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# Neurocops: The Politics of Prohibition and the Future of Enforcing Social Policy from Inside the Body

Richard Glen Boire

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NEUROCOPS: THE POLITICS OF PROHIBITION AND THE  
FUTURE OF ENFORCING SOCIAL POLICY FROM *INSIDE* THE  
BODY

RICHARD GLEN BOIRE<sup>1</sup>

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#### ABSTRACT

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 voluntarily 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 voluntarily choose to use such medications, some people will be compelled to use them. This article concludes that in the absence of extraordinary circumstances, governmental action forcing or coercing a person to use a pharmacotherapy drug would violate a number of important legal rights. 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.

#### I. INTRODUCTION

With funding and other encouragement provided by the United States 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 II examines various factors that raise a reasonable concern that these pharmaceuticals will migrate from voluntary use to compulsory use within certain population segments. Section III of this article 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. Section IV identifies and discusses a number of constitutional and other legal issues that will arise should use of these drugs be mandated for some people.

#### II. 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 United States 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, “[I]n order to fight and defeat this enemy, it is necessary to wage a new, all-out offensive.”<sup>2</sup> The ambitious goal of the drug war is to eradicate all use of illegal drugs, giving rise to “Drug-Free Workplaces,”<sup>3</sup> “Drug-Free Borders,”<sup>4</sup> “Drug-Free Families,”<sup>5</sup> “Drug-Free Communities,”<sup>6</sup> and ultimately a “Drug-Free America.”<sup>7</sup>

On June 17, 1971, President Nixon requested a \$155,655,000 budget to wage the war on drugs for the 1972 fiscal year.<sup>8</sup> Thirty-three years later, the federal budget requested for the war on drugs reached \$12.6 billion dollars for the 2005 fiscal year.<sup>9</sup> 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 twelve or older) defy the law each month by using an illegal drug.<sup>10</sup>

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 United States Drug Enforcement Administration (DEA) has vowed not to “punt on the third down.”<sup>11</sup> 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 Colombian 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

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<sup>2</sup>President Richard Nixon, Remarks About an Intensified Program for Drug Abuse Prevention and Control, (June 17, 1971), in 3 Public Papers of the Presidents of the United States: Richard Nixon 202 (1971), available at [http://www.nixonfoundation.org/Research\\_Center/PublicPapers.cfm?BookSelected=1971#P584\\_18482](http://www.nixonfoundation.org/Research_Center/PublicPapers.cfm?BookSelected=1971#P584_18482).

<sup>3</sup>Drug-Free Workplace Act of 1988, 41 U.S.C. §§ 701-07 (2005).

<sup>4</sup>Drug-Free Borders Act of 2001, S. 92, 107th Cong. (2001) (introduced by Senator Phil Gramm).

<sup>5</sup>Drug-Free Families Act of 2001, S. 89, 107th Cong. §131 (2001).

<sup>6</sup>21 U.S.C. § 1521 (2005).

<sup>7</sup>Anti-Drug Abuse Act of 1988, Pub. L. No. 100-690, 102 Stat. 4181 (1998).

<sup>8</sup>Peter B. Goldberg & James V. DeLong, *Federal Expenditures on Drug-Abuse Control*, in DEALING WITH DRUG ABUSE: A REPORT TO THE FORD FOUNDATION (1972), <http://www.druglibrary.org/schaffer/library/studies/dwda/staff5.htm> (last visited June 20, 2005).

<sup>9</sup>Office of Nat’l Drug Control Policy, *Summary: FY 2005 National Drug Control Budget* (Feb. 2004), available at [http://www.whitehousedrugpolicy.gov/publications/policy/budgets/um04/budget\\_highlights.pdf](http://www.whitehousedrugpolicy.gov/publications/policy/budgets/um04/budget_highlights.pdf).

<sup>10</sup>Substance Abuse & Mental Health Services Admin.: Office of Applied Studies, *Results from the 2002 National Survey on Drug Use and Health: National Findings*, DHHS Publ’n No. SMA 03-3836, NSDUH Series H-22 (2003).

<sup>11</sup>*Let’s Don’t Punt on the Third Down* (Commonwealth Club of California radio broadcast, February 12, 2002) (DEA Administrator Asa Hutchinson commenting), transcript available at <http://www.commonwealthclub.org/archive/02/02-02hutchinson-speech.html>.

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 blood stream 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.

### III. PHARMACOTHERAPY DRUGS

The pharmacotherapy drugs that are the subject of this paper fall into one of three general classes: brain receptor blockers; molecule binders; or metabolism modifiers.

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.<sup>12</sup> Partial agonists are compounds that bind to receptors, but cause a relatively small amount of activation.<sup>13</sup> Antagonists are compounds that enter receptor sites, but do not produce any physiological activity; they simply block the receptors.<sup>14</sup> 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.

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.<sup>15</sup> Because the illegal molecule is then unable to make it into the brain, it is prevented from producing any psychotropic effects.

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.<sup>16</sup> The best known of these metabolism-modifiers is Antabuse<sup>®</sup> (disulfiram), a drug primarily used to discourage people from drinking alcohol.

#### A. Target: Opiates

Some pharmacotherapy drugs that block or reduce the effects of psychotropic drugs are already available. The best known is an 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, reportedly 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,

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<sup>12</sup>STEDMAN'S MEDICAL DICTIONARY 37 (27th Ed. 2000).

<sup>13</sup>*Id.*

<sup>14</sup>*Id.*, "antagonist."

<sup>15</sup>See for example, discussion of "TA-CD," *infra*, pp. 221.

<sup>16</sup>See, *infra* pp. 225.

methadone substantially reduces the unpleasant effects associated with heroin withdrawal.

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<sup>®</sup>. In 1994, the United States Food and Drug Administration (FDA) also approved the use of naltrexone for alcohol addicts. Naltrexone is currently sold under the trade name "reVia," for the treatment of alcohol addiction.<sup>17</sup>

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.<sup>18</sup> There are a number of reasons why naltrexone has not been a popular medicine. 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<sup>®</sup> (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.<sup>19</sup> Second, naltrexone cannot be given until after a

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<sup>17</sup>See Barr Pharmaceutical's Product Guide, available at <http://www.barrlabs.com/productguide.php> (last visited Nov. 19, 2006).

<sup>18</sup>Clifford Goodman et al., Market Barriers to the Development of Pharmacotherapies for the Treatment of Cocaine Abuse and Addiction: Final Report (The Lewin Group, 1997), available at <http://aspe.hhs.gov/health/reports/cocaine/final.htm> (last visited June 20, 2005).

<sup>19</sup>The "Naltrexone Safety Identification Card" that DuPont provides reVia users states:

TO MEDICAL PERSONNEL TREATING ME IN AN EMERGENCY: This patient is taking the oral opioid antagonist reVia<sup>®</sup>, formerly known as Trexan<sup>®</sup> (naltrexone hydrochloride).

In an emergency situation with patients receiving fully blocking doses of reVia<sup>®</sup>, a suggested plan of management is regional anesthesia, conscious sedation with a benzodiazepine, use of non-opioid analgesics, or general anesthesia. In a situation requiring opioid analgesia, the amount of opioid required may be greater than usual and the resulting respiratory depression may be deeper and more prolonged. A rapidly acting opioid analgesic that minimizes the duration of respiratory depression is preferred. The amount of analgesia administered should be titrated to the needs of the patient. Non-receptor mediated actions may occur and should be expected (e.g., facial swelling, itching, generalized erythema, or bronchoconstriction), presumably due to histamine release. Irrespective of the drug chosen to reverse reVia<sup>®</sup> (naltrexone hydrochloride) blockade, the patient should be monitored closely by appropriately trained personnel in a setting equipped and staffed for cardiopulmonary resuscitation. For medical emergencies, call your regional Poison Control Center. Further information may be obtained by calling: 1-800-4PHARMA.

patient is fully detoxified from opiates. If an active opiate user takes naltrexone, it will precipitate sudden and violent withdrawal.<sup>20</sup>

Another problem for the marketers 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 marijuana alone.<sup>21</sup> 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 United States Food and Drug Administration (FDA) approved two new medications for treating opiate addiction, both developed by Reckitt Benckiser Pharmaceuticals. The new drugs, Subutex<sup>®</sup> (buprenorphine hydrochloride) and Suboxone<sup>®</sup> tablets (buprenorphine hydrochloride and naloxone hydrochloride), contain buprenorphine, a partial opioid agonist.<sup>22</sup> 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<sup>23</sup>), 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.<sup>24</sup>

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<sup>20</sup>V.W. Tornabene, *Narcotic Withdrawal Syndrome Caused by Naltrexone*, in 81:6 ANNALS OF INTERNAL MED. 785-7 (1974).

<sup>21</sup>M. Haney, A. Bisaga, & R.W. Foltin, *Interaction Between Naltrexone and Oral THC in Heavy Marijuana Smokers*, in 166(1) PSYCHOPHARMACOLOGY (BERL.) 77-85 (2003), abstract available at <http://link.springer.de/link/service/journals/00213/contents/02/01279/s00213-002-1279-8ch002.html> (last visited Nov. 19, 2006).

<sup>22</sup>See product website at <http://www.suboxone.com/patients/suboxone> (last visited Nov. 19, 2006).

<sup>23</sup>ORLAAM<sup>®</sup> (Levomethadyl hydrochloride acetate) is a synthetic opioid agonist that was approved by the FDA for the management of opiate dependence in 1995. 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." See letter from Michael Schobelock, Assoc. Director, Medical Affairs Dep't, Roxane Laboratories, to Healthcare Professional [Community] (August 23, 2003), available at <http://www.fda.gov/cder/drug/shortages/orlaam.htm>.

<sup>24</sup>United States Food and Drug Administration (FDA): Center for Drug Evaluation and Research, Subutex (Buprenorphine Hydrochloride) Suboxone Tablets (Buprenorphine Hydrochloride and Naloxone Hydrochloride), available at [http://www.fda.gov/cder/drug/info/page/subutex\\_suboxone/default.htm](http://www.fda.gov/cder/drug/info/page/subutex_suboxone/default.htm) (last visited Nov. 19, 2006).

*B. Target: Cocaine*

With an estimated two million people in the United States using cocaine at least once a month,<sup>25</sup> 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.”<sup>26</sup> The drug is being developed by Xenova, a 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.<sup>27</sup>

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 affects. In October of 2003, Xenova began testing TA-CD in a randomized, placebo-controlled clinical trial involving 132 human subjects.<sup>28</sup>

Another anti-cocaine drug is under development by DrugAbuse Sciences, Inc., a California company whose business plan is built solely upon developing pharmacotherapy drugs. DrugAbuse 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.<sup>29</sup>

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<sup>25</sup>Substance Abuse and Mental Health Services Administration (SAMHSA), Office of Applied Studies, 2003 National Survey on Drug Use & Health: Detailed Tables, Table 1.21A, <http://www.oas.samhsa.gov/nhsda/2k3tabs/Sect1peTabs1to66.htm#tab1.21a> (last visited Nov. 19, 2006).

<sup>26</sup>The term “vaccine” is used by Xenova to describe TA-CD. The company’s website description of TA-CD states: “Xenova is developing a therapeutic vaccine, TA-CD, for the treatment of cocaine dependence, for which there is no currently available effective treatment. . . . TA-CD is designed to induce cocaine-specific *antibodies* which bind to cocaine in the blood, blocking its uptake into the brain. Therefore, the human physiological response to cocaine is altered, reducing the reinforcing properties of cocaine and permitting patients to break the cycle of addiction and abuse. The active ingredient of the TA-CD vaccine is a protein conjugate: a cocaine derivative coupled to recombinant cholera toxin B (rCTB). The finished TA-CD vaccine consists of the protein conjugate adsorbed onto aluminum hydroxide gel adjuvant in saline. The vaccine is administered by intramuscular injection and it is anticipated that a short course of injections will be required to induce antibody responses.” Xenova Group plc, TA-CD: Background, [http://www.xenova.co.uk/dc\\_ta\\_cd.html](http://www.xenova.co.uk/dc_ta_cd.html) (last visited June 14, 2005).

<sup>27</sup>Patrick Zickler, *Blood-borne Medications Could Intercept Drugs Before They Reach the Brain*, in 14 NIDA NOTES 2 (1999), [http://165.112.78.61/NIDA\\_Notes/NNVol14N2/medications.html](http://165.112.78.61/NIDA_Notes/NNVol14N2/medications.html) (last visited Feb. 21, 2005).

<sup>28</sup>Xenova Group plc, *supra* note 26.

<sup>29</sup>DrugAbuse Sciences, New Products in Development, *available at* <http://www.drugabusesciences.com/products.asp> (last visited June 20, 2005).



*C. Target: Marijuana*

A number of pharmaceutical companies are working to develop drugs that will block the marijuana "high" sought by the world's estimated 162 million regular marijuana users.<sup>30</sup> 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."<sup>31</sup> 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, uterus, ovary, testis, bone marrow, thymus, tonsils, and adrenal gland.<sup>32</sup>

Working with a grant from the National Institute of Drug Abuse (NIDA), scientists have created an anti-marijuana drug that occupies the brain's CB1 receptors, thereby blocking marijuana from entering its host receptors.<sup>33</sup> Created by the French pharmaceutical firm Sanofi-Synthelabo, and named "SR141716," the drug may become the ultimate "buzzkill."<sup>34</sup>

In a test conducted in 2002, sixty-three adult males who smoked marijuana after taking ninety milligrams of SR 141716 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 blockading the brain receptors that THC normally plugs into.<sup>35</sup> The subjects reported that SR141716 reduced their marijuana high by as much as 75 percent.

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<sup>30</sup>*Trends: Consumption – Cannabis*, GLOBAL ILLICIT DRUG TRENDS 2003 (UN Office on Drugs and Crime: UN Int'l Drug Control Program Research Section, Vienna, Aus.), at 136, [http://www.unodc.org/pdf/trends2003\\_www\\_E.pdf](http://www.unodc.org/pdf/trends2003_www_E.pdf) (last visited June 14, 2005).

<sup>31</sup>Institute of Medicine: Division of Neuroscience and Behavioral Health, *Chapter 2: Cannabinoids and Animal Physiology*, in MARIJUANA AND MEDICINE: ASSESSING THE SCIENCE BASE 1.1, 2.9 (Janet E. Joy et al. eds., 1999), <http://www.rism.org/isg/dlp/ganja/analyses/Marijuana%20and%20Medicine%20a.html> (last visited June 16, 2005).

<sup>32</sup>*Id.* at 2.38.

<sup>33</sup>Press Release, National Institute on Drug Abuse, Potential Medication Can Reduce Effects of Smoke Marijuana in Humans (April 12, 2001), at <http://www.drugabuse.gov/MedAdv/01/NR4-12.html>.

<sup>34</sup>Patrick Zickler, NIDA NOTES Staff Writer, *Cannabinoid Antagonist Reduces Marijuana's Effects in Humans Research Findings*, in 17(3) NIDA Notes (Oct. 2002), available at [http://www.nida.nih.gov/NIDA\\_Notes/NNVol17N3/Cannabinoid.html](http://www.nida.nih.gov/NIDA_Notes/NNVol17N3/Cannabinoid.html).

<sup>35</sup>Marilyn A. Huestis et al., *Blockade of Effects of Smoked Marijuana by the CB1-Selective Cannabinoid Receptor Antagonist SR141716*, in 58(4) JOURNAL ARCHIVES OF GENERAL PSYCHIATRY, at 322-328 (April 2001), abstract available at <http://archpsyc.ama-assn.org/cgi/content/abstract/58/4/322>.

Sanofi-Synthelabo believes a different formulation of the compound may also be effective in blocking the effects of cocaine.<sup>36</sup> Sanofi-Synthelabo is set to begin Phase II clinical trials aimed at determining whether SR141716 might also reduce the effects and desire for alcohol.<sup>37</sup> Under the tradenames “Acomplia” and “Rimonabant,” the company is working to release the drug as an obesity and anti-smoking treatment.<sup>38</sup>

#### D. Targeting Legal Drugs

##### 1. Target: Nicotine

At last count, approximately 70.8 million people in the United States regularly use some type of tobacco product.<sup>39</sup> 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, which are available in four different forms: gum, patch, inhaler, and microtab.<sup>40</sup> Products such as Nicorette<sup>®</sup> gum and the NicoDerm CQ<sup>®</sup> 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.<sup>41</sup>

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<sup>36</sup>Robert Mathias, *Study Opens Promising New Approach to Developing Medications To Prevent Relapse to Cocaine Use*, in 17(3) NIDA NOTES (Oct. 2002), [http://www.drugabuse.gov/NIDA\\_notes/NNVol17N3/Promising.html](http://www.drugabuse.gov/NIDA_notes/NNVol17N3/Promising.html).

<sup>37</sup>See National Institutes of Health, United States Department of Health and Human Services, Protocol No. 04-AA-0072, Clinical Trial of the Cannabinoid CB1 Receptor Antagonist, SR141716 (Rimonabant), to Reduce Voluntary Ethanol Drinking in Healthy, Non-Treatment Seeking Individuals Who Consume Between 20 and 50 Drinks Per Week (National Institute on Alcohol Abuse and Alcoholism sponsoring the study), *available at* [http://clinicalstudies.info.nih.gov/detail/A\\_2004-AA-0072.html](http://clinicalstudies.info.nih.gov/detail/A_2004-AA-0072.html) (last visited June 14, 2005).

<sup>38</sup>Gina Kolata, *Will a New Drug Melt the Pounds? It May, but Doctors Urge Caution*, N.Y. TIMES, Dec. 5, 2004, § 1, at 1.

<sup>39</sup>National Institute on Drug Abuse, NIDA InfoFacts: Cigarettes and Other Nicotine Products, *at* <http://www.drugabuse.gov/infofacts/tobacco.html> (last visited Nov. 19, 2006).

<sup>40</sup>GlaxoSmithKline has a website devoted to the Nicorette family of products. See GlaxoSmithKline, <http://www.nicorette.com> (last visited Nov. 19, 2006).

<sup>41</sup>According to a 1997 report prepared by United States Department of Health and Human Services, Office of Health Policy, “Sales in the second quarter of 1996 increased over 100% from the sales in the first quarter, rising from \$37 million to \$78 million. During 1996 alone, the sales from Nicorette surpassed \$225 million dollars. This figure is comparable to target peak annual revenues for new drugs of major pharmaceutical companies.” “Case Study:

Today, over one-third of Nicorette users report that while they are no longer addicted to cigarettes; they are now addicted to Nicorette.<sup>42</sup> 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 twelve pieces of Nicorette she chewed each day cost her more than \$15,000 over the years, without curing her addiction to nicotine.<sup>43</sup>

In May 1997, GlaxoSmithKline (then known as Glaxo Wellcome, Inc.) received FDA approval to market a sustained-release version of the antidepressant Wellbutrin<sup>®</sup> (bupropion hydrochloride) to smokers under the name Zyban<sup>®</sup>.<sup>44</sup>

Nabi Biopharmaceuticals in Florida is developing what it terms a nicotine "vaccine."<sup>45</sup> Named NicVAX<sup>™</sup> (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 sixty-four percent.<sup>46</sup> It is currently being tested in humans in the United States and the Netherlands.<sup>47</sup>

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."<sup>48</sup>

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Nicorette," in *Market Barriers to the Development of Pharmacotherapies for the Treatment of Cocaine Abuse and Addiction: Final Report*, available at <http://aspe.hhs.gov/health/reports/cocaine/final.htm> (last visited Nov. 19, 2006).

<sup>42</sup>Petra Bartosiewicz, *A Quitter's Dilemma: Hooked on the Cure*, N.Y. TIMES, May 2, 2004, § 3, at 8.

<sup>43</sup>*Id.*

<sup>44</sup>See letter from Dep't of Health & Human Services: Food & Drug Admin., to Glaxo Wellcome (May 14, 1997) (on file with author), available at [http://www.fda.gov/cder/foi/nda/97/20711\\_ZYBAN,%20100MG%20AND%20150MG\\_APPROV.PDF](http://www.fda.gov/cder/foi/nda/97/20711_ZYBAN,%20100MG%20AND%20150MG_APPROV.PDF).

<sup>45</sup>See Nabi Biopharmaceuticals, Key Facts about Nicotine Addiction and NicVAX<sup>™</sup>, [http://www.nabi.com/pdf/pipe\\_nicotine\\_nicvax.pdf](http://www.nabi.com/pdf/pipe_nicotine_nicvax.pdf) (last visited July 22, 2004).

<sup>46</sup>Press Release, Nabi Bioharmaceuticals, Nicotine Vaccine Date for Nabia-NicVAX Published in Peer Review Journal (Dec. 17, 1999), available at <http://yoko001.hp.infoseek.co.jp/vaccine/mecha/purpose/merit/media/list/NabiPress.htm>.

<sup>47</sup>Press Release, Nabi Biopharmaceuticals, Nabi BioPharmaceuticals Initiates NicVAX<sup>™</sup> Phase II Trial, Investigational Vaccine for the Prevention and Treatment of Nicotine Addiction (Aug. 5, 2003), available at <http://phx.corporate-ir.net/phoenix.zhtml?c=100445&p=irol-newsArticle &ID=438522&highlight=>.

<sup>48</sup>Barbara Shine, *Nicotine Vaccine Moves Toward Clinical Trials*, in 15(5) NIDA NOTES (Oct. 2000), available at [http://165.112.78.61/NIDA\\_Notes/NNVol15N5/Vaccine.html](http://165.112.78.61/NIDA_Notes/NNVol15N5/Vaccine.html) (last visited June 16, 2005).

## 2. Target: Alcohol

In the 1940s, 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.<sup>49</sup> The discovery led to a new “treatment” for excessive alcohol use. Marketed under the trade name Antabuse<sup>®</sup> 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.<sup>50</sup> 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.<sup>51</sup> Symptoms usually disappear within sixty 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.<sup>52</sup>

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.<sup>53</sup> Even alcohol absorbed through the skin, such as through the use of aftershaves, perfumes or shampoos, can trigger negative reactions.<sup>54</sup>

### *E. Pharmacotherapy Drugs: Good, Bad, Both, or Beyond?*

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. For people who find that their use of drugs is causing problems in their lives, future pharmacotherapy drugs may provide safe and effective tools for ending or reducing excessive or harmful drug use. The development of these drugs should be encouraged and their voluntary use supported.

Yet, the development of pharmacotherapy drugs – like drug prohibition itself — is driven at least as much by politics, power, and profits than by genuine public

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<sup>49</sup>“Antabuse,” THE COLUMBIA ENCYCLOPEDIA, (6th ed. 2005), available at <http://www.bartelby.com/65/an/Antabuse.html> (last visited Nov. 19, 2006).

<sup>50</sup>See Odyssey Pharmaceuticals, Inc., How Does Antabuse Work? <http://www.antabuse.com/productTable.asp?id=16>.

<sup>51</sup>PHYSICIANS DESK REFERENCE 594 (33rd ed., 1979).

<sup>52</sup>*Id.* See also R. Fox, *Disulfiram-Alcohol Side Effects* (Letter to the Editor), 204 J. AM. MED. ASS’N 271 (1968); see also C.A. Cahill, *Safety of Disulfiram*, 287(18) NEW ENG. J. MED. 935-36 (1972).

<sup>53</sup>R.S. Koff et al., *Alcohol in Cough Medicines Hazard to Disulfiram User* (Letter to the Editor), 215 J. AM. MED. ASS’N 1988 (1971).

<sup>54</sup>See The Carlat Report on Psychiatric Treatment, Antabuse (disulfiram) Fact Sheet, [http://www.thecarlatreport.com/fact\\_sheets/antabuse.php](http://www.thecarlatreport.com/fact_sheets/antabuse.php) (last visited June 21, 2005).

health concerns.<sup>55</sup> If health concerns justified criminal prohibition, then cigarettes and alcohol would be illegal. Use of cigarettes is estimated to kill in excess of 440,000 people each year in the United States.<sup>56</sup> 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.”<sup>57</sup> Likewise, excessive alcohol consumption leads to as many as 85,000 deaths each year,<sup>58</sup> an estimated 27,485 of which are just from alcohol-induced cirrhosis of the liver.<sup>59</sup>

Marijuana stands in stark contrast to alcohol and nicotine, in just about every respect. Marijuana is the most commonly used illegal drug in the world, regularly used by an estimated 144 million people worldwide.<sup>60</sup> According to United States Government statistics, 40.4 percent of Americans have tried marijuana during their lifetime.<sup>61</sup> It is one of the most studied drugs in history, and is regarded by many

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<sup>55</sup>See PHARMACIA CORPORATION, PHARMACIA, 2001 ANNUAL REPORT 24, available at [http://media.corporate-ir.net/media\\_files/NYS/PHA/reports/ar2001.pdf](http://media.corporate-ir.net/media_files/NYS/PHA/reports/ar2001.pdf). The development of pharmacotherapy medications for legal drugs like alcohol and nicotine, is driven primarily by profit motives. In 2001, Pharmacia, acquired by Pfizer in 2003, advised investors that, “Nicorette currently controls about half of the worldwide smoking cessation market” with sales in 2001 of \$299 million. See also Press Release, Decision Resources, The Market for Smoking Cessation Therapies Will More Than Triple Over the Next Ten Years, Predicts Decision Resources (June 10, 1998), available at <http://www.forces.org/articles/files/pharma.htm> (referencing a 1998 study valuing the “smoking cessation market” at \$450 million and predicting it will reach nearly \$1.5 billion by 2007).

<sup>56</sup>The Center for Disease Control (CDC): Nat’l Ctr. For Chronic Disease Prevention & Health Promotion, Tobacco Information and Prevention Source (TIPS), <http://www.cdc.gov/tobacco/issue.htm>.

<sup>57</sup>NATIONAL INSTITUTE ON DRUG ABUSE RESEARCH REPORT SERIES: NICOTINE ADDICTION, Publ’n No. 01-4342 (1998), available at <http://www.nida.nih.gov/researchreports/nicotine/nicotine.html> (last visited June 20, 2005).

<sup>58</sup>Ali H. Mokdad, PhD et al., *Actual Causes of Death in the United States, 2000*, 291(10) J. AM. MED. ASS’N 1238, 1241 (Mar. 10, 2004), corrected in 293(3) J. AM. MED. ASS’N 298, 298 (Jan. 19, 2005).

<sup>59</sup>Young-Hee Yoon, PhD et al., Surveillance Report # 63: Liver Cirrhosis Mortality in the United States, 1970-2000 1 (2004), available at <http://www.niaaa.nih.gov/publications/surveillance63/cirr00.htm> (last visited June 20, 2005). See also Nat’l Institute on Alcohol Abuse & Alcoholism, 10th Special Report to the U.S. Congress on Alcohol and Health 24 ALCOHOL RES. & HEALTH 3 (2000), available at <http://pubs.niaaa.nih.gov/publications/arh24-1/toc24-1.htm> (last visited June 20, 2005) (reporting that alcohol also has deleterious effects on other body systems including the brain, the immune system, and the cardiovascular system).

<sup>60</sup>*Trends: Consumption – Cannabis*, supra note 30, at 136.

<sup>61</sup>The number of Americans twelve years and older who used marijuana in 2003 (25,231,000) is greater than the entire population of Texas as of 2000 (20,851,820). SAMHSA, OFFICE OF APPLIED STUDIES, RESULTS FROM THE 2003 NATIONAL SURVEY ON DRUG USE AND HEALTH: DETAILED TABLES: TABLE 1.1A ILLICIT DRUG USE IN LIFETIME, PAST YEAR, AND PAST MONTH AMONG PERSONS AGED 12 OR OLDER: NUMBERS IN THOUSANDS, 2002 AND 2003 (2003), <http://www.drugabusestatistics.samhsa.gov/NHSDA/2k3tabs/Sect1peTabs1to66.htm> (last visited May 26, 2005); UNITED STATES CENSUS BUREAU REPORT FOR 2000: SUMMARY FILE 4, <http://www.census.gov> (last visited June 21, 2005).

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.<sup>62</sup>

While nicotine and alcohol are legal for adult use,<sup>63</sup> a person who smokes marijuana - even an adult in the privacy of his or her own home - commits a federal crime.<sup>64</sup> Even a cancer patient, whose own doctor approves of his or her medical use, commits a federal crime by using marijuana.<sup>65</sup>

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.” Given the abundance of CB1 receptors in the brain, blocking them indiscriminately with an antagonist like SR141716 may produce complex physiological and psychological effects that have yet to be understood or even identified. Further, considering that less than three percent of marijuana smokers voluntarily seek treatment,<sup>66</sup> it is clear that SR141716 is a drug

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<sup>62</sup>UNITED STATES DEP’T OF JUSTICE, DRUG ENFORCEMENT AGENCY, IN THE MATTER OF MARIJUANA RESCHEDULING PETITION 58, Docket No. 86-22 (Sept. 6, 1988), *available at* <http://www.ukcia.org/pollaw/lawlibrary/young.htm> (last visited Nov. 19, 2006).

<sup>63</sup>To be clear, I am not suggesting that cigarettes or alcohol should be prohibited. Alcohol prohibition was a failure in all respects, again confirming that drug prohibition produces a net harm for individuals and society. *See* JOSEPH R. GUSFIELD, *SYMBOLIC CRUSADE: STATUS POLITICS AND THE AMERICAN TEMPERANCE MOVEMENT* (U. Ill. Press, 2d ed. 1986); *see also* MARK THORNTON, *ALCOHOL PROHIBITION WAS A FAILURE* (Cato Inst. 1991), <http://www.cato.org/pubs/pas/pa-157.html> (last visited Apr. 7, 2006).

<sup>64</sup>21 U.S.C. § 844 (2000).

<sup>65</sup>*Gonzales v. Raich*, 125 S. Ct. 2195 (2005). 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 United States 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), *certiorari denied*, *Walters v. Conant*, 540 U.S. 946 (2003).

<sup>66</sup>“Marijuana was the second most common illicit drug responsible for treatment admissions in 2001, accounting for fifteen percent of TEDS admissions”; however, “[m]ore than half (57 percent) of marijuana admissions were referred to treatment through the criminal justice system.” SAMHSA, OFFICE OF APPLIED STUDIES, TREATMENT EPISODE DATA SET (TEDS), 1992-2001: NATIONAL ADMISSIONS TO SUBSTANCE ABUSE TREATMENT SERVICES (2003), <http://www.dasis.samhsa.gov/teds01/TEDS2K1Chp3.htm#Marijuana> (last visited Apr. 7, 2006).

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. In 1895, Bayer began production of diacetylmorphine and coined the name "heroin." In 1898, they introduced it as a commercial 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. The next year, a thriving black market was operating in New York's Chinatown.<sup>67</sup>

Today in the United States, 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.<sup>68</sup> 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.<sup>69</sup> 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.<sup>70</sup>

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<sup>67</sup>Heroinaddiction.com, History of Heroin and Opium Timeline, [http://www.heroinaddiction.com/heroin\\_timeline.html](http://www.heroinaddiction.com/heroin_timeline.html) (last visited Apr. 7, 2006).

<sup>68</sup>Risk of overdose is increased because users have no way of accurately determining the appropriate dose of street heroin. In February 2005, the Canadian Institutes of Health Research began a two-year, \$8.1 million clinical trial designed to provide pharmaceutical-grade heroin to 470 habitual heroin users. The Canadian study follows earlier studies in Switzerland and the Netherlands that found that heroin-assisted therapy reduces both the individual and social harms associated with chronic heroin use. See Press Release, Canadian Institutes of Health Research, North America's First Clinical Trial of Prescribed Heroin Begins Today (Feb. 9, 2005), <http://www.cihr-irsc.gc.ca/e/26516.html>; see also Press Release, Canadian Institutes of Health Research, The NAOMI Project: Montreal Components of the Canadian Study Using Medically Prescribed Injection Heroin to be Conducted by the CHUM (Jan 6, 2005), available at <http://www.cihr-irsc.gc.ca/e/28330.html>.

<sup>69</sup>Increasing the availability of sterile syringes through syringe exchange programs, pharmacies, and other outlets reduces unsafe injection practices such as needle sharing, curtails transmission of HIV/AIDS and hepatitis C, increases safe disposal of used syringes, and helps heroin users obtain drug information, treatment, and detoxification. See Amy Smoyer, Needle Exchange "Programs" and Public Policy in Spain (2001), available at [http://cira.med.yale.edu/about\\_us/smotherspain.doc](http://cira.med.yale.edu/about_us/smotherspain.doc) (last visited Apr. 7, 2006).

<sup>70</sup>According for the Centers for Disease Control and Prevention, "Since the [HIV] epidemic began, injection drug use has directly and indirectly accounted for more than one-third (thirty-six percent) of AIDS cases in the United States." Centers for Disease Control and Prevention, "Drug-Associated HIV Transmission Continues in the United States," <http://www.cdc.gov/hiv/resources/factsheets/idu.htm> (last visited Nov. 19, 2006).

Between 1992 and 1995, injection drug users accounted for forty-three percent of all reported hepatitis C virus (HCV) infections and that "HCV infection is acquired after initiation of injection more rapidly than other viral infections, with one study reporting that fifty percent to eighty percent of new injectors tested positive for anti-HCV within six to twelve months after beginning injection." Miriam J. Alter & Linda A. Moyer, *The Importance of Preventing Hepatitis C Virus Infection Among Injection Drug Users in the*

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.<sup>71</sup> Yet, 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.<sup>72</sup> 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 socio-political construct.<sup>73</sup> 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.<sup>74</sup>

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 discussed in the next section of this article, suggests that use of pharmacotherapy drugs may not remain strictly voluntary for long. Rather, certain segments of the population could find use

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*United States*, 18 J. ACQUIRED IMMUNE DEFICIENCY SYNDROMES & HUM. RETROVIROLOGY S1, S6-S10 (1998), *abstract at* <http://www.aegis.com/news/ads/1998/AD981509.html> (last visited Apr. 7, 2006).

<sup>71</sup>John Strang, et al., *Heroin Overdose: The Case for Take-Home Naloxone*, 312 BRIT. MED. J. 1435-36 (1996), *available at*, <http://bmj.bmjournals.com/cgi/content/full/312/7044/1435> (last visited Apr. 7, 2006). Shane Darke & Wayne Hall, *The Distribution of Naloxone to Heroin Users*, 92(9) ADDICTION 1195-1199 (1997).

<sup>72</sup>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. Press Release, Drug Policy Alliance, San Francisco Begins Distributing Naloxone to Heroin Addicts (Nov. 21, 2003), *available at* [http://www.lindesmith.org/news/11\\_21\\_03naloxone.cfm](http://www.lindesmith.org/news/11_21_03naloxone.cfm).

<sup>73</sup>Peter Cohen, *Drugs as a Social Construct* (1990) (unpublished Ph.D. dissertation, Universiteit van Amsterdam), <http://www.cedro-uva.org/lib/cohen.drugs.toc.html> (last visited Dec. 5, 2003); Craig Reinerman & Harry G. Levine, *The Crack Attack: Politics and Media in America's Latest Drug Scare*, in CRACK IN AMERICA: DEMON DRUGS AND SOCIAL JUSTICE 18, 20-24 (Craig Reinerman & Harry G. Levine eds., 1997); Craig Reinerman et al., *Scapagoating and social control in the construction of a public problem: Empirical and critical findings on cocaine and work*, in 9 RES. L. DEVIANCE & SOC. CONTROL 37-62 (1988).

<sup>74</sup>BMA Professional and Scientific Division, *Living with Risk*, in THE BRITISH MEDICAL ASSOCIATION GUIDE (John Wiley & Sons 1987).



of these drugs becoming compulsory. If this is the case, these brain-policing drugs present an emerging threat to individual freedom and civil liberties.

*F. From Drug War to Drug Epidemic*

Compared to other new pharmaceuticals that enter society and primarily face 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 United States 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.<sup>75</sup> 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.<sup>76</sup>

Beginning in the 1990s, the United States 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 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."<sup>77</sup>

"The metaphor of a war on drugs is misleading," wrote then-Drug Czar General Barry McCaffrey<sup>78</sup> in a section of the report titled "An Enduring Challenge:"

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<sup>75</sup>See Thomas Nicholson et al., *Is Recreational Drug Use Normal?*, 7 J. SUBSTANCE USE 1-8 (2002), <http://duncan-associates.com/Is-Recreational-Drug-Use-Normal.pdf> (last visited Apr. 7, 2006); see also Ethan A. Nadelmann, *Drug Prohibition in the United States: Costs, Consequences, and Alternatives*, 245 SCIENCE 939 (1989), [http://www.science.smith.edu/departments/Biochem/Chm\\_357/drug\\_wars.pdf](http://www.science.smith.edu/departments/Biochem/Chm_357/drug_wars.pdf) (last visited Apr. 7, 2006); see also M.E. Jarvik, *The Drug Dilemma: Manipulating the Demand*, in 250 SCIENCE 387 (1990); see also A. Goldstein, & H. Kalant, *Drug Policy: Striking the Right Balance*, in 249 SCIENCE 1513 (1990); see also C. Winick, *Social Behavior, Public Policy, and Nonharmful Drug Use*, in 69 (3) MILLBANK Q. 437 (1991).

<sup>76</sup>21 U.S.C. § 844 (a) (2000) ("It shall be unlawful for any person knowingly or intentionally to *possess* a controlled substance . . .") (emphasis added).

<sup>77</sup>Office of National Drug Control Policy, *The National Drug Control Strategy: 1997, The Purposes and Nature of Strategy*, available at <http://www.ncjrs.gov/htm/chapter1.htm> (last visited Apr. 7, 2006).

<sup>78</sup>Six months after his resignation as "Drug Czar," Barry McCaffrey joined the board of directors of Drug Abuse Sciences, Inc., "the world's first pharmaceutical company worldwide devoted solely to developing medications for the treatment of addiction." (Press Release. (2001, July 24). Drug Abuse Sciences, available at <http://web.archive.org/web/20020212064926/drugabusesciences.com/Articles.asp?entry=123> (last visited December 4, 2006). Drug Abuse Sciences, views drug abuse and dependence as "chronic disease of the brain." (*Id.*) Upon announcing McCaffrey as a new board member, Elizabeth M. Greetham, Drug Abuse

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.<sup>79</sup>

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.<sup>80</sup>

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.<sup>81</sup>

McCaffrey's analogy to cancer is calculated. Cancer is the ultimate modern-day illness, the master disease we most fear. Author Susan Sontag who lived a significant portion of her life fighting breast and uterine cancer, 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.<sup>82</sup>

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. Sontag notes that the:

controlling metaphors in descriptions of cancer, are, in fact, drawn from...the language of warfare. . . . [T]alk of siege and war...has with cancer, a striking literalness and authority. Not only is the clinical course

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Sciences' CEO said, "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." (*Id.*)

<sup>79</sup>*Id.*

<sup>80</sup>*Id.*

<sup>81</sup>*Id.*

<sup>82</sup>SUSAN SONTAG, *ILLNESS AS METAPHOR AND AIDS AND ITS METAPHORS* 82-83 (1990).

of the disease and its medical treatment thus described, but the disease itself is conceived as the enemy on which society wages war.<sup>83</sup>

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, which reported “[j]ust 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.”<sup>84</sup>

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.”<sup>85</sup>

Perhaps of most concern 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.<sup>86</sup>

The way a problem is conceptualized or defined often dictates what measures will be employed to solve it.<sup>87</sup> The fact that the government characterizes illegal

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<sup>83</sup>*Id.* at 64-66.

<sup>84</sup>Office of National Drug Control Policy, The National Drug Control Strategy: 2001, Ch. 3, § 2, Medications for Drug Addiction, *available at* [http://www.ncjrs.org/ondcppubs/publications/policy/ndcs01/chap3\\_2.html#9](http://www.ncjrs.org/ondcppubs/publications/policy/ndcs01/chap3_2.html#9) (last visited Apr. 7, 2006).

<sup>85</sup>Office of National Drug Control Policy, The National Drug Control Strategy, Healing America’s Drug Users: Getting Treatment Resources Where They Are Needed, Budget Highlights, [http://www.whitehousedrugpolicy.gov/publications/policy/ndcs03/iheal\\_amer\\_us r.html](http://www.whitehousedrugpolicy.gov/publications/policy/ndcs03/iheal_amer_us r.html) (last visited Apr. 7, 2006).

<sup>86</sup>*Id.*

<sup>87</sup>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.

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 “National Priority 1” of the 2003 National Drug Control Strategy is titled “Stopping Use Before It Starts: Education and Community Action.”<sup>88</sup> Although the 2003 report focuses on in-school lessons which teach 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.<sup>89</sup> 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.<sup>90</sup>

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.”<sup>91</sup>

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ANDREW WEIL, *THE NATURAL MIND: A REVOLUTIONARY APPROACH TO THE DRUG PROBLEM* 1, 193 (1st ed. 1972).

<sup>88</sup>Office of National Drug Control Policy, *The National Drug Control Strategy, Stopping Using Before It Starts: Education and Community Action*, [http://www.whitehouse.gov/publications/policy/ndcs03/istop\\_use.html](http://www.whitehouse.gov/publications/policy/ndcs03/istop_use.html) (last visited Apr. 7, 2006).

<sup>89</sup>*See*, *Bd. of Educ. v. Earls*, 536 U.S. 822 (2002).

<sup>90</sup>Office of National Drug Control Policy, *The 2002 National Drug Control Strategy, National Priorities II: Healing America’s Drug Users*, *available at* <http://www.whitehousedrugpolicy.gov/publications/policy/03ndcs/2priorities.html> (last visited May 7, 2003) (bold emphasis added; italics original).

<sup>91</sup>“Healing America’s Drug Users: Getting Treatment Resources Where They Are Needed,” *In the National Drug Control Strategy: 2003. op.cit.*

## IV. NEUROCOPS: LEGAL ISSUES RAISED BY COMPULSORY PHARMACOTHERAPY

The compelled use of pharmacotherapy, whether “compassionate” or otherwise, would raise a number of legal issues. Given that the United States Government has adopted a policy framed by a metaphor that combines fighting war and illness, and which expressly analogizes the use of illegal drugs to cancer, the potential for infringing on constitutional guarantees and other legal rights is apparent. It is well known and widely accepted that treating cancer often requires drastic measures that 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.”<sup>92</sup> Inasmuch as substantial damage has already been done to the United States Constitution in order to fight the war on drugs,<sup>93</sup> signs foreshadow a continued erosion of individual freedoms justified as an unavoidable side-effect of waging war on the “cancer” of illegal drug use.

Among the rights implicated by compulsory use of pharmacotherapy drugs are the rights to bodily integrity, privacy, and freedom of thought, as well as the right to provide informed consent before receiving medical treatment. For prisoners, the Eighth Amendment protection against cruel and unusual punishment is also implicated.

*A. Privacy and Liberty Interests Implicated by Involuntary Pharmacotherapy*

In one of his earliest legal opinions, and while still serving as a state court judge, Justice Cardozo, sounded a chord that has echoed through many subsequent cases, writing in 1914 that “[e]very human being of adult years and sound mind has a right to determine what shall be done with his own body.”<sup>94</sup> The Supreme Court has routinely recognized that a fundamental aspect of privacy is the “freedom to care for one’s health and person, [free] from bodily restraint or compulsion.”<sup>95</sup> This principle was affirmed by the United States Supreme Court in 1990, when in the *Cruzan* case, the Majority noted, “[t]he principle that a competent adult has a constitutionally protected liberty interest in refusing unwanted medical treatment may be inferred from our prior decisions.”<sup>96</sup> Unfortunately, the precise nature and root of this liberty interest remains vague. Professor Winick, for example, notes that “[a]lthough the Supreme Court’s recent decisions . . . recognize that involuntary medication may implicate a constitutionally protected liberty interest, they do not explore the nature of that interest and leave unresolved many of the substantive and procedural

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<sup>92</sup>SONTAG, *supra* note 82, at 65.

<sup>93</sup>See A Report of The Special Committee on Drugs and the Law of the Association of the Bar of the City of New York A Wiser Course: Ending Drug Prohibition (June 14, 1994), <http://www.drugtext.org/library/reports/nylawyer/nylawyer.htm> (“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.”).

<sup>94</sup>*Schloendorff v. Soc’y of N.Y. Hospital*, 105 N.E. 92, 93 (N.Y. 1914), *overruled in part* by *Bing v. Thunig*, 143 N.E.2d 3 (N.Y. 1957).

<sup>95</sup>*Doe v. Bolton*, 410 U.S. 179, 213 (1973) (Douglas, J., concurring).

<sup>96</sup>*Cruzan v. Director, Mo. Dep’t of Health*, 497 U.S. 261, 278 (1990).

constitutional questions raised by involuntary treatment.”<sup>97</sup> The right to refuse unwanted medical treatment appears to be derived from the common law tort of battery, combined with liberty interests protected by the Due Process Clause of the Fourteenth Amendment, including the right to bodily integrity, the right of privacy, and a general principle of individual autonomy.<sup>98</sup> In practice, these interests have been protected by the legal requirements of informed consent.

Yet, compelling a person to use a pharmacotherapy drug seems to implicate more than the bodily integrity rights noted above. Also at stake is the right to “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.”<sup>99</sup>

Unfortunately, the right to freedom of thought is woefully underdeveloped given the capabilities of modern psychopharmacology and continuing advances in the neurosciences. 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.<sup>100</sup> Because pharmacotherapy drugs target brain function,

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<sup>97</sup>BRUCE J. WINICK, *THE RIGHT TO REFUSE MENTAL HEALTH TREATMENT*, 15 (1st ed. 1997).

<sup>98</sup>See F. ROZOVSKY, *CONSENT TO TREATMENT: A PRACTICAL GUIDE* § 1.3 LEGAL THEORIES OF CONSENT; see also WINICK, *supra* note 97, at 189, 222 (concluding that the involuntary administration of antipsychotic medication, psychosurgery, and electronic stimulation for the brain implicate a liberty interest protected by due process,” and are “so serious and long-lasting that the liberty interest invaded by these treatments should be considered fundamental,” requiring heightened judicial scrutiny when sought to be imposed coercively).

<sup>99</sup>*Palko v. Connecticut*, 302 U.S. 319, 326-27 (1937), *overruled by Benton v. Maryland*, 395 U.S. 784 (1969).

<sup>100</sup>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<sup>®</sup> 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, “[a]ntidepressants were the world’s third-largest therapy class in 2000[.]” IMS Health, *Expanding and Protecting an Antidepressant’s Sales*, available at [http://www.ims-global.com/insight/news\\_story/0107/news\\_story\\_010726a.htm](http://www.ims-global.com/insight/news_story/0107/news_story_010726a.htm). Global pharmaceutical sales of antidepressants and mood stabilizers was 19.8 billion in 2005. The same year, Global antipsychotic drug sales reached 16.2 billion. Ims Health, *Leading Therapy Classes by Global Pharmaceutical Sales*, [http://www.imshealth.com/ims/portal/front/articleC/0,2777,6599\\_77478579\\_77479683,00.html](http://www.imshealth.com/ims/portal/front/articleC/0,2777,6599_77478579_77479683,00.html). 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] [a]ntipsychotic prescriptions totaled eleven million in 1998.” CATHERINE HARRINGTON ET AL., *THE LEWIN GROUP, ACCESS AND UTILIZATION OF NEW ANTIDEPRESSANT AND ANTIPSYCHOTIC MEDICATIONS* (2000), available at <http://aspe.hhs.gov/search/health/reports/Psychmedaccess/index.htm#TOC> (last visited Aug. 20, 2000). I should underscore that, in my opinion, the development of such drugs is to be applauded for their potential to aid millions of suffering people who voluntarily use them.

often blocking entire classes of receptors, they will undoubtedly have some effects on how a person thinks. The pharmacotherapy drug SR141716, for example, indiscriminately blocks the brain's CB1 receptors. As a result, even the brain's natural endocannabinoids are blocked from entering their home receptors. These endocannabinoids are believed to play a major role in how we feel stress and pain, how we sleep, how we modulate food intake, and even how well we remember.<sup>101</sup>

For the right to freedom of thought to mean anything, it can no longer exist in a Cartesian quarantine, blind to the connection between our thoughts and our brains. To avoid eroding freedom of thought from below, it must be found to inherently protect the integrity of a person's underlying functional neurochemistry.<sup>102</sup> Coercive pharmacotherapy would substantially violate that integrity and thus should be seen as infringing the right to freedom of thought.

### B. Informed Consent

The principle of informed consent was first articulated in the Nuremberg Code, the first sentence of which states: "[t]he voluntary consent of the human subject is absolutely essential."<sup>103</sup> Today, all fifty states have laws that protect informed consent. These laws require that before performing medical experiments, procedures, or treatments, medical personnel must make certain disclosures to patients and obtain the patient's consent.<sup>104</sup>

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<sup>101</sup>Mark Greener, *Pharmacy Update: A Gift From the Gods?*, in CHEMIST & DRUGGIST MODULE 1328 (Feb. 19, 2005), <http://www.dotpharmacy.co.uk/up1328.pdf> (last visited June 27, 2005).

<sup>102</sup>See Brief Amicus Curiae of the Center for Cognitive Liberty & Ethics in Support of the Petition for Certiorari, *Sell v. United States*, 539 U.S. 166 (2003) (No. 02-5664), available at [http://supreme.usatoday.findlaw.com/supreme\\_court/briefs/02-5664/02-5664.ami.pet.ccle.pdf](http://supreme.usatoday.findlaw.com/supreme_court/briefs/02-5664/02-5664.ami.pet.ccle.pdf) (last visited June 27, 2005) (arguing the merits of cognitive liberty and security and elaborating the concepts of "cognitive liberty" and "cognitive security" as necessary components of the right to freedom of thought is the project of a longer article by the author currently in progress).

<sup>103</sup>See Jay Katz et al., *Experimentation with Human Beings: The Authority of the Investigator, Subject, Professions, and State in Human Experimentation Process*, 305-306 (1972) (containing full text of the Nuremberg Code).

<sup>104</sup>JONATHAN P. TOMES, *LAW INFORMED CONSENT: A GUIDE FOR THE HEALTHCARE PROFESSIONAL*, 69-102 (1993). California, for example, has an informed consent provision in its Penal Code, which in pertinent part states:

It is hereby recognized and declared that all persons, including all persons involuntarily confined, have a fundamental right against enforced interference with their thought processes, states of mind, and patterns of mentation through the use of organic therapies; that this fundamental right requires that no person with the capacity for informed consent who refuses organic therapy shall be compelled to undergo such therapy . . . .CAL. PENAL CODE § 2670 (2005).

Another provision, however, appears to specifically exempt Antabuse, and similar metabolism modifiers from the informed consent requirements, stating "[n]othing in this article shall be construed to prevent the administration of drugs not connected with a program of conditioning and intended to cause negative physical reactions to ingestion of alcohol or drugs." CAL. PENAL CODE § 2670.5(3)(f) (2005).

In general, informed consent requires the satisfaction of two conditions. First, trained medical personnel must tell the patient 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.<sup>105</sup> Coercion is clearly anathema to informed consent: [i]nformed 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."<sup>106</sup>

Coercion, whether "compassionate" or otherwise, is still coercion. Indeed, "compassionate coercion" can be more insidious. As Justice Brandeis 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."<sup>107</sup>

Although it is a criminal offense to use or possess drugs such as marijuana, opium, and cocaine for nonmedical purposes,<sup>108</sup> a person who desires medical treatment for his or her drug use does not forfeit the right to decide whether to utilize

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<sup>105</sup>The American Medical Association's (AMA) "General Statement on Informed Consent," Code of Medical Ethics, states:

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.

AMERICAN MEDICAL ASSOCIATION: COUNCIL ON ETHICAL AND JUDICIAL AFFAIRS, AMA CODE OF MEDICAL ETHICS § E-8.08 (1981), <http://www.ama-assn.org/ama/pub/category/8488.html> (last visited Jan. 7, 2005).

<sup>106</sup>45 FR 78600.

<sup>107</sup>*Olmstead v. United States*, 277 U.S. 438, 479 (1928) (Brandeis, J., dissenting).

<sup>108</sup>Depending on the circumstances and the jurisdiction, it is sometimes legal to use these drugs for *medical* purposes. Eight states currently allow sick people to use marijuana for medical purposes, although the federal government is hostile and has indeed prosecuted medical users and caregivers in states with medical marijuana protections. Opium and cocaine are both Schedule II substances, which under federal law can be used with a doctor's prescription.



drug-based medical treatment. There is no “drug war exception” to informed consent requirements.

The only exceptions to requirements for informed consent, besides emergencies, concern persons who have been declared mentally incompetent, or who are too young to make their own medical decisions. What, exactly, is meant by “mentally incompetent” remains vague. “Although the competency question is...of critical importance,” notes Professor Winick in his comprehensive examination of the right to refuse mental treatment, “no general agreement exists concerning the appropriate legal standard for ascertaining competency to provide informed consent.”<sup>109</sup> While “Substance Dependence” and “Substance Abuse” are diagnostic categories within the Diagnostic and Statistical Manual of Mental Disorders (DSM-IV), a diagnosis pursuant to the DSM-IV is insufficient for a de facto legal finding of mental incompetence.<sup>110</sup> The DSM-IV itself instructs “[I]n most situations, the clinical diagnosis of a DSM-IV disorder is not sufficient to establish the existence for legal purposes of a ‘mental disorder, ‘mental disability,’ ‘mental disease,’ or ‘mental defect.’ In determining whether an individual meets a specified legal standard (e.g., for competence...), additional information is usually required beyond that contained in the DSM-IV diagnosis.”<sup>111</sup> No court has gone so far as to equate the mere use or abuse of illegal drugs with mental incompetence. In only rare circumstances will a person’s use, or even addiction to, an illegal drug render that person “mentally incompetent” such that he or she should be exempted from informed consent requirements.

Accordingly, for the vast majority of people, including those who use illegal drugs, the rights to bodily integrity, privacy, and freedom of thought, along with the right of informed consent should stand as a strong and broad barrier to coercive pharmacotherapy.

### *C. At Risk Targets for Coercive Pharmacotherapy*

In practical terms, however, some people are more at risk of coercive pharmacotherapy than others. From 1907 to 1978, over 60,000 Americans were forcibly sterilized under state sterilization laws.<sup>112</sup> These laws targeted criminals, the mentally handicapped, people with low IQs, and those suffering from mental illness. The enforcement of state and federal drug prohibition laws has been disproportionately focused on the poor and on people of color. As speakers at a 2002 civil rights conference lamented, “[o]ur 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

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<sup>109</sup>WINICK, *supra* note 97, at 349.

<sup>110</sup>In addition to the general dependence and abuse diagnosis defined by the DSM-IV, there is also a range of more specific diagnosis based on the particular substance (e.g., alcohol, cannabis, cocaine, etc.) involved. See AMERICAN PSYCHIATRIC ASSOCIATION, DIAGNOSTIC AND STATISTICAL MANUAL OF MENTAL DISORDERS (4th ed. 1994).

<sup>111</sup>*Id.* at xxiii.

<sup>112</sup>PHILIP REILLY, THE SURGICAL SOLUTION: A HISTORY OF INVOLUNTARY STERILIZATION IN THE UNITED STATES 87 (1991).

civil rights progress.”<sup>113</sup> 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.<sup>114</sup>

People who have been arrested for drug offenses, who are serving time in prison, or who rely on public assistance or other public benefits (including the country’s 59 million public school children)<sup>115</sup> are likely the most vulnerable targets for coercive pharmacotherapy.

### 1. Pharmacotherapy and Public Education

Each year roughly ninety-seven percent of American school children are vaccinated against childhood diseases as a precondition to attending school.<sup>116</sup> 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,<sup>117</sup> and today nearly every state has laws requiring children to 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.<sup>118</sup>

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. Government rhetoric, however, is already laying the groundwork for responding to such parental objections. According to the 2001

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<sup>113</sup>Ronald H. Welch & Carlos T. Angulo, *Justice On Trial: Racial Disparities in the American Criminal Justice System* (Washington, DC: Leadership Conference on Civil Rights/Leadership Conference Education Fund, May 2000), p. v.

<sup>114</sup>Human Rights Watch, *Punishment and Prejudice: Racial Disparities in the War on Drugs*, Key Recommendations, <http://www.hrw.org/campaigns/drugs/war/key-reco.htm>.

<sup>115</sup>United States Census Bureau, *School Enrollment – Social and Economic Characteristics of Students: October 2003 1* (2005), available at <http://www.census.gov/prod/2005pubs/p20-554.pdf> (last visited June 27, 2005).

<sup>116</sup>Centers for Disease Control and Prevention, *Vaccination Coverage Among Children Enrolled in Head Start Programs and Licensed Child Care Centers and Entering School – United States and Selected Reporting Areas, 1999–2000 School Year*, 50(39) *MORBIDITY AND MORTALITY WKLY. REP.* 846, 849 (2001), <http://www.cdc.gov/mmwr/PDF/wk/mm5039.pdf> (last visited June 27, 2005).

<sup>117</sup>*Jacobson v. Massachusetts*, 197 U.S. 11 (1905).

<sup>118</sup>*See In re Christine M.*, 595 N.Y.S.2d 606, 607 (N.Y. Fam. Ct. 1992) (petition alleging that “the subject child Christine . . . is a neglected child within the meaning of Family Court Act . . . in that ‘the respondent [parent] . . . refuses to have Christine immunized in accordance with the recommendations of a physician’”).

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 and "place people at increased risk for a wide variety of other illnesses."<sup>119</sup> For example, elaborating on how drug abuse breeds infectious disease, former "Drug Czar" General McCaffrey writes:

Drug abuse, whether directly or indirectly, is now a major vector for the transmission of infectious diseases, including 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.<sup>120</sup>

American schoolchildren are already subject to reduced constitutional protections, especially when illegal drugs are concerned. 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."<sup>121</sup>

In that case, the Supreme Court stated:

[t]he 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.<sup>122</sup>

In the same opinion the Court remarked, "[s]choolchildren 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."<sup>123</sup>

On December 1, 2003, NIDA published an official notice seeking grant applications focusing on "the identification, evaluation, and development of safe and

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<sup>119</sup>The Office of National Drug Control Policy, *supra* note 77, at Introductory Pgph.

<sup>120</sup>Office of National Drug Control Policy, The 2001 National Drug Control Strategy, Ch. 1, § 4, The Public-Health Dimension of Substance Abuse, <http://www.ncjrs.org/ondcppubs/publications/policy/ndcs01/chap1.html#4> (last visited June 27, 2005).

<sup>121</sup>*Bd. of Educ. v. Earls*, 536 U.S. 822, 825 (2002); *see also* 20 U.S.C. § 1091(r) (2005) ("A student who has been convicted of any offense under any Federal or State law involving the possession or sale of a controlled substance shall not be eligible to receive any grant, loan, or work assistance . . . during the period beginning on the date of such conviction and ending after the interval specified . . .").

<sup>122</sup>*Earls*, 536 U.S. at 836.

<sup>123</sup>*Id.* at 830-31.

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.<sup>124</sup>

On such a landscape, there is at least a reasonable possibility 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 efforts to require children to accept various pharmacotherapy “vaccines” as a precondition to attending public school or to participating in sports and other extracurricular activities.

Indeed, in July 2004, the British newspaper *The Independent* reported:

A radical scheme to vaccinate children against future drug addiction is being considered by ministers . . . Under the plans, doctors would immunize children at risk of becoming smokers or drug users with an injection. The scheme could operate in a similar way to the current nationwide measles, mumps and rubella vaccination program.<sup>125</sup>

Such plans, should they ever be implemented, would clearly violate the right to informed consent if not entirely voluntary. Despite government rhetoric equating drug use with infectious disease and pharmacotherapy drugs with “vaccinations,” the analogies fail. Drug use bears no relationship to infectious diseases like measles, mumps, or rubella, and pharmacotherapy is not a “vaccine.” Further, while the cases that have upheld drug testing of public school children have been premised on the “important interest in detecting and preventing drug use among its students,”<sup>126</sup> and on the interest of “prevent[ing] and deter[ing] the substantial harm of childhood drug use,”<sup>127</sup> interests that could just as easily be offered in support of pharmacotherapy, a major distinction exists between drug testing and coercive pharmacotherapy. Currently, drug testing is performed on fluids or hair removed from the child’s body in a relatively noninvasive manner. While government examination of a child’s bodily fluids or hair raises significant privacy issues (issues which the courts have placed secondary to the state’s interest in deterring and preventing illegal drug use by school children), those privacy issues pale in comparison to the very direct affront to

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<sup>124</sup>National Institutes of Health, National Institute on Drug Abuse, RFD-DA-04-014, Medications Development for Cannabis-Related Disorder (2003), <http://grants.nih.gov/grants/guide/rfa-files/RFA-DA-04-014.html> (last visited June 29, 2005).

<sup>125</sup>Sophie Goodchild & Steve Bloomfield, *Children to Get Jabs Against Drug Addiction: Ministers Consider Vaccination Scheme. Heroin, Cocaine and Nicotine Targeted*, THE INDEPENDENT (UK), July 25, 2004, <http://cocaine.org/vaccine/uk.html> (last visited June 29, 2005).

<sup>126</sup>*Earls*, 536 U.S. at 825.

<sup>127</sup>*Id.* at 836.

bodily integrity and privacy that would be raised by government requiring a student to take a particular pharmacotherapy drug *into* his or her body and brain.<sup>128</sup>

## 2. Pharmacotherapy and Public Assistance

Future recipients of public assistance might conceivably be threatened with compulsory pharmacotherapy as a condition to receiving benefits. Although studies indicate that welfare recipients do not use or abuse illegal drugs in any greater percentage than working people,<sup>129</sup> the stereotype of “drug-using welfare recipients” is widespread and has resulted in increased government control and even 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.<sup>130</sup>

Federal law imposes a lifetime bar on any individual convicted of a drug felony from receiving food stamps.<sup>131</sup> People convicted of drug felonies are also barred from voting in many states. 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.<sup>132</sup>

In 1996, Congress ended the federal welfare system as an entitlement program. Under the new Personal Responsibility and Work Opportunity Reconciliation Act of 1996, cash assistance for individuals is now limited and can be conditioned on meeting job-seeking requirements and adhering to “personal responsibility codes.”<sup>133</sup> One provision of the new Act authorizes states to impose mandatory drug testing as a prerequisite to receiving state assistance.<sup>134</sup> As a result, Louisiana passed a law in

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<sup>128</sup>While the precise roots and scope of the “liberty” interest remain unarticulated, the Supreme Court has recognized that “[t]he forcible injection of medication into a nonconsenting person’s body represents a substantial interference with that person’s liberty.” *Washington v. Harper*, 494 U.S. 210, 229 (1990).

<sup>129</sup>According to a federal study, “[t]he percentage of welfare recipients using, abusing, or dependent on alcohol or drugs [is] relatively small and consistent with the general US population and those not receiving welfare benefits.” B. Grant, & D. Dawson, *Alcohol and Drug Use, Abuse, and Dependence among Welfare Recipients*, 86 AM. J. HEALTH 1450 (1996).

<sup>130</sup>42 U.S.C. §§ 1437d(s), 1437d(t) (2005); *see also* 42 U.S.C. § 1437d(l)(6) (2005) (codifying “one-strike” eviction policies that allow public housing agencies to immediately evict tenants on the basis of any criminal drug activity occurring on or off the premises); *see also* *Dep’t of Hous. v. Rucker*, 535 U.S. 125 (2002) (upholding a local Public Housing Authority’s power to evict an entire family based on the one-strike policy, regardless of any prior knowledge on the part of the leaseholder).

<sup>131</sup>21 U.S.C. § 862a(a)(2) (2005). *But see* 21 U.S.C. § 862a(d)(1)(A) (2005) (allowing states to opt out of all or part of the ban. Twenty-nine states have exercised that right.).

<sup>132</sup>P. Thomas, *Study Suggests Black Male Prison Rate Impinges on Political Process*, THE WASHINGTON POST, Jan. 30, 1997, at A3.

<sup>133</sup>*See* 42 U.S.C. §§ 601-02, 604 (2005).

<sup>134</sup>21 U.S.C. § 862b (2005).

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.<sup>135</sup>

In early 2005, the 109<sup>th</sup> Congress debated a bill to deny federal welfare funding to any state that does not drug test those applying for or receiving welfare benefits.<sup>136</sup> In 1999, Michigan legislators passed a similar law conditioning public assistance on passing a random drug test.<sup>137</sup> The law was 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.<sup>138</sup>

Three basic versions of legislation that might endeavor to connect public aid to pharmacotherapy can be anticipated. In order of increasing concern, these laws 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 as a precondition to receiving public aid.

#### *a. Reimbursing Voluntary Pharmacotherapy*

Programs reimbursing public assistance recipients for the expense of voluntary pharmacotherapy appear to raise few legal concerns. All fifty states, for example, currently have programs reimbursing indigent people for the cost of surgery to implant the long-acting contraceptive device Norplant<sup>®</sup>.<sup>139</sup>

Studies have shown that it is good public policy to provide free drug treatment for those who seek treatment but cannot afford it.<sup>140</sup> If informed and voluntary use of

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<sup>135</sup>Robyn Meredith, *Testing Welfare Applicant for Drugs*, N.Y. TIMES (late ed.), May 30, 1999, at A14, <http://www.mapinc.org/drugnews/v99/n575/a04.html?1690> (last visited June 29, 2005).

<sup>136</sup>See The Personal Responsibility, Work, and Family Promotion Act of 2005, H.R. 240, 109th Cong., *available at* [http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=109\\_cong\\_bills&docid=f:h240ih.txt.pdf](http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=109_cong_bills&docid=f:h240ih.txt.pdf) (last visited June 29, 2005).

<sup>137</sup>MICH. COMP. LAWS § 400.571 (2005).

<sup>138</sup>Marchwinski v. Howard, 113 F. Supp. 2d 1134 (D. Mich. 2000), *aff'd en banc*, 60 Fed. Appx. 601 (6th Cir. 2003).

<sup>139</sup>'Norplant' is a registered trademark of the Population Council. It is a long-acting implantable contraceptive device for women, approved by the FDA for general use on December 10, 1990. Consisting of six match-sized plastic capsules containing the synthetic hormone levonorgestrel, 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. See Drugs.com, Norplant Information Page, [http://www.drugs.com/MTM/N/Norplant\\_System.html](http://www.drugs.com/MTM/N/Norplant_System.html); see also Dorothy E. Roberts, *In the Context of Welfare and Reproductive Rights: The Only Good Poor Woman: Unconstitutional Conditions and Welfare*, 72 DENV. U.L. REV. 931 (1995).

<sup>140</sup>See C. PETER RYDELL & SUSAN S. EVERINGHAM, CONTROLLING COCAINE: SUPPLY VERSUS DEMAND PROGRAMS xvi (1994), *available at* <http://www.rand.org/publications/MR/MR331/> (last visited June 29, 2005) ("Domestic enforcement costs 4 times as much as

pharmacotherapy will aid in the treatment process, no reason exists to exclude it from reimbursement. Public funds for voluntary pharmacotherapy ought to be available to subsidize that treatment, especially when the government is enthusiastically willing to spend thousands of dollars to arrest and imprison that same person for using a controlled substance.

Unfortunately, federal funds are predominantly allocated to policing and enforcing criminal drug prohibition, rather than to funding treatment on demand. In 2002, for example, less than twenty percent of the federal drug control policy budget was allocated to funding treatment programs.<sup>141</sup>

Nothing is coercive about reimbursing an indigent person for the costs of medical treatment. More worrisome is that people living in poverty typically have reduced access to professional medical advice concerning elective procedures. As a result, they may find it 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. Indeed, some of the pharmacotherapy drugs are so new that data concerning their long-term side effects has yet to be collected or analyzed. Without sufficient access to medical information and advice, consent to undergo pharmacotherapy, while perhaps voluntary, would not be informed, and hence would not satisfy the requirements of informed consent.

*b. Financial Incentive to Undergo Pharmacotherapy*

Another foreseeable form of future 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 also receive an additional bonus payment if he or she agreed to undergo pharmacotherapy.

Less than a year after the Norplant contraception device was approved, a Kansas legislator introduced a bill 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.<sup>142</sup> After the bill failed, its author proposed a second bill that would have made the insertion of Norplant a condition of probation for women convicted of certain drug possession offenses.<sup>143</sup> That bill also did not pass. Representative David Duke of Louisiana (an admitted 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

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treatment for a given amount of user reduction, 7 times as much for consumption reduction, and 15 times as much for societal cost reduction.”)

<sup>141</sup>Office of National Drug Control Policy, *The 2003 National Drug Control Strategy: Budget Highlights*, Budget Summary 6, Table 2 (2002).

<sup>142</sup>H.R. 2089, 74th Leg., 2d Sess. (Kan. 1991) (defeated).

<sup>143</sup>H.R. 2255, 74th Leg., 2d Sess. (Kan. 1991) (died in committee); see Stephanie Denmark, *Birth-Control Tyranny*, N.Y. TIMES, October 19, 1991, at A23; see also Kerry Patrick, *Poor Women and Society Benefit by Linking Norplant, Welfare Aid*, WICHITA EAGLE, (Wichita, Kansas) March 4, 1991, at 11A.

Norplant.<sup>144</sup> All told, at least thirteen states have considered bills that would link state welfare payments to the use of Norplant.<sup>145</sup>

Legislation proposing “bonus” payments for low-income people who agree to undergo pharmacotherapy would likely meet the same unsuccessful political end as efforts to provide bonuses for using Norplant. Assuming, however, that such legislation was successfully enacted in the future, it would raise difficult informed consent issues.

In order to obtain the added financial “bonus” some low-income people, even those who do not use or desire to use illegal drugs, might be tempted to undergo pharmacotherapy. The desire to rise above poverty is a powerful drive, and could lead some people to undergo pharmacotherapy even if it was contraindicated or potentially risky given other pre-existing health concerns. Courts would have to decide whether such economic “coercion” is sufficient to vitiate “voluntary” consent. Being poor in a capitalist system is to be inherently disempowered within that system, causing economic decisions to take on what some might argue are shades of coercion. Even if this is not legally sufficient to constitute coercion, it raises the moral issue of whether government ought to intentionally exploit such economic disadvantages. Further, as discussed in the preceding section, low-income people have reduced access to medical information concerning the purposes, risks, and effects of pharmacotherapy, raising questions that the person’s consent to undergo pharmacotherapy in order to receive a “bonus” payment might be based on insufficient information to satisfy the requirements of informed consent.

*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 public assistance on the use of a pharmacotherapy drug. Under this potential legislative scheme, only those who agree to undergo pharmacotherapy would be eligible for public aid.

Though none of the bills have passed, legislators in several states have sought to condition public assistance on the use of Norplant. 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.”<sup>146</sup> A similar bill was introduced but failed to pass in Florida.

While less coercive than being physically forced to undergo pharmacotherapy, a parent who is dependant upon receiving government assistance in order to pay rent or buy food for his or her children would undoubtedly feel powerless to refuse pharmacotherapy if it meant forfeiting necessary financial assistance. Such a scheme

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<sup>144</sup>H.R. 1584, 17th Reg. Sess. (La. 1991); Maralee Schwartz, *Duke Presses Louisiana Birth Control*, THE WASHINGTON POST, May 29, 1992, at A14.

<sup>145</sup>See Gwendolyn Mink, *The Day, Berry & Howard Visiting Scholar: Welfare Reform in Historical Perspective*, 26 CONN. L. REV. 879 (1994).

<sup>146</sup>S. 2895, (Miss. 1992) (defeated); See David S. Coale, *Norplant Bonuses and the Unconstitutional Conditions Doctrine*, 71 TEX. L. REV. 189, 195 (1992); see also ALAN GUTTMACHER INSTITUTE, *NORPLANT: OPPORTUNITIES AND PERILS FOR LOW-INCOME WOMEN* (SPEC. REP. 1) (Dec. 1992).



would be overtly and intentionally premised on economic coercion and would thus weigh heavily against a finding that “consent” to undergo pharmacotherapy was truly voluntary. Combined with very limited and sometimes non-existent access to professional medical advice, such a legislative scheme would prey upon the poor and encourage the antithesis of informed consent.

In addition, under the Due Process Clause of the Fourteenth Amendment, the government must satisfy the strict scrutiny test in order to allocate public benefits by conditioning that allocation on the waiver of a fundamental right. Thus, if directly imposing pharmacotherapy on a person is found to substantially infringe on the combined rights to privacy, bodily integrity, and freedom of thought, conditioning public assistance on waiving those rights would be unconstitutional unless the government can show that the pharmacotherapy condition serves a compelling state interest and is narrowly tailored to advance that interest.<sup>147</sup> This is known as the Unconstitutional Conditions Doctrine.

Assuming the government’s interest is to reduce or deter the use of illegal drugs by those on public assistance, forced pharmacotherapy is a grossly overbroad means of advancing that interest. As already noted, most people who receive public assistance do not use illegal drugs, and never will. Accordingly, demanding that they all undergo pharmacotherapy in order to receive public assistance would be the antithesis of a “narrowly tailored” means of advancing the government’s interest in enforcing drug prohibition. Even for those aid recipients who are found to use illegal drugs, coercing them to take pharmacotherapy drugs as a precondition to receiving aid is overbroad. The vast majority of drug treatment programs, both in-patient and out-patient, operate with only talk therapy, counseling, encouragement, and monitoring. Therefore, imposing pharmacotherapy even on those aid recipients who are found to use illegal drugs is, not the least restrictive means of reducing or deterring their use of drugs.

### 3. Pharmacotherapy and the Criminal Justice System

Today, of the two million prisoners in the United States (roughly one in every 140 U.S. residents) approximately one quarter are serving time for drug convictions.<sup>148</sup> The United States Supreme Court has held that “convicted prisoners do not forfeit all constitutional protections by reason of their conviction and confinement in prison.”<sup>149</sup> The unique security issues in prison, however, have also led the Court to recognize that the same standard directed to the alleged constitutional violations of nonprisoners does not apply to prisoners. “When a prison regulation impinges on inmates’ constitutional rights, the regulation is valid if it is reasonably related to legitimate penological interests.”<sup>150</sup> This reduced standard, combined with the fact that “rehabilitation” is one of the traditional purposes of the

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<sup>147</sup>Reno v. Flores, 507 U.S. 292, 302 (1993); see Charles R. Bogle, *Unconscionable Conditions: A Contractual Analysis of Conditions on Public Assistance Benefits*, 94 COLUM. L. REV. 193 (1994).

<sup>148</sup>Page M. Harrison & Allen J. Beck, PhD, Bureau of Justice Statistics, *Prisoners in 2002*, Tables 15 & 18, BJS Bull. No. NCJ 200248 (July 2003), <http://www.ojp.usdoj.gov/bjs/pub/pdf/p02.pdf>.

<sup>149</sup>Bell v. Wolfish, 441 U.S. 520, 545 (1979).

<sup>150</sup>Turner v. Safley, 482 U.S. 78, 89 (1987).

criminal justice system, invites the conclusion that pharmacotherapy medicines, which are characterized as “treating” drug addiction, could potentially find their way into prisoners’ blood streams without their 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 in the battle against users of illegal drugs. 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.”<sup>151</sup>

In the near future, a person sentenced to prison for a drug offense might conceivably be forced to take a pharmacotherapy drug as part of his or her “rehabilitation.” Further, given that illegal drugs can reportedly be found in just about every prison in America and because prisoners are politically weak and generally regarded unsympathetically by the general populace, one can even imagine prison officials moving to mandate pharmacotherapy drugs for all inmates as a means of maintaining prison security and safety.

The United States Supreme Court has made clear that “central to all other corrections goals is the institutional consideration of internal security within the corrections facilities themselves.”<sup>152</sup> Further, because judges are removed from the day-to-day challenges and realities that commonly face prison officials and because operation of correctional facilities is “the province of the Legislative and Executive Branches of our Government, not the Judicial,” prison administrators are accorded “wide-ranging deference in the adoption and execution of policies and practices that in their judgment are needed to preserve internal order and discipline and to maintain institutional security.”<sup>153</sup>

Prison officials might argue rationally that mandatory pharmacotherapy for all prisoners is a means of increasing the safety of both prisoners and prison workers. Pharmacotherapy within prisons would presumably alter the ratio of benefit to risk for those prisoners able to obtain an illegal drug inside prison. Some prisoners forced to take pharmacotherapy would presumably find that the benefits of using an illegal drug with attenuated effects is outweighed by the risk of being caught with an illegal drug and having his or her sentence increased. This might lead to a reduced demand for drugs within prison and to a corresponding reduction in supply.

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<sup>151</sup>Press Release, The White House: Office of the Press Secretary, The President’s National Drug Control Strategy (Feb. 12, 2002), *available at* <http://www.whitehouse.gov/news/releases/2002/02/20020212-2.html>.

<sup>152</sup>*Pell v. Procnier*, 417 U.S. 817, 823 (1978).

<sup>153</sup>*Bell*, 441 U.S. at 547.

*a. Informed Consent**i. Prisoners*

Unless a court has determined that a prisoner is mentally incompetent, the informed consent requirements discussed earlier retain their validity within the prison context.<sup>154</sup>

While no court, let alone the United States Supreme Court, has ruled on the circumstances in which a prisoner can be forced to undergo pharmacotherapy for illegal drug use, the Supreme Court has placed strict limits on when prison officials can force a prisoner to take psychiatric medication.<sup>155</sup>

A prisoner can be compelled to take psychiatric medication in only two circumstances. First, if he suffers from a serious mental illness and that illness renders him mentally incompetent to make his own medical decisions, then 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.<sup>156</sup> 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 psychiatric medication.<sup>157</sup>

As discussed earlier, no court has ever found that the use of illegal drugs alone constitutes “mental incompetence.” Indeed, no court has found that physical addiction to a drug, by itself, constitutes “mental incompetence.” Thus, forced treatment with pharmacotherapy merely because a prisoner used or is addicted to, an illegal drug would not satisfy the existing tests for when prisoners can be forced to undergo psychiatric treatment. Likewise, even if a psychiatrist found that a

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<sup>154</sup>Under Maryland law, a prisoner who is found to be addicted to drugs may be placed on a supervised methadone treatment plan, but treatment cannot begin without the prisoner’s written informed consent. MD. CODE ANN., CORR. SERVS. § 9-603 (2004).

<sup>155</sup>*Vitek 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 penumbral right to privacy, bodily integrity, or personal security.”); *Runnels v. Rosendale*, 499 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.’ In the case of antipsychotic drugs . . . that interference is particularly severe . . .”) (quoting *Washington v. Harper*, 494 U.S. 210, 229 (1990)).

<sup>156</sup>*See Sell v. United States*, 539 U.S. 166, 182 (2003) (“Every 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.”).

<sup>157</sup>*Washington v. Harper* 494 U.S. 210, 227 (1990). Federal regulations set forth specific procedures that must be followed before prisoners can be forced against their will to take a psychotropic medicine. *See* 28 C.F.R. 549.43.

prisoner's illegal drug use or addiction constituted a "substance abuse disorder" within the DSM-IV, this finding alone does not constitute mental incompetence.<sup>158</sup> Therefore, forcing a prisoner to undergo pharmacotherapy would not be justified unless that prisoner's drug use was producing a mental illness that led him or her to pose a danger to others within the prison. These rules instruct that in all but extraordinary circumstances, and only after findings that comply with due process, prison authorities would be acting unlawfully if they were to compel a prisoner to take a pharmacotherapy drug against his or her will. Unless a prisoner is dangerous to others or is determined to be mentally incompetent, he or she has a right to refuse pharmacotherapy drugs and a right to give informed consent before receiving them.

ii. Parolees and Probationers

In addition to the roughly two million Americans currently serving time behind bars, an additional 4.8 million Americans are on parole or probation.<sup>159</sup> The overwhelming majority of people charged with violating federal or state drug prohibition laws are placed on probation, rather than incarcerated.<sup>160</sup> 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.<sup>161</sup> Most states have laws that require sentencing courts to impose various conditions on probationers conditions that 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 professor 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."<sup>162</sup>

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<sup>158</sup> "[M]ental illness or disability is insufficient in itself to constitute incompetence." (PAUL S. APPELBAUM & THOMAS G. GUTHIEL, *CLINICAL HANDBOOK OF PSYCHIATRY AND LAW* 220 (2d ed. 1991).

<sup>159</sup> Bureau of Justice Statistics, Probation and Parole Statistics: Summary Findings, at <http://www.ojp.usdoj.gov/bjs/pandp.htm> (last visited Dec. 28, 2004); Bureau of Justice Statistics, Prison Statistics: Summary Findings, available at <http://www.ojp.usdoj.gov/bjs/prisons.htm> (last modified Apr. 24, 2005); see also Bureau of Justice Statistics, Corrections Statistics: Summary Findings, available at <http://www.ojp.usdoj.gov/bjs/correct.htm> (last visited Mar. 1, 2005) ("In 2003, 6.9 million people were on probation, in jail or prison, or on parole at yearend 2003 -- 3.2% of all U.S. adult residents or 1 in every 32 adults.").

<sup>160</sup> Lauren E. Glaze & Seri Palla, Bureau of Justice Statistics, Probation and Parole in the United States, 2003, BJS Bull. No. NCJ 205336 (July 2004), <http://www.ojp.usdoj.gov/bjs/pub/pdf/ppus03.pdf>.

<sup>161</sup> *Burns v. United States*, 287 U.S. 216, 220 (1932).

<sup>162</sup> Andrew Horwitz, *Coercion, Pop-Psychology, and Judicial Moralizing: Some Proposals for Curbing Judicial Abuse of Probation Conditions*, 57 WASH. & LEE L. REV. 75 (2000) (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.<sup>163</sup> 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 court will almost assuredly attempt to impose pharmacotherapy as a condition of granting probation to a defendant in a drug case. There is precedent.

In 1992, the 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 three months.<sup>164</sup>

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 seventy-five 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 preoccupations."<sup>165</sup> Its use in men is not without side effects, some of which include:

increased appetite, weight gain of fifteen to twenty pounds, 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 the blood pressure, hypertension, phlebitis,

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<sup>163</sup>See SAMHSA, *Office of Applied Studies, The Dasis Report: How Men and Women Enter Substance Abuse Treatment* (Sep. 2001), <http://www.drugabusestatistics.samhsa.gov/2k1/enterTX/enterTX.htm> ("For men, the most frequent source of referral to drug treatment is through the criminal justice system. [In 1998], [s]ome 39 percent of men, compared to 25 percent of women, entered treatment as the result of a judicial process . . . . Sixty-two percent of adult men entering treatment for marijuana abuse were sent by the criminal justice system . . .").

<sup>164</sup>American Academy of Family Physicians, *Depo-Provera: An Injectable Contraceptive*, available at <http://www.familydoctor.org/handouts/043.html> (last visited July 5, 2005).

<sup>165</sup>Fred S. Berlin, *The Paraphilias and Depo-Provera: Some Medical, Ethical and Legal Considerations*, 17 BULL. AM. ACAD. PSYCHIATRY L. 233, 235 (1989); see also Berlin & Meinecke, *Treatment of Sex Offenders With Antiandrogenic Medication: Conceptualization, Review of Treatment Modalities, and Preliminary Findings*, 138(5) AM. J. PSYCHIATRY 604 (1981); see also Letter From Public Citizen Health Research Group to Connecticut Depo-Provera Task Force (Oct. 17, 1983), at p. 8 (The Connecticut Department of Correction appointed a study group to consider the use of the drug for male sex offenders in 1983, but the committee rejected the proposal primarily because of the committee's "very real concerns about the safety of this drug."); see also Pierre Gagne, *Treatment of Sex Offenders With Medroxyprogesterone Acetate*, 138(5) AM. J. PSYCHIATRY 644 (1981) (stressing that MPA therapy treatment be undertaken only with the patient's informed consent and that it be accompanied by counseling); see also *People v. Gauntlett*, 352 N.W.2d 310, 315-316 (Mich. Ct. App. 1984).

diabetic sequelae, thrombosis (leading to heart attack), and shrinkage of the prostate and seminal vessels.<sup>166</sup>

While for some men suffering from an unhealthy obsession with sex, voluntary use of MPA could prove helpful, but use of MPA quickly expanded beyond voluntary use. California, Florida, Georgia, Iowa, Louisiana, Montana, and Oregon have all passed chemical castration statutes.<sup>167</sup> While these statutes vary, most provide a legislative authorization for court-imposed MPA injections as a probation condition for certain sexual offenses.<sup>168</sup> Similarly, while Norplant is considered very reliable and many women use it voluntarily, use of Norplant 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.<sup>169</sup> Others have also.<sup>170</sup>

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<sup>166</sup>Larry Helm Spalding, *Florida's 1997 Chemical Castration Law: A Return to the Dark Ages*, 25 FLA. ST. U. L. REV. 117, 125 (1998) (citations omitted).

<sup>167</sup>CAL. PENAL CODE § 645 (2005) (permitting MPA treatment for parolees who have committed specified sex offense); FLA. STAT. § 794.0235 (2005) (providing for administration of MPA treatment to persons convicted of sexual battery, but medical expert must first find that the defendant is an appropriate candidate for treatments and the court order must specify duration of treatment); GA. CODE ANN. § 42-9-44.2 (2004) (giving the Board of Pardons discretionary authority to administer MPA treatment coupled with mandatory counseling as a condition of parole for child molesters); IOWA CODE § 903B.1 (2004) (providing that persons convicted of certain first time sex offenses may undergo hormonal intervention therapy as a condition of release); LA. REV. STAT. ANN. § 15:538 (2005) (allowing for the use of MPA as part of a voluntary treatment plan that convicted sex offenders has to undertake if they are to receive probation or parole); MONT. CODE ANN. § 45-5-512 (2004) (providing for MPA treatment of sex offenders); OR. REV. STAT. § 144.625 (2003) (establishing pilot MPA treatment program for certain sex offenders). In addition, in 1996 and 1997, chemical castration bills were introduced in Alabama, Arizona, Colorado, Hawaii, Michigan, Mississippi, Missouri, New Jersey, New York, Oregon, and Tennessee. Larry Helm Spalding, *Florida's 1997 Chemical Castration Law: A Return to the Dark Ages*, 25 FLA. ST. U.L. REV. 117, 139 n.14 (1998).

<sup>168</sup>In 1984, a Michigan judge conditioned a man's grant of probation in a sexual misconduct case on the man's use of Depo-Provera. *People v. Gauntlett*, 352 N.W.2d 310, 311 (Mich. Ct. App. 1984). The man appealed, arguing that the condition was “unconstitutional as cruel and unusual punishment, a violation of fundamental rights of liberty, privacy, bodily integrity, equal protection, and procedural and substantive due process.” *Id.* at 314. The Michigan Appellate Court reversed the Depo-Provera condition, but did so without reaching the constitutional issues. Rather, the appellate court held that use of MPA in males for the purpose of decreasing sex drive “fails as a lawful condition of probation because it has not gained acceptance in the medical community as a safe and reliable medical procedure.” *Id.* at 316. The appellate court also raised concerns about informed consent, noting that both prisoners and mentally incompetent persons “enjoy a greater degree of protection from extraordinary medical procedures.” *Id.*

<sup>169</sup>*People v. Johnson* (Cal. Super. Ct., Tulare County 1991) (No. 29390). The woman's “attorney, who had not been at the probation hearing, asked the court to set aside the terms of the probation in view of [the woman's] medical unsuitability for Norplant treatment, her constitutional right to privacy, and the statutory argument that Norplant was unrelated to her rehabilitation.” Melissa E. Fraser, Note, *Gender Inequality in In Vitro Fertilization*:

Further, while no reliable information has been found on its prevalence today, some courts have conditioned a grant of probation for alcohol-related offenses on the probationer using Antabuse. In the late 1970s, the federal government funded pilot programs testing the use of Antabuse as a probation condition in some drunk-driving and public intoxication cases. A total of thirteen county court systems received funding under the "Demonstration Programs in Antabuse."<sup>171</sup> A law review analysis of the pilot program found that it was an unconstitutional invasion of privacy, cruel and unusual punishment, and failed to comply with the requirements for informed consent.<sup>172</sup> The article concluded that "[b]ecause Antabuse's effects are highly invasive, and because the judicial context of such programs is inherently coercive, courts should not employ the drug at all. Instead they should adopt rehabilitation schemes . . . that attempt to re-educate alcohol offenders without the use of drugs."<sup>173</sup>

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 knowledge, training, or time necessary to make the required advisements to the defendant for each particular pharmacotherapy drug, let alone to assess the defendant's own unique healthcare and treatment issues. 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 incarceration and "medical treatment" with a pharmacotherapy drug is inherently coercive.<sup>174</sup> There are very few things that people will avoid more than going to jail or prison. Any alternative to loss of physical freedom, separation from family and friends, and loss of employment and income, will have an undeniably attractive appearance. It is hard to see how such an inherently coercive situation—one that essentially forces a

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*Controlling Women's Reproductive Autonomy*, 2 N.Y. CITY L. REV. 183, 207 (1998) (citations omitted). The Judge refused to reconsider the condition, and on appeal, the merits of the condition were not discussed because the woman was found to have violated her probation by using drugs. *Id.* Thus, the Norplant condition was moot on appeal. *Id.* See *Birth Curb Order Is Declared Moot*, N.Y. TIMES, Apr. 15, 1992, at A23; see also Matthew Rees, *Shot in the Arm: The Use and Abuse of Norplant. Involuntary Contraception and Public Policy*, THE NEW REPUBLIC (Washington D.C.), Dec. 9, 1991, at 16.

<sup>170</sup>In the aforementioned law review note, Melissa Fraser documented three other women who agreed to use Norplant as part of plea agreements. Fraser, *supra* note 169, at 207.

<sup>171</sup>T. J. Springer, Program Level Evaluation of ASAP Diagnosis, Referral and Rehabilitation Efforts, in VOL. I – DESCRIPTION OF ASAP DIAGNOSIS, REFERRAL AND REHABILITATION FUNCTIONS (Sept. 1976); Corey H. Marco & Joni Michel Marco, *Antabuse Medication in Exchange for a Limited Freedom – Is it Legal?*, in 5(4) AM. J.L. & MED. 295, 296 n.10 (Winter 1980).

<sup>172</sup>Marco & Marco, *supra* note 171 at 297-98.

<sup>173</sup>*Id.* at 330.

<sup>174</sup>See *People v. Gauntlett*, 352 N.W.2d 310, 316-17 (Mich. Ct. App. 1984) (holding that Depo-Provera probation condition was not compatible with requirements of informed consent).

person to barter his or her natural neuro- and biochemistry in exchange for freedom—is compatible with the requirements of voluntary and informed consent.

*b. Cruel and Unusual Punishment*

The Eighth Amendment prohibits “cruel and unusual punishment,” and many state constitutions provide independent protections.<sup>175</sup> Every citizen of the United States, whether free, incarcerated, on parole, or on probation, is protected by the Eighth Amendment.

However, because the Eighth Amendment’s protection only pertains to “punishment,” future advocates for compulsory pharmacotherapy within the criminal justice system will likely aim to characterize pharmacotherapy as “rehabilitative” or “treatment-oriented” in nature, in an effort to distinguish it from “punishment.”<sup>176</sup> Although the term “pharmacotherapy” linguistically implies that the drugs provide “therapy” or treatment, it would clearly be superficial to conclude on that basis alone that they are not subject to analysis under the Eighth Amendment. Neither the industry moniker “pharmacotherapy” nor a future legislative statute as authorizing “therapy” or “treatment” via use of such drugs is conclusive in determining whether a prisoner’s Eighth Amendment rights have been implicated.<sup>177</sup>

The therapeutic value of pharmacotherapy as a coercive “treatment” for illegal drug use has yet to be determined, let alone accepted within the medical community. Additionally, while voluntary and informed use of pharmacotherapy by prisoners may well prove therapeutic and rehabilitative, imposing it against a prisoner’s will may actually be counterproductive. Forced pharmacotherapy precludes a prisoner from utilizing nondrug methods for coming to physical and psychological terms with the roots of his or her use of illegal drugs. The effect is to deny the prisoner the opportunity to build the self-will and self-confidence necessary for sustainable rehabilitation and to resist problem drug use beyond the prison walls and without the pharmacotherapy drug. This is true even if the pharmacotherapy is combined with traditional counseling or talk-therapy.

Pharmacotherapy is also not without side effects. Indeed, it is possible that ancillary and adverse side-effects alone may render some coercive pharmacotherapy on prisoners, parolees, or probations “cruel and unusual.”<sup>178</sup> Most of the pharmacotherapy drugs are so new that it has yet to be determined whether they will

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<sup>175</sup>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.

<sup>176</sup>*See* *Trop v. Dulles*, 356 U.S. 86 (1958) (discussing how only “punishment” is limited by the guarantees of the Eighth Amendment).

<sup>177</sup>*Id.* at 95 (“[E]ven 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 1136, 1139-40 (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 motivation, can avoid the applicability of the Federal Constitution”).

<sup>178</sup>*Nelson v. Heyne*, 355 F. Supp. 451, 455 (D. Ind. 1972), *aff’d*, 491 F.2d 352 (7th Cir. 1974) (holding it is cruel and unusual punishment to inject juveniles in a correctional institute with tranquilizing drugs that can have significant side effects).



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 effects or other serious adverse reactions from the drug. These side effects will vary from pharmacotherapy to pharmacotherapy, and in some cases may rise to the level that might be considered psychological and/or physiological cruelty.

In June 2004, for example, researchers published a case study of a woman who developed multiple sclerosis following obesity treatment with a CB1 receptor antagonist.<sup>179</sup> In 2003, Roxane Laboratories, Inc., discontinued sale and distribution of the opioid agonist ORLAAM, as a result of "increasing reports of severe cardiac-related adverse events." 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, and as yet undetermined.

Some pharmacotherapy drugs will undoubtedly receive FDA approval, but for uses other than treating illegal drug use. For example, Sanofi-Syhelabo has sought FDA approval for a version of SR141716 that will be marketed under the name "Acomplia" as an aid for overcoming obesity, overeating, or smoking.<sup>180</sup> Compelling a prisoner to use a drug like SR141716 for "off label"<sup>181</sup> pharmacotherapy purposes could arguably constitute experimental use, raising obvious concerns about the law and ethics of using prisoners as human guinea pigs.<sup>182</sup>

Here again, the difference between voluntary and informed use by prisoners and use compelled or coerced by the courts or legislature is critically significant. There is an unfortunate worldwide history of prisoner-abuse, including within the United States.<sup>183</sup> In the 1920, United States prisoners were routinely labeled as genetically

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<sup>179</sup>B.W. Van Oosten et al., *Multiple Sclerosis Following Treatment with a Cannabinoid Receptor-1 Antagonist*, in 10:3 MULTIPLE SCLEROSIS 330-31 (2004).

<sup>180</sup>Matt Apuzzo, Associated Press, *Quit Smoking with a Pill? Researchers Say New Drugs Show Promise*, March 8, 2005; Kolata, *Will a New Drug Melt the Pounds? It May, but Doctors Urge Caution*, N.Y. TIMES, Dec. 5, 2004, at A25.

<sup>181</sup>Because the FDA does not regulate the practice of medicine, physicians may lawfully prescribe a medication for uses beyond the scope of the FDA's approved indication(s). Drug companies, however, may only advertise a drug for FDA-approved indications. See *In Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 350 (2001) (observing that "off-label" use is "an accepted and necessary corollary of the FDA's mission to regulate in this area without directly interfering with the practice of medicine.").

<sup>182</sup>See Beck, James M. and Elizabeth D. Azari, 1998. *FDA, Off-Label Drug Use, and Informed Consent: Debunking Myths and Misconceptions*. 53 FOOD DRUG COSM. L.J. 71 (arguing that "off-label" use of a drug does not constitute experimental use if primarily employed to benefit the patient).

<sup>183</sup>For discussions concerning informed consent and medical experimentation on prison populations, see Vernon H. Mark & Robert Neville, *Brain Surgery in Aggressive Epileptics: Social and Ethical Implications*, in 226:7 J. AM. MED. ASS'N 765 (eds. Robert Hunt & John Arras, 1977); ROBERT M. VEATCH, *CASE STUDIES IN MEDICAL ETHICS* 267-71(1977); Barbara

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-1970s.<sup>184</sup> The American eugenics movement reached its zenith in 1927 with the United States 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.<sup>185</sup> 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 as considered appropriate. Utilitarianism was the ethic of the day.”<sup>186</sup>

The history of homosexuality and the law is also instructive. Until 1973, “homosexuality” was listed as a psychiatric disorder in the Diagnostic and Statistical Manual of Mental Disorders. Up until June 2003, when the United States Supreme Court declared them unconstitutional, thirteen states had laws making it a criminal offense to engage in consensual homosexual sex.<sup>187</sup> 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.<sup>188</sup> “Treatment,” in addition to counseling, included penile

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L. Bernier, *Class, Race, And Poverty: Medical Technologies And Socio-Political Choices*, 11 HARV. BLACKLETTER L.J. 115 (1994).

<sup>184</sup>Paul Lombardo, *Eugenic Sterilization Laws*, <http://www.eugenicsarchive.org/html/eugenics/essay8text.html> (last visited July 12, 2005).

<sup>185</sup>*Buck v. Bell*, 274 U.S. 200, 207 (1927) (“It is better for all the world, if instead of waiting to execute degenerate offspring for crime, or to let them starve for their imbecility, society can prevent those who are manifestly unfit from continuing their kind. . . . Three generations of imbeciles are enough) (citations omitted) (quoting Justice Holmes). Not until 1942 did the United States Supreme Court hold that it was unconstitutional to permanently sterilize people convicted of criminal offenses. *Skinner v. Oklahoma* 316 U.S. 535 (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 (2005); W. VA. CODE § 27-16-1 (2005). It is unlikely that these laws, if challenged, would withstand constitutional scrutiny.

<sup>186</sup>*Grimes v. Kennedy Krieger Inst., Inc.*, 782 A.2d 807, 836 (Md. 2001) (citations omitted).

<sup>187</sup>*See Lawrence v. Texas*, 539 U.S. 558 (2003).

<sup>188</sup>*See, e.g.*, James Garland, *The Low Road to Violence: Governmental Discrimination as a Catalyst for Pandemic Hate Crime*, 10 L. & SEX. 1, 75-76, 75 nn.355 & 357 (2001); George Chauncey, *The Postwar Sex Crime Panic*, in TRUE STORIES FROM THE AMERICAN PAST 160 (William Graebner ed., McGraw-Hill 1993); Estelle B. Freedman, *Uncontrolled Desires: The Response to the Sexual Psychopath, 1920-1960*, in 74 J. AM. HIST. 83 (1987); an Alabama law “reform” commission announced that gay people are “persons with abnormal tendencies” who “have forfeited certain of their standings,” and warned that Alabama would make itself

plethysmograph (PPG) shocks (electronic shock triggered by penile erection) and forced drugging. Some state laws even permitted the forcible sterilization of homosexuals.<sup>189</sup> Drug use, like homosexuality, has a ubiquitous presence throughout history and across cultures.<sup>190</sup> Like homosexuality, drug use and drug prohibition are subjects of contention and controversy. The discussion of these 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, may tomorrow be seen as cruel, unusual, and even barbaric punishment.

Although there are several interpretive camps constellated around the Cruel and Unusual Punishment Clause, as punishment, it is hard to conclude that coercive pharmacotherapy is anything other than cruel and unusual.<sup>191</sup>

The basic concept underlying the Eighth Amendment is nothing less than the dignity of man. While the State has the power to punish, the Amendment stands to assure that this power be exercised within the limits of civilized standards. Fines, imprisonment and even execution may be imposed depending upon the enormity of the crime, but any technique outside of the bounds of these traditional penalties is constitutionally suspect.<sup>192</sup>

There are few images more chilling to civilized standards than government agent’s force-injecting a mentally competent nondangerous prisoner with brain-changing drugs. 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 Biblical notions of retributive punishment such as “eye for an eye, tooth for a tooth” and forward to a “neuron for a neuron.” Using a drug to block specific receptors in a prisoner’s brain is like injecting a thief with a drug that paralyzes his or her hands, or like injecting a Peeping Tom with a chemical that causes cataracts. It is overbroad and akin to torture or barbarism. Brain receptors, like eyes and teeth, have far more “legal uses” than those that are forbidden. All these uses would be disrupted or denied by imposing on prisoners the crippling chemical effects of coercive pharmacotherapy.

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“known as a place where it is tough for [such] persons.” COMMISSION TO STUDY SEX OFFENSES, INTERIM REPORT TO THE ALABAMA LEGISLATURE, June 12, 1967, at 5 n.17.

<sup>189</sup>George Painter, *The Sensibilities of Our Forefathers: The History of Sodomy Laws in the United States* (2003), <http://www.sodomylaws.org/sensibilities/utah.htm> (last visited July 18, 2005).

<sup>190</sup>Antonio Escobedo & Ken Symington, *A Brief History of Drugs: From the Stone Age to the Stoned Age*, (1999); Jonathan Ott, *Pharmactheon: Entheogenic drugs, Their Plant Sources and History* (1993).

<sup>191</sup>See Raymond A. Lombardo, *California's Unconstitutional Punishment For Heinous Crimes: Chemical Castration of Sexual Offenders*, 65 *FORDHAM L. REV.* 2611 (1997) (noting various interpretive approaches to the Cruel and Unusual Punishment Clause, and concluding that “chemical castration” with MPA is an unconstitutional punishment because it violates the aspirational principles against inhumane treatment embodied in the Clause).

<sup>192</sup>*Trop v. Dulles*, 356 U.S. 86, at 100 (1958).

## V. CONCLUSION

While the state has long had the power to restrain a person's body (e.g. handcuffing arms and legs or imprisonment), 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. First, from external policing to internal policing, and second, from restraining a person's physical body and behavior to directly restraining a person's brain function and thought processes. Such a dramatic extension of government power would be unprecedented.

In *Stanley v. Georgia*,<sup>193</sup> the United States Supreme Court struck down a Georgia law that banned the private possession of obscene material. "Our whole constitutional heritage," explained the Court, "rebels at the thought of giving government the power to control men's minds."<sup>194</sup> Justice Harlan, concurring in *United States v. Reidel*, 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."<sup>195</sup>

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, permitting 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 brain states, grants the state the ultimate power over the individual's body and mind. Such an action should be seen as implicating the interests in bodily integrity, privacy, and freedom of thought - a combined interest in the person that ought to require the very highest imaginable justification to breach. A lesser standard is incompatible with a democracy built upon the premise of individual freedom and limited government.

Sixty years ago the United States Supreme Court opined, "[f]reedom to think is absolute of its own nature; the most tyrannical government is powerless to control the inward workings of the mind."<sup>196</sup> This is no longer the case. Pharmacotherapy drugs give the government that power. Tyranny over the mind is no longer beyond the reach of the government. The question for the future is whether the government, in its naïve quest for a drug-free world, can resist that tyrannical power.

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<sup>193</sup>*Stanley v. Georgia*, 394 U.S. 557 (1969).

<sup>194</sup>*Id.* at 565.

<sup>195</sup>*United States v. Reidel*, 402 U.S. 351, 359 (1971) (Harlan J., concurring).

<sup>196</sup>*Jones v. Opelika*, 316 U.S. 584, 618 (1942).