylocaine) will be given. I understand that I may feel burning when this happens. Then, the pellet will be inserted. Afterwards, the wound will be bandaged.

I have been encouraged to return to The NaltrexZone to check the effect of the pellet, have an additional pellet insertion or to take oral naltrexone (ReVia) to maintain the opiate blocking condition.

3. POSSIBLE RISKS AND SIDE EFFECTS

The risks from the implantation of the pellet include possible infection, soreness, bruising, swelling and scarring at the incision site. In addition, I understand I may also feel some discomfort afterwards at the spot where the pellet was placed. There is also the possibility that the pellet will not be effective for the full 60 days. There is also the risk that the pellet will not work at all. The effectiveness of the pellet can be monitored. Because oral naltrexone has no significant side effects, it is not expected that there will be significant side effects with the pellet. It is possible though, that implanting the pellet will result in new side effects.

I recognize that during the course of the procedure, unforeseen conditions may necessitate additional or different procedures than those explained. I, therefore, further authorize and request that The NaltrexZone perform such procedures as deemed necessary and desirable, including admitting me to a hospital for continued

treatments. The authority granted under this paragraph 4 shall extend to remedy conditions that are not known to or could not reasonably be anticipated by the above physicians and medical professionals at the time the therapy is commenced.

I consent to the administration of local, intravenous and/or general anesthetic agents by The NaltrexZone The risk of anesthesia has been explained to me.

I am aware that the practice of Medicine and Surgery is not an exact science and I acknowledge that no guarantees have been made or implied to me as to the results of the procedure or my satisfaction with the results; nor are there any guarantees against unforeseeable and/or unexpected results.

4. FOLLOW UP AND AFTER CARE

I agree to inform The NaltrexZone of any change in my address, and I agree to cooperate with them in my care and comply with their instructions or prescriptions until completely discharged from their care.

I have been provided with written instructions pertaining to the period after the implantation of the pellet.

I understand that in order for my treatment for addiction to be effective, I will need to attend support meetings such as participation in a 12-step recovery program. I understand that I will be contacted for follow up. I understand that The NaltrexZone recommends that I return for a follow up appointment at least once after the therapy.

I have carefully read the foregoing consent for the therapy. This consent form has been explained to me and I have had an opportunity to ask questions concerning it.

I understand and accept the above and hereby authorize The NaltrexZone, to perform the therapy.

I understand and accept the above and hereby authorize The NaltrexZone and/or their assistants to perform the therapy.

Signed and dated:

(Patient or legal guardian) (Date)

(Witness) (Date)

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WARNING!

You must be clean before you take naltrexone, otherwise, you will get VERY sick. The withdrawal is WORSE than any you have ever experienced. It is recommended that you be clean for 7-10 days to prevent this from happening unless you have recently taken naltrexone.

An injection of naloxone, a short acting type of naltrexone, may be administered to patients prior to receiving a pellet. If you are clean 7-10 days or taking naltrexone by pellet or pill there will be no effect from this injection. If NOT, in about 10 minutes you will start getting sick. It will wear off in about an hour but we will not put in a pellet.

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HOW DOES NALTREXONE WORK?

Naltrexone (trade name ReVia) is a medication that blocks the effects of heroin, methadone and other prescription pain medications. It has been used for over 20 years. There are very few side effects from naltrexone and none of them serious. It is difficult to determine whether the symptoms one experiences initially after detoxification are due to the naltrexone or remnants of the withdrawal syndrome.

Naltrexone works by entering the brain and nervous system and attaching itself to small areas called receptor sites. In order for heroin and other opiates to produce their effect, it must attach to these receptor sites. However, naltrexone blocks the opiates from attaching to these receptor sites.

The purpose of naltrexone is that it can prevent relapse. Naltrexone is not addictive. Even after several months there are no withdrawal symptoms if you stop it suddenly.

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WHO CAN TAKE NALTREXONE?

Naltrexone would be appropriate for any opiate addict who wants to stop using opiates but who has never managed for long or at all except in prison, or one who thinks that relying on will power or counseling alone will not work for them. Naltrexone is not a mood altering drug and is therefore not objectionable to most individuals who advocate abstinence. We advise all patients to seek counseling, particularly group therapy and most particularly active participation in 12-step recovery programs. We can't over-emphasize the importance of living a 12-step life. Participation in a 12-step recovery program is the single most important form of follow-up care. We believe there is no substitute for the therapeutic value of one addict helping another.

If an addict discontinues the use of naltrexone, he must start again with a 10-14 day abstinence period. There are very few side effects from naltrexone and none of them serious. It is difficult to determine whether the symptoms one experiences initially after detoxification are due to the naltrexone or remnants of the withdrawal syndrome. Such symptoms generally cease within a week or two. Taking additional naltrexone is of no consequence. However, if you take naltrexone while you are physically addicted to heroin or other opiates, it will cause severe withdrawal symptoms within a few minutes.

If you stop taking naltrexone and start using heroin again, you could kill yourself if you took your usual dose of heroin right away.

The current price of naltrexone is approximately \$4-5.00/pill. Most prescription programs cover this medication.

It is recommended that patients wear a Medic-Alert tag (bracelet or necklace) that would inform a treating physician that the patient is on naltrexone maintenance therapy in the event that the patient is not able to communicate this information. The physician would obviously need to prescribe a non-opiate medication if pain relief was required.

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Black Box Warning Re:Liver Toxicity

January 21, 2000

CONFIDENTIAL - ATTORNEY - CLIENT PRIVILEGE

Alma Saravia
Flaster, Greenberg, Wallenstein, Roderick, Spigel,
Zuckerman, Skinner & Kirchner, P.C.
Commerce Center
1810 Chapel Avenue West, Third Floor
Cherry Hill, New Jersey 08002-4609

Re: Naltrexone

Dear Ms. Saravia:

You have asked us to review the black box warning which appears in the Revia (naltrexone hydrochloride) package insert (PI), the data supporting that warning and the warning's current clinical relevance. Based on our review, it appears that the black box warning for Revia is based on evidence from a small trial in a population for which the drug is not labeled and in which no clinically-relevant adverse events were noted. The original studies in the within-label patients -- opiate dependent addicts -- do not support the warning. Clinical experience and literature published subsequent to Revia's approval have apparently led the addiction treatment medical community to largely consider these warnings to be unnecessary. Our analysis is provided below.

Revia is an oral tablet dosage form of naltrexone which is FDA approved for both the treatment of alcohol dependence and the effects of exogenously administered opioids. The PI for Revia notes that the black box warning is primarily based on results of a single, small (50 patient), placebo-controlled study in an off-label patient population (obesity patients) using six times the recommended dose. In that study a substantial portion of the Revia patients developed serum transaminase elevations of three to nineteen times baseline within eight weeks of beginning treatment. The clinical relevance of this data is not

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apparent. The patients demonstrated no clinical signs of liver malfunction, and their transaminase levels returned to or approached baseline values within weeks of discontinuing treatment.

In addition to the PI, we reviewed the FDA Medical Officer's Summary Basis of Approval (SBA) for Revia to search for any additional evidence on the hepatotoxic potential of the drug and FDA's basis for requiring the black box warning. The SBA is an internal FDA document which sets out the reviewer's analysis of the data. The SBA does include a safety review of the obesity trials, and a conclusion based on that data that, at doses four to seven times the recommended dose, Revia "has the *potential* to cause apparently reversible hepatocellular injury in a substantial proportion of patients to whom it is administered for several weeks" (emphasis added). The dose range referred to by the medical officer would be 200-350 mg per day. The Medical Officer goes on to minimize the relevance of that study to the treatment of opioid addiction and concludes, "Clinical experience using [Revia] in detoxified, formerly opioid dependent individuals at the dose recommended in the [Revia] labeling fails to provide a basis for substantive concern about [Revia's] safety."

Results of the only placebo-controlled study in detoxified opioid dependent patients do not implicate Revia as a hepatotoxin. In that study no new laboratory abnormalities developed and there were no differences detected between the placebo and naltrexone groups. In fact, in summarizing the safety evidence from studies in this population the medical officer stated that "the enumeration of treatment emergent signs, symptoms, and abnormal laboratory findings that occurred in the clinical trials of [Revia] in detoxified opioid-dependent populations did not display a sequence or pattern that implicated [Revia] treatment as the cause of the abnormalities detected." The Medical Officer specifically emphasized that "this statement applies to the occurrence of elevated serum transaminase levels."

While FDA did not clearly articulate why a black box warning was included in the Revia PI, such a warning is typically reserved for drugs with a greater quantity and quality of clinical data in the NDA indicating that the drug may be hepatotoxic. The clinical data submitted in the NDA did not show that naltrexone was hepatotoxic in the patients who would actually be administered the drug at the recommended dose.

In 1988, Brahen confirmed the lack of effect of naltrexone on hepatic enzymes of opioid dependent patients. His research involved a within-label group of patients receiving

the recommended dose for a period longer than the obesity group submitted in the NDA.

benefit of admitting patients with the sole problem of elevated hepatic enzymes generally exceeds the risk." (J Clin Pharmacol, 28(1)68-70 1988 Jan.)

Moreover, according to Dr. Charles O'Brien, Professor and Chief of Psychiatry at the University of Pennsylvania Veterans Medical Center, Revia is routinely prescribed to detoxified opioid dependent patients without the subsequent liver function monitoring recommended in the black box warning. In fact, Dr. O'Brien noted that notwithstanding the fact that patients in this population often have underlying liver disease due to years of illicit drug use, Revia is routinely prescribed.

It appears from our review that the black box warning for Revia was supported by very tenuous data and has not been found warranted by subsequent research or clinical experience.



Please let us know if we can provide you with any further information.

Sincerely,

Jeffrey N. Gibbs

JNG/rag

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Drug-related hospital morbidity following heroin dependence treatment with methadone or naltrexone implantation

Arch Gen Psychiatry 2008;65(4):457-465.

This trial, published in the Archives of General Psychiatry, sought to evaluate the longer-term effects of heroin dependence treatment on patient's drug use and associated hospital morbidity. The authors note that the focus of research in this area has been on shorter-term changes and health effects, and this study was carried out to address this lack of data. They compared two treatments: methadone maintenance treatment (MMT) and naltrexone implants. Although MMT has been widely studied and shown to be of benefit, the abuse of other drugs in those on treatment has not been studied and there have been concerns that it enables the co-use of illicit opioids. Naltrexone (opioid antagonist) implants were developed in an attempt to overcome the non-compliance seen with the oral version; however there is concern that users will adopt new non-opioid drugs as a substitute for heroin.

The study was a retrospective longitudinal follow-up, using data collected prospectively via a hospital reporting system in Perth to identify patients receiving initial treatment for heroin dependence with either MMT (n=522) or a naltrexone implant (n=314) between January 1 2001 and December 30 2002. All drug-related hospital morbidities recorded during the 6 months pre-treatment and 3.5 years post-treatment were recorded.

The main findings were as follows:

- Following naltrexone implant treatment (NIT), the risk of opioid-related overdose at 3.5 years was reduced (OR 0.23; 95% CI 0.11-0.48) and there was evidence for a decreased risk with increasing age (OR 0.31 [95% CI, 0.15-0.68] for a 35-year-old patient versus a 25-year-old match. No statistically significant effect of MMT on this endpoint was observed at either 6 months or three years.
- NIT was associated with a reduction in the risk for other opioid-related hospitalisations after 3.5 years (OR, 0.64; 95% CI, 0.46-0.89). No significant changes for this outcome were observed for patients in the MMT group.
- In the shorter term (6 months), the risk of non-opioid

overdoses was statistically significantly increased in older patients (aged 35 years) receiving either treatment (OR of 5.03 [95% CI, 1.18-21.54] for those receiving MMT and OR of 16.31 [95% CI, 3.07-86.53] for those receiving NIT. There was no change in younger patients and no statistically significant effects for either treatment were seen at 3.5 years.

- NIT was associated with an increased risk of other non-opioid related hospitalisations (e.g. dependence and withdrawal) at 3.5 years (OR of 1.52; 95% CI 1.04-2.23). The risk appeared to remain constant however in those receiving MMT.
- There were 6 drug-related deaths: 5 after MMT and 1 after naltrexone implantation.

The authors conclude that "naltrexone implants, but not methadone maintenance, has long-term benefits in reducing opioid-related hospital morbidity. However, long-lasting and increased non-opioid drug-related morbidity following naltrexone implantation is particularly concerning. Similar studies are required to confirm these findings".

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An Anti-Addiction Pill?

By BENOIT DENIZET-LEWIS
The New York Times Magazine
Published: June 25, 2006

Last month, the Picower Institute for Learning and Memory at the Massachusetts Institute of Technology was host to a conference about addiction for a small, invitation-only crowd of neuroscientists, clinicians and public policy makers. It was an unusual gathering. Addiction conferences are usually sober affairs, but M.I.T. offered a lavish cocktail reception (with an open bar, no less). More important, the conference was a celebration of the new ways scientists and addiction researchers are conceptualizing, and seeking to treat, addiction. While many in the treatment field have long called addiction a "disease," they've used the word in vague and metaphorical ways, meaning everything from a disease of the mind to a disease of the spirit. Many assumed that an addict suffers from a brain-chemistry problem, but scientists had not been able to peer into our heads to begin to prove it.

Discuss medical approaches to treating addiction. Now they can, using advances in brain-imaging technology. And they tend to agree on what they see, although not necessarily on how to fix it: addiction — whether to alcohol, to drugs or even to behaviors like gambling — appears to be a complicated disorder affecting brain processes responsible for motivation, decision making, pleasure seeking, inhibitory control and the way we learn and consolidate information and experiences. This new research, in turn, is fueling a vast effort by scientists and pharmaceutical companies to develop medications and vaccines to treat addiction. The National Institute on Drug Abuse and the National Institute on Alcohol Abuse and Alcoholism are studying, or financing studies on, more than 200 addiction medications.

The search for pharmacology to treat addiction is not new. The history of addiction treatment in America is rife with supposed miracle medications and "cures," most of which turned out to be useless. But there are a handful of drugs — some developed in the mid-1900's, others in the last decade or so — that are being used to help addicts quit. For heroin addiction, there's methadone and buprenorphine, both of which bind to and activate opioid receptors in the brain. Each essentially substitutes for heroin by activating the same brain receptors as the drug, but many addiction doctors prefer buprenorphine, which the Food and Drug Administration approved in 2002, because it causes less of a high and less dependence.

For alcohol, Antabuse, which makes people physically ill if they drink, has been on the market since 1948, although it isn't widely used. Addiction scientists are more hopeful about another anti-alcoholism drug, naltrexone, which was originally developed to treat opioid addiction but was approved for the treatment of alcoholism in 1994. Studies have found it can help some alcoholics abstain from or cut down on their

drinking, and two pharmaceutical companies recently teamed up to produce Vivitrol, a long-acting, injectable form of naltrexone, which the F.D.A. approved in April. Some hope Vivitrol will sidestep a huge challenge facing those seeking pharmacological solutions for addiction: unless they're getting high from it, most addicts aren't model medicine takers. (Vivitrol requires a monthly shot from a doctor.)

None of the medications currently approved to treat addiction are perfect, and in many ways they are the products of some of our earlier advances in neuroscience. In the last few years, though, scientists say they've learned a staggering amount about how addiction affects the brain, and neuroscientists and other addiction researchers are eagerly testing and developing a new generation of anti-addiction medications.

"In 5 or 10 years, we will be treating addiction very differently," predicts Nora Volkow, a psychiatrist and the director of the institute on drug abuse, who attended the M.I.T. conference and presented a lecture, "Addiction: The Neurobiology of Free Will Gone Awry," in an intense and rapid-fire speaking style. (Besides being a leading American thinker about addiction, Volkow is the great-granddaughter of Leon Trotsky.) What Volkow means is that in a decade or so, we may actually start treating addiction effectively. Addiction is one of the nation's biggest public health problems, costing \$524 billion (including lost wages and costs to the public health care and criminal justice systems) each year. The majority of the estimated 20 million alcoholics and drug addicts in America (and millions more compulsive gamblers, overeaters and sex addicts, if you accept an expanded understanding of addiction) never get help. Those who do often relapse repeatedly, sometimes returning to treatment centers 5, 10 or 15 times (if they don't die first). And many of those who "recover" simply trade one addiction for another — addicts call this dance "switching seats on the Titanic."

The Dopamine Connection

For much of the past two decades, Volkow and other neuroscientists exploring the physiological basis of addiction have tried to explain it by studying the brain chemical dopamine, which functions as a neurotransmitter, sending signals between cells in the brain. Dopamine affects a variety of critical functions, including learning, memory, movement, emotional response and feelings of pleasure and pain.

Dopamine was originally thought to serve as a kind of pleasure signal in the brain, telling us when something feels good or rewarding. But scientists now believe that dopamine is more a predictor of salience — that is, it tells us, and then helps us to remember, what we should focus on. When you see a person you are strongly attracted to, scientists can now see a spike of dopamine in your brain. If you are hungry and smell a food you like, dopamine also increases. But even unpleasant experiences — like physical pain or the fear of an intruder in the house — can cause a dopamine spike. (Some hypothesize that different dopamine receptor cells are

responsible for firing during rewarding or aversive situations.)

Drugs, particularly cocaine and methamphetamines, cause a large increase in the amount of dopamine secreted and pooling between brain cells, leading to feelings of euphoria. With regular, repeated "addictive" drug use, though, the brain eventually responds by reducing its normal release of dopamine. Studies also show a simultaneous decrease in the number of dopamine receptors created. That, in turn, makes the brain's reward system less likely to respond to behaviors (romance, a good meal, the company of friends) that produce a normal dopamine surge. The addicted brain essentially becomes pathologically selective, dependent on bigger and bigger blasts of, say, cocaine to feel rewarded.

Perhaps most fascinating to addiction researchers is how an increase in dopamine creates a craving — and an expectation of a reward. In a study published earlier this month in *The Journal of Neuroscience*, Volkow used a brain scan to look at the dopamine releases in 18 cocaine addicts while they watched two videos: one of nature scenes, the other of people using cocaine. Volkow found that dopamine increased while the addicts watched the cocaine video and that the severity of the increase matched their self-reported level of craving for the drug. "For these people, their lives and experience had taught them that when they see others using cocaine, they're probably about to get rewarded with drugs, too," Volkow told me. "So even though they consciously knew that they weren't going to get cocaine after watching the video, their brains had learned to expect the reward."

Scientists posit that cue-induced dopamine spikes and craving essentially overpower the brain's well-meaning frontal cortex, which is responsible for planning and decision making. The institute on drug abuse is currently financing studies of medications that could potentially blunt that process, interfering with the release of dopamine when an addict sees a conditioned cue.

Dopamine also travels to the parts of the brain responsible for solidifying memory, like the amygdala, which learns and stores emotional memories (including the high of drugs). Some researchers hypothesize that through a combination of medicine and behavioral therapy, addicts could "unlearn" these powerful memories and associations, making them less likely to relapse when they see a cue. "Potentially, you could put an addict in a virtual-reality situation where you show them videotapes of friends they used to use drugs with, or whatever their strongest triggers are," Eric Nestler, a neuroscientist and addiction specialist at the University of Texas Southwestern Medical Center, told me earlier this month. "But now, the cue isn't associated with any kind of rewarding response. So then you can give a medication, which we're making progress on developing, that enhances memory formation. Essentially, you'd be teaching them something new — that a line of white powder means nothing special."

Dopamine may also make some people more vulnerable to addiction. Recent studies in both animals and humans have indicated that those with low levels of dopamine D2 receptors, which regulate the release of dopamine in the

brain, are more likely to find the experience of taking drugs pleasurable. Some researchers, like Volkow, suggest that people with fewer D2 receptors experience a less intense reward signal, causing them to overindulge in order to feel satisfied.

In one experiment, Volkow increased the level of dopamine D2 receptors in rats that had low levels. After the increase, the rats significantly curtailed their intake of alcohol, which they had eagerly gulped down before. Unfortunately, we don't yet know how to safely increase the number of dopamine D2 receptors in humans.

In fact, we don't yet know how to do much when it comes to dopamine and addiction. Understanding how the neurotransmitter works may help us to understand addiction better, but it hasn't led to any effective medications, the ultimate goal of many researchers. Because addiction seems to disrupt so many different brain regions, neuroscientists are now casting a wider net in their pursuit of effective medications. For some, the new frontier involves the brain's two major "workhorse" neurotransmitters: GABA and glutamate.

Getting the Brain's Brakes to Work

Walter Ling, a neurologist and the director of the Integrated Substance Abuse Programs at U.C.L.A., likes to explain complex brain processes using simple metaphors. GABA, he says, is to a brain what a braking system is to a car. "The brain works by inhibition," he told me recently. "At some point you realize that your car is a great car not because of its engine but because it has a great braking system. GABA is the brakes. If your brakes don't work well, you crash."

GABA (gamma-aminobutyric acid) is the brain's major inhibitory transmitter, and its role, in essence, is to keep glutamate, the main excitatory transmitter, from overwhelming us. In the extreme, too much glutamate can cause a seizure and too much GABA can put us in a coma. Researchers are particularly interested in the brain's critical balance of GABA and glutamate — some hypothesize that addictive craving is the result of too much glutamate or too little GABA. "We've been able to measure GABA in living brains for some time, but measuring glutamate in living human brains has just become feasible in the last few months," says Frank Vocci, the director of the division on pharmacotherapies and medical consequences at the institute on drug abuse. "What's been shown is that people with alcohol and cocaine problems have less GABA in their brains, and we do know that medications that increase GABA have shown some efficacy in treating addiction." (Vocci says that it isn't yet clear whether the absence of GABA is a cause of addiction or a result.) The seizure medication topiramate, for example, works on both GABA and glutamate and has helped some alcoholics in initial trials quit or cut back on their drinking. The muscle relaxant baclofen, which essentially mimics the effects of GABA, may also help some cocaine addicts quit. Both are

being tested further by the institute.

Hythiam, a Los Angeles-based health care services management company that made national news in the spring when it plastered Chris Farley's face — with the words "It Wasn't All His Fault" — on a series of Los Angeles billboards, is particularly interested in GABA's role in addiction. The company is aggressively marketing its Prometa protocol for cocaine, alcohol and methamphetamine addiction, which involves therapy and medications, both oral and intravenously injected, not usually used to treat addiction: flumazenil, approved by the F.D.A. to treat overdoses of Valium and Xanax, and gabapentin, approved to relieve neuropathic pain. While no double-blind placebo studies have tested Prometa's effectiveness (two are under way), addiction-medicine doctors around the country who have administered the protocol report encouraging results. Prometa appears to reduce anxiety and craving by enhancing the brain's GABA receptors, says David Smith, the former president of the American Society of Addiction Medicine and now the director for medical affairs at Hythiam and the head of a Prometa treatment center in Los Angeles. Sanjay Sabnani, Hythiam's senior vice president for strategic development, says: "It's all hypothesis at this point, because we haven't sliced open anyone's brain yet, but it seems that normalizing the GABA receptor takes away the craving and anxiety that one would typically experience in the absence of the drug. And it doesn't appear to be happening because of will power, love, God, discipline, family support or anything else. It seems to be happening because the protocol resets a faulty mechanism in the brain." Yet, several addiction scientists told me they were skeptical that Prometa works, and some criticized Hythiam for promoting it before it has been rigorously tested.

The Prescription Model

Hythiam was among a handful of companies publicizing their anti-addiction medications last month at the American Society of Addiction Medicine conference in San Diego. Several were armed with charts, graphs and clinical-study results (particularly the ones that found their medications most effective), and their eager young marketing and sales teams talked about doing for addiction what the pharmaceutical industry did for depression: medicalizing it, and destigmatizing it in the process.

They know it won't be easy. A series of recent surveys sponsored by the National Council on Alcoholism and Drug Dependence and by Faces and Voices of Recovery, a recovery advocacy group, found that half the public called addiction a personal weakness. Among those who did see addiction as a disease, most put it in a special category of diseases that people get by making poor choices. In a 2004 poll of the general public, two-thirds said they believed that a stigma — usually defined as a thing that disgraces a person or injures one's reputation — exists for people in recovery from addiction.

The pharmaceutical companies came to San Diego to argue

that addiction is a chronic and recurring disease like diabetes or hypertension — and no one, they say, tells a diabetic to try to tough it out without insulin. They don't discount the importance of environment in inducing addictive behavior or psychosocial interventions as part of the recovery process; in fact, most stress therapy as an essential adjunct to their products. But they insist that medications will stabilize addicts and make the deeper therapeutic and spiritual work more effective.

In the exhibition hall, the prime booth location near the entrance belonged to Alkermes and Cephalon, the two pharmaceutical companies producing and marketing Vivitrol, the recently approved, injectable form of naltrexone, prescribed for alcoholics. Alkermes and Cephalon are initially focusing on doctors who specialize in addiction, but they plan eventually to market the drug directly to primary care physicians, most of whom are used to sending their addicted patients to treatment centers and groups like Alcoholics Anonymous. "It would require a complete paradigm shift," Doug Neale, a product director at Cephalon, told me, "but we'd like to see the day when a patient who is struggling with alcoholism can walk into their primary care doctor's office, say, 'Doc, I'm drinking too much and can't seem to stop,' and the doctor will have a handful of options for medications that he could prescribe."

But Ling, the U.C.L.A. researcher, cautions that we still have a way to go before we can effectively treat most addicts medically. "In general, we have a pretty good handle on dealing with opioid addiction," he says. But "if you look at the various studies of alcohol-abuse drugs, the results are mixed at best," he continues, adding: "These kinds of mixed findings mean that the drug maybe works for some people, but it's not working all that great. And we're still far off from having a handle on treating people addicted to stimulants like cocaine and methamphetamine."

A Higher Power Versus Medicine

John Schwarzlose, the president of the Betty Ford Center, says he isn't convinced that treating alcoholics and drug addicts with more drugs — particularly if they aren't proved effective — is a good idea. He points out that millions of addicts around the world have recovered without the help of medication. "We're open to medications that will actually work, but the fact is that today 12-step treatment is still the best treatment there is," he told me. "Nothing even comes close. And until something does, we like to try to keep most of our patients as drug-free as possible."

Many addiction treatment centers share that view, which made for a strange scene in the exhibition hall at the society of addiction medicine conference. The treatment centers, most of which advocate a behavioral and spiritual solution to addiction, promoted their centers right next to pharmaceutical companies boasting novel medical solutions. "Why can't these two camps come together?" Smith, the medical director

of Hythiam, said as he sat in front of the company's booth. "They need to come together. In medicine, if something isn't working, you try something new. In addiction, if someone goes to treatment and fails, for years we've just sent them back again and again and expected different results. That's insanity. And we're starting to realize that. The field of addiction treatment is changing right before our eyes, and it's only going to continue to change. Advances in neuroscience and pharmacology will change everything."

Those changes could lead to addiction vaccines. Several are already in development. The British company Xenova Group Plc has created what it says are effective vaccines for cocaine and nicotine addiction (NABI Biopharmaceuticals in Florida has also developed a nicotine vaccine). The vaccines, which the institute on drug abuse and others are testing, work by producing antibodies to a specific drug, binding to the drug when it enters the bloodstream and keeping it from entering the brain. An effective vaccine won't stop craving or treat any underlying pathology (making it an inadequate solution, some say), but it will make it nearly impossible for an addict to get high on that particular substance.

And if it is combined with medications that could blunt craving, some addiction specialists believe that we'll stop using the word "treat" and start using the word "cure." Matthew Torrington, an addiction-medicine doctor in Los Angeles who works with Smith at his Prometa center, attended the society's conference and told me that he believes we can essentially eliminate addiction in America.

"With the scientific advances we're making in understanding how the human brain works," he says, "there's no reason we can't eradicate addiction in the next 20 or 30 years. We can do it by fixing the part of the brain that turns on you during drug addiction and encourages you to kill yourself against your will. I think addiction is the most beatable of all the major problems we face. And I think we will."

The Stress Culture

It's not the first time a doctor has predicted the end of addiction. In his book "Slaying the Dragon: The History of Addiction Treatment and Recovery in America," William L. White recounts how in the 1800's, countless "medications" like Knights' Tonics for Inebriates promised to remove "the craving for a stimulant that those who have been addicted to the use of ardent spirits know so well." In the 1905 Sears, Roebuck & Company catalog, a person struggling with opium or morphine addiction could buy a bottled "cure" for 69 cents.

Most of these miracle potions were promoted as a result of important scientific and medical breakthroughs. Science, it seems, has always been just about to save us from addiction. "But it has never lived up to its promise," says Bruce Alexander, emeritus professor of psychology at Simon Fraser University in British Columbia, "and I don't believe the science will live up to its promise now, either. Addiction doesn't demand a scientific solution."

Alexander is among a vocal group of addiction researchers

who argue that focusing on a pill to treat addicts fails to address the primary cause of becoming and staying hooked: our unhappy, disconnected lives. Beginning in the late 1970's, Alexander and his team of researchers at Simon Fraser set out to study the role of our environment on addictive behavior. Until that point, most scientists studying addiction put rats in small, individual cages and watched as they eagerly guzzled drug-laced solutions and ignored water and food, sometimes dying in the process. This phenomenon was noted — first by researchers, then drug czars, then parents trying to keep their children off drugs — as proof of the inherently addictive quality of drugs and of the inevitable addiction of any human who used them. This was false, of course. Most people who use drugs don't become addicted.

So what made all those lab rats lose their minds? Bruce Alexander and his research team had a rather simple hypothesis: The rats had awful lives. They were stressed, lonely, bored and looking to self-medicate. To prove it, Alexander created a lab-rat heaven he called Rat Park. The 200-square-foot residence featured bright balls and tin cans to play with, painted creeks and trees to look at and plenty of room for mating and socializing.

Alexander took 16 lucky rats and plopped them into Rat Park, where they were offered water or a sweet, morphine-based cocktail (rats love sweets). Alexander offered the same two drinks to the control group of rats he left isolated in cages. The results? The rat-parkers were apparently having too much fun to bother with artificial highs, because they hardly touched the morphine solution, no matter how sweet Alexander and his colleagues made it. The isolated and arguably depressed rats, on the other hand, eagerly got high, drinking more than a dozen times the amount of the morphine solution as the rats in paradise.

When I spoke with Alexander recently, he predicted that unless we undergo a "cultural renaissance" and all start living in a human version of his rat park (which he conceded isn't likely), we won't be eradicating addiction anytime soon. While Volkow of the institute on drug abuse doesn't agree with Alexander that developing addiction medications is a fruitless enterprise, she does say that a positive and nurturing environment, particularly during childhood and adolescence, is a strong protector against addiction. Volkow says that addicts are more likely to have been unnecessarily stressed during childhood (from neglect; emotional, physical or sexual abuse; or poverty) and that they're less able to deal with stress as adults.

Studies show that animals who are stressed during early development are more likely to self-administer drugs later in life and that living in an enriched environment — one with a minimal amount of strain and anxiety, like Rat Park — appears to protect animals from developing addictive behavior.

And remember the dopamine D2 receptors that some hypothesize may protect us from abusing drugs? There is evidence that our environment can affect those, too. In 2003, researchers at the Wake Forest School of Medicine measured the levels of dopamine D2 receptors of 20

macaque monkeys while they were housed in isolation. They then assigned the monkeys to social groups of four monkeys each, letting natural social hierarchies develop. Three months later, they tested the levels of D2 receptors again.

The dominant monkeys — who, the theory goes, were much less stressed and anxious than the subordinate ones — had 20 percent higher D2 receptor function, while the submissive ones were unchanged. The monkeys were then taught how to self-administer cocaine by pressing a lever, with researchers finding that the dominant monkeys took significantly less cocaine than the subordinate ones.

Interestingly, though, when the animals that seemed to be protected from addiction were given cocaine repeatedly, the number of their D2 receptors eventually went down, and they then became addicted. The moral of the monkey story, Volkow says, is that environment — if good or bad enough — can sometimes trump genetics and biology.

"Some people may be naturally better protected against addiction than others," Volkow says, "but that's not enough to keep someone from becoming addicted. The same thing is true for those who are genetically predisposed. We know from twin and family studies that about 50 percent of a person's vulnerability to addiction is genetic. But if you're never exposed to illegal drugs, or if you grow up and live in an environment without trauma and too many stressors, you probably won't become addicted."

If It's Not One Addiction, It's Another

What Volkow and other researchers can't yet explain is why we choose one particular manifestation of addiction over another. Why do some of us become addicted to cocaine, while others are hooked on alcohol or cigarettes? Researchers hypothesize that environmental availability and genetic predisposition both play a part, but they don't know for sure.

Further complicating the question is that many people are addicted to more than one thing. Howard Shaffer, director of the division on addictions at the Cambridge Health Alliance, an affiliate of Harvard Medical School, suggests a "syndrome model" of addiction: each outwardly unique manifestation of addiction is actually part of the same underlying disorder. Shaffer's syndrome model argues that behavioral addictions (like gambling, sex and eating) can be just as powerful as an addiction to heroin or crystal meth, and his belief is gaining acceptance among neuroscientists and addiction researchers, many of whom used to dismiss this idea as a product of an American culture that's addicted to calling everything an addiction.

But by studying the brain's reward and pleasure systems, researchers are discovering that drugs and powerfully rewarding behaviors like gambling and sex affect it in similar ways. Neurologists at the University Medical Center Hamburg-Eppendorf in Germany, for example, found that

pathological gamblers, like drug addicts, have a sluggish reward system that doesn't react normally to pleasing stimuli. The scientists used an M.R.I. scanner to compare the brain responses of 12 gambling addicts and 12 nonaddicted people to a card-guessing game. Subjects were told to pick a playing card, and if the card turned out to be red, they won a euro.

The game activated the ventral striatum, an important part of the brain's reward system. Those nonaddicts who picked a winning card had increased blood flow to the striatum, but the gambling addicts who picked the right card had much less of it (their reward system was less active). It was as if their brains, which were accustomed to powerful rewards, were saying, "You call this silly prize a reward?" The same kind of indifference to basic rewards has been seen in the ventral striatum of cocaine addicts.

"People addicted to gambling and drugs look a lot alike," Shaffer told me when I visited him in his office in March. "Gamblers have to increase their bets to get the same level of excitement, just like someone addicted to drugs who has to keep using more to get an effect. When addicted gamblers cut back, they experience withdrawal symptoms that look like stimulant withdrawal. They get depressed, they're irritable and they have trouble sleeping. And if they gamble again, they can make the symptoms go away for the short run."

While Shaffer focuses much of his recent behavioral addiction research on gamblers, Volkow studies overeaters and also finds many similarities to drug addicts and alcoholics — including the fact that obese subjects have lower levels of dopamine D2 receptors than those who eat normally. "Because we know that many people are addicted to more than one thing and that many people switch addictions," she told me at the M.I.T. conference, "in my own research I'm mostly interested in developing medications that could work across a variety of addictions."

An Addict's Perspective

What do addicts think about all this focus on their brains? William C. Moyers, a recovery advocate (and the son of the journalist Bill Moyers) who for 12 years has been free of crack and alcohol, was invited to speak at the M.I.T. conference. In a room full of scientists and addiction researchers obsessed with the intricacies of the human brain, Moyers read a lecture that reminded them that treating addiction might be even more complicated than they thought.

"I have an illness with origins in the brain. . .but I also suffered with the other component of this illness," he told the gathered researchers and scientists, some of whom dutifully took notes. "I was born with what I like to call a hole in my soul. . .A pain that came from the reality that I just wasn't good enough. That I wasn't deserving enough. That you weren't paying attention to me all the time. That maybe you didn't like me enough."

The conference room was as quiet as it had been all day. "For us addicts," he continued, "recovery is more than just

taking a pill or maybe getting a shot. . .Recovery is also about the spirit, about dealing with that hole in the soul."

Benoit Denizet-Lewis is a contributing writer for the magazine. He is working on a book about addiction in America.

Photo Gallery



Dr. Rahim Shafa holds a Naltrexone pellet before implant surgery.
(Ken McGagh photo)

Major hope for addicts: Leonard Morse Hospital is on cutting edge with pellet implants

By Cathy Flynn / News Staff Writer
Sunday, August 22, 2004

HOLLISTON -- Withdrawing from heroin was never easy for Charlie, an addict for two years.

"Whenever I tried to stop, I would feel like s--- for about two weeks," he said. "I'd go through the most insane depression and anxiety. I wanted to rip my insides out.

"Withdrawal is a thousand times worse than the flu. If I had a gun, I would have killed myself."

But today, Charlie, with a band wrapped around his upper arm, is a gaunt but determined soldier fighting an enemy that has ravaged his body, his relationships and his finances for years.

Under the armband and deep inside Charlie's arm is a 3/4-inch pellet of a drug called Naltrexone, embedded by a doctor at Leonard Morse Hospital in Natick. For the next two months, any heroin introduced into his system will make him feel very sick instead of high.

"I feel like a million bucks," said Charlie this week, less than a day after the surgery, while recovering at a friend's home with his mother Ann nearby. (Both Charlie and Ann asked that their real names not be used.)

The Naltrexone pellet works by blocking the effects of heroin and other opiates, and reducing the physical craving for the drug for two months. This gives addicts the strength they need to address their psychological cravings, another important step in recovery.

But there's a problem: The pellets are hard to get because they have not been approved by the Food and Drug Administration. Nor are they covered by insurance.

While addicts can use an FDA-approved, short-acting Naltrexone pill and Suboxone, another short-term pill, to withdraw, both pills have drawbacks.

Addicts and doctors point out that pills depend too much on the addict's willingness to take regular doses. A lapse can trigger withdrawal symptoms, and consequently, the craving for the illicit drug overcomes them. In addition, Suboxone, which is a narcotic, is hard to get because the U.S. Drug Enforcement Agency limits the doctors who can administer it.

Dr. Rahim Shafa, the Leonard Morse doctor who implanted Naltrexone in Charlie's arm, said that 40 of his patients have benefited from the pellets, which deliver a non-narcotic, slow-release dose that doesn't depend on the addict's remembering to take a pill.

"It's like a woman who doesn't want to get pregnant," said Shafa. "She can take a pill every day, or she can go on Norplant" (a contraceptive implant, which is less dependent on human error).

Shafa said the therapy has helped all but one of his patients kick their heroin addictions. The one who failed tried to test the drug's efficacy by consuming 50 bags of heroin in one day...far more than most addicts consume.

While the therapy seems promising, it too has its drawbacks. It is not recommended for people with damaged livers. Addicts must be ready to make a non-reversible decision about treatment. And the addict must go through a more conventional withdrawal and be clean for 10 days before the doctor implants the pellet. Charlie's doctors sedated him for a week to buffer the physical cravings.

But right now the biggest problem is lack of availability. Since the Naltrexone pellet has yet to be approved by the FDA, only five clinics in the U.S., including one at Leonard Morse Hospital in Natick, can dispense it under a special licensing arrangement with Pellet Technologies, the company run by pellet inventor Dr. Lance Goberman. Without FDA approval, insurance won't cover the cost.

Shafa said that while he tries to keep the costs of the implants as low as possible (around \$1,000), it still drives away many cash-depleted addicts. He estimates that full FDA approval for the pellets will require at least three years and several million dollars in testing.

"Insurance covers a stay in the detox center, but the companies are even shying away from that," said Shafa. "They're only taking the sickest of the crowd."

"The \$1,000 would be a lot cheaper for the insurance company than sending an addict to detox for five days, which is not long enough," said Charlie.

For the region's growing number of heroin addicts -- lured by its cheap price, much cheaper than OxyContin and other narcotics -- the chance for a relatively inexpensive and painless withdrawal like the pellet can't come fast enough. Experts who deal with addicts say the spaces in conventional detox facilities have become more rare as the number of addicts soars.

"I tried to get a kid in a (detox) program recently, and it's a

30-day period to even get a callback from these places," said Bill Phillips, who runs New Beginnings, a Framingham-based recovery program for drug and alcohol abusers. "They are backed up because of the influx of drugs.

"Also, insurance companies only pay for the first two to three days in a detox center, and how can that possibly help? You have to be totally detoxed to figure things out, before you can even consider going to Alcoholics Anonymous and Narcotics Anonymous."

Phillips said he has seen many addicts relapse after a regimen of Suboxone pills because they can't summon the willpower to avoid the settings and people that got them hooked in the first place.

"You can't be around the old friends and the old places anymore," he said. "The pills are only a temporary thing, like a cop slowing you down for traffic. You need an 'after' plan."

Phillips said the fastest-growing group of addicts is young people living in MetroWest's affluent suburbs.

"This is an epidemic," he said. "I know of five people who died from it...all from the Framingham, Milford and Ashland area." Most of them get started for recreational reasons, he added.

"The kids I deal with are affluent -- they are upper class; they have access to money and the freedom to go to parties in Worcester and Boston, where they get the drugs."

Others get hooked on heroin after they get addicted to painkillers following a medical problem. One of Shafa's patients, a heroin addict, moved to the drug after he became hooked on Percocet following wisdom tooth surgery.

Chris, a Hopkinton man who has been through Phillips' program, said many addicts become that way because they have addictive personalities.

"An addiction is hereditary," he said. "If you have that addictive trait, you can become more dependent on a substance."

Chris is now recovering thanks to Suboxone.

Charlie was taking Percocet and OxyContin after back surgery, became addicted and began buying those drugs illegally after his doctor refused to refill his prescriptions. When the drugs got too expensive and hard to find, he moved to heroin, and eventually was paying \$300 a day to shoot up 10 bundles, or 40 bags, of the drug.

His painting business began to falter, and he kept asking Ann for money "to pay his painters." The money actually went to his dealers.

Then, one day, Charlie's fiancée found him shooting up at their Hopkinton home. She rushed him into detox, and stayed by his side. Eventually, his relapses drove her away.

"I lost a \$300,000 home, my girlfriend of 12 years, my car, my yellow Lab dog...everything," Charlie said.

And he said he knows several people who lost their lives, including some from Hopkinton and Ashland.

The addiction also tested Charlie's relationship with his mother. Ann had to sell her Hopkinton home because her finances were depleted by Charlie's bills. This week she moved to a smaller Northborough home, which has an in-law suite for her son.

"I had to take away his car to keep him away from his dealer," she said. "The stress of thinking that my son would die was too much. I knew there would come a day when I would see him in a casket."

Will the Naltrexone pellets become an easy way for Charlie and others to break free? Like her son, Ann is putting all her hopes in the implant.

"This surgery happened for a reason," she said.

Charlie, who said he hopes to become a counselor for addicts some day, said he has been in touch with U.S. Rep. Jim McGovern, D-3rd, and U.S. Sen. Edward Kennedy, D-Mass., to push for putting the pellets on the fast track with the FDA.

"People need to be helped," he said, "because they can't control this."

The NaltrexZone(TM)

One South Centre Street
Suite 301
Merchantville, New Jersey 08109
856-663-4447

FROM NEW YORK AND NORTH

1. Follow **New Jersey Turnpike (Interstate 95)** South to **Exit 4** from New York.
2. From Exit 4 of NJ Turnpike go **North on Route 73** to Route 38.
3. Take **Route 38 West** two miles. (You will pass the Cherry Hill Mall on the right hand side of Route 38.)
4. After you pass the Cherry Hill Mall, **turn right at the first traffic light onto Chapel Avenue (North)**.
5. Proceed approximately 1.5 miles on Chapel Avenue until you come to a small circle. Do not turn around on the circle,
but bear to the **right through the circle. This becomes Centre Street.**
6. Proceed on Centre Street through **two traffic lights**.
7. We are located at the end of the block (after the second traffic light) at **ONE SOUTH CENTRE STREET on the right**.
There is a pharmacy on the opposite side of the street - Rite Aid.
8. **Turn right into the parking lot.** We are on the third floor.

FROM BALTIMORE AND SOUTH

1. Follow **Interstate 95 North** to the **Betsy Ross Bridge**.
2. Cross over the bridge into New Jersey.
3. Follow the overhead signs to "**Cherry Hill/ Haddonfield**" **Rt. 644**.
4. Take that exit. You will be on Haddonfield Road.
5. Continue to the 2nd traffic light - **Park Avenue**.
6. Turn **left** on Park Avenue.
7. Continue to the 3rd traffic light - **Centre Street**.
8. Turn **Right** on Centre Street.
9. Go down 1/2 block.
10. We are located at the end of the block (after the second traffic light) at **ONE SOUTH CENTRE STREET on the right**.
There is a pharmacy on the opposite side of the street - Rite Aid.
11. **Turn right into the parking lot.** We are on the third floor.

FROM PHILADELPHIA AND WEST

1. From Western Pennsylvania follow **Pennsylvania Turnpike** to Valley Forge Exit via **Interstate 76 to Interstate 676** to **Philadelphia**.
2. Follow **Interstate 676 (Schuylkill Expressway)** to exit for **Benjamin Franklin Bridge**..
3. After crossing the Benjamin Franklin Bridge, follow **Route 30 East to Route 130 North**.
4. Continue on **Route 130 North** for one mile. Watch for the signs for **Maple Avenue**. The sign will say **Merchantville via Federal Street**. Then it will say Maple Avenue.
5. **Turn right onto Maple Avenue. Go three traffic lights.**
6. Turn **Left onto Centre Street**. Proceed one and one-half blocks. Our office is on the right side of the street next to the Midlantic Bank at **ONE SOUTH CENTRE STREET on the right**..

7. **Turn right into the parking lot.** We are on the third floor.