THREATS TO COGNITIVE LIBERTY:
PHARMACOTHERAPY
AND THE
FUTURE OF THE DRUG WAR
The Center for Cognitive Liberty & Ethics (CCLE) is a nonprofit research and policy center devoted to protecting freedom of thought. Our mission is to develop and implement social policies that preserve and enhance freedom of thought into the 21st century.

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Executive Summary

Over the next decade an increasing number of new “pharmacotherapy” medications will become available with the potential to tremendously impact the use and abuse of illegal drugs and the overall direction of national and international drug policy. These pharmacotherapy medications are designed to block or significantly reduce the “highs” elicited by illegal drugs. Used as part of a drug treatment program, pharmacotherapy medications may provide valuable assistance for people seeking a chemical aid in limiting or eliminating problem drug use. However, the tremendously politicized nature of the “drug war” raises substantial concerns that, in addition to those who choose to use such medications, some people will be compelled to use them. In the absence of extraordinary circumstances, governmental action forcing or coercing a person to use a pharmacotherapy drug would violate a number of constitutional guarantees and other legal rights protecting people from forced medical treatment. Among the rights implicated by compulsory use of pharmacotherapy drugs are the right to informed consent, the right to bodily integrity and privacy, the protection against cruel and unusual punishment, and the right to freedom of thought.

INTRODUCTION

In this report, the Center for Cognitive Liberty & Ethics (CCLE) examines what we believe could become a significant future threat to cognitive liberty. With funding and other encouragement provided by the U.S. federal government, pharmaceutical companies are developing a new breed of drugs specifically intended to diminish or entirely block the effects of illegal drugs. The aim of these new “pharmacotherapy” drugs is to inhibit at the biochemical level the very ability of a person to experience the psychotropic effects of certain illegal drugs. Section I of this report begins with an overview of these new drugs: how they work, who is designing and marketing them, and how they may benefit those seeking a chemical aid in limiting problem drug use. In Section II we take a careful look at various factors that raise a reasonable concern that these pharmaceuticals will migrate from voluntary use to compulsory use within certain population segments. Section III identifies and discusses a number of constitutional and other legal issues that will arise should use of these drugs be mandated for some people. In Section IV, the final section of this report, we present our recommendations and conclusions.
1.1 FROM DEMAND REDUCTION TO DESIRE REDUCTION
1.2 PHARMACOTHERAPY DRUGS
1.3 PHARMACOTHERAPY: GOOD, BAD OR BOTH?
1.1 **FROM DEMAND REDUCTION TO DESIRE REDUCTION**

The United States is currently leading the world in an all-out “war on drugs.” The modern version of this war was declared on June 17, 1971, when former U.S. President Richard Nixon called on Congress to approve the Special Action Office of Drug Abuse Prevention that would consolidate Federal resources against “America’s public enemy number one.” Nixon declared that “in order to fight and defeat this enemy, it is necessary to wage a new, all-out offensive.” The ambitious goal of the drug war is to eradicate all use of illegal drugs, giving rise to “Drug-Free Workplaces,” “Drug-Free Borders,” “Drug-Free Families,” “Drug-Free Communities” and ultimately a “Drug-Free America.”

On June 17, 1971, President Nixon requested a $155,655,000 budget to wage the war on drugs for fiscal year 1972. Thirty-two years later, the federal budget requested for the war on drugs reached $12.6 billion dollars for the fiscal year 2005. Despite the federal government’s dedication to its task, and heavy-handed threats of imprisonment, fines, property forfeiture, loss of employment and even removal of one’s children, the Substance Abuse and Mental Health Services Administration (SAMHSA) estimates that 19.5 million Americans (age 12 or older) defy the law each month by using an illegal drug.

Even with widespread violation of the drug prohibition laws, and amidst rising national and international recognition of the folly of fighting a “war” on drugs, the US Drug Enforcement Administration (DEA) has vowed not to “punt on the third down.” Alongside efforts to reduce the supply and demand of illegal drugs, the federal government has begun pursuing a new tactic, one that expands the drug war battlefield from the Columbian coca farms and the Middle Eastern poppy fields, to a new terrain directly inside the bodies and brains of drug users.

In this new extension of the drug war, termed “pharmacotherapy,” the federal government is partnering with large and small pharmaceutical companies to develop a new breed of pharmaceutical drugs designed to padlock the brains of drug users so that even if a person ingests an illegal drug, the drug will be intercepted within the bloodstream or otherwise blocked from entering the brain. The American government’s hope is that demand for illegal drugs can be reduced, in part, by chemically eliminating the very desire to use an illegal drug.

1.2 **PHARMACOTHERAPY DRUGS**

The pharmacotherapy drugs that are the subject of this report fall into one of three general classes: (1) brain receptor blockers; (2) molecule binders; or (3) metabolism modifiers.
a) Receptor Blockers

The first class of drugs works by entering specific drug receptor sites on the surfaces of brain cells or neurons, thereby blocking illegal drug molecules from plugging into those receptor sites. Of these blockers, there are three basic types: agonists, partial agonists, and antagonists. Agonists are compounds that bind to receptors and produce significant physiological activity. Partial agonists are compounds that bind to receptors, but cause a relatively small amount of activation. Antagonists are compounds that enter receptor sites, but do not produce any physiological activity; they simply block the receptors. All of these compounds work by occupying receptor sites on the surfaces of neurons, thereby preventing molecules of the illegal drug from docking and producing their psychotropic effects.

b) Molecule Binders

In addition to receptor blocking compounds that act upon the neurotransmitter system, the second class of pharmacotherapy drugs works within the bloodstream, binding to an illegal drug molecule and thereby making it too large to pass through the blood-brain barrier. Because the illegal molecule is then unable to make it into the brain, it is prevented from producing any psychotropic effects.

c) Metabolism Modifiers

The final class of pharmacotherapy drugs alters the metabolism of certain target drugs, thereby causing a build up of toxic metabolic products that make a person feel extremely ill. The best known of these metabolism-modifiers is Antabuse® (disulfiram), a drug primarily used to discourage people from drinking alcohol.

1.21 Target: Opiates

Some pharmacotherapy drugs that block or reduce the effects of psychotropic drugs are already available. The best known is a agonist named methadone, which was initially developed as a long-acting analgesic. Methadone has been used for over thirty years as a government-sanctioned substitute for heroin and other illegal opiates. Methadone occupies the same opioid receptor site as heroin, but whereas heroin produces a significant feeling of euphoria, methadone, when used orally as prescribed, produces little euphoria. A methadone user who takes a typical street dose of heroin will feel practically no effect from the heroin because the methadone will have already entered the brain’s opioid receptor sites thus blocking the heroin from entering. Additionally, by occupying opioid receptor sites, methadone substantially reduces the unpleasant effects associated with withdrawing from heroin.

Another drug currently used to treat heroin addiction is naltrexone. This drug was created by DuPont Merck Pharmaceutical Corporation, and has
been available for use since the 1980s. Unlike methadone, which produces mild pleasurable effects, naltrexone is an antagonist that blocks the brain’s receptors for heroin and other opiates, and does not produce any pleasurable effects. When initially marketed as a treatment for heroin and other opiate addiction, it was named Trexan®. In 1994 the US Food and Drug Administration (FDA) also approved the use of naltrexone for alcohol addicts. When used to treat alcohol addiction, DuPont sells naltrexone under the trade name ReVia®.

DuPont has encountered several hurdles in marketing naltrexone to heroin and alcohol addicts. Presently, naltrexone is used by less than one percent of self-reported opiate addicts. There are a number of reasons why naltrexone has not been a popular medicine. First, the brain’s receptors cannot be labeled as “good” or “bad,” or as “government approved” versus “unapproved.” The opioid receptors play multiple roles, from pain reduction to euphoria production. Naltrexone fills the brain’s opioid receptors indiscriminately, which means it cannot tell an illegal opiate (like heroin) from a legal opiate painkiller such as Vicodin® (hydrocodone). As a result, a person taking naltrexone is placed in the precarious position of not being amenable to conventional opiate-based painkillers. For this reason, people taking naltrexone are advised to carry a card with them at all times, advising emergency medical personnel that the most common medications used to treat serious pain will have little or no effect on them.

Second, naltrexone cannot be given until after a patient is fully detoxified from opiates. If an active opiate user takes naltrexone, it will precipitate sudden and violent withdrawal.

Another problem for the makers of naltrexone was recently uncovered by researchers testing the drug on marijuana smokers. To the researchers’ surprise, people who were given naltrexone and then smoked marijuana reported that they felt greater psychotropic effects from the marijuana than if they had simply smoked the marijuana alone. In other words, while naltrexone blocks the psychotropic effects of alcohol, heroin and opium, it appears to increase the effects of marijuana.

In October 2002, the FDA approved two new medications for treating opiate addiction, both developed by Reckitt Benckiser Pharmaceuticals. The new drugs, Subutex® (buprenorphine hydrochloride) and Suboxone® tablets (buprenorphine hydrochloride and naloxone hydrochloride) contain buprenorphine, a partial opioid agonist. Like methadone, buprenorphine binds to the brain’s opioid receptors, but produces significantly reduced pleasurable effects than heroin.

Subutex and Suboxone are unique not so much for their chemical makeup or mode of operation, but for the regulatory hurdles they overcame. Unlike other pharmacotherapies for heroin addiction (e.g., methadone, naltrexone, ORLAAM), which can only be dispensed by specialized “Opioid Treatment Clinics,” specially-trained doctors are permitted to prescribe Subutex and Suboxone drugs in a standard office setting under the Drug Addiction Treatment Act (DATA) of 2000.
1.22 Target: Cocaine

With an estimated two million people in the United States using cocaine at least once a month,12 a number of pharmaceutical companies are working to develop drugs that will block the effects of cocaine. The National Institute of Drug Abuse (NIDA) has allocated $12 million to a five-year test of a “cocaine vaccine” currently known only as “TA-CD.”13 The drug is being developed by Xenova pharmaceutical company, and works inside the body by attaching itself to cocaine molecules and rendering them too large to pass through the blood-brain barrier.

In an early test, TA-CD was injected into mice, which were then fed cocaine. According to the researchers, none of the cocaine entered the brains of the mice. With periodic boosters, the “vaccine” reportedly remained effective for more than a year.14

In 1999, TA-CD was tested on human subjects. Volunteers were injected with the “cocaine vaccine” once a week for four weeks and, according to researchers, “antibody responses” lasted almost three months without any adverse effects. In October of 2003, Xenova began testing TA-CD in a randomized, placebo-controlled clinical trial involving 132 human subjects. They expect to complete this study in 2005 and move into Phase III studies.15

Another anti-cocaine drug is under development by Drug Abuse Sciences, Inc., a California company whose business plan is built solely upon developing pharmacotherapy drugs. Drug Abuse Sciences is racing to develop “DAS-431,” a “cocaine vaccine” that the company aims to release in both an injectable form as well as an inhalable aerosol.16

1.23 Target: Marijuana

A number of pharmaceutical companies are working to develop drugs that will block the marijuana “high” sought by the world’s estimated 144 million regular marijuana users.17 In 1988, researchers identified the receptors in the brain to which the marijuana molecule attaches. Named “Cannabinoid Receptor 1” (CB1), it became the site of intensive scientific research, subsequently leading to the discovery that the brain naturally produces several compounds that fit the CB1 receptors. One of these natural compounds was named “anandamide” from “ananda,” the Sanskrit word for “bliss.”

CB1 receptors are “extraordinarily abundant in the brain.”18 They are particularly ubiquitous in the basal ganglia and the cerebellum, which regulate and coordinate body movements. CB1 receptors are also abundant in the hippocampus, which plays a central role in learning and memory, and in the cerebral cortex, which is involved in integrating higher cognitive functions. To a lesser extent CB1 receptors can also be found in the heart, lung, prostate, ovary, testis, bone marrow, thymus, tonsils, and adrenal gland.19

Working with a grant from NIDA, scientists have created an anti-marijuana drug that occupies the brain’s CB1 receptors, thereby blocking marijuana from entering its host receptors.20 Created by the French pharmaceuti-
Pharmaceutical firm Sanofi-Synthelabo, and named “SR141716,” the drug may be the ultimate “buzzkill.”

In a test conducted in 2002, sixty-three adult males who smoked marijuana after taking 90 milligrams of SR141716 reported significant reductions in how “high” or “stoned” they felt. Even though blood tests showed that THC (tetrahydrocannabinol, the primary psychoactive principle in marijuana) was coursing through their veins, SR141716 was blocking the brain receptors that THC normally plugs into. The subjects reported that SR141716 reduced their marijuana high by as much as 75 percent.

Sanofi-Synthelabo believes a different formulation of the compound may also be effective in blocking the effects of cocaine. Under the tradename “Rimonabant,” Sanofi-Synthelabo is set to begin Phase II clinical trials aimed at determining whether SR141716 might also reduce the effects and desire for alcohol.

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**SR141716 vs. MARIJUANA EFFECTS**

“Participants received either placebo or active SR141716 before smoking marijuana and were then asked to describe, on a scale from 0 (not at all) to 100 (extremely), “How high do you feel now?” “How stoned on marijuana are you now?” and “How strong is the drug effect you feel now?” SR141716 (90 mg) reduced the maximum mean rating of the drug effects. Participants who received SR141716 also experienced smaller increases in heart rate after smoking marijuana.”

1.24 Targeting Legal Drugs

a) Target: Nicotine

At last count 71.5 million people in the United States use some type of tobacco product. The effects of nicotine on the brain are complex, but it is well established that the drug stimulates the production of dopamine, a neurotransmitter that produces feelings of pleasure and euphoria. Cigarette smokers enjoy the pleasurable effects of this legal dopamine surge. An increasing number of nicotine users, however, are becoming concerned about the associated health problems; each year two out of three cigarette smokers decide to try to quit smoking.

For many, quitting smoking does not mean quitting nicotine. The leading products in the smoking cessation market are Nicotine Replacement Therapy (NRT) products, marketed by pharmaceutical company GlaxoSmithKline. NRT products are available in four different forms: gum, patch, inhaler, and microtab. Products such as Nicorette® gum and the NicoDerm CQ® patch work by releasing nicotine into the body in a way that is reportedly less harmful than smoking tobacco. Nicorette’s market dominance is, in part, due to the fact that although it began as a prescription medication in 1984, the FDA approved it (and NicoDerm CQ) for over-the-counter sales in 1996. As a result, sales of both products soared.

Today, over one-third of Nicorette users report that while they are no longer addicted to cigarettes; they are now addicted to Nicorette. One such Nicorette user told the New York Times that after giving up cigarettes with the aid of Nicorette, she then found it exceptionally difficult to quit Nicorette. “I felt almost like a drug addict,” she said, estimating that the 12 pieces of Nicorette she chewed each day cost her more than $15,000 over the years, without curing her addiction to nicotine.

In May 1997, GlaxoSmithKline (then known as Glaxo Wellcome, Inc.) received FDA approval to market a sustained-release version of the antidepressant Wellbutrin® (bupropion hydrochloride) to smokers under the name Zyban®. Today, Zyban has captured one quarter of the smoking cessation market.

Nabi Biopharmaceuticals in Florida is developing what it terms a nicotine “vaccine.” Named NicVAX™ (Nicotine Conjugate Vaccine), the drug stimulates the human immune system to produce nicotine-specific antibodies that bind to nicotine molecules in the blood system, blocking nicotine from reaching the brain. A person who smokes a cigarette after taking NicVAX, does not feel any of the pleasurable effects normally associated with nicotine; as a result the person’s interest in smoking should diminish.

When tested in laboratory rats, NicVAX reduced the amount of nicotine reaching the brain by 64 percent. It is currently being tested in humans in the United States and the Netherlands.

U.S. DRUG USE STATS

- In 2002, an estimated 19.5 million Americans, or 8.3 percent of the population aged 12 or older, were current illicit drug users. Current drug use means use of an illicit drug during the month prior to the survey interview.
- Marijuana is the most commonly used illicit drug. 14.6 million people used marijuana at least once per month in 2002.
- In 2002, an estimated 2 million persons (0.9 percent of the US adult population) were current cocaine users, 567,000 of whom used crack.
- In 2002 hallucinogens were used by 1.2 million persons, including 676,000 users of Ecstasy.
- There were an estimated 166,000 current heroin users.
- An estimated 6.2 million persons, or 2.6 percent of the population aged 12 or older, were current users of psychotherapeutic drugs taken nonmedically. An estimated 4.4 million used pain relievers, 1.8 million used tranquilizers, 1.2 million used stimulants, and 0.4 million used sedatives.
- An estimated 120 million Americans aged 12 or older reported being current drinkers of alcohol in the 2002 survey (51.0 percent).
- An estimated 71.5 million Americans (30.4 percent of the population aged 12 or older) reported current use (past month use) of a tobacco product in 2002.

Source: 2002 National Survey on Drug Use and Health (US). [The report itself acknowledges that these figures underestimate the number of actual drug users. See “Appendix A: Description of the Survey.”]
The National Institute of Drug Abuse (NIDA) is taking the “vaccine” moniker literally. In the agency’s NIDA Notes newsletter, the institute reported that NicVAX might be useful not only for those people who want to stop smoking, but also as an inoculation for people who have never smoked. According to NIDA Notes, NicVAX “may even prove useful as an inoculation against nicotine addiction, much like those that protect children from tetanus, measles, and polio.”

b) Target: Alcohol

In the 1930s, workers at a rubber plant became violently ill after drinking alcohol. The cause of the illness was traced to tetraethylthiuram disulfide (aka disulfiram), a chemical used in the manufacturing plant. The discovery led to a new “treatment” for excessive alcohol use. Marketed under the trade name Antabuse® by the Wyeth-Ayerst Company, disulfiram prevents the body from properly eliminating alcohol, thereby causing a toxic accumulation of acetaldehyde in a drinker’s blood. When acetaldehyde builds up in the body, it causes a person to feel violently ill. A person who takes Antabuse and subsequently drinks alcohol will, within about fifteen minutes, experience a pounding headache, shortness of breath, violent vomiting, blurred vision, chest pain and dizziness. Symptoms usually disappear within 60 minutes, but can last for up to four hours. The Physicians Desk Reference lists “death” as a possible reaction when alcohol is consumed by a person taking Antabuse, and reports of actual deaths do exist.

Because Antabuse causes toxic concentrations of acetaldehyde whenever any alcohol is present, the consumption of any alcohol-containing medicines (cough syrup, flu medicines, mouthwash, etc.) or alcohol-containing foods can produce adverse reactions. Even alcohol absorbed through the skin, such as through the use of aftershaves, perfumes or shampoos, can trigger negative reactions.

1.3 Pharmacotherapy Drugs: Good, Bad or Both?

For people who decide that their use of a psychotropic drug is becoming problematic, pharmacotherapy drugs such as Zyban, naltrexone, or SR141716 may provide much-desired assistance in quitting or reducing drug use. While some people working in the drug treatment field are opposed to “using one drug to treat another” most people have welcomed the development of these new medicines. The CCLE looks forward to the time when pharmacotherapy medications will provide individuals with safe and effective tools to voluntarily mediate their use of drugs. For people who find that their use of drugs is causing problems in their lives, pharmacotherapy may prove beneficial in ending or reducing excessive or harmful use. The development of these drugs should be encouraged, and the CCLE supports their use by people who voluntarily choose to use them.
Step 1. Preclinical Testing
The company studies compound in laboratory and in animals, examining biological activity on targeted disease. Initial evaluation of safety.

Step 2. Investigational New Drug Application (IND)
The company files an IND with the U.S. Food and Drug Administration (FDA) seeking permission to test compound in humans, and describing results of preclinical tests. The IND automatically becomes effective unless the FDA rejects it within 30 days.

Step 3. Clinical Trials, Phase I
Compound is tested in 20 –100 healthy human volunteers to determine how the compound is absorbed, distributed, and metabolized in humans. Compound’s safety profile, dosage range, and duration of activity are assessed.

Step 4. Clinical Trials, Phase II
Compound is tested in 100 to 500 volunteer patients suffering with the targeted disease to assess compound’s effectiveness.

Step 5. Clinical Trials, Phase III
Compound is tested in 1,000 to 5,000 patients in clinics and hospitals. Physicians monitor patients closely to confirm efficacy and identify adverse events.

Step 6. New Drug Application (NDA)
All data is analyzed and presented to FDA.

Step 7. Approval
Compound is approved for physicians to prescribe if FDA concludes that it is safe and effective at treating the targeted disease. NOTE: Once a drug receives FDA approval for a targeted disease, a physician can prescribe it for other reasons.

Source: Adapted from http://www.fda.gov/cder/handbook/develop.htm
The CCLE is not unaware, however, that the development of pharmaceutical drugs – like drug prohibition itself — is driven more by politics and profits than by genuine public health concerns. If health concerns justified criminal prohibition, then cigarettes and alcohol would be illegal. Use of cigarettes is estimated to kill in excess of 425,000 people each year in the U.S. Dr. Alan Leshner, while serving as the head of the National Institute of Drug Abuse said that “[t]he use of tobacco products may be the Nation’s most critical public health problem.” Likewise, excessive alcohol consumption leads to as many as 85,000 deaths each year, 25,000 of which are just from alcohol-induced cirrhosis of the liver.

Marijuana stands in stark contrast to alcohol and nicotine, in just about every way. Marijuana is the most commonly used illegal drug in the world, regularly used by an estimated 144 million people worldwide. According to U.S. Government statistics, 40.4 percent of Americans have tried marijuana during their lifetime. It is one of the most studied drugs in history, and is regarded by many experts as far safer than alcohol. In 1988, Judge Francis Young, Chief Administrative Law Judge for the DEA at the time, presided over an extensive hearing on marijuana and concluded:

In strict medical terms marijuana is far safer than many foods we commonly consume. For example, eating ten raw potatoes can result in a toxic response. By comparison, it is physically impossible to eat enough marijuana to induce death. Marijuana, in its natural form, is one of the safest therapeutically active substances known to man.

While nicotine and alcohol are legal for adult use, a person who smokes marijuana – even an adult in the privacy of his or her own home – commits a federal crime. Even a cancer patient, whose own doctor approves of his or her medical use of marijuana, also commits a federal crime.

Given that marijuana has been safely used for centuries, while the anti-marijuana drug SR141716 has no history of human use, one cannot help but question whether “the cure” might be worse than “the illness.” And further, considering that less than three percent of marijuana smokers voluntarily seek treatment, it’s clear that SR141716 is a drug born almost entirely from the fact that the major harm associated with using marijuana is political in nature rather than medical.

Indeed, experts are increasingly pointing out that the policy of criminal drug prohibition is responsible for producing medical harm. Take, for example, heroin (diacetylmorphine), the drug commonly characterized as one of the most damaging of all illegal drugs. Heroin was created by the Bayer Pharmaceutical company in 1895 and was available as an over-the-counter pain medication until 1924. Today, as a result of criminal prohibition, heroin is only available on the black market and is commonly adulterated with admixtures that increase the health risks, including the likelihood of overdose. Additionally, under criminal prohibition, most states do not allow heroin users to obtain sterile syringes; users are left to re-use syringes and share these with other users.
One result is that needle sharing among injection drug users is now a major force driving the HIV/AIDS and hepatitis C epidemics in America.52

Perhaps most apropos for the topic of this report, a number of studies suggest that distributing naloxone hydrochloride to the friends and family of heroin users could save lives by providing people with an immediate way to treat a heroin overdose.53 The amount of the federal drug control budget allocated for efforts to supply naloxone to heroin users and those closest to them for voluntary use in emergency situations is zero.54 Thus, even with respect to heroin, drug prohibition cannot be defended as a rational federal policy designed to reduce medical harm.

What any given society, at any given time, views as unacceptable psychotropic drug use is largely a sociopolitical construct.55 As aptly noted by the British Medical Association:

Almost every psychoactive drug known to humanity, from alcohol to opium, has been regarded by some government and society as a dire threat to public order and moral standards, and by another government and another society as a source of harmless pleasure. Further, nations and governments sometimes change their views completely. Almost every society has at least one drug whose use is tolerated, while drugs used in other cultures are generally viewed quite differently and with deep suspicion. Mexican Indians may have disapproved of alcohol, but they used mescaline. Most Muslim cultures forbid alcohol, but they tolerate cannabis and opium.56

That being the case, a nation’s drug control policy becomes a tool for social control, a tool that can be directed and re-directed at the will of politicians and other powerful interests. This factor, along with several others that we discuss in the next section of this report, strongly suggest that use of pharmacotherapy drugs may not remain strictly voluntary for long. Rather, certain segments of the population could find use of these drugs becoming compulsory. If this is the case, as we believe it could be, these brain-policing drugs present an emerging threat to freedom of thought and to cognitive liberty.
### MEET THE NEUROCOPS

<table>
<thead>
<tr>
<th>Trade Name (Chemical)</th>
<th>ORLAAM (Levomethadyl hydrochloride acetate)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Company</td>
<td>Roxane Laboratories</td>
</tr>
<tr>
<td>Status</td>
<td>FDA approved 1995 for treatment of opioid</td>
</tr>
<tr>
<td>Target</td>
<td>dependence, withdrawn from market 2003/4.</td>
</tr>
<tr>
<td>Operation</td>
<td>Receptor blocker (mild agonist)</td>
</tr>
<tr>
<td>Acamprosate (calcium acetyl homotaurinate)</td>
<td>Rimonabant (SR141716)</td>
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<tr>
<td>Lipha S.A.</td>
<td>Sanofi-Synthélabo</td>
</tr>
<tr>
<td>Approved in Europe to reduce alcohol craving.</td>
<td>Phase III study completed as obesity treatment. Also being studied as treatment for marijuana dependence.</td>
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<tr>
<td>Receptor blocker</td>
<td>Receptor blocker (CB-1 cannabinoid antagonist)</td>
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<td>Antabuse (disulfiram)</td>
<td>Subutex (buprenorphine hydrochloride)</td>
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<td>Manufactured by PLIVA®, Inc. and distributed by Odyssey Pharmaceuticals, Inc.</td>
<td>FDA approved alcohol treatment. Also being tested as a cocaine treatment.</td>
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<td>Approved for cocaine treatment.</td>
<td>Metabolism Modifier</td>
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<td>Buprenorphine Depot (injectable, extended release form of buprenorphine)</td>
<td>DAS-431</td>
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<td>DrugAbuse Sciences</td>
<td>DrugAbuse Sciences, Inc.</td>
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<td>Pre-clinical development</td>
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<td>Receptor blocker (partial opioid agonist)</td>
<td>Receptor blocker (partial opioid agonist)</td>
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<td>Methadone</td>
<td>TA-CD (a cocaine derivative coupled to recombinant cholera toxin B)</td>
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<td>Distributed by Roxane Laboratories, Inc.</td>
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<td>FDA approved narcotic analgesic and heroin substitute.</td>
<td>Phase II</td>
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<tr>
<td>Receptor Blocker (agonist)</td>
<td>Molecule Binder designed to bind to cocaine in the blood and prevent cocaine molecule from crossing blood-brain barrier.</td>
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<td>Naltrel (Naltrexone)</td>
<td>Trexan, Revia (Naltrexone)</td>
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<td>DrugAbuse Sciences</td>
<td>DuPont Pharma</td>
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<td>Phase II trials</td>
<td>FDA approved alcohol and opioid treatment. Also being tested as a cocaine treatment.</td>
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<td>Receptor blocker (long acting injectable version of naltrexone)</td>
<td>Receptor blockers (agonist)</td>
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<td>Nicorette (Nicotine)</td>
<td>Vigabatrin (gamma-vinyl GABA, GVG)</td>
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<td>GlaxoSmithKline</td>
<td>Catalyst Pharmaceutical Partners</td>
</tr>
<tr>
<td>FDA approved (OTC) smoking cessation aid.</td>
<td>Approved in Europe to treat epilepsy. GABA inhibitor that blocks drugs like cocaine and nicotine from raising brain's dopamine levels.</td>
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<td>Receptor blocker.</td>
<td>Vivitrex (Naltrexone)</td>
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<tr>
<td>Nabi Biopharmaceuticals</td>
<td>In Phase III testing for alcohol treatment.</td>
</tr>
<tr>
<td>Phase II testing for smoking cessation.</td>
<td>Receptor blocker. (Vivitrex is a long acting (approx. 1 month) injectable version of naltrexone).</td>
</tr>
<tr>
<td>Molecule Binder designed to block nicotine from crossing blood-brain barrier.</td>
<td>Zyban (Bupropion)</td>
</tr>
<tr>
<td>GlaxoSmithKline</td>
<td>FDA approved for treating nicotine dependence.</td>
</tr>
<tr>
<td>A sustained-release version of the antidepressant Wellbutrin.</td>
<td></td>
</tr>
</tbody>
</table>
2.1 From drug war to drug epidemic
2.2 Neurocops: from voluntary to compulsory treatment
2.1 FROM DRUG WAR TO DRUG EPIDEMIC

Compared to other new pharmaceuticals that enter society facing primarily marketing challenges, the new pharmacotherapy drugs are unique because of the highly politicized environment in which they will be introduced. As discussed above, the development of these drugs cannot be separated from the political environment.

Since its very inception, the US government’s drug policy rhetoric and enforcement policies have conflated drug use with drug abuse. Research, however, indicates that the vast majority of people who use illegal drugs—like the vast majority of people who use legal drugs—do so without creating problems for themselves or others. Yet, the drug war paints one broad stroke that casts all illegal drug users as abusers. The fact that a person uses an illegal drug responsibly is not taken into account under present federal laws. Indeed, whether or not the person even uses the drug is irrelevant, as the federal law makes it a criminal offense merely to possess an illegal drug.

Beginning in the 1990s, the U.S. Government began to re-engineer its drug prohibition metaphor, recasting drug users not so much as “the enemy,” but rather as victims suffering from the “disease” of drug use and who desperately need treatment. In 1997 the disease metaphor was officially consecrated when the opening paragraph of that year’s National Drug Control Strategy report compared “drug abuse” to an “insidious cancer,” which “diminishes the potential of our citizens for full growth and development.”

“The metaphor of a war on drugs is misleading,” wrote then-Drug Czar General Barry McCaffrey in a section of the report titled “An Enduring Challenge”:

Wars are expected to end. Addressing drug abuse is a continuous challenge; the moment we believe ourselves to be victorious and free to relax our resolve, drug abuse will rise again. Furthermore, the United States does not wage war on its citizens, many of whom are the victims of drug abuse. These individuals must be helped, not defeated.

In this same section, General McCaffrey expanded the disease metaphor, writing:

A more appropriate analogy for the drug problem is cancer. Dealing with cancer is a long-term proposition. It requires the mobilization of support mechanisms — human, medical, educational, and societal, among others — to check its spread, deal with its consequences, and improve the prognosis. Resistance to its spread is necessary, but so is patience, compassion, and the will to carry on against its inroads. Pain must be managed while the root cause is attacked. The road to recovery is long and complex.

… The National Drug Control Strategy focuses government resources to help Americans make the right decisions — for
their individual well-being and for society — and to reduce the cancer of drugs in America.61

McCaffrey’s analogy to cancer is calculated. Cancer is the ultimate modern-day illness, the master disease we most fear. Susan Sontag has pointed out that “the use of cancer as a metaphor…amounts to saying, first of all, that the event or situation is unqualifiedly and unredeemably wicked. It enormously ups the ante. … To describe a phenomenon as a cancer is an incitement to violence. The use of cancer in political discourse encourages fatalism and justifies “severe” measures.”62 Although the rhetoric used by McCaffrey suggests an abandonment of the “war” metaphor (and with it the strategies, tactics, and fervor drawn upon in “wartime”), it is clear that the cancer metaphor is not so much a replacement for the war metaphor but rather a new front in that war. “The controlling metaphors in descriptions of cancer,” notes Sontag, “are, in fact, drawn from…the language of warfare…. talk of siege and war…has with cancer, a striking literalness and authority. Not only is the clinical course of the disease and its medical treatment thus described, but the disease itself is conceived as the enemy on which society wages war.”63

Just as our best scientists have been working for decades to find a “cure for cancer,” the “cancer of drugs” is now an illness in need of a medical cure. This line of thinking was made explicit in the 2001 National Drug Control Strategy report, which reported “just like other chronic diseases such as hypertension, diabetes, and cancer, for which medications have been developed, drug addiction is a disease that merits medication for its treatment.”64 Section II of the 2003 National Drug Control Strategy report, titled “Healing America’s Drug Users,” opens with a historical anecdote about how London’s 1854 cholera plague was stopped when Dr. John Snow realized that the infection was spreading via contaminated city water. The report views Dr. Snow’s strategy of “block[ing] the vectors that spread contagion,” as a way to “help us fight a modern epidemic—the spread of drug use and addiction.”65

Perhaps of most concern to the CCLE is the fact that the 2003 National Drug Control Strategy report drops even the pretense of distinguishing drug abuse from drug use. In fact, the 2003 report expressly targets “drug users” as the primary “vectors of contagion,” asserting:

[Drug use] spreads because the vectors of contagion are not addicts in the streets but users who do not yet show the consequences of their drug habit. Last year, some 16 million Americans used an illegal drug on at least a monthly basis, while 6.1 million Americans were in need of treatment. The rest, still in the “honeymoon” phase of their drug-using careers, are “carriers” who transmit the disease to others who see only the surface of the fraud. Treatment practitioners report that new users in particular are prone to encouraging their peers to join them in their new behavior.66

The way a problem is conceptualized or defined often dictates what measures will be employed to solve it.67 The fact that the government characterizes illegal drug users as “carriers” and “vectors of contagion,” and that some
of the new pharmacotherapy drugs have been given the moniker “vaccines,” would dovetail with a future move to make the use of pharmacotherapy drugs compulsory, at least for some segments of the population. Already “Priority 1” of the 2003 National Drug Control Strategy is titled “Stopping Use Before It Starts.” Although the 2003 report focuses on in-school lessons teaching students how illegal drug use is bad for a student’s health, the federal government’s focus on students has already gone far beyond “drug education.” Today, public school authorities are empowered to conduct random urine testing of students who wish to participate in any extracurricular activities, including the chess club. The new wave of pharmacotherapy drugs promises the ultimate tool for “Stopping Use Before It Starts.” Indeed, the 2002 National Drug Control Strategy report coined the new term “compassionate coercion,” noting:

… the overwhelming majority of users characterized with dependence or abuse do not see themselves as actually needing drug treatment. This tendency is particularly pronounced among adolescents and young adults. Of the estimated 3.9 million individuals who needed but did not receive treatment in 2000, fewer than 10 percent—just 381,000—reported actually thinking that they needed help. … But the obvious conclusion one would draw from the data is in fact the correct one: most people who need drug treatment do not think they have a problem. To borrow a popular phrase, they are in denial. If there were ever any question about the role of coercion in getting people into treatment, these findings should answer it.

Most drug users—the lucky ones, at least—are no strangers to coercion. People in need of drug treatment are fortunate if they run up against the compassionate coercion of family, friends, employers, the criminal justice system, and others. Such pressure needs no excuse; the health and safety of the addicted individual, as well as that of the community, require it.

The 2003 National Drug Control Strategy report adds that in addition to confrontations by family members and law enforcement officers, drug users may well require “the use of innovative techniques for fighting addiction, such as specialized pharmaceuticals.”

2.2 NEUROCOPS: FROM VOLUNTARY TO COMPULSORY TREATMENT

If, as the CCLE is concerned, the new pharmacotherapy drugs might later be mandated for certain segments of the population, who is most at risk? From 1907–1978 over 60,000 Americans were forcibly sterilized under state sterilization laws. These laws targeted criminals, the mentally handicapped, people with low IQs, and those suffering from mental illness.
Today the state and federal drug war is disproportionately focused on the poor and people of color. As speakers at a 2002 civil rights conference lamented, “Our criminal laws, while facially neutral, are enforced in a manner that is massively and pervasively biased. The injustices of the criminal justice system threaten to render irrelevant fifty years of hard-fought civil rights progress.” Nowhere is this truer than in the drug war. As noted by Human Rights Watch:

The racially disproportionate nature of the war on drugs is not just devastating to black Americans. It contradicts faith in the principles of justice and equal protection of the laws that should be the bedrock of any constitutional democracy; it exposes and deepens the racial fault lines that continue to weaken the country and belies its promise as a land of equal opportunity; and it undermines faith among all races in the fairness and efficacy of the criminal justice system. Urgent action is needed, at both the state and federal level, to address this crisis for the American nation.

People who have been arrested for drug offenses, or who are serving time in prison or jail for drug offenses, or who rely on public assistance or other public benefits would be the most vulnerable and likely first targets of any mandatory pharmacotherapy.

### 2.2.22.22.22.22.2 11111 Prisoners, Parolees, and Probationers

Today, of the two million prisoners in the United States, roughly one quarter are serving time for drug convictions. The US Supreme Court has held that “convicted prisoners do not forfeit all constitutional protections by reason of their conviction and confinement in prison.” However, because “rehabilitation” is one of the traditional purposes of criminal punishment, it is easy to see how pharmacotherapy medicines, which are characterized as “treating” drug addiction, could find their way into prisoners’ blood streams without their consent. In the near future, a person sentenced to prison for a drug offense might conceivably be forced to take an anti-drug medicine as part of his or her “rehabilitation.” Further, given that illegal drugs can reportedly be found in just about every prison in America, one can even imagine prison officials moving to mandate pharmacotherapy drugs for all inmates, regardless of their crime, as a means of maintaining prison security and safety.

In addition to the two million Americans currently serving time behind bars, an additional 4.7 million Americans are on parole or probation. Given a current prison, parole and probation population of roughly 6.7 million people just in the United States, the companies that are developing pharmacotherapy drugs cannot be unaware of this truly captive market. In an interview with the Wall Street Reporter, DrugAbuse Sciences CEO, Elizabeth Greetham, expressed excitement over the size of the pharmacotherapy “market.” After noting government statistics stating that 22 million individuals in the U.S. and Europe are alcoholics and eight million suffer from addiction to heroin, cocaine or methamphetamine, Ms. Greetham flushed:
We believe there are potentially more than double the number, if the undiagnosed patients are included. The numbers, to reiterate, are published by governments both in the U.S. and Europe. If we treat 300,000 patients for six months and charge typical daily therapy of around $4 per day, which is the usual charge for new medications today, we can generate $250 million worth of revenues to DrugAbuse Sciences. These numbers represent only 2.5 percent of the known treated market. Given the possible under-diagnosis, and since there’s very little competition in this field, we believe that addiction will be a multi-billion dollar market. DAS will only have to scratch the surface to be very successful for our investment group.78

Like any good entrepreneur, Ms. Greetham knows that any “market” can be grown with clever partnerships and marketing. Building the market for her company’s products is one of her primary goals. Again speaking to the Wall Street Reporter, Ms. Greetham stated:

…our company reminds me of Eli Lilly and Prozac in the depression field. In 1984, when I wrote up Prozac for the first time on Wall Street, there was a $200 million market for depression. The market today is now $10 billion. As Prozac and other products came in, the depression market evolved and elevated depression from being a closet disease to a fully recognized and accepted disease state. Our goal is to develop that addiction market and bring addiction out of the closet by bringing effective medications to the physician and patient. Financially, we can be highly successful, but we can also make a major breakthrough for society.79

One obvious way to grow her market would be to partner with the criminal justice system in an effort to have her company’s products made mandatory for the roughly 1,200,000 people arrested for drug offenses each year. DrugAbuse Sciences is in an excellent position to lobby for such coercive sales arrangements. In 2001, General Barry McCaffrey left his post as Director of the U.S. Office of National Drug Control Policy, and took a position on the DrugAbuse Sciences Board of Directors.80

a) “Chemical Castration:” A case study in criminal justice

In 1992, the US FDA approved a long-acting contraceptive device containing synthetic progestin medroxyprogesterone acetate (MPA) hormones. Manufactured by Pfizer, Inc., it is sold under the trade name Depo-Provera®. It is typically injected into a woman’s buttocks or upper arm, and renders her temporarily sterile for up to 3 months.81

Researchers discovered that MPA also had effects on men. When injected into a man, MPA accelerates the metabolism of testosterone while also suppressing its production. The result is a reduction of up to 75 percent in the amount of testosterone in the man’s body, thus “lowering the intensity of inappropriate sexual cravings and the frequency of unacceptable erotic pre-
occupations.” Its use in men is not without side effects, some of which include:

- increased appetite
- significant weight gain
- fatigue
- mental depression
- hyperglycemia
- impotence
- abnormal sperm
- lowered ejaculatory volume
- insomnia
- nightmares
- dyspnea (difficulty in breathing)
- hot and cold flashes
- loss of body hair
- nausea
- leg cramps
- irregular gall bladder function
- diverticulitis
- aggravation of migraine
- hypogonadism
- elevation of blood pressure
- hypertension
- phlebitis
- diabetic sequelae
- thrombosis (leading to heart attack)
- shrinkage of the prostate and seminal vessels

[Citations omitted.]

For some men suffering from an unhealthy obsession with sex, MPA could prove a helpful medicine. But, use of MPA quickly expanded beyond voluntary use. California, Florida, Georgia, Iowa, Louisiana, Montana, and Oregon have all passed chemical castration statutes. While these statutes vary, most provide a legislative authorization for court-imposed MPA injections as a probation condition for certain sexual offenses.

2.22 Public Assistance Recipients

People who rely heavily on public benefits also appear to be at an increased risk of finding themselves compelled to take pharmacotherapy drugs. This includes not only those Americans who receive welfare and other public assistance, but also the country’s 53.3 million public school children.

a) Public School Children

Each year roughly 97 percent of American school children are vaccinated against childhood diseases as a precondition to attending school. Almost 100 years ago, the United States Supreme Court ruled that there was nothing in the Constitution or elsewhere to prevent a state from mandating compulsory vaccination; today almost every state has laws requiring that children be vaccinated prior to entering the public school system. Parents who refuse to have their children vaccinated have been charged with neglect and even child abuse.

Many parents would undoubtedly rise in protest to any effort to include pharmacotherapy “vaccines” in the childhood vaccine program because drug use is not an infectious disease; however, government rhetoric is already laying the groundwork for responding to such parental objections. According to the 2001 National Drug Control Strategy, drug addiction, like infectious and biological diseases that can weaken a person’s immune system or bodily integrity, can also provide a fertile ground for other diseases to attack, “placing people at increased risk for a wide variety of other illnesses.” Elaborating on how drug disease breeds infectious disease concern, General McCaffrey writes:

Drug abuse, whether directly or indirectly, is now a major vector for the transmission of infectious diseases, including
Since its discovery just over 200 years ago, vaccination has become one of the most successful ways of treating infectious diseases. Infectious diseases tormented humans indiscriminately for thousands of years until a small town English doctor named Edward Jenner popularized vaccination as a medical treatment beginning in 1796. In earlier years, people had realized that once a person survived an initial infection or disease, it seldom, if ever, came back as strong. In the midst of a major smallpox epidemic that occurred at the end of the 18th century, Dr. Jenner discovered that by injecting a small amount of cowpox into a person, the person would become slightly ill for a short time, but would then recover, becoming almost immune to the otherwise deadly smallpox. Even though Dr. Jenner did not understand how or why the technique worked, there was no doubting its effectiveness, and vaccinations for smallpox quickly swept the industrially developing world.

It would take another hundred years before French chemist Dr. Louis Pasteur formally determined how the injection of weakened germs into the body could protect against a disease normally caused by those germs. Thus was born the modern technique of vaccination: intentionally injecting people with weakened or dead pathogens, and thereby triggering their immune system to produce antibodies against the injected virus. Before long, pharmaceutical companies were in the business of actually creating these weakened viruses and selling them in the form of vaccines. By the mid-twentieth century, vaccines existed for a host of infectious diseases including: polio, measles, mumps, rubella, hepatitis B and Hemophilus type B.

acquired immunodeficiency syndrome (AIDS), hepatitis B, hepatitis C, and tuberculosis. Increasing numbers of such cases are being reported among the partners of intravenous drug users. Most HIV-infected newborns have mothers who acquired this disease through their own drug use or sexual activity with a drug user.91

American schoolchildren are already subject to reduced constitutional protections. In 2002, the United States Supreme Court upheld drug testing of public school students wishing to participate in extracurricular activities on the ground that a public school has an “important interest in detecting and preventing drug use among its students.”92

In that case, the Supreme Court stated:

…the need to prevent and deter the substantial harm of childhood drug use provides the necessary immediacy for a school testing policy. Indeed, it would make little sense to require a school district to wait for a substantial portion of its students to begin using drugs before it was allowed to institute a drug-testing program designed to deter drug use.

Given the nationwide epidemic of drug use, and the evidence of increased drug use in Tecumseh schools, it was entirely reasonable for the School District to enact this particular drug testing policy.93

In the same opinion the Court remarked, “Schoolchildren are routinely required to submit to physical examinations and vaccinations against disease… Securing order in the school environment sometimes requires that students be subjected to greater controls than those appropriate for adults.”94

Lastly, on December 1, 2003, the National Institute of Drug Abuse (NIDA) published an official notice seeking grant applications focusing on “the identification, evaluation and development of safe and effective pharmacological treatments for cannabis-related disorders (CRDs).” A section of this notice, titled “Targeting Children,” explained:

Given the extent of the use of cannabis in the general population and the medical and psychological consequences of its use, particularly the clinically significant psychosocial impairment, there is a great public health need to develop safe and effective therapeutic interventions. The need to develop treatments targeting adolescents and young adults is particularly relevant in view of their disproportionate use patterns.95

Under the totality of the circumstances, the CCLE is thus concerned that government rhetoric equating the use of illegal drugs with infectious disease, combined with the already watered-down constitutional rights of children who attend public school, may set the stage for requiring the use of various pharmacotherapy “vaccines” as a precondition to attending public school or to participating in sports and other extracurricular activities.
b) Welfare and other Public Aid

The CCLE is also concerned that future recipients of public assistance may be threatened with compulsory pharmacotherapy as a condition to receiving benefits. Although studies indicate that welfare recipients do not use drugs in any greater percentage than working people, the stereotype of “drug-using welfare recipients” is widespread and has resulted in increased government control and denial of certain benefits.

Users of illegal drugs, for example, are excluded from the Fair Housing Act. Public housing can be denied to any person who has been convicted of a felony drug offense or who is known to currently use illegal drugs, even if they are in a drug treatment program.

Federal law imposes a lifetime bar on any individual convicted of a drug felony charge from receiving food stamps. People convicted of drug felonies are also barred from voting. The Washington Post reported in 1997 that 1.46 million black men out of a total voting population of 10.4 million have lost their right to vote due to felony convictions.

In 1996, Congress ended the federal welfare system as a cash assistance entitlement program. Under the new Personal Responsibility and Work Opportunity Reconciliation Act of 1996 (PRWORA), cash assistance for individuals is now limited and can be conditioned on meeting job-seeking requirements and adhering to personal responsibility codes. One provision of the new act authorizes states to impose mandatory drug testing as a prerequisite to receiving state assistance. As a result, Louisiana passed a law in 1997 requiring drug testing for welfare recipients and certain public employees. (A task force subsequently decided to limit testing to only those applicants who indicated on a questionnaire that they use illegal drugs). In 1998, Florida implemented a similar system. New Jersey, Minnesota, South Carolina and Wisconsin also randomly drug test welfare recipients with felony drug convictions.

In 1999 Michigan legislators passed a law conditioning public assistance on passing a random drug test. It was quickly struck down by a federal court, which ruled that the law’s suspicionless drug testing provisions were an unconstitutional infringement on aid recipients’ Fourth Amendment rights.

c) Norplant®: A case study in public assistance

Norplant® is a long-acting implantable contraceptive device for women. The FDA approved it for general use on December 10, 1990. Consisting of six match-sized plastic capsules containing the synthetic hormone Levonorpregestrel, the Norplant capsules are surgically implanted in a woman’s upper arm. Once implanted, the device releases levonorgestrel for as long as five years. During this period, the implanted woman is effectively sterile.

Norplant is considered very reliable and many women use it voluntarily. Use of Norplant, however, did not remain exclusively voluntary for long.
Less than one month after Norplant received FDA approval, a California court offered a woman a choice between serving a seven-year sentence for child abuse, or serving only one year and having Norplant implanted while on probation. The woman “chose” Norplant.107

Legislators in several states have seen Norplant as a way to entice welfare mothers to undergo temporary sterilization. A bill proposed in Mississippi sought to mandate the use of Norplant for female welfare recipients, requiring “women with four or more children to be implanted with Norplant in order to qualify for or continue to be eligible for public assistance.”108

A Kansas Legislator introduced a bill in 1991, that would have paid welfare mothers $500 if they would consent to using Norplant, and an additional $50 for each year that they remained on the contraceptive.109 After the bill failed, its author proposed a second bill that would make the insertion of Norplant a condition of probation for women convicted of certain drug possession offenses.110 The bill did not pass. Representative David Duke of Louisiana, (a former leader in the Ku Klux Klan who ran for President of the United States in 1992) unsuccessfully introduced a similar bill in 1991, which would have paid welfare mothers $100 per month if they agreed to Norplant.111

Judicial and legislative efforts to impose Norplant in such coercive circumstances raise concerns that similar efforts by judges and legislators may surround the new pharmacotherapy drugs.
III

3.1 Constitutional and other legal concerns
3.2 The right to informed consent
3.3 Cruel and unusual punishment
3.4 Freedom of thought
3.1 CONSTITUTIONAL AND OTHER LEGAL CONCERNS

The compelled use of pharmacotherapy would raise a number of constitutional and other legal issues. Inasmuch as the US government has adopted an illness metaphor, and expressly analogized the use/abuse of drugs to cancer, the potential for constitutional violations is underscored. It is well known and widely accepted that treating cancer often requires drastic measures, which knowingly compromise the health of other body systems. When treating cancer, notes Susan Sontag, “[i]t is impossible to avoid damaging or destroying healthy cells (indeed, some methods used to treat cancer can cause cancer), but it is thought that nearly any damage to the body is justified if it saves the patient’s life.”112 Inasmuch as substantial damage has already been done to the US Constitution in order to fight the war on drugs,113 all signs foreshadow a continued narrowing of our rights, justified as an unavoidable side-effect of waging war on the “cancer” of drug use/abuse.

Among the rights implicated by compulsory use of pharmacotherapy drugs, is the right to provide informed consent before receiving medical treatment, the constitutional protections against cruel and unusual punishment, bodily integrity and privacy, and the right to freedom of thought. Because our assessment leads us to conclude that three segments of society (prisoners, probationers, and public benefit recipients) are most likely to come under pressure for compulsory pharmacotherapy, we address their unique concerns within each section.

3.2 THE RIGHT TO INFORMED CONSENT

As discussed earlier, the 2002 National Drug Control Strategy report coined the term “compassionate coercion” and promoted it as a key element for success. The White House press release announcing the report explained that in addition to pressure from family, friends, employers, and the community, “[c]ompassionate coercion also uses the criminal justice system to get people into treatment.”114

How exactly “compassionate coercion” will work in practice has yet to be seen, but the term itself, especially when accompanied by statements like those surrounding the 2002 and 2003 reports, foreshadow interventionist government actions that would be at stark odds with a number of well-established legal rights.

The Supreme Court has recognized a constitutional right to bodily integrity that includes the right of a person to make voluntary and informed decisions about medical treatment.115 The government’s concept of “compassionate coercion” appears to turn upside-down the individual’s right to informed consent. All fifty states have laws that protect informed consent. These laws require that before performing medical procedures or treatments, medical personnel must make certain disclosures to patients and obtain the patient’s consent.116
In general, informed consent requires the satisfaction of two conditions. First, trained medical personnel must tell the person to be treated what alternative treatments exist, the benefits and dangers associated with the proposed treatment, and the disadvantages of forgoing treatment. Second, once the person has received all the relevant medical information, he or she must freely and voluntarily decide whether or not to undergo the treatment.\footnote{Coercion is anathema to informed consent, as emphasized by a US Department of Health and Human Services regulation defining informed consent:}

\begin{quote}
Informed consent means the knowing consent of an individual or his legally authorized representative, so situated as to be able to exercise free power of choice without undue inducement or any element of force, fraud, deceit, duress, or other form of constraint or coercion.\footnote{Coercion, whether “compassionate” or otherwise, is still coercion. Indeed, “compassionate coercion” can be more insidious. As one of America’s most prominent Supreme Court justices warned decades ago: “Experience should teach us to be most on our guard to protect liberty when the government’s purposes are beneficent... . The greatest dangers to liberty lurk in insidious encroachment by men of zeal, well meaning but without understanding.”}
\end{quote}

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Although it is a criminal offense to use or possess drugs like marijuana, opium, and cocaine for nonmedical purposes, a person who desires medical treatment for his or her drug use does not forfeit the right to decide whether to utilize drug-based medical treatment. There is no “drug war exception” to informed consent requirements. The only exception to requirements for informed consent arises when a person has been declared mentally incompetent, or is too young to make his or her own medical decisions. The overwhelming majority of people who use illegal drugs do not fall into either category and thus the doctrine of informed consent should stand as a strong barrier to coercive pharmacotherapy.

\section*{3.21 Prisoners}

As noted in Section II of this report, people serving time in prison – especially for drug offenses – would appear to be prime candidates for coercive pharmacotherapy. Prisoners are politically weak and generally regarded unsympathetically by the general populace. Further, prisoners appear to be one of the express targets for “compassionate coercion,” which “uses the criminal justice system to get people into treatment.”\footnote{Coercion, whether “compassionate” or otherwise, is still coercion.}

Although prisoners do not enjoy the same rights as nonincarcerated Americans, prisoners retain their right to give informed consent before being the subject of a medical procedure or treatment. Thus, unless a court has determined that a prisoner is mentally incompetent, the informed consent requirements discussed in the previous section retain their validity within the prison context.

While no court, let alone the United States Supreme Court has ruled on the circumstances in which a prisoner can be forced to undergo pharmaco-
therapy for illegal drug use, the Supreme Court has placed strict limits on when prison officials can force a prisoner to take psychotropic medication. A prisoner can be compelled to take psychiatric medication in only two circumstances. First if he suffers from a serious mental illness that renders him mentally incompetent to make his own medical decisions, prison medical authorities are permitted to forcibly treat the prisoner, so long as the treatment is in the best interests of the prisoner and complies with due process. Second, a prisoner whose mental illness leads him or her to engage in dangerous behavior that threatens to harm other prisoners or prison staff, may be forcibly treated with psychotropic medication. This ruling is based on the unique safety and security issues within prisons.

These rulings instruct that in all but extraordinary circumstances (those meeting the factors noted in the above cases) prison authorities would be acting unlawfully if they were to compel a prisoner to take a pharmacotherapy drug against his or her will. The mere fact that a person has used illegal drugs is not regarded by clinicians as a “mental disorder,” and an insufficient reason to find the person mentally incompetent. Thus, unless a prisoner is dangerous to others, or is truly mentally incompetent, he or she has a right to refuse pharmacotherapy drugs and a right to give informed consent before receiving them.

3.22 Probationers

The overwhelming majority of people charged with violating federal or state drug prohibition laws are placed on probation, rather than incarcerated. The United States Supreme Court has held that the purpose of probation in criminal cases is to provide a period of grace in order to aid the rehabilitation of an offender. Most states have laws that require sentencing courts to impose various requirements on probationers, which must be satisfied in order to successfully complete probation and thereby avoid spending time in custody. So long as they are reasonably related to rehabilitation and are not blatantly unconstitutional, relatively few limitations exist on a trial judge’s discretion to impose particular probation conditions. As one law review author noted:

Courts have quite accurately described the scope of the sentencing court’s discretion as “breathtaking,” and commentators have observed that any legislative limitations on that discretion are “conspicuously absent.” One recent media account suggested that the content of special conditions “is limited only by the sentencing judge’s imagination.” [Footnotes omitted.]

People granted probation in drug cases are routinely required to: waive their Fourth Amendment rights by agreeing to be searched at any time; submit to regular and sometimes random drug testing; and successfully complete a drug treatment program. Considered in light of the federal government’s acknowledgment that “compassionate coercion also uses the
criminal justice system to get people into treatment,” some future courts may attempt to impose pharmacotherapy as a condition of granting probation in drug cases. As discussed in Section II, several states have enacted laws that authorize courts to impose the use of Norplant® or Depo-Provera® on grants of probation. Further, while no reliable statistics exist on its prevalence, the CCLE is aware that some courts have conditioned a grant of probation for alcohol-related offenses on the probationer using Antabuse.129

As noted earlier, informed consent requires, at a bare minimum, adequate information about the possible risks and benefits of a given medical treatment, as well as an environment free of coercion. A criminal courtroom is an unlikely venue for satisfying either requirement for informed consent. Few judges, prosecutors, probation officers, or defense attorneys have the medical training necessary to make the required advisements to the defendant. Thus, a defendant who is offered probation on the condition that he or she undergo pharmacotherapy will likely be placed in the position of having to make a medical treatment decision without the appropriate information, thereby vitiating informed consent. Further, being forced to choose between imprisonment or “medical treatment” with a pharmacotherapy drug is inherently coercive. There are very few things that people will avoid more than going to jail or prison. Informed consent is incompatible with inherently coercive situations that force a person to barter his or her natural neuro- and biochemistry in exchange for freedom.

### 3.23 Public Assistance Recipients

As discussed in Section II, the history of legislation seeking to link certain public assistance benefits with the use of the implantable contraceptive Norplant, suggests that future legislation might be premised on conditioning certain public benefits, in particular, “welfare” on the use of pharmacotherapy. Such legislation, should it be introduced, would raise substantial informed consent concerns. The CCLE can anticipate several versions of legislation that would connect public aid to pharmacotherapy. In order of increasing concern, these are: 1) offering to reimburse public benefit recipients for the cost of undergoing pharmacotherapy; 2) offering a financial incentive (e.g., a “bonus” payment), for agreeing to undergo pharmacotherapy; 3) requiring pharmacotherapy in order to receive public aid.

#### a) Reimbursing Voluntary Pharmacotherapy

Reimbursing public assistance recipients for the costs of voluntary pharmacotherapy would be good public policy, just as it is good public policy to provide low-income persons with drug treatment on demand. If a person in poverty voluntarily seeks drug treatment, with or without pharmacotherapy, they should not be turned away for lack of money, especially when the government is enthusiastically willing to spend thousands of dollars to arrest and imprison that same person for using a controlled substance. In this case, money devoted to arresting drug users would be far better spent, by reallo-
cating it to reimbursing indigent people for the costs of voluntarily undergoing pharmacotherapy or non-drug treatment. As long as accurate information is provided to the person concerning the purposes, risks and effects of pharmacotherapy, the CCLE’s analysis concludes that reimbursing low-income people (as well as the non-poor) for the costs of voluntary pharmacotherapy satisfies the requirements of informed consent.130

b) Financial Incentive to Undergo Pharmacotherapy

Another foreseeable form of public benefit legislation might offer a financial incentive, or bonus, for agreeing to undergo pharmacotherapy. In this scenario, the public aid recipient would receive the standard aid payment regardless of whether he or she underwent pharmacotherapy, but would receive an additional bonus payment if he or she agreed to undergo pharmacotherapy. Such a scheme would raise difficult informed consent issues. In order to obtain the added financial benefit, many low-income people, even those who do not use or desire to use illegal drugs, might decide to undergo pharmacotherapy. The desire to rise above poverty, even just a bit, is a powerful drive, and could lead some people to undergo pharmacotherapy even if it was contraindicated or potentially risky given other health issues they might be dealing with. Fundamentally, the CCLE believes that what economic “coercion” may exist in this scenario is little, if at all, different from the “coercive” aspect of any economic decision. More worrisome, we believe, is that people living in poverty typically have reduced access to professional medical advice concerning elective procedures. As a result, they may find it very difficult to obtain general information about the potential health risks associated with a particular pharmacotherapy drug, as well as specific information regarding their own health concerns vis-à-vis such a drug. Consent under such circumstances would not be informed.

c) Conditioning Public Benefits on Pharmacotherapy

The most inherently coercive type of foreseeable legislation linking pharmacotherapy with public aid would be the direct conditioning of such aid on the use of a pharmacotherapy drug. Under this potential legislative scheme, only those who agreed to undergo pharmacotherapy would be eligible for public aid. While less coercive than being physically forced to undergo pharmacotherapy, a parent who is dependant upon receiving Aid For Dependant Children in order to pay rent or buy food for his or her kids would undoubtedly feel powerless to refuse pharmacotherapy if it meant forfeiting the financial aid. Such a scheme would be overtly and intentionally premised on economic coercion, and would thus vitiate the possibility of free and uncoerced consent. Combined with the very limited, and sometimes completely absent, access to professional medical advice – making it difficult for the person to obtain information about the risks and effects of pharmacotherapy – such a legislative scheme would encourage the antithesis of informed consent.
3.3 CRUEL AND UNUSUAL PUNISHMENT

Compelling a prisoner, parolee or probationer to take a pharmacotherapy drug, assuming the person is not mentally incompetent or dangerous, is akin to torture or barbarism. It treats the person as a means, rather than an end, and ought to be considered cruel and unusual punishment.

There is an unfortunate worldwide history of prisoner-abuse, including within the United States. In the 1920s, U. S. prisoners were routinely labeled as genetically unfit and then forcibly sterilized. Believing that such sterilization improved society, approximately 60,000 incarcerated or mentally handicapped people were sterilized in the United States between 1907 and the mid-1970’s.

The American eugenics movement reached its zenith in 1927 with the Supreme Court’s decision in *Buck v. Bell*, wherein the Court upheld the sterilization of mentally challenged women as both constitutional and good for society. The highest court of Maryland recently deplored this unfortunate chapter of American jurisprudence:

“[O]ur own use of prisoners, the institutionalized retarded, and the mentally ill to test malaria treatments during World War II was generally hailed as positive, making the war ‘everyone’s war.’ Likewise, in the late 1940’s and early 1950’s, the testing of new polio vaccines on institutionalized mentally retarded children was considered appropriate. Utilitarianism was the ethic of the day.”

Not until 1942 did the United States Supreme Court hold that it was unconstitutional to permanently sterilize people convicted of criminal offenses.

The Eighth Amendment prohibits “cruel and unusual punishment,” and many state constitutions provide independent protections. Prisoners, parolees, and probationers all come within the Eighth Amendment’s protection. Forcing such a person to undergo pharmacotherapy against his or her will, when other less invasive, less intrusive, and less coercive means are available for treating the person, is a form of torture and retribution. Blocking a person’s brain receptors with a pharmacotherapy drug because their crime was filling those receptors with an illegal drug, harkens back to archaic notions of retributive punishment such as “an eye for an eye, or a hand for a hand.”

Pharmacotherapy is not without side effects, and these may well render its compulsory use on prisoners, parolees or probationers “cruel and unusual.” Most of the pharmacotherapy drugs are so new that it has yet to be determined whether they will produce long-term side effects, or even what health risks may arise after several weeks, months or years of use. Inasmuch as many of the pharmacotherapy drugs work by targeting parts of the brain, and others work by systemically altering a person’s metabolism, the health risks associated with their use are potentially significant. Compelling a prisoner to use pharmacotherapy drugs would force that person to risk suffering side

Cyberpunk science fiction drizzles in coercive pharmacotherapy. In the quintessential cyberpunk novel, *Neuromancer* (1984) an “addiction” to cyberspace becomes the target not of government, but corporate retributive malice. The protagonist has his delicate nervous system damaged with the forced application of a Russian mycotoxin to punish him for data thievery. As a condition of employment, his pancreas is replaced and his liver is blocked so that he cannot experience the effects of amphetamines.
effects or other serious adverse reactions from the drug. This would be both psychologically and physiologically cruel.

Future proponents of compulsory pharmacotherapy within the criminal justice system will likely characterize pharmacotherapy as “rehabilitative” or “treatment-oriented” in nature, in an effort to distinguish it from “punishment.” Although the term “pharmacotherapy” implies that the drugs provide a sort of “therapy,” it would be superficial to conclude on that semantic basis that they could not be used for nontherapeutic purposes. Future legislation seeking to authorize the compulsory use of “pharmacotherapy” for some or all prisoners, parolees, or probationers, under the guise of “treatment” or “rehabilitation” would not be immune to judicial scrutiny under the Eighth Amendment. The legislative classification of a statute as authorizing “therapy” or “treatment” is not conclusive in determining whether there has been a violation of the Eighth Amendment.139

Until 1973, “homosexuality” was listed as a psychiatric disorder in the Diagnostic and Statistical Manual of Mental Disorders (DSM). Up until June 2003, when the United States Supreme Court declared them unconstitutional,140 thirteen states had laws making it a criminal offense to engage in consensual homosexual sex. In some of these states, people who admitted that they were homosexual, or who were “accused” of being gay or lesbian, were subject to involuntary confinement under mental health laws, and subjected to “reparative therapy” designed to forcibly convert them into heterosexuals.141 “Treatment,” in addition to counseling, included penile plethysmograph shocks (electronic shock triggered by penile erection), drug-ging, and hypnosis. Some state laws even permitted the forcible sterilization of homosexuals.142

Drug use, like homosexuality, has a ubiquitous presence throughout history and across cultures.143 Like homosexuality, drug use and drug prohibition is the subject of contention and controversy. The discussion of both topics is often influenced by ignorance, fear and avoidance, conflicting moral and religious dogmas, and contrasting political aims. History has a way of showing that the forced “treatments” of today, will tomorrow be seen as cruel, unusual, and barbaric punishment.

3.4 FREEDOM OF THOUGHT

Consciousness may turn out to be the ultimate mystery, resistant to self-interrogation. Whatever may be at the roots of human consciousness, there is no debate that what, and how, a person thinks is deeply intertwined with his or her functional neurochemistry.144 Simply put, controlling what chemicals can or cannot reach a person’s brain synapses, directly affects how that person thinks. As a result, compelling a person to use a pharmacotherapy drug not only implicates the person’s traditional rights to bodily integrity and informed consent, it also implicates the fundamental right to freedom of thought.

Americans have always cherished freedom of thought. While the phrase “freedom of thought” is not explicitly used in the United States Constitution,
it has long been recognized as a fundamental right of equal stature to the express constitutional guarantees. As Supreme Court Justice Benjamin Cardozo observed, “freedom of thought ... is the matrix, the indispensable condition, of nearly every other form of freedom. With rare aberrations a pervasive recognition of that truth can be traced in our history, political and legal.”

The Supreme Court has repeatedly recognized that freedom of thought is one of the most elementary and important rights inherent in the First Amendment. Without freedom of thought, freedom of speech is moot. You cannot express what you cannot think. Likewise, you can only express what you can think. Chemical manipulation of the brain, therefore, could become the ultimate prior restraint on speech.

In West Virginia State Board of Education v. Barnette, 319 U.S. 624 (1943), the Supreme Court, in an 8-1 decision, invalidated a school requirement that compelled a flag salute on the ground that it was an unconstitutional invasion of “the sphere of intellect and spirit which it is the purpose of the First Amendment to our Constitution to reserve from official control.” The First Amendment, declared the Court, gives a constitutional preference for “individual freedom of mind” over “officially disciplined uniformity for which history indicates a disappointing and disastrous end.” At the center of our American freedom, is the “freedom to be intellectually and spiritually diverse.”

In Wooley v. Maynard, 430 U.S. 705 (1977), the Supreme Court invalidated a New Hampshire statute that required all noncommercial vehicle license plates to bear the state motto “Live Free or Die,” finding the requirement inconsistent with “the right of freedom of thought protected by the First Amendment.”

In Stanley v. Georgia, 394 U.S. 557 (1969), the Supreme Court struck down a Georgia law that banned the private possession of obscene material, finding the law “wholly inconsistent with the philosophy of the First Amendment.” “Our whole constitutional heritage,” explained the Court, “rebels at the thought of giving government the power to control men’s minds.” Justice Harlan, concurring in United States v. Reidel, 402 U.S. 351 (1971), characterized the constitutional right protected in Stanley as “the First Amendment right of the individual to be free from governmental programs of thought control, however such programs might be justified in terms of permissible state objectives,” and as the “freedom from governmental manipulation of the content of a man’s mind....” If “[o]ur whole constitutional heritage rebels at the thought of given government the power to control men’s minds,” as made clear by the United States Supreme Court, then our whole constitutional heritage must likewise rebel at the thought of giving government the power to compel a person to use a pharmacotherapy drug – a drug designed and intended to lockdown certain receptor sites in the brain.

Inasmuch as one’s thoughts and thought processes are the very core of one’s individuality and the root of both freedom and responsibility, permit-
ting the state to forcibly pierce a person’s body to insert a pharmacotherapy drug that is designed to patrol or police that person’s body for the purpose of controlling possible brainstates, grants the state the ultimate power over the individual. Such a power is incompatible with a democracy built upon the premise of individual freedom and limited government. It is a clear violation of the fundamental right to freedom of thought.
IV

4.1 RECOMMENDATIONS

4.2 CONCLUSION
4.1 RECOMMENDATIONS

Based on our analysis as detailed in this report, the CCLE makes the following recommendations to policy makers, judges and other interested organizations and individuals.

1. Pharmacotherapy drugs hold great promise for people who desire a chemical aid for limiting or eliminating their use of certain drugs. Their development should be encouraged and their voluntary use supported.

2. Public benefits should not be conditioned on the use of pharmacotherapy drugs, nor should the government provide a bonus for using them. A portion of federal and state funds currently devoted to arresting users of illegal drugs should be reallocated to provide funds for reimbursing, in whole or in part, poor and indigent people who make an informed and voluntarily decision to undergo pharmacotherapy or other drug treatment.

3. Federal and state lawmakers should enact laws providing that no person shall be required to use a pharmacotherapy drug as a condition to receiving public assistance or any other public benefit.

4. Federal and state lawmakers should enact laws providing that in the absence of extraordinary circumstances clearly stated on the record and subject to appellate review, the use of pharmacotherapy may not be imposed as a term of a criminal sentence, or as a condition for parole or probation.

5. Courts should find that in the absence of extraordinary circumstances government actions that compel a person to use a pharmacotherapy drug are unconstitutional violations of the right to freedom of thought, the right to bodily integrity and privacy, and of statutory and common law rights to informed consent. In the case of prisoners, parolees, or probationers who are compelled to use a pharmacotherapy drug against their will, courts should additionally find that the Eighth Amendment protection against cruel and unusual punishment is violated.
4.2 CONCLUSION

While the state has long had the power to restrain a person’s body (e.g., by handcuffing arms and legs, or imprisoning), the compelled use of pharmacotherapy would open chilling new dimensions in the power relationship between citizens and their government. Compulsory use of pharmacotherapy would signal a striking expansion of the state’s policing mechanisms on at least two new fronts: 1) from external policing to internal policing; and 2) from restraining a person’s physical body and behavior, to directly restraining a person’s thoughts and thought processes. Such a dramatic extension of government power would be unprecedented.

Sixty years ago the United States Supreme Court opined, “[r]eedom to think is absolute of its own nature; the most tyrannical government is powerless to control the inward workings of the mind.” *Jones v. Opelika*, 316 U.S. 584, 618 (1942). No longer. Pharmacotherapy drugs now give the government that power. The question for the future is whether the introduction of these drugs into society will be done in such a way that preserves freedom of thought by upholding informed consent and rejecting compulsory treatment programs, or whether certain people will be coerced into using pharmacotherapy, thereby promoting governmental tyranny of thought processes.


A 2003 report by the nonprofit Drug Policy Alliance takes issue with the math behind federal budget accounting, noting that budget “conceals billions of dollars spent on incarcerating drug offenders and certain law enforcement efforts by excluding these categories from the budget, while including inflated expenditures on treatment services.” According to the Drug Policy Alliance, the actual amount spent is closer to $20 billion. Drug Czar’s Office Masks True Costs of War on Drugs in Federal Budget Released Today. (2003, February 12). Drug Policy Alliance. http://www.drugpolicy.org/news/pressroom/pressrelease/pr021203.cfm (for press release)


11 ORLAAM® (Levomethadyl hydrochloride acetate) is a synthetic opioid agonist which was approved by the FDA for the management of opiate dependence in 1996. After receiving increasing number of reports of severe heart problems associated with use of ORLAAM, it was removed from the European market in 2001. In August 2003, Roxane Laboratories, the manufacturers of ORLAAM, announced that it would be discontinuing the sale and distribution of ORLAAM “after the current inventory is depleted” (estimated to occur in Spring 2004). Schobelock, Michael. (August 23, 2003) “Product Discontinuation Notice, ORLAAM® (Levomethadyl hydrochloride acetate) Oral Solution, 10 mg/ml, CII. http://www.fda.gov/cder/drg/shortages/orlaam.htm.


20 Ibid.


41 Koff, Papadimas, & Honig. “Alcohol in Cough Medicines Hazard to Disulfiram
48 Ibid.
54 Ibid.
57 Substance Abuse and Mental Health Services Administration. (2003). Results from the 2002 National Survey on Drug Use and Health: Detailed Tables. Table 1.1.B. (Office of Applied Studies, Department of Health and Human Services). Rockville, MD. http://www.samhsa.gov/oaas/nhsda/2k2ndsduh/Sect1peTabs1to18.pdf; The number of Americans who have used marijuana in the last year (25,755,000) is greater than the entire population of Texas (20,851,820). (Ibid. And United States Census Bureau Report for 2000. Summary File 4. http://www.census.gov/)
60 19 U.S.C. 844
61 Although nine states currently provide legal protections for patients who use marijuana for medical purposes, the federal government is staunchly opposed to even the medical use of marijuana. The US Department of Justice even went so far as to threaten physicians with the loss of their prescribing privileges for so much as discussing marijuana’s medicinal properties with their patients. However, the Ninth Circuit Court of Appeals ruled that doctors have a First Amendment right to freely discuss any potentially beneficial treatment, including marijuana, with patients. The United States Supreme Court, refused to hear the Justice Department’s appeal of the Ninth Circuit ruling, thereby letting the ruling in favor of doctors and patients stand. Conant v. Walters, 309 F.3d 629. 9th Cir. (2002). conlanon denied Walters v. Conant, 124 S.C. 387, 157 L.Ed.2d 276 (U.S. October 14, 2003). Given the abundance of CB1 receptors in the brain, blocking them indiscriminately with an antagonist like SR141716 is likely to produce complex physiological and psychological effects that have yet to be understood or even identified. In 2003, for example, Roxane Laboratories, Inc., discontinued sale and distribution of the opioid agonist ORLAAM, as a result of a “increasing reports of severe cardiac-related adverse events.” (See note 10). Given that CB1 receptors are ten times more abundant in the brain than opioid receptors, the possibilities for adverse events from blocking CB1 are clearly substantial.
62 “Marijuana was the second most common illicit drug responsible for treatment admissions in 2001, accounting for 15 percent of TEDS admissions”; however, “[m]ore than half (57 percent) of marijuana admissions were referred to treatment through the criminal justice system.” Substance Abuse and Mental Health Services Administration. Treatment Episode Data Set (TEDS) 1992-2001: National Admissions to Substance Abuse Treatment Services: Office of Applied Studies, Department of Health and Human Services. http://www.dasis.samhsa.gov/teds01/TEDS2K1Chp3.htm#Marijuana
63 In 1895 The Bayer Company began production of diacetylmorphine and coined the name “heroin.” In 1898 they introduced it as a substitute for morphine and it began to gain fame for helping morphine addicts with their habit. In 1924 the Heroin Act made manufacture and possession of heroin illegal. By the very next year, a thriving black market was operating in New York’s Chinatown. Retrieved April 7, 2004 from http://www.heroinanddiction.com/heroin_timeline.html


A handful of cities and states are instituting naloxone distribution programs despite federal government heel dragging. A new naloxone distribution program in San Francisco is underway, based on successful programs that have been operating in New Mexico and Chicago. Others are planned for Baltimore and New York City in the near future. (San Francisco Begins Distributing Naloxone to Heroin Addicts," Drug Policy Alliance, November 21, 2003. (Retrieved April 20, 2004 from http://www.drugpolicy.org/news/11_21_03naloxone.cfm.)


Subdivision (a) of 21 U.S.C. 844, provides in pertinent part: "It shall be unlawful for any person knowingly or intentionally to possess a controlled substance..." (emphasis added).


Ibid.


Ibid. pp. 64-66.


Ibid.

Thirty years ago, Dr. Andrew Weil noted: "Until the models that produce the current laws, decisions, and actions about drugs change, nothing about drugs will change, hence the uselessness of pressing for legal reforms as a means of solving the drug problem. Counter productive laws against possession and sale of drugs are not causes of problems; they are symptoms of problems at the level of conceptions, of mental images, just as physical symptoms of illness are effects of mental states." Weil, A. (1972) The Natural Mind Boston MA: Houghton Mifflin Co. p.193.

Ibid.


1 The company’s press release announcing that McCaffrey has joined
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18 Ibid.
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20 The company’s press release announcing that McCaffrey has joined DrugAbuse Sciences, quotes Ms. Greetham stating: “We are extremely fortunate to have General McCaffrey as a board member. He will be of immense assistance to the company in the critical policy and political arenas surrounding the treatment of addiction in the U.S. Americans understand that a chronic disease like addiction requires effective medical intervention over a long period of time. Effective treatment will require parity in medical coverage for all Americans. While this change is underway, General McCaffrey can provide valuable guidance in designing our programs to best accommodate these new programs.” (Press Release. 2001, July 24). DrugAbuse Sciences. Retrieved April 8, 2004 from http://www.drugabusesciences.com/Articles.aspx?entry=129
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94 42 U.S.C. § 1437d(s) and § 1437d(t). “One-strike” eviction policies allow public housing agencies to immediately evict tenants on the basis of any criminal drug activity occurring on or off the premises. 42 U.S.C. § 1437d(6). See also Department of Housing and Urban Development v. Rucker, 535 U.S. 125, 122 S.Ct. 1230 (2002), [upholding a local Public Housing Authority’s right to evict an entire family based on the one-strike policy, regardless of any prior knowledge on the part of the leaseholder.]
100 “Medications Development for Cannabis-related Disorder.” RFA Number: RFA-DA-04-014 (December 1, 2003).
103 “Chapter 7 , State Informed Consent Laws.” Essay with citations to codes and cases in footnotes.
104 “A Wiser Course: Ending Drug Prohibition: A Report of The Special Committee on Drugs and the Law of the Association of the Bar of the City of New York, June 14, 1994 ["One of the more insidious effects of the "war on drugs" has been the gradual erosion of the rule of law and the public’s civil liberties.” http://www.drugtext.org/library/reports/nylawyer/nylawyer.htm
112 Sontag, op.cit. p. 65.
113 Olmstead v. United States, 277 U.S. 438, 479 (1928) (Brandeis, J., dissenting).
115 Depending on the circumstances, it is legal to use these drugs for medical purposes. Eight states currently allow sick people to use marijuana for medical purposes. Eight states currently allow sick people to use marijuana for medical purposes. Eight states currently allow sick people to use marijuana for medical purposes.
117 The American Medical Association’s (AMA) *General Statement on Informed Consent,* Code of Medical Ethics:

> “The patient’s right of self-decision can be effectively exercised only if the patient possesses enough information to enable an intelligent choice. The patient should make his or her own determination on treatment. The physician’s obligation is to present the medical facts accurately to the patient or to the individual responsible for the patient’s care and to make recommendations for management in accordance with good medical practice. The physician has an ethical obligation to help the patient make choices from among the therapeutic alternatives consistent with good medical practice. Informed consent is a basic social policy for which exceptions are permitted: (1) where the patient is unconscious or otherwise incapable of consenting and harm from failure to treat is imminent; or (2) when risk disclosure poses such a serious psychological threat of detriment to the patient as to be medically contraindicated. Social policy does not accept the paternalistic view that the physician may remain silent because divulgence might prompt the patient to forego needed therapy. Rational, informed patients should not be expected to act uniformly, even under similar circumstances, in agreeing to or refusing treatment.” AMA Code of Ethics sec. E-808 (1981). http://www.ama-assn.org/ama/pub/category/8488.html (for relevant text)
118 39 Fed. Reg. 18913
121 See In the Matter of Christine M., 595 N.Y.S.2d 606, 607 (N.Y. Fam. Ct. 1992) in which a three-year old child was considered "neglected" by the authorities because the parent refused a measles vaccine.
medical purposes. Opium and cocaine are both Schedule II substances, which (like Ritalin) can be used with a doctor’s prescription.


122 V. Jones, 445 U.S. 480, 493-94 (1980) ["A criminal conviction and sentence of imprisonment extinguish an individual’s right to freedom from confinement for the term of his sentence, but they do not authorize the State to . . . subject him to involuntary psychiatric treatment without affording him additional due process protections."]; Rogers v. Okin, 634 F.2d 650, 653 (1st Cir. 1980) ["[A] person has a constitutionally protected interest in being left free by the state to decide for himself whether to submit to the serious and potentially harmful medical treatment . . . as part of the penurnal right to privacy, bodily integrity, or personal security"]; Runnels v. Rosendale, 495 F.2d 733, 735 (9th Cir. 1974) ["[performing a hemorrhoidectomy without the prisoner’s consent implicated the prisoner’s right to refuse medical treatment]; Riggins v. Nevada, 504 U.S. 127, 134 (1992) ["The forcible injection of medication into a nonconsenting person’s body . . . represents a substantial interference with that person’s liberty."]

123 See, Sell v. United States, 539 U.S. 166, 213 (2003) ["[e]very State provides avenues through which, for example, a doctor or institution can seek appointment of a guardian with the power to make a decision authorizing medication — when in the best interests of a patient who lacks the mental competence to make such a decision."]


128 For men, the most frequent source of referral to drug treatment is through a criminal justice system. (Figure 3. Criminal Justice Referrals, by Sex and Primary Substance: 1998. http://www.samhsa.gov/oas/2k1/enterTX/index.html) some 39 percent of men, compared to 25 percent of women, entered treatment as the result of a judicial process. Sixty-two percent of those who entered treatment as a result of a judicial process were small time, nonviolent offenders. In 2000, 30 percent of drug offenders fell into this category. Eighteen percent of drug offenders were sentenced to prison in 2000 and 45 percent were sentenced to probation. The substance world is not the only world. Other worlds need treatment of their own.


132 *Buck v. Bell*, 274 U.S. 200 (1927). This case gave rise to Justice Holmes’s infamous quotation that “three generations of imbeciles are enough.” Id. at 207. Evidence later indicated that Carrie Buck, the woman whose sterilization was upheld, was not mentally handicapped. Her child, who died at the age of eight, was a member of her school’s honor roll.


134 Skinner v. Oklahoma 316 U.S. 535, 538 (1942). Despite the Skinner decision a handful of states continue to have laws allowing for the compulsory sterilization of criminals or the mentally incompetent. See, e.g., MISS. CODE ANN. § 41-45-1 (1991); N.C. GEN. STAT. § 35-36 (1990); W. VA. CODE § 27-16-1 (1988). It is unlikely that these laws, if challenged, would withstand constitutional scrutiny.

135 The Eighth Amendment provides: “Excessive bail shall not be required, nor excessive fines imposed, nor cruel and unusual punishments inflicted.” U.S. Const. amend. VIII. Many state constitutions also provide independent protections against cruel and unusual punishment.


137 Nelson v. Hayne 355 F. Supp. 451, 455 (N.D. Ind. 1972) [holding it is cruel and unusual punishment to inject juveniles in a correctional institute with tranquilizing drugs that can have significant side effects].

138 See, e.g., *Trop v. Dulles*, 356 U.S. 86, 95 (1958) [“even a clear legislative classification of a statute as ‘nonpenal’ would not alter the fundamental nature of a plainly penal statute”]; *Knecht v. Gillman*, 488 F.2d 1180, 1189-40 (8th Cir. 1973) [noting that “the mere characterization of an act as ‘treatment’ does not insulate it from eighth amendment scrutiny”]; and that “neither the label which a State places on its own conduct, nor even the legitimacy of its action, can make the applicability of the Federal Constitution].


142 *The Only Good Poor Woman: Unconstitutional Conditions and Welfare*. 72
Altering a person’s brain chemistry for the purpose of altering how that person thinks is the basis of a pharmaceutical sector with approximately $20 billion in global sales. The sale of Prozac® and similar “antidepressant” drugs is currently one of the most profitable segments of the pharmaceutical drug industry. According to IMS Health, a fifty-year-old company specializing in pharmaceutical market intelligence and analyses, “antidepressants, the #3-ranked therapy class worldwide, experienced 18 percent sales growth in 2000, to $13.4 billion or 42 percent of all audited global pharmaceutical sales.” IMS Health, “Antidepressants”. http://www.imshealth.com/public/structure/navcontent/1,3272,1034-1034-0,00.html (for summary). Sales of “antipsychotic” drugs are currently the eighth largest therapy class of drugs with worldwide sales of $6 billion in the year 2000, a 22 percent increase in sales over the previous year. See IMS Health, “Antipsychotics.” http://www.imshealth.com/public/structure/navcontent/1,3272,1035-1035-0,00.html (for summary). A report published by the Lewin Group in January 2000, found that within the Medicaid program alone, “Antidepressant prescriptions totaled 19 million in 1998...[and] antipsychotic prescriptions totaled 11 million in 1998.” Lewin Group. (2000, January). Access and Utilization of New Antidepressant and Antipsychotic Medications. The CCLE underscores that the development of such drugs is to be applauded for their potential to aid millions of suffering people who voluntarily use them.


Id. at 642.

Id. at 637.

Id. at 641.

Id. at 641-42.

Id. at 714.

Id. at 556-566.

Id. at 565.

Id. at 565.

Id. at 359 (Harlan J., concurring).
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