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The Food and Drug Administration and Drug Legalization:

A Brief Model of Regulation

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Introduction: FDA Regulation of Legalized Narcotics¹

Drug legalization² entails the free-market availability of all currently illegal drugs; in such a regime, “the entire illicit drug trade would become legal: manufacture, transportation, sale, purchase, possession, use.”³ All currently illegal drugs would become as available to consumers as any other prescription or non-prescription drug approved by the Food and Drug Administration (FDA).⁴ The FDA seems the natural regulator of newly-legalized drugs (NLD’s) because the FDA already regulates “almost every object placed into or around the human body.”⁵ While many advocates of legalizing drugs suggest that the FDA should regulate NLD’s, very little has been written about *how* the FDA would regulate once illicit drugs like legal drugs.⁶ For instance, California Superior Court Justice James Gray, a proponent of drug legalization, envisions a drug legalization regime

in which a person goes to his local supermarket for groceries. He puts into his cart some frozen lemonade, chocolate chip cookies, aspirin grapes—and a six-pack of cocaine. A friend has recommended the “Big Kick” brand of cocaine and the store is having a special sale: six hits for the price of four. In this scenario, all of the products in this man’s cart are sold in a “legalized” or “free” market.

Under such a program, the FDA would ensure the cleanliness and purity of all these products, and see to it that they were labeled accurately for their contents and strength. This is how the FDA regulates the sale of aspirin, a fully “legalized” drug in this country.⁷

This paper offers a brief model of FDA regulation of currently illegal narcotics in the United States. Given

¹The author **does not in any way** advocate the legalization of illegal narcotics. Rather, this is a practical application of the FDCA and FDA case law to what would be an interesting agency challenge.

²As distinguished from drug decriminalization. In contrast, drug decriminalization entails purposeful non-enforcement of drug laws. Drug decriminalization is best exemplified by the Netherlands. “The juridical formulation is, of course, much more complicated, but practically speaking the use of cannabis products has been legalized; every town has at least one ‘hash and coffee shop,’ and the possession of less than 30 grams is not prosecuted by the police. In spite of this liberalization of use of soft drugs, *trafficking* in cannabis products is still forbidden.” Otto Janssen, *Normalization of the Drugs Problem: An Outline of the Dutch Drugs Policy, in De-Americanizing Drug Policy* 127 (ed., Lorenz Böllinger, 1994) [hereinafter BÖLLINGER].

³Richard Lawrence Miller, *THE CASE FOR LEGALIZING DRUGS* 138 (1991) [hereinafter MILLER].

⁴*Id.*

⁵Roesann B. Termini, *The Legal Authority of the United States Food and Drug Administration to Regulate Tobacco: Calling on Congress*, 74 ST. JOHN’S L. REV. 63 (2000), citing 61 Fed. Reg. at 44,619 and 44,628 (1996) [hereinafter TERMINI].

⁶This paper does not consider the possible regulation of NLD’s by the Bureau of Alcohol, Firearms and Tobacco (BATF) or BATF involvement in the hypothetical legalized drug regime.

that nearly three out of four Americans believe that the drug war has failed,⁸ recent calls from prominent liberal and conservative thinkers to legalize drugs, and state “compassionate use” ballot initiatives, future drug legalization is at least conceivable in the United States.

Yet, how would the FDA regulate NLD’s under its current statutory mandate and agency discretion. To answer this question, this paper applies current FDA regulation procedures, derived from the Food, Drugs, and Cosmetic Act (FDCA)⁹ to the regulation of NLD’s.¹⁰

Part One of this paper considers the trend toward drug legalization in the United States: the apparent failure of the drug war, calls for legalization from prominent Americans, state medical marijuana referenda, and the historical analogies cited by proponents of drug legalization to America’s failed alcohol prohibition regime (1920-33). Secondly, it describes a hypothetical drug legalization regime, using the marketing of recreational and medicinal marijuana as hypothetical NLD’s. Thirdly, it considers the threshold question of whether the FDA indeed has statutory authority to regulate NLD’s without statutory amendment to the FDCA.

Part Two of this paper describes the FDA premarket approval process of the regulatory drug legalization model in detail. First, it considers how the FDA would regulate the introduction of NLD’s into the market by private manufacturers. Secondly, it considers whether the FDA should consider NLD’s new drugs or old under the current new drug application (NDA) process.

Part One: The Trend Toward Drug Legalization

Introduction: The Failure of American Drug Prohibition

Americans have been spending more money on drugs; the government has been spending more money to fight drugs and incarcerating more drug offenders. In 2000, roughly 14 million Americans were illicit drug users according to a National Household Survey on Drug Abuse (NHSDA) study.¹¹ In 1999, Americans spent \$63.2

⁸According to a poll conducted by the Pew Research Center for People and the Press. *See* Walter Shapiro, *Nation waits for insanity to stop in the drug war*, USA TODAY, Mar. 23, 2001, at A13.

⁹21 U.S.C. §301 (2001)

¹⁰The only model NLD considered in this paper is marijuana.

¹¹*See* NATIONAL HOUSEHOLD SURVEY ON DRUG ABUSE, Office of Applied Studies, U.S., Department of Health and Human

billion on illicit drugs.¹² The United States government spends a total of forty billion dollars per year in the war on drugs.¹³ The number of incarcerated men and women, mostly persons of color, in state and federal prisons has quadrupled in recent years because of America's tough drug laws.¹⁴ According to Judge James Gray, excessive American drug consumption and excessive government funding of the war on drugs are part of a historical trend. "The common theme throughout this country's history of Drug Prohibition is that the federal government has been increasingly active, but both federal and state governments have continually passed tougher and tougher laws. With each upping of the ante, however, the situation has become worse."¹⁵ One result of the America's tough drug law enforcement is the rise of the so-called prison-industrial complex and the human costs felt by the American inner-cities—e.g., skyrocketing incarceration rates, unemployment, and poverty.¹⁶ Convicts jailed during the 1980s and 1990s for drug crimes "now account for more than 30% of all inmates."¹⁷ The drug war has had a disproportionate impact on blacks on Latinos. One commentator has even found the disparity in drug sentencing "reminiscent of the Black Codes and Jim Crow laws—ethnic discrimination against blacks by legal enforcement to contain and control. The sentencing disparity is an obvious disregard for equal protection under the law."¹⁸ For this reason, many proponents of drug legalization claim that the drug war has devastated the inner city and minority communities. "Competing American gangs intimidate and assault, and sometimes murder, anyone who opposes them as they fight over the large illicit profits from drugs. This has helped devastate many inner-city neighborhoods because poor

Services (2000), at <<http://www.samhsa.gov/oas/nhsda/2knhsda/chapter2.htm>> (March 12, 2002).

¹²Office of National Drug Control Policy, 1999, *What America's Users Spend on Illegal Drugs, 1988-1999*; cited in NATIONAL DRUG CONTROL STRATEGY, 2000 ANNUAL REPORT, at 114.

¹³Gary S. Becker, *It's Time to Give Up the War on Drugs*, BUSINESS WEEK, Sept. 17, 2001, at 32.

¹⁴See GRAY, *supra* note 7, at 29.

¹⁵See GRAY, *supra* note 7, at 16.

¹⁶I.e., the massive increase in federal and state prison spending to accommodate prisoners convicted of drug-related crimes. "The war provides a place for both semiskilled and skilled workers. Many of those who once held professional positions and semiskilled jobs in manufacturing now find themselves building and operating the infrastructure of the prison-industrial complex.... Many states and localities depend on prison construction and operation as an integral part of their economies." Kevin Alexander Gray, *A Call for an Anti-War Movement* in HOW TO LEGALIZE DRUGS 169 (Jefferson Fish ed. 1998) [hereinafter FISH].

¹⁷Gary S. Becker, *It's Time to Give Up the War on Drugs*, BUSINESS WEEK, Sept. 17, 2001, at 32.

¹⁸See FISH, *supra* 16 note, at 166.

blacks and Hispanics in these neighborhoods are the main foot soldiers in drug supply networks. They earn what may appear to be pathetically little, given the risks they take, but their earnings often are higher than what they could get in legal jobs.”¹⁹

Calls for Legalization from Prominent Americans

As a result of the failures of the American war on drugs, some prominent intellectuals, policymakers, and lawyers, from both sides of the political spectrum, have called for legalization.²⁰ Milton Friedman epitomizes calls for drug legalization from prominent American intellectuals:

¹⁹Gary S. Becker, *It's Time to Give Up the War on Drugs*, BUSINESS WEEK, Sept. 17, 2001, at 32.

²⁰Corcoran, David, *Legalizing Drugs: Failures Spur Debate*, N.Y. TIMES, Nov. 27, 1989, at A15.

Twenty-five years ago, President Richard M. Nixon announced a “War on Drugs.” I criticized the action on both moral and expedient grounds in my Newsweek column of May 1, 1972, “Prohibition and Drugs”: “On ethical grounds, do we have the right to use the machinery of government to prevent an individual from becoming an alcoholic or a drug addict? For children, almost everyone would answer at least a qualified yes. But for responsible adults, I, for one, would answer no.... That basic ethical flaw has inevitably generated specific evils during the past quarter century, just as it did during our earlier attempt at alcohol prohibition.

....

As I wrote in 1972: “... addicts and pushers are not the only ones corrupted. Immense sums are at stake. It is inevitable that some relatively low-paid police and other government officials—and some high-paid ones as well—will succumb to the temptation to pick up easy money.”

2. Filling the prisons. In 1970, 200,000 people were in prison. Today, 1.6 million people are. Eight times as many in absolute number, six times as many relative to the increased population. In addition, 2.3 million are on probation and parole. The attempt to prohibit drugs is by far the major source of the horrendous growth in the prison population.

There is no light at the end of that tunnel. How many of our citizens do we want to turn into criminals before we yell “enough”?

3. Disproportionate imprisonment of blacks....

....

5. Compounding the harm to users. Prohibition makes drugs exorbitantly expensive and highly uncertain in quality. A user must associate with criminals to get the drugs, and many are driven to become criminals themselves to finance the habit. Needles, which are hard to get, are often shared, with the predictable effect of spreading disease....

....

Can any policy, however high-minded, be moral if it leads to widespread corruption, imprisons so many, has so racist an effect, destroys our inner cities, wreaks havoc on misguided and vulnerable individuals and brings death and destruction to foreign countries?²¹

Like Friedman, other journalists, lawyers, and policymakers, and intellectuals, both liberal and conservative, have questioned the efficacy of America’s war on drugs. Other proponents of drug legalization include conservatives like William F. Buckley, economist Thomas Sowell, and former Secretary of State George P. Schultz, and liberals like former Baltimore Mayor Kurt Schmoke, Phil Donahue, George Carlin, Alan Dershowitz, Michael Kinsley, David Letterman, Andy Rooney, Carl Sagan, and Garry Trudeau.²² All have advocated

²²See GRAY, *supra* note 7, at 4; Kirby R. Cundiff, *Crime and the Drug War*, Schaffer Library on Drug Policy, at <http://www.druglibrary.org/schaffer/DEBATE/cundiff1.htm>.

some form of drug legalization as the perhaps the last solution to America's failed drug war.²³ Even former drug czar Barry R. McCaffrey, an opponent of drug legalization, has argued for some changes to the current drug war strategy.²⁴ McCaffrey noted that the solution to drug abuse is "to engage in a more coherent, rational way [to treat] the chronically addicted as we encounter them in our communities."²⁵

Proponents of some form of drug legalization cite many justifications: efficacy, wasted federal dollars, rising incarceration rates (the prison industrial complex) and the disproportionate incarceration on minority communities, the legality of tobacco and alcohol,²⁶ libertarian ideals, etc. Other proponents argue that drug legalization is simply a more efficient and practical solution to the drug problem. For instance, a Rand study found that current drug policy is much less cost-effective than other non-enforcement methods.²⁷

While there has been little traditional public support for drug legalization,²⁸ proponents argue that some sort of drug legalization is inevitable given the history of American prohibition, public frustration with the war on drugs, and recent state initiatives for compassionate use of marijuana for terminally ill patients.²⁹

State Referenda: Medical Marijuana

The rising number of states enacting medical marijuana referenda may also signal gradually increasing popularity for some form of drug legalization.³⁰ Currently, eight states have approved ballot initiatives that

²³E.g., property crime. Pointedly, there is also a strong chorus of economists, policy makers and specialists arguing that legalization *is not* the solution to America's drug problem. For an excellent critique of the drug legalization movement, see James Q. Wilson, *Legalizing Drugs Makes Matters Worse*, SLATE, Sept. 2, 2000, § Q.

²⁴Christopher S. Wren, *A Drug Warrior who Would Rather Treat than Fight*, N.Y. TIMES, Jan. 8, 2001, at A12.

²⁵*Id.*

²⁶"The focus here is not how dangerous drugs are or how much damage drug users inflict upon themselves. If these factors were decisive, then surely alcohol and tobacco would be banned.... Rather, the proper focus is how effective drug laws are in preventing damage from drugs, compared with the amount of injury the laws themselves cause." James Ostrowski, CATO POLICY ANALYSIS, No. 121, May 25, 1989, at 7.

²⁷"A Rand Study found that drug treatment is seven times more cost-effective than domestic law enforcement in addressing drug abuse, eleven times more cost-effective than our attempt to interdict illicit drugs as they come across our borders, three times more cost effective than our drug eradication overseas." GRAY, *supra* note 7, at 181.

²⁸See e.g., "Poll finds 90% Favor Keeping Drugs Illicit," N.Y. TIMES, Sept. 15, 1988, at A26.

²⁹See e.g., David G. Evans, *High Court Was Right to Nix Medicinal Pot*, THE RECORD (Bergen County, NJ), May 22, 2001, at L15.

³⁰*But see*, Richard M. Evans, *What is "Legalization"? What Are "Drugs"?*, GRAY, *supra* note 16, at 370 (noting that "These measures and initiatives, worthy though they may be for medical and industrial purposes, bear no connection to legalization.

legalize medical marijuana.³¹ This movement began in 1996 with two medical marijuana initiatives in California and Arizona.³² In 1996, California voters approved a state ballot initiative called the “Compassionate Use Act.”³³ This act decriminalized the use of medical marijuana by terminally ill patients who received a recommendations from a physician.³⁴ The act also immunized physicians from state prosecution for recommending the drug for medical purposes.³⁵ As a result of the of the successful California³⁶ and Arizona³⁷ medical marijuana referenda in 1996, the White Office of National Drug Control Policy established a two-year study on the safety of medical marijuana. The authors, 11 independent experts at the Institute of Medicine, found that “marijuana smoke was even more toxic than tobacco smoke and could cause cancer, lung damage and pregnancy complications” and recommended use only by the terminally ill.³⁸

American Alcohol Prohibition: A Harbinger of Failed Drug Prohibition Policy?

One of the most powerful arguments offered for ending drug prohibition are the similarity of problems caused

Exempting small categories of people from the prohibition laws (e.g., chemotherapy patients, licensed hemp farmers) has little to do with repealing prohibition entirely and allowing access to most adults.

³¹See Erik R. Neusch, “Medical Marijuana’s Fate in the Aftermath of the Supreme Court’s New Commerce Clause Jurisprudence,” 72 UCOLR 201 (2001), n.1 [hereinafter NEUSCH]. These states include, California (Cal. Health & Safety Code § 113625.(3) (West Supp. 2000); Colorado, *see* Colo. Const. amend. XX; Nevada, *see* NV. Const. Art. 4., § 38; Alaska, codified at Alaska Stat. §§ 17.37.010-.080 & 11.71.090 (Michie 1999); Arizona, codified at Ariz. Rev. Stat. § 13-3412.01 (1999); Maine, codified at Me. Rev. Stat. Ann. Tit. 22, § 2383-B (West 1999); Oregon, codified at Or. Rev. Stat. §§ 475.300-.375(1999); and Washington state, codified at Wash. Rev. Code § 69.51A.005-.902 (1999). *See generally id.* “In fact, a number of states decriminalized the possession of marijuana for certain cases long before the California and Arizona initiatives. Louisiana has passed such a measure three times since 1981, and Virginia has had a similar one on the books since 1979. More recently, 1994 saw Ohio give medical marijuana a thumbs up...”. *See* CNN, “Weed Wars—State marijuana initiatives open,” (visited Feb. 23, 2002) <<http://www.cnn.com/HEALTH/9702/weed.wars/issues/focus/index.html>>. ¶13.

³²Specifically, advocates note that “smoking marijuana has shown particular effectiveness in treating the AIDS wasting syndrome and the nausea and vomiting associated with chemotherapy. NEUSCH, *supra* note , “Medical Marijuana’s Fate in the Aftermath of the Supreme Court’s New Commerce Clause Jurisprudence,” 72 UCOLR 201(2001).

³³*See* Cal. Health & Safety Code § 11362.5(e) (West Supp. 2000). “Arizona voters approved a similar initiative in the 1996 election only to have the legislature effectively repeal it; however, in 1998, Arizona voters once again authorized the medical use of marijuana,” *see* NEUSCH *supra* note 31 (citing Steve Yozwiak, *Voters Reinstate Marijuana Law*, ARIZ. REPUB., Nov. 4, 1998, at A1.).

³⁴*See* Cal. Health & Safety Code § 11362.5(e) (West Supp. 2000).

³⁵*Id.*

³⁶Cal. Health & Safety Code § 1136.25(3)(West Supp. 2000).

³⁷Ariz. Rev. Stat. § 13-3412.01 (1999).

³⁸Christopher S. Wren, “Smoke and Heat,” N.Y. TIMES, Mar. 19, 1999, at A10 (paraphrasing McCaffery as stating that “most nonviolent addicts behind bars belong in treatment centers not in prison where they learn to become better criminals”).

by the drug war and those caused by American Prohibition (1920-1933). One commentator notes, “The new public debate about drug laws has increased interest in the effects of prohibition on public health, the economy, and social problems.”³⁹ For instance, drug proponents have noted that, as with drug prohibition, alcohol prohibition “was massively and openly violated, and alcohol was readily available in most of the United States.” Program officer for the Drug Policy Alliance, Robert Sharpe, offers another oft-repeated parallel between liquor and drug prohibition when he notes that alcohol prohibition “financed organized crime and violence, while failing miserably at preventing use.”⁴⁰ Judge Gray notes that during the Prohibition period, “federal funding for law enforcement efforts was increased from \$2.2 million in 1920 to \$12 million in 1929, and the federal prison population increased between 1920 and 1932 from 3,000 to 12,000, with two-thirds the inmates incarcerated from alcohol and other drug offenses.”⁴¹

Hypothetical Drug Legalization Regime for a Brief FDA Regulatory Model

Proponents of drug legalization cite a number of competing theoretical drug legalization models—some in which the government markets and provides legalized drugs and others entailing a free market approach to legalization.⁴² Consequently, it is important to state certain assumptions about this brief FDA regulatory model. First, it should be assumed that private drug companies, not the government, will manufacture and market the NLD’s to the public, no differently than drug companies now manufacturer and market over-the-counter and prescription drugs. This is the free-market approach championed by famous drug legalization proponent and libertarian Dr. Thomas Szaz.⁴³ As mentioned earlier, other proponents of drug legalization argue that the government should itself produce the drugs and offer them to drug addicts.⁴⁴ However, the

³⁹ See Harry G. Levine and Craig Reinerman, *De-Americanizing Drug Policy: The Search for Alternatives for Failed Repression*, 21 Peter Lang (1994).

⁴⁰ To the Editor, Robert Sharpe, “Harm Reduction as Alternative,” N.Y. TIMES, Oct. 16, 2001, at F3.

⁴¹ See GRAY *supra* note 7, at 23.

⁴² “Over the past two decades a wide variety of plans have been put forward in the name of legalization. Most seem to fall into one of three general categories: decriminalization plans, limitation plans, and regulation and taxation plans. Falling outside this grouping are calls for outright legalization in which drugs would be produced, bought and sold like any ordinary commodity.” Richard M. Evans, *What is “Legalization”? What Are “Drugs”?*, *supra* note 370 (1998).

⁴³ Richard M. Evans, *What is “Legalization”? What Are “Drugs”?*, in HOW TO LEGALIZE DRUGS 370 (1998).

⁴⁴ See GRAY, *supra* note 7 at 222 (“One possibility would be to allow the purchase of heroine, cocaine and marijuana by adults

free market approach is commensurate with the purposes of drug legalization:

If drugs are to be treated under the law like tomatoes, magazines, medicines, or toothpaste, it is hardly necessary to conjure a new set of rules about where and to whom they can be sold, or to what extent they may become ingredients in other products, or how they are to be taxed, and if their potency is to latch on to the existing commodity that best illustrates the favored approach. Free market proponents can bring clarity and spirit to the debate over how to legalize drugs....

Thus, this model presumes that there is free-market availability of currently illegal drugs. As noted above, the free-market approach decreases problems associated with the current drug war: excessive availability lessens the possibility of black markets, drug—related crime, etc. For this reason, it should also be assumed that NLD's would be sold as over the counter drugs in this hypothetical regime.⁴⁵ Because the purpose of drug legalization, here, is to avoid the negative consequences of prohibition drugs should be available with few restrictions. As one commentator notes, "Because so many problems associated with illicit drugs are due to legal restrictions, we must be generous about access. For example, requiring prescriptions would merely generate income for Dr. Feel Goods and prescription pad printers. If [currently illegal drugs] are legalized they must be available over the counter."⁴⁶

Thirdly, we should assume that the FDA Commissioner will be diligent, but non-resistant to the ongoing drug legalization regime. The FDA commissioner will not be a "maverick," nor a reformer (e.g., former FDA Commissioner David Kessler).⁴⁷ In other words, we assume that the FDA Commissioner would follow general FDA policy (issuing regulations, court enforcement)⁴⁸ to ensure the safety of drugs by avoiding misbranding and adulteration, but would not frustrate the marketing and distribution NLD's. Put differently, the FDA

at state-licensed package stores. Dosage units of drugs that are not sold on the streets for about \$10 would be sold for about \$2.50 at these package stores, which would eliminate the profitability of illegal sales at one simple stroke.").

⁴⁵Thus, the FDA would most likely consider marijuana a new drug. See 21 U.S.C.A § 321(p)(1)(2001). See Part Two.

⁴⁶MILLER, *supra* note 3, at 138.

⁴⁷Kessler was considered a maverick or reformist FDA commissioner. See e.g., Editorial, *Preserve David Kessler's Legacy*, N.Y. TIMES, Nov. 27, 1996, at A24; Jeffrey Goldberg, *Big Tobacco's Endgame*, N.Y. TIMES, June 21, 1998, at §6, 36.

⁴⁸FOOD AND DRUG LAW: CASES AND MATERIALS, 1236 (Peter Barton Hutt and Richard A. Merrill eds., Foundation Press 2d ed. 1996)[hereinafter HUTT & MERRILL].

Commissioner's stance on NLD's would probably be similar to her stance on regulating cigarettes. Here, FDA would play the role that one commentator describes when discussing the recent tobacco industry settlements with states attorneys general:

Recent pressure on the tobacco industry appears to be giving rise to a new form of legalization that may come to be called the "new cigarette model." The "landmark settlement" reached in June 1997 between the tobacco industry, state attorneys general, and plaintiffs provides for the elimination of advertising and marketing designed for underage smokers; stronger warning labels on cigarettes [sic] packs; full disclosure of ingredients; prohibition of tobacco use in public places, work places and fast-food restaurants; and regulation as well by the Food and Drug Administration. Notably, there is no talk of prohibition. If these restrictions are codified, and the new cigarette scheme is successful in curbing smoking by the young, reducing threat to the public health, and reimbursing government its costs is entirely possible that the new cigarette model could provide a legalization protocol at least for marijuana, if not for other drugs as well.⁴⁹

Finally, for the sake of simplicity, the only particular drug considered in detail in this model will be marijuana for marketing by a private drug companies as both a recreational drug and, separately, as a medical drug used to treat chemotherapy side effects and AIDS wasting syndrome..

The FDA's Jurisdiction over Newly Legalized Drugs without Amendment to FDCA

Without statutory amendment to the FDCA, it is unclear whether the FDA has authority to regulate NLD's. Before passage of the Controlled Substances Act,⁵⁰ the FDA had responsibility for enforcing the Drug Abuse Control Statute "to prevent the abuse of depressant and stimulant drugs... which also have a legitimate use."⁵¹ And, before 1970, "Federal control of narcotic drugs, marijuana and other drugs used for recreational and nonmedical purposes was shared among several agencies and rested on a haphazard cluster of laws enacted since 1900."⁵² The FDA's ability to assert jurisdiction over NLD's would best be drawn

⁵⁰ See Controlled Substances Act, 21 U.S.C.A § 801 (2002)

⁵¹ HUTT & MERRILL, *supra* note 48, at 535.

⁵² *Id.*

from the FDA's historical attempts to assert jurisdiction over tobacco products in 1996.⁵³ There appears to be little history of the FDA directly regulating narcotics because, according to Judge James Gray,

The Pure Food and Drug Act of 1906 led directly to the demise of the patent medicine industry, not by prohibiting these substances, but simply by requiring that all medications contain accurate labeling of their contents. Subsequent amendments to the act required the labels to contain accurate information about the strength of the drugs and to state that federal purity standards had been met. This act, combined with various governmental educational efforts encouraging people not to use any medications containing narcotics, resulted in a prompt, substantial, and permanent decline in the sales of these products.⁵⁴

Further, the Harrison Act and *Webb v. United States*,⁵⁵ which together made it impossible for doctors to legally give out prescription drugs for addicts suffering narcotics withdrawal. According to Judge Gray, this decision "inaugurated the Drug Prohibition era in which we still live. As a result, people, including those who were already accidentally addicted to these drugs, were forced to turn to the criminal black market in order to obtain these substances."⁵⁶ Because the FDA has never regulated illegal drugs, it is important to determine, what, if any jurisdiction the FDA would have over NLD's without an amendment to the FDCA.

Current FDA Jurisdiction over Tobacco Products as an Indicator of FDA's Jurisdiction over NLD's.

The best indicator of the FDA's authority to regulate NLD's, without amendment to the FDCA, is the FDA's current authority to regulate tobacco products: if the FDA has authority to regulate cigarettes, it could be argued that the FDA should have authority regulate NLD's. However, the Supreme Court recently

⁵³Regulations Restricting the Sale and Distributions of Cigarettes & Smokeless Tobacco to Protect Children and Adolescents; Final Rule, 61 Fed. Reg. 44,399(1996).

⁵⁵GRAY, *supra* note 7, at 22; *See* 249 U.S. 96 (1919)(holding that it was constitutional to prohibit retail sales of morphine by a druggist without a physician's prescription.)

⁵⁶GRAY, *supra* note 7, at 22.

held in *FDA v. Brown & Williamson*⁵⁷ that the FDA does not have authority to regulate cigarettes.⁵⁸ Although the Supreme Court has settled this jurisdictional issue, there are several good arguments offered by proponents of FDA jurisdiction over tobacco products the FDA could use to argue for authority to regulate NLD's in a legalized drug regime.

Arguments Against FDA Jurisdiction: Supreme Court Holding in *FDA v. Brown & Williamson*

The Supreme Court enunciated the strongest arguments against the FDA's authority to regulate tobacco products in *FDA v. Brown & Williamson*: (1) the FDCA jurisdiction does not specifically include smoking products; (2) the legislative failure of proposed amendments extending FDCA jurisdiction to smoking products; and (3) Congress' enactment of separate "tobacco-specific" legislation.⁵⁹ In 1996, the FDA issued a final rule in which it determined that nicotine was a drug and that cigarettes and smokeless tobacco are "drug-delivery devices."⁶⁰ A group of tobacco manufacturers, retailers and advertisers filed suit in the Middle District of North Carolina against the FDA.⁶¹

In *FDA v. Brown & Williamson*, the Court affirmed the Fourth Circuit Court of Appeals and found held that Congress had not granted the FDA jurisdiction to regulate tobacco products. The Court stated that the purpose of the FDCA, read as a whole, was to ensure all products regulated by the FDA were "safe" and effective for intended use.⁶² Justice O'Connor noted that this "essential purpose pervades the FDCA."⁶³

The Court buttressed this conclusion with the pervading safety and effectiveness purpose of the FDCA:

⁵⁷*FDA v. Brown & Williamson Tobacco Corp. et. al.*, 120 S. Ct. 1291 (2000).

⁵⁸*Id.* (affirming the decision of the Fourth Circuit that Congress had not granted the FDA jurisdiction to regulate tobacco products).

⁵⁹Rodney A. Morris, *Sssmokinnn': the Supreme Court Burns the FDA's Authority to Regulate Tobacco in FDA v. Brown & Williamson Tobacco Corp.*, 34 CRLR 1111, 1122 (June 2001).

⁶⁰"Regulations Restricting The Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents." 61 Fed. Reg. 44,418 (1996). "The agency also determined that the only way to reduce the amount of tobacco-related illness and mortality was to reduce the level of addiction, a goal that could be accomplished only by preventing children and adolescents from starting to use tobacco," the FDA then promulgated regulations concerning that advertising, promotion, labeling of tobacco products, etc. 120 S.Ct. 1291, 1298.

⁶¹*See Coyne Beahm, Inc. v. FDA*, 966 F. Supp. 1374 (M.D.N.C. 1997), *rev'd sub nom. Brown & Williamson Tobacco Corp. et. al. v. FDA*, 153 F.3d (4th Cir.), *reh'g and reh'g en banc denied*, 161 F.3d (4th Cir. 1998), and cert. granted, *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 1086 (1999), and *aff'd*, 120 S.Ct. 1291 (2000).

⁶²*Id.* at 1301.

⁶³*Id.*

the FDA’s premarket approval process for new drugs, classification of devices, ability to withdraw approval, etc.⁶⁴

The Court found there was insufficient evidence of congressional intent to permit the FDA to regulate tobacco products. First, the court noted that Congress had never passed an initiative granting the FDA authority to regulate tobacco products. Justice O’Connor noted that Congress “explicitly considered granting the FDA jurisdiction to regulate tobacco products” under several initiatives, none of which passed.⁶⁵ Second, the Court found Congress’ enactment of separate “tobacco-specific” legislation of tobacco products additional evidence of its intent not to confer cigarette regulation authority on the FDA.⁶⁶ The Court noted: “Congress has enacted six separate pieces of legislation since 1965 addressing the problem of tobacco use and human health.”⁶⁷ The Court also noted, in dicta, that the FDA agency history demonstrated a policy of not asserting authority to regulate cigarettes.⁶⁸ As Justice O’Connor noted, the FDA asserted its authority in 1996 after “having expressly disavowed any such authority since its inception.”⁶⁹

Potential Arguments for FDA Jurisdiction over Cigarettes: the *FDA v. Brown & Williamson* Dissent and Middle District Court Holding

The best arguments for FDA’s regulatory jurisdiction over cigarettes, and by extension, NLD’s, are found in the *FDA v. Brown & Williamson* dissent and the holding of the lower North Carolina Middle District Court in *Coyne*, reversed by the majority in *FDA v. Brown & Williamson*. The dissent in *FDA v. Brown*

⁶⁴*Id.*

⁶⁵*Id.* at 1306.

⁶⁶*Id.*

⁶⁷*Id.* at 1306.

⁶⁸E.g., Justice O’Connor noted: “Congress has acted against the backdrop of the FDA’s consistent and repeated statements that it lacked authority under the FDCA to regulate tobacco....” *Id.* at 1306.

⁶⁹*Id.* at 125. *But see United States v. 46 Cartons, More or Less, Containing Fairfax Cigarettes*, 113 F. Supp. 336 (D.N.J. 1953); *United States v. 354 Bulk Cartons Trim Reducing-Aid Cigarettes*, 178 F. Supp. 847 (D.N.J. 1959).

*Williamson*⁷⁰ made two salient arguments in favor of FDA jurisdiction over tobacco products: (1) tobacco products meet the statutory definition of “articles other than food intended to affect the structure or any function of the body”⁷¹ and (2) taken as a whole, the FDCA gives the FDA authority to regulate cigarettes.

The dissent noted that cigarettes also met the statutory definition of the Pure Food and Drug Act, which is “medicines and preparations recognized by the United States Pharmacopoeia... and any substance or mixture of substances intended to be used for the cure, mitigation, or prevention of disease.”⁷² The dissent cited the evidence of experts who believed that the statute contained purposefully broad statutory language. Secondly, the dissent found that taken as a whole, the FDCA gave the FDA authority to regulate cigarettes. Justice Breyer noted that “the statute’s basic purpose – the protection of public health – supports the inclusion of cigarettes within its scope. Thirdly, the dissent did not find the FDA’s historical reluctance to assert jurisdiction over tobacco products to undercut its subsequent assertion of jurisdiction in 1996. Justice Breyer stated: “Nor is it surprising that such a statutory delegation of power could lead after many years to an assertion of jurisdiction that the 1938 legislators might not have expected. Such a possibility is inherent in the very nature of a broad delegation.”

The holding of the lower Middle District of North Carolina in *Coyne* reversed by the Fourth District Court and Supreme Court, found that the FDA had regulatory power over tobacco products.⁷³ The plaintiffs claimed that Congress “has clearly withheld from the FDA jurisdiction over tobacco products” because “neither the text of the FDCA nor its direct legislative history addresses tobacco products.”⁷⁴ Applying a *Chevron* analysis to the FDCA, the Middle District court found that Congress had not directly spoken to

⁷⁰120 S. Ct. 1291.

⁷¹*Id.* at 1316 (quoting 21 U.S.C. § 321(g)(1)(C)).

⁷²*Id.* at 1317 (quoting Pure Food and Drug Act, ch. 3915, § 6, 34 Stat. 769).

⁷³*Coyne Beahm, Inc. v. FDA*, 966 F. Supp. 1374 (1997).

⁷⁴966 F.Supp 1374, n.3.

the issue of whether the FDA has jurisdiction to regulate tobacco, and thus the question before the Middle District Court was whether the FDA's assertion of jurisdiction was a "permissible construction"⁷⁵ of the FDCA. In contrast to the majority in *FDA v. Brown & Williamson*, the Middle District Court found that the "legislative history's silence regarding tobacco products does not indicate that Congress clearly intended to exempt such products from the Act."⁷⁶

The Middle District Court also considered relevant legislative history that demonstrated that the FDA had once maintained that it did not have jurisdiction over tobacco products, but did not believe this foreclosed subsequent agency assertion of jurisdiction.⁷⁷ "FDA officials testified before congressional committees on numerous occasions that the agency lacked jurisdiction to regulate tobacco products.... In addition to expressing its view to Congress that it lacked jurisdiction to regulate tobacco products, FDA defended that position in court."⁷⁸ Nevertheless, although the legislative history demonstrated that FDA had maintained that it lacked jurisdiction over tobacco products, the Middle District Court found that Congress never acquiesced to the FDA's position. Specifically, the Middle District Court did not find this legislative history convincing because it did not meet the extraordinary circumstances test required for a court to rely on un-enacted bills and statements by members of Congress relevant to a determination of congressional intent.⁷⁹ Finally, the Middle District Court found that, under *Chevron*, the FDA could adapt its position to new evidence about tobacco. "FDA contends that it has not altered its interpretation of the FDCA but rather has applied its longstanding interpretation to new evidence.... [T]he court finds FDA's contention reasonable."⁸⁰ As Termini notes, "Past agency policy regarding tobacco should not be held to dictate all future regulatory schemes. New findings show, unlike past agency information, that smoking affects the structure

⁷⁵*Id.* (quoting *Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, at 842).

⁷⁶*Id.* at 1381.

⁷⁷See *ASH v. Harris*, 655 F.2d 236 (D.C. Cir. 1980).

⁷⁸966 F.Supp 1374, at 1382-3.

⁷⁹See *Bob Jones University v. United States*, 461 U.S. 574, 600-02; *United States v. Riverside Bayview Homes, Inc.* 474 U.S. 121, 137 (1985).

⁸⁰966 F.Supp 1374, at 1384.

and function of the body.”⁸¹ Moreover, “the Fourth Circuit ignored, and the United States Supreme Court did not reach, the issue of newly acquired evidence regarding the FDA’s jurisdiction over tobacco and the Agency’s regulatory premise.”⁸²

Putting aside arguments for FDA jurisdiction over tobacco products as an indicator of FDA jurisdiction over NLD’s, the FDA has historically had, albeit small, regulatory jurisdiction over narcotics. The FDA was given responsibility in the Drug Abuse Control Amendments of 1965.⁸³ The Drug Abuse Control Amendments amended the FDCA to allow the Secretary of Health and Human Services to “exempt any depressant or stimulant drug from the application or all or part of this section when he finds that regulation of its manufacture, compounding, processing, possession, and disposition... is not necessary for the protection of the public health.”⁸⁴ The Act also gave the power to FDA officers “to conduct examinations, investigations, or inspections under this act, relating to depressant or stimulant drugs... when so authorized by the Secretary.”⁸⁵ Further, even after the repeal of earlier statutes and enacted the Controlled Substances Act, the FDA may still approve “an NDA for any controlled substance that has a legitimate medical use.”⁸⁶

Applying Arguments to FDA Model Regulation of NLD’s

Based on the Court’s holding in *FDA v. Brown & Williamson* that the lacks jurisdiction over tobacco products, the FDA probably has no jurisdiction over NLD’s without an amendment to the FDCA. Presumably, however, in this drug legalization regime, the FDA would be the chosen regulator of NLD’s and the FDCA would be thus amended to include regulation of NLD’s. Nevertheless, the arguments rejected by the Court

⁸¹TERMINI, *supra* note 5, at 85-6.

⁸²TERMINI, *supra* note 5, at 87.

⁸³DRUG ABUSE CONTROL AMENDMENTS OF 1965, July 15, 1965, 89 P.L. 74; 79 Stat. 226. “To protect the public health and safety by amending the Federal Food, Drug, and Cosmetic At to establish special controls for depressant stimulant drugs and counterfeit drugs, and for other purposes....”

“Sec. 2. The Congress hereby finds and declares that there is a widespread illicit traffic in depressant stimulant drugs moving in or other wise affecting interstate commerce; that use of such drugs, when not under the supervision of a licensed practitioner, often endangers safety on the highways....”

⁸⁴*Id.*, § 511(f)(11)(1965).

⁸⁵*Id.* at § 8(a)(1965).

⁸⁶HUTT & MERRILL, *supra* note 48, at 536.

in *FDA v. Brown & Williamson* remain compelling arguments that could be relevant to the FDA if, in a drug legalization regime, it were given such a radical regulatory charge. For instance, even if Congress amended the FDCA to grant FDA clear statutory regulatory jurisdiction over cigarettes, the FDA’s jurisdiction could be challenged by NLD-manufacturing companies unhappy with FDA regulatory rulemaking and enforcement.

In conclusion, while the FDA would appear not to have jurisdiction over cigarettes, nor NLD’s, without an amendment to the FDCA, there is a basis in the FDCA for NLD regulation. Further, it could be argued that regardless of the holding in *FDA v. Brown & Williamson*, and the FDA’s traditional refusal to assert jurisdiction over cigarettes, would become irrelevant in a drug legalization regime because narcotics were not legalized at the time Congress enacted the FDCA, nor its amendments. Finally, a legal realist might find the Court’s holding in *FDA v. Brown & Williamson* was a reaction to FDA Commissioner David Kessler’s maverick advocacy of several radical administrative changes; however, under this legal realist analysis, if the FDA Commissioner were merely attempting to regulate the legalization of drugs in the future, the Court might look more favorably at the salient arguments accepted by the Middle District Court in *Coyne* and the dissent in *FDA v. Brown & Williamson*.

Part II: A Model Plan for Regulation of Illegal Drugs by the FDA⁸⁷ The FDA Pre-Market Approval

⁸⁷The regulation of NLD’s by the FDA and application of the current FDCA to NLD’s raises other fascinating FDCA regulatory issues quickly addressed, here, but worth further examination:

1(a). Misbranding [§ 352(a)-(b)(a)]: A recreational drug would likely be marketed with few medicinal claims. However marijuana manufacturers could make unsupported medical claims. The FDA could prosecute unsupported medical claims by drug manufacturers under § 352(a)-(b)(2001). Most likely, the marketing of NLD’s would follow the current cigarette model—that is, offering no medicinal claims. In fact, drug manufacturers might present Surgeon General’s Warnings—e.g., “cancer, addiction, driving impairment”, etc.—on NLD packages.. See 21 U.S.C. § 352; *Research Laboratories, Inc. v. United States*, 167 F.2d 410 (1948)(affirming orders to destroy seized, misbranded product and holding that keeping the product off the market served the public good).

1(b). Habit forming substances [352(d)]. Under § 352(d), marijuana manufacturers would have to place habit forming warnings on marijuana packages (“Warning – May be Habit forming.”). Section 352(d) should possibly be amended to require a stronger warning for NLD’s—e.g., “Warning – This drug is highly addictive.” See 21 U.S.C.A. § 352(d)(2001).

2. Directions For Use (352(f)(1)). The FDA would have to regulate proper directions for use. Some drugs might be more

Process Applied to Newly Legalized Drugs⁸⁸

Presuming that the FDA has, or is given, jurisdiction to regulate NLD's, how would it regulate marijuana? How would marijuana be introduced onto the market? Given the FDA's limited resources, what priorities would set in regulating the marketing of marijuana in a legalized drug regime (and by extension an array of once-illegal narcotics)? Given that, historically, the mission of the FDA has been to ensure that "human and animal drugs are safe and effective," how can the FDA approve of drugs that are, highly addictive at best, and physically dangerous at worst? Presumably, the FDA will follow its normal agency course, issuing "regulations to particularize specific requirements of the FD&C Act"⁸⁹ since "[m]ost illicitly manufactured or illicitly refined drug is contaminated or adulterated."⁹⁰

Introducing NLD's into the Market: New Drug Application

safely ingested by one means as opposed another. While directions for use usually applies to medically indicated drugs, the FDA could apply directions for use to NLD's. FDA enforcement of proper directions for use could avoid more dangerous uses of NLD's. For instance, "it appears that compulsive cocaine use may develop even more rapidly if the substance is smoked rather than snorted." to avoid an *Alberty Food Products Co. v. United States*, 185 F. 2d 321 (appellant had to rely on outside sources for information about drug use). See also 21 U.S.C.A. § 352(f)(1)(2001).

3. Intended Use. Here the intended use would be recreation unless the FDA approved marijuana for treating AIDS wasting symptoms and side-effects of chemotherapy. According to 21 C.F.R. § 201.5, intended use "means directions under which the layman can use a drug safely and for the purposes for which it is intended." Intended use may give rise to "adequate directions for use claims." See 21 C.F.R. § 201.5. See also *United States v. Article of Drug... Designated B-Complex Cholinol Capsules*, 362 F.2d 923, 925 ("Whether labeling contains 'adequate directions for use' of an article necessarily depends upon what it is intended to be used for."). This issue may be less relevant with marijuana, which is smoked, than with other drugs, such as cocaine or heroin, which can be administered in many ways. For example, there are several methods of administering cocaine. "The major routes of administration of cocaine are sniffing or snorting, injecting, and smoking (including free-base and crack cocaine). Snorting is the process of inhaling cocaine powder through the nose where it is absorbed into the bloodstream through the nasal tissues. Injecting is the act of using a needle to release the drug directly into the bloodstream. Smoking involves inhaling cocaine vapor or smoke into the lungs where absorption into the bloodstream is as rapid as by injection." Infobox: Crack and Cocaine, 13546, <<http://www.drugabuse.gov/Infobox/cocaine.html>> National Institute on Drug Abuse, National Institutes of Health, visited March 19, 2002.

⁸⁸The new drug application process raises an interesting question about the possibility of "me-too" generic marijuana. This issue is addressed in *Hoffmann-LaRoche, Inc. v. Weinberger*, 425 F. Supp. 890 (D.D.C. 1975).

⁸⁹Hutt & Merrill, *supra* note 48, at 1237.

⁹⁰See BÖLLINGER, *supra* note 2, at 123.

Companies intending to sell marijuana to the public in the legalized drug regime would most likely have to apply for a New Drug Application (NDA) under § 321(p)(1) of the FDCA. Also, Marijuana has deleterious effects on users' mind and body:

Someone who smokes marijuana regularly may have many of the same respiratory problems as tobacco smokers. These individuals may have daily cough and phlegm, symptoms of chronic bronchitis, and more frequent chest colds. Continuing to smoke marijuana can lead to abnormal functioning of lung tissue injured or destroyed by marijuana smoke.

Regardless of the THC content, the amount of tar inhaled by marijuana smokers and the level of carbon monoxide absorbed are three to five times greater than among tobacco smokers. This may be due to the marijuana users' inhaling more deeply and holding the smoke in the lungs and because marijuana smoke is unfiltered.

Although marijuana manufacturers would most likely have to make NDA applications to market recreational and medical marijuana, the current FDCA would may have little effect on the ultimate safety of drugs on users. In the least, section 321(p)(1) could be used to regulate the claims of marijuana manufacturers marketing marijuana as a medicine. Under current the current FDA statute, a marijuana company would have to submit data to the FDA and there is a determination that “there is a lack of substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended or suggested in the proposed labeling thereof...”⁹¹ Conversely, this provision would probably have little effect on companies who advertised marijuana for recreational purposes—e.g, as promoting a sense of well-being because it can be scientifically proven that marijuana promotes a sense of well-being in users.⁹² Nevertheless, the NDA process could curb unreasonable claims of marijuana manufacturers and also ensure drug purity.

Yet, introduction of marijuana would create several paradoxical agency problems for the FDA. The reality

⁹¹21 U.S.C.A. § 321(p)(1) (2001).

⁹²Infobox: Marijuana, 13551, <<http://www.drugabuse.gov/Infobox/marijuana.html>> National Institute on Drug Abuse, National Institutes of Health, visited February 20, 2002.

of the drug legalization regime—that the FDA must make NLD’s available to the public in to avoid the costs of drug prohibition—would undercut the FDA’s ultimate authority to deny all marijuana company’s NDAs for marijuana products. That is, by virtue of the legalized drug regime, the FDA must accept a new drug application from at least one marijuana company, or marijuana would once again only be available on the black market. On the other hand, even a circumscribed new drug policy would permit FDA involvement in the manufacture of marijuana and prevent weakening of the agency’s ability to determine new drug status generally.⁹³

Ironically, under current NDA provisions, marijuana companies might not be able market marijuana to AIDS and cancer patients but the same companies could possibly market marijuana as a recreational drug. First, in legalized drug regime, the FDA would have to approve marijuana for consumers *in some form*. It is not certain whether marijuana companies could market marijuana as a medicine (e.g., to alleviate pain and discomfort of AIDS wasting syndrome and the effects of chemotherapy.) Although there is some evidence in their favor, it is unlikely that a marijuana manufacturer marketing smoked marijuana to AIDS and cancer patients could produce scientific sufficient evidence to get FDA approval. For instance, the effectiveness of smoked marijuana “has been rejected by the American Medical Association, the National Multiple Sclerosis Society, the American Glaucoma Society, the American Academy of Ophthalmology and the American Cancer Society.”⁹⁴ Further, medical organizations have found smoked marijuana inappropriate for cancer and AIDS patients, citing its negative effects on immune functions.⁹⁵ In contrast, a marijuana company could possibly market marijuana as alleviating stress or promoting a sense of well-being in users.⁹⁶

⁹³An exception to the FDA’s jurisdiction to determine new drug status could weaken the agency’s ability to regulate other drugs not involved in the drug legalization regime. As Hutt and Merrill note, “The Supreme Court’s holdings in *Bentex* and *CIBA* that FDA has ‘primary jurisdiction’ to determine new drug states was a major victory for the agency.” HUTT & MERRILL, *supra* note 48, at 510.

⁹⁴David G. Evans, *High Court Was Right to Nix Medicinal Pot*, THE RECORD (Bergen County, NJ), May 22, 2001, at L15.

⁹⁵*Id.*

⁹⁶“Once securely in place, THC kicks off a series of cellular reactions that ultimately lead to the high that users experience when they smoke marijuana.” Infobox: Marijuana, 13551, <<http://www.drugabuse.gov/Infobox/marijuana.html>> National Institute on Drug Abuse, National Institutes of Health, visited February 20, 2002.

Nevertheless, even these claims should be subject to scrutiny. For instance, it is believed that “whether an individual has positive or negative sensations after smoking marijuana can be influenced by heredity”⁹⁷ and other factors. Moreover, the NDA process could require manufacturers to identify dangerous drug interactions with prescription and over-the-counter drugs and negative side effects such as “problems with memory and learning; distorted perception; difficulty in thinking and problem-solving; loss of coordination; and increased heart rate, anxiety, and panic attacks.”⁹⁸ Further, marijuana drug manufacturers would have to provide “information, both favorable and unfavorable... obtained through investigations,”⁹⁹ and “contain information on the process by which the drug is made and how the quality of the drug will be assured.”¹⁰⁰ Consequently, although the NDA process could produce paradoxical results, it could also ensure better purity and safer use for marijuana users.

Safety Standard Prong

The safety standard prong of the NDA process would be valuable for two reasons in this legalized drug regime. First, it could make it more difficult for marijuana manufacturers to market marijuana as a traditional medication—specifically, in the case of medical marijuana. Secondly, under the risk-benefit analysis employed by the FDA, recreational marijuana could potentially be approved.

Using the current risk-benefit safety standard, the FDA could approve recreational marijuana. The FDA approval process is influenced by public opinion. Presumably, in a drug legalization regime, public opinion would hold that the benefits of available narcotics (no black market, no drug-related crime; fewer drug-related societal costs) would outweigh the risks *to users* (addiction, drug interaction, overdose, etc.). If this were the case, the overwhelming public opinion in favor of drug legalization might allow the FDA to approve the marketing of marijuana. According to former FDA Commissioner George Larrick:

⁹⁷*Id.*

⁹⁸*Id.*

⁹⁹HUTT & MERRILL, *supra* note 48, at 519.

¹⁰⁰*Id.*

The decision to approve a drug for marketing, or to withdraw an earlier approval requires a weighing of the benefit to be expected from use of the product against the risk inherent in its use....

But over a period of time, the direction of the Government's decisions will inevitably be influenced by public reaction.... The judgments of society are not necessarily consistent with the scientific facts. Neither are they always logical. They can be and sometimes are arbitrary. Even so, neither the executive nor the legislative branches can ignore them. If it should become the overwhelming public view that society should drastically limit the risk no matter how much good a drug can do, then we would be forced to remove from the market many drugs whose good far outweighs their harm.¹⁰¹

Larrick's statement suggests that the FDA could approve marijuana. Pointedly, Larrick's example (where society's view is to limit the risk of an otherwise beneficial drug) is the very opposite of what would be the public opinion supporting the legalization of drugs—e.g., avoiding the societal costs of drug prohibition. Further, Larrick notes that public opinion is “sometimes arbitrary” and may not necessarily always be a good influence on the FDA approval process. Nevertheless, to the extent that public opinion can influence the FDA to approve a drug, public opinion could be a powerful factor in the risk-benefit analysis, allowing the FDA to approve the use of marijuana.

Effectiveness Prong

Like the safety standard, the effectiveness standard could prevent inaccurate marketing of marijuana as a traditional medicine where it is proven ineffective. Given that, according to some research, “marijuana has shown particular effectiveness in treating the AIDS wasting syndrome and the nausea and vomiting associated with chemotherapy,” private drug companies may attempt to market medicinal marijuana.¹⁰² Nevertheless, claims of the effectiveness of medical marijuana has been contested.¹⁰³ The NDA process could be very valuable in determining the ultimate effectiveness of medicinal marijuana because

Advantages of Approving Marijuana through Grandfather Clause

The FDA might also consider the possibility of using the § 321(p)(1) grandfather clause to avoid undercutting

¹⁰²NEUSCH, *supra* note 31, at 214.

¹⁰³David G. Evans, *High Court Was Right to Nix Medicinal Pot*, THE RECORD (Bergen County, NJ), May 22, 2001, at L15.

its primary jurisdiction¹⁰⁴ to determine new drug status.¹⁰⁵ Under § 321(p)(1):

Any drug.... not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs as safe and effective for use under the conditions prescribed... except that such a drug not so recognized shall not be deemed to be a “new drug” if at any time prior to the enactment of this chapter it was subject to the Pure Food and Drugs Act of June 30, 1906.

It is conceivable that marijuana was recognized by the Pure Food and Drugs Act of June 30, 1906. According to Judge Gray, besides a few state and city ordinances, “no laws addressed any currently illicit substance” until the 1906 passage of the Pure Food and Drugs Act.¹⁰⁶ And, it was not until 1914 when the Harrison Act and *Webb v. United States* (1919), which held that it was illegal for doctors to dispense prescription drugs to alleviate the symptoms of narcotics withdrawal, made legal use of narcotics illegal. Eight years passed between the passage of the Pure Food and Drugs Act and the Harrison Act, thirteen years between the Pure Food and Drugs Act and the *Webb* decision. Assuming that the Pure Food Drugs Act did not create an outright ban of narcotics, marijuana use could be “grandfathered” by the FDA under § 321(p)(1). Another reason for approving marijuana under the grandfather clause is that the NDA process, like the general principles of the FDA itself, are purity and safety of drugs. One of the strongest arguments against FDA jurisdiction over tobacco products in *Brown & Williamson* was that tobacco products are inherently unsafe. And, the purpose of the FDA is to ensure the purity and safety of drugs. The majority noted in *Brown & Williamson*, “In view of the FDA’s conclusions regarding health effects of tobacco use, the agency would have no basis for finding any such reasonable assurance of safety. Thus, once the FDA fulfilled its statutory obligation to classify tobacco products, it could not allow them to be marketed.”¹⁰⁷ Implicit in the Court’s reasoning is that the FDA’s mission (ensuring purity and safety of drugs) is not commensurate

¹⁰⁴HUTT & MERRILL, *supra* note 48, at 510.

¹⁰⁵See HUTT & MERRILL, *supra* note 48, at 498.

¹⁰⁶GRAY, *supra* note 7, at 21.

¹⁰⁷120 S.Ct. 1291, at 1303.

with approving recreational drugs like cigarettes, or marijuana, that are necessarily unhealthy.

On the other hand, use of the grandfather clause to approve marijuana may equally weaken the credibility of the FDA approval process, and by extension the credibility of the FDA. According to *U.S. v. Allan Drug Corp.*, “The exception or the Grandfather Clause was perpetuated verbatim by [by the 1962 Amendments] so that a drug not generally recognized as safe or effective on the date of the Amendment would not be deemed to be a new drug on that date if its labeling contained the same representations concerning the conditions of its use.”¹⁰⁸

¹⁰⁸See HUTT & MERRILL, *supra* note 48, at 498.

Conclusion

Predictions: Ability of the FDA to Accommodate Challenge of Regulating NLD's

If agency history is an indicator, the FDA could surmount the administrative challenge of regulating NLD's.

The FDA has accommodated governmental growth, budgetary cutbacks, and remains insulated from some of the public pressures facing other governmental bodies. The FDA “has grown in size as the federal government has grown, assuming larger responsibilities as private ordering gave way to regulation in many areas...”¹⁰⁹ Of course, a drug legalization regime would be more complex and more costly than the hypothetical regulation of medicinal and recreational marijuana marketed by private drug companies. Hopefully, the FDA would receive additional funding commensurate with the task of regulating NLD's. If not, the new charge of regulating once-illegal drugs could amount to a budgetary cutback, given the many responsibilities of the agency. However, in the past, the FDA has survived budget cutbacks. For instance, the “FDA fared relatively well in maintaining its budget during the general reductions of the 1980s.”¹¹⁰ And in the case that the FDA did not receive necessary budget increase to regulate NLD's, it might, as it has in the past employ innovative regulation that is “less suspicious and more inventive”¹¹¹ in ensuring the safety and purity of once illegal narcotics.

Amendment to the FDCA Necessary to Meet Jurisdictional and Institutional Challenges

The FDA could best regulate NLD's with a statutory amendment to the FDCA to both ensure jurisdiction over NLD's and to maintain the credibility of the agency. In a drug legalization regime, not only should the Controlled Substances Act be necessarily amended to make narcotics legal to the public, but the Controlled Substances Act and the FDCA should offer specific jurisdiction to the FDA to regulate NLD's. The Fourth Circuit and Supreme Court rulings against FDA jurisdiction in *FDA v. Brown & Williamson* “stemmed

¹⁰⁹See HUTT & MERRILL, *supra* note 48, at 5.

¹¹⁰See HUTT & MERRILL, *supra* note 48, at 17.

¹¹¹See HUTT & MERRILL, *supra* note 48, at 20.

from directly from congressional inaction and prior actions by the FDA negating assertion of jurisdiction.”¹¹² First, the FDA probably does not have jurisdiction over currently-illegal narcotics, and certainly has no jurisdiction over tobacco products.¹¹³ The FDCA has been amended often, and several times to expand the power of the FDA.¹¹⁴ While, as discussed in Part One, there are indeed arguments favoring FDA jurisdiction over NLD’s in the current FDCA, such an amendment would avoid unnecessary litigation.

¹¹²TERMINI, *supra* note 5, at 85.

¹¹³*See* Controlled Substances Act, 21 U.S.C.A § 801 (2001); 120 S.Ct. 1291.

¹¹⁴*See* HUTT & MERRILL, *supra* note 48, at 13.