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(Article begins on next page)

Toward Rational Regulation of Marijuana in the United States: FDA's Role in Consumer Choice and Safety

Christopher P. Edelson

Introduction

The Food and Drug Administration is an agency dedicated to maintaining the health and safety of the American public. For as long as people have been purchasing and consuming foods and drugs there have been the problems of adulteration and imperfect consumer information. In some cases, FDA acts to protect the consumer against dangers he or she cannot protect him or herself from by prohibiting access to food containing invisible pathogens or drugs intended for specific maladies beyond lay diagnosis. In other cases, FDA decides the best approach is to allow for informed consumer choice through labeling and disclosure requirements. Generally, the latter approach is applied to areas of aesthetic choice, but even when products are potentially harmful (containing saturated fats, cholesterol, nicotine, caffeine, saccharine, preservatives) FDA is reluctant to ban them. Ultimate choice is left to the informed consumer, especially in areas of subjective choice, e.g. whether to consume a lollipop with a worm inside it or chocolate covered ants.

The policy of informed consumer choice has not been applied to marijuana. Even though medical opinion and empirical data show marijuana is far less harmful than legal products like alcohol and cigarettes, marijuana is an illegal substance in the United States, placed in the most restrictive category

Schedule I of the Controlled Substances Act. Instead of placing jurisdiction in the hands of FDA to monitor marijuana, we as a country have chosen to give jurisdiction to the Department of Justice. Instead of allowing FDA to protect the public against adulteration, we force 12 million American consumers of marijuana to purchase blindly and illicitly, not knowing what they are getting. (Forced in the sense that if people choose to use marijuana, they are unprotected against adulteration. Of course, free will is involved, but the fact is that millions of Americans who are otherwise law-abiding citizens become patrons of the black market when marijuana is illegal, as millions of Americans did in the days of alcohol prohibition.)

It is hard to imagine buying alcohol without knowing its potency or even whether it has been adulterated with some more dangerous substance but this is the state of affairs in the area of marijuana. Despite an otherwise prevailing free market philosophy and the lessons of history with respect to alcohol prohibition, consumer choice is rejected in favor of marijuana prohibition. In a time of acknowledged fiscal crisis where no program is considered sacred but few taxes are politically viable, we refuse the receipts that could be reaped from taxed sales of legal marijuana and devote resources to a wasteful and counterproductive war on drugs.

Demonization, mythology, politics, and irrational laws have conspired to produce a misguided marijuana policy in twentieth century America. Will we continue this unworkable, wasteful, and irrational policy into the next century? The first section of this paper will argue for a more rational marijuana

policy, marked by FDA regulation, informed consumer choice, and decriminalization. We will look at the history of marijuana use to understand the myths that have shaped past regulation and the realities that should guide reform.. We will examine the costs and benefits of legalization and consider arguments for and against legalization. The second section will examine the legal obstacles to rational regulation. Currently the Department of Justice (DoJ) has jurisdiction of marijuana under the Controlled Substances Act. Choices concerning health, safety, medical opinion, and consumer choice that more properly belong to FDA fall under DoJ and Drug Enforcement Agency (DEA) control. For years, the DEA has blocked rational reconsideration of marijuana regulation.

I. How Could We Rationally Regulate Marijuana in the United States?

A. History

Marijuana has been used around the world as a spice, medicine, and stimulant for centuries. While some societies have tolerated use, many governments before ours have unsuccessfully tried to prohibit use. In our own century, marijuana use is common in various cultures. As of 1969 the National Institute of Mental Health estimated that there were between 200 and 250 million marijuana users worldwide.¹ Current medical opinion pronounces marijuana non-addictive and relatively harmless when consumed occasionally. There has never been a case of a marijuana overdose. The carcinogens in marijuana smoke enter the average marijuana smoker's body at a much lower level than the aver-

¹*Licit and Illicit Drugs: The Consumers Union Report on Narcotics, Stimulants, Depressants, Inhalants, Hallucinogens, and Marijuana*, Edward M. Brecher, eds. Consumer Reports, Little, Brown, and Company, Boston, 1972, p.402.

age cigarette smoker endures—the average marijuana smoker consumes a handful of cigarettes a week, the average cigarette smoker consumes 20 cigarettes each day.²

Marijuana has been a part of life in the New World since the seventeenth century. Marijuana was grown as hemp in North America for two centuries before the Civil War. Even George Washington kept track of his marijuana crop in diary entries. The U.S. Pharmacopeia listed marijuana from 1850-1942 and medicinal uses ranged from migraine headaches, gout, and rheumatism to cholera and mental depression. Fluid extracts of marijuana were marketed by companies including Parke Davis, Squibb, and Burroughs Wellcome and sold over the counter by drugstores in the early twentieth century. Marijuana cigarettes, strangely enough, were sold as an asthma remedy. There is also evidence of occasional recreational use.³ Today there are an estimated 12 million marijuana users in the United States.⁴

The movement to outlaw marijuana in this country did not gear up until after the repeal of alcohol prohibition. The movement built a mythology of marijuana misinformation, replete with tales of crazed addicts committing murders while high on the drug. Anti-marijuana crusaders managed to convince Congress to take action in 1937 with the Marijuana Tax Act. Even though the American Medical Association pointed out that the case against marijuana was

²*Drug Prohibition in the United States: Costs, Consequences, and Alternatives*, Science 9/1/89, p.944, vol. 245, Ethan A. Nadelman.

³*Licit and illicit Drugs: The Consumers Union Report on Narcotics, Stimulants, Depressants, Inhalants, Hallucinogens, and Marijuana*, Edward M. Brecher, eds. Consumer Reports, Little, Brown, and Company, Boston, 1972, pp.403-406. [referred to below as Brecher]

⁴18 Hofstra L. Rev. 751, 769 (1990)

built on exaggerated horror stories that demonized marijuana and made rational policy design impossible, Congress passed the bill outlawing non-medical untaxed uses of marijuana.⁵

It is unclear what motivated the prohibitionists— perhaps the same Puritanical impulses that motivated alcohol prohibition. A more cynical observer might point to the liquor industry’s interest in wiping out competition once alcohol prohibition ended. Whatever the impulses, the ensuing wave of propaganda warped public opinion concerning marijuana. A Gallup Poll in 1969 showed that only 3% of Americans realized marijuana was not addictive and nearly 30% mistakenly believed marijuana use harmed the nervous system or led to the use of stronger drugs.⁶ In a later section we will examine the Justice Department’s role in derailing rational policy, especially after 1970.

B.What Would a Rational Marijuana Policy Look Like?

FDA has a vital role to play in correcting public misinformation regarding marijuana. FDA’s role in protecting the public health and safety is equally implicated; consumers who purchase marijuana in 1995 do not know what they are buying and are unprotected against adulteration. Marijuana’s medicinal utility is denied to critically ill patients. Rational marijuana policy could reap savings of resources currently devoted to a never-ending war on drugs. Informed consumers could substitute safer marijuana for more harmful substances like alcohol. It is clear that FDA’s traditional role as guardian of consumer health and safety would be fulfilled if distribution of marijuana were

⁵Brecher, pp. 413-418.

⁶Brecher, p.421.

subject to FDA regulation. In these times of fiscal austerity, costbenefit analysis also favors regulated public sale of marijuana—revenues could be collected in tax, a costly war on marijuana could end.

The purpose of the Food, Drug, and Cosmetic Act has been described as to protect the consumer from those forms of adulteration and misbranding, from which, because of the expanding complexity of modern life, he is to a large extent unable to protect himself⁷ Much of the impetus for reform at the beginning of this century was rooted in the work of muckrakers like Upton Sinclair who discovered all sorts of hidden debris in food. Even though we tolerate a de minimis level of filth in food today, few consumers would want to buy a product containing unknown ingredients. It would be preposterous to sell beer and liquor of undisclosed alcohol content to unsuspecting drinkers. Of course this is precisely the situation we force on millions of marijuana users in this country. As Ethan Nadelman aptly points out, nothing resembling an underground Food and Drug Administration has arisen to impose quality control on the illegal drug market and provide users with accurate information on the drugs they consume. So marijuana smokers smoke marijuana that was grown with dangerous fertilizers, sprayed with the herbicide paraquat, or mixed with more dangerous substances.⁸ Instead of following market principles by respecting the large demand for marijuana, we needlessly and shortsightedly force Americans to use marijuana at their peril.

American culture and FDA policy often defer to consumer choice.

⁷4 FDC L.Q. 552, 556 (1949)

⁸Science, 9/1/89 p.942, Ethan Nadelman. (from now on cited as Nadelman)

In a modern capitalist economy, we expect government regulators to protect public health while making the widest array of safe consumer goods available to us. Informed consumer choice is a valued ideal—from pigs' feet to Hotlix, from saccharin to color additives, Americans demand free choice. When a product, like marijuana, is generally regarded as safe and has been used safely for centuries, government prohibition seems like an imposition of one set of aesthetic values on all consumers. Rational policy in this area would accept the fact that some people like to smoke marijuana, like some people like to eat the Hotlix worm. Rational regulators would focus on providing consumers with the best information to make informed choices about marijuana, from labeling to education. Hard facts would replace the myths surrounding this demonized product.

Some commentators have pointed out that society could derive added benefit if alcohol drinkers switched to marijuana. In contrast with marijuana, alcohol is an extremely dangerous drug. It is abused by 18 million Americans, at a social cost estimated at over \$100 billion a year. There are thousands of deaths linked directly to alcohol. 20,000 die on the roads each year in alcohol-related accidents. Cirrhosis of the liver was the eighth leading cause of death in this country as of May, 1989. About 75 other diseases are associated with alcohol use and abuse and it is involved in nearly half of all suicides and violent crimes.⁹ Every fall at colleges around the country, unconscious students are rushed to hospitals to have their stomachs pumped after overdosing on alcohol. By contrast there is little evidence that occasional marijuana use

⁹18 Hofstra L.Rev. 751, 766-767 (1990) See also Nadelman at p.945

does much harm at all.¹⁰ There is not one case of anyone ever having died from a marijuana overdose.¹¹ The effect of too much marijuana seems to be sleep. There is evidence that marijuana smoking tends to replace alcohol consumption, and in light of the enormous costs associated with alcohol consumption and the relatively harmless nature of marijuana, one could imagine a rational regulatory policy including a shift from alcohol to marijuana use as one of its goals.¹²

One would expect there to be an important reason to justify brushing aside the fundamental policies of informed consumer choice and safety when we choose not to regulate the marijuana smoked by millions of Americans. It is hard to find one, and easy to find reasons to change our approach. Marijuana is not just a recreational drug—it has medicinal uses for patients with glaucoma, multiple sclerosis, and cancer. It has shown promise in increasing the appetite of AIDS patients suffering from the wasting syndrome. Should we keep telling patients in pain that they cannot have access to this harmless drug that could markedly improve their quality of life?¹³

We have seen that FDA has a role to play in protecting public health, facilitating informed consumer choice, and dispelling myths about the dangers of marijuana. Cost-benefit analysis is another argument for FDA jurisdiction over marijuana. Scarce FDA resources would be wisely spent on establishing regulated marijuana sales in light of the enormous savings we as a society could realize by pulling out of the war on marijuana.

¹⁰Nadelman, pp.943-97

¹¹Nadelman, p.943.

¹²Brecher, p.432.

¹³Nadelman, p.942.

As politicians emphasize cost-cutting, it makes sense to analyze current marijuana policy from a standpoint of fiscal responsibility. It does not make sense to spend money enforcing prohibition of a relatively harmless substance when the money could be put to better use feeding the hungry, housing the homeless, training the unskilled, educating our youth, or healing the sick. Transferring jurisdiction over marijuana from DEA to FDA would free up wasted resources. Even after adding the necessary monies to FDA's budget, there would be quite a bit of overall savings, as we shall see.

The history of marijuana prohibition reveals a misguided, ineffective regulatory policy that seems to do more harm than good. In 1988 police arrested 600,000 people each year solely for possession of an illicit drug, which was usually marijuana. Instead of collecting tax revenues from sales of legal marijuana, the government spends over \$10 billion annually on enforcement of drug laws. The success of interdiction efforts aimed at reducing the amount of marijuana imported into the United States has been limited. Domestic producers have filled the gap and the U.S. has become one of the world's top producers of marijuana. Even when marijuana is successfully kept away from the public, users simply switch to more dangerous and more potent drugs like alcohol, cocaine, and heroin when they have no access to marijuana.¹⁴

Political candidates emphasize the threat crime poses to society, but there is seldom any analysis of *why* crime is such a problem. One of the causes is drug prohibition. As mentioned above, thousands of arrests each

¹⁴Nadelman, pp.939-941. See also Brecher at p.435 for description of marijuana users switching to harder drugs when marijuana is not available.

year involve non-violent offenses. We often hear about the lack of prison space and how violent offenders go through a revolving door when they enter prison, quickly returning to the streets. But we choose to arrest thousands of non-violent offenders and to fill our prisons with drug criminals.¹⁵ Law enforcement does not focus on violent crimes, murders, armed robberies, domestic abuse, rape, or big money white collar crime—unless they tie in to drug enforcement. In fact, [un many cities, urban law enforcement has become virtually synonymous with drug enforcement.¹⁶

Some might argue that drug violators are inherently violent or evil and that law enforcement is properly focused on drug enforcement. It is simply not true that marijuana users are provoked to violence when they use marijuana. Any suspicion about a link between marijuana inmates were imprisoned for drug crimes. use and violence probably is connected to the mythology and demonization of marijuana that dates back to the 1930's and was discussed in an earlier section of this paper. It is not clear that cocaine or heroin are more violence-provoking than alcohol, but those drugs are not the subject of this paper. For the purposes of an argument to rationalize the regulation of marijuana, it is enough to point out that any violence associated with marijuana stems from our irrational policy choice and not from marijuana consumption per se. By criminalizing marijuana use, we create the conditions for a black market. Any thoughtful criminal would be remiss to overlook the vast sales potential of illegal drugs. Currently, more than half of all organized crime revenues are

¹⁵Nadelman, p.940—as of 1989, 1/3 of 50,000 federal inmates and 1/10 of 550,000 state

¹⁶Nadelman, p.941.

believed to derive from the illicit drug business.¹⁷ By legalizing the sale of marijuana, we could begin to put a real dent in organized crime. Politicians who claim to be tough on crime but support drug prohibition ought to be asked why they support a policy that gives comfort and sustenance to organized crime.

The costs of drug prohibition are wasted law enforcement resources, unregulated sales of adulterated marijuana, lost tax revenues that could derive from legal sales of marijuana, violence associated with organized criminal drug trafficking and sales, and diversion of public attention away from real problems onto a phony war against marijuana and other drugs. The benefits are more difficult to see. Some argue that drug prohibition reduces the use of marijuana. This may be true, but there are still millions of users we force to surreptitiously purchase marijuana. And increased marijuana use might not be a negative thing if the public does indeed substitute marijuana for more dangerous drugs like alcohol. This would bring a quantifiable savings in health costs and an unquantifiable savings in human lives not lost to drunk drivers, cirrhosis of the liver, domestic abuse or any of the other dangers associated with alcohol abuse.¹⁸ One could argue that marijuana should not be accessible to children but of course marijuana need not be legally saleable to minors. Some argue that not enough is known about the long term effects of marijuana on the brain. This is a more troubling argument. However, currently legal drugs like nicotine and alcohol have long term destructive health effects that we know about and this does not halt their sales. If FDA decides that it is in fact a concern, it could

¹⁷Nadelman, p.941.

¹⁸Nadelman p.943—all of the health costs of marijuana, cocaine, and heroin combined amount to only a fraction of those caused by [cigarettes and alcohol].

require labeling indicating that use of marijuana may produce long term harm to the brain, similar to the Surgeon General's warning on packs of cigarettes. The very fact that marijuana is illegal makes it difficult to gather information about its effects—scientific studies are curbed, users are reluctant to participate in surveys or investigations. And the long list of arguments for legalization cited previously outweigh this one uncertainty.

II. Legal Obstacles to Rational Regulation of Marijuana

A. The Current Regulatory Framework

There are formidable legal obstacles standing in the way of legalization and rational FDA regulation of marijuana. Marijuana is specifically excluded from the Food, Drug, and Cosmetic Act and placed under Department of Justice jurisdiction by the Controlled Substances Act of 1970.¹⁹ Petitions to the Attorney General and appeals to the judicial system over the past two decades have failed to achieve re-classification of marijuana under the Controlled Substances Act.²⁰ Marijuana is currently classified as a Schedule I substance, the category reserved for the most dangerous and addictive substances that possess no medicinal value.²¹ The current regulatory scheme is wildly inappropriate, based on transparent myths about marijuana instead of thoughtful evaluation of scientific knowledge.

Rational reform depends on a courageous regulator or legislator who can point out that it is time to re-think an irrational regulatory scheme.

¹⁹Marijuana is specifically exempted by 21 U.S.C. sec.321(v)(3). The Controlled Substances Act begins at 21 U.S.C. section 801.

²⁰*NORML v. DEA* 559 F.2d 735, 748 (D.C. Circuit, 1977), *NORA'IL v. DEA* 930 F.2d 936,

²¹21 U.S.C. 812(b)(1)

There are several possible ways in which reform could proceed. The Controlled Substances Act provides some procedural avenues for challenging the classification of substances. Under 21 U.S.C. sections 811(a)(2), (b) the Attorney General in consultation with the Department of Health and Human Services has the authority to decontrol or reschedule controlled substances. As noted, petitions to the Department of Justice as represented by the Drug Enforcement Agency (DEA) have not produced rescheduling of marijuana.²² The Attorney General also has the authority to register a manufacturer to produce Schedule [substances if it is in the public interest to do so²³ This is an intriguing possibility, but again the past intransigence of the Justice Department and DEA discourages much optimism in seeing this provision invoked.

Another possibility is Congressional action. Congress could rework the statutory treatment of marijuana, placing it within the Food, Drug, and Cosmetic Act and allowing FDA to regulate. However, given the effect of years of anti-drug propaganda on the American public it would probably be political suicide for a politician to advocate such measures in 1995. It would take a brave, selfless, farsighted leader to challenge anti-drug stereotypes in a dogged, relentless campaign against irrationality. And even a campaign of this type would probably fail to convince a dogmatic Congress and a misinformed public.

FDA could play an important role in straightening out a misinformed public. Obviously, this would be a politically dangerous policy choice

²²*NORML v. DEA* 559 F.2d 735, 748 (D.C. Circuit, 1977)

²³21 U.S.C. sec.823(a)

and it would probably be illegal for FDA to produce literature debunking marijuana myths at this point. Given limited resources, it is not surprising that FDA chooses to avoid the topic of marijuana reform.

B. Past Challenges to an Irrational Regulatory Scheme

Legal challenges to the Controlled Substances Act have focused on the rationality of the statute. Given the utter irrationality of marijuana regulation, this seems an appropriate challenge. However, courts have consistently refused to overrule Congress and have sometimes used cases involving marijuana as an opportunity to embrace unsubstantiated myths about marijuana.

In U.S. v. Kuch 288 F.Supp. 439 (D.C., 1968), a case decided before the Controlled Substances Act was enacted, a defendant claimed that the Marijuana Tax Act interfered with her religious beliefs and practices. In holding that the First Amendment does not give unbridled freedom to smoke marijuana or use LSD, the court seemed to be guided more by rejection of the Sixties counterculture than by rational inquiry in evaluating the dangers of marijuana use. The court wrote that [t]here is abroad among some in the land today a view that the individual is free to do anything he wishes. A nihilistic, agnostic and antiestablishment attitude exists. ²⁴This statement reveals some of the emotional and political bases for opposition to legalized marijuana. Marijuana was an emblem of the 1960's in many ways and legalization no doubt represented a form of anarchy to those who looked askance at the counterculture. It is interesting to consider these words in light of our almost unbridled faith in the

²⁴288 F.Supp. 439, 445

free market today. In a sense, there is a view today that producers are free to produce whatever they wish. This is linked to capitalism and the free market philosophy. Government regulation is deemphasized, even scorned. Ironically, the words once used to condemn marijuana as an emblem of unbridled freedom could now be part of a free market argument for legalizing marijuana in the interests of consumer choice.

Following passage of the Controlled Substances Act in 1970, a series of challenges to the statute have been reviewed and rejected by the courts.²⁵ Courts have been understandably reluctant to reject Congress's actions. The real problem, however, is not that Congress is asserting authority instead of the courts. The real problem is that health and drug experts are not included in the discussion. Marijuana is outlawed because it is said to be addictive and hazardous to health.²⁶ FDA's mission is to protect the public health and provide information that lets consumers make informed choices. It would make more sense to give FDA the authority and resources to regulate marijuana than to continue vesting authority in bodies like Congress and DEA that have shown no ability to rationally evaluate and handle the problem of marijuana. The National Organization for the Reform of Marijuana Laws (NORML) has attempted to convince DEA and the courts that marijuana policy should be rationalized. Over the past twenty years, DEA has successfully played a delaying game, stubbornly refusing to reconsider marijuana policy in the face of court decisions

²⁵U.S. v. LaFroschia 354 F.Supp. 1338 (U S D C, S.D N.Y, 1973) holding that there is a rational basis for placing marijuana on Schedule I See also U.S. v. Kiffer 477 F.2d 349 (2d Circuit, 1973) and U.S. v. Bergdoll 412 F.Supp. 1308 (Delaware, 1976)

²⁶21 U.S.C.sec.812(b)(1) see also U.S. v. Kuch 288 F.Supp. 439, 446

urging reconsideration. The D.C. Circuit found that Congress had intended that the Department of Health, Education, and Welfare play a role in evaluating the scheduling of marijuana under the Controlled Substances Act and that DEA had attempted to shut out HEW input in the past. The D.C. Circuit's analysis of marijuana was reasonable and thoughtful—medical evidence concerning the safety of marijuana was considered instead of anecdotal myths about marijuana's inherent evil.²⁷ However, remand did not produce a rescheduling of marijuana.

In 1991 NORML reached the D.C. Circuit again after DEA had rejected an administrative law judge's recommendations that marijuana be reclassified. This time, the court was susceptible to DEA's circular argument that marijuana could not be medically useful because only a minority of U.S. doctors recommended marijuana for medical use. This argument is flawed because it seems unlikely that most doctors would reject our cultural biases against marijuana. It might make sense to consider the opinions of doctors who actually had studied marijuana but to consider the opinions of doctors in general does not seem likely to produce an informed judgment as to marijuana's safety or medical usefulness. Also, the court was only asked to consider whether marijuana was effective as a medicine. The irrational policy of restricted recreational use was not examined.²⁸

The court did point out that part of DEA's 8 factor test for rescheduling could not be relevant to marijuana. Three of the factors ask whether the

²⁷*NORAsfL v. DEA* 559 F.2d 735, 748 (D.C. Circuit, 1977)

²⁸*NORML v. DEA* 930 F.2d 936, 939 (D.C. Cir. 1991)

drug is generally available, used by a substantial of medical practitioners, and recognized in generally accepted pharmacopeia. As a Schedule I drug, there is no way marijuana could be generally available or used by a substantial number of doctors—drugs placed in Schedule I are not widely available.²⁹ Other courts have been sympathetic to the arguments for reform. The Second Circuit in *U.S. v. Kiffer* admitted that it is apparently generally accepted that most users [of marijuana] do not suffer any significant ongoing harm. The Second Circuit only deferred to Congress because the present state of knowledge of the effects of marihuana is still incomplete and marked by much disagreement and controversy.³⁰ It is a problem that not enough is known about the long term effects of marijuana use. One could argue that long term studies are called for before legalization occurs. However, currently legal drugs like nicotine and alcohol have long term destructive health effects. It is not enough to say that we do not understand everything about marijuana and therefore it cannot be legal. As mentioned earlier, the very fact that marijuana is illegal makes it difficult to gather information about its effects—scientific studies are curbed, users are reluctant to participate in surveys or investigations.

C. Proposed FDA Regulation of Marijuana

The question of how FDA should regulate marijuana could be answered in several ways. Marijuana could be a prescription drug subject to a New Drug Application (NDA) and available only as a medicine. Marijuana could be readily available over the counter for recreational and medicinal pur-

²⁹ *NORML v. DEA* 930 F.2d, 940

³⁰ *U.S. v. Kiffer* 477 F.2d 349, 353 (2nd Circuit, 1973)

poses Marijuana could be subject to a dual system of regulation: marijuana sold for recreational purposes would be regulated by standards of purity and marijuana making a therapeutic claim could be subject to a NDA and sold on a prescription basis.

FDA should promulgate a dual system depending on whether the product is sold for recreational purposes or for medicinal purposes. FDA should assert jurisdiction under 21 U.S.C. sec. 201(g)(1). The D.C. Circuit in *ASH v. Harris* held that manufacturer intent is dispositive in the area of cigarette regulation (or lack thereof).³¹ The D.C. Circuit did not find the requisite manufacturer intent to bring cigarettes under sec. 201(g)(1)(C) of the Food, Drug, and Cosmetic Act. However, a direct application of the *ASH* holding is not desirable—one of the arguments for changing regulatory policy with respect to marijuana is so that FDA can protect consumers from adulterated product. The failure to bring cigarettes under FDA jurisdiction has proved to be a mistake. Cigarette manufacturers were found to have surreptitiously added nicotine to their cigarettes in order to enhance the addictive effects of their product. Consumers were deceived as to the product they were buying and consuming.

Marijuana could be distinguished from cigarettes and placed under FDA control. There is no reason to believe that marijuana manufacturers could be trusted not to adulterate their product. Unsupervised manufacturers would have incentive to adulterate their product to make it cheaper. Although competitors theoretically act as a monitor against adulterators, the threat of

³¹*ASH v. Harris* 655 F.2d 236 (D.C. Cir. 1980), holding that nicotine cigarettes are not subject to FDA regulation because manufacturer intent to affect the structure or any function of the body of man was not established.

adulteration of marijuana is too important to be left to market forces. It would be a shame if marijuana were finally legalized but consumers still found themselves at the mercy of manufacturers, with no protection against adulteration. FDA's role in public safety points the way to a system that polices against manufacturer adulteration.

While recreational marijuana could be brought under the Food, Drug, and Cosmetic Act under 21 U.S.C.201(g)(1)(C), marijuana intended for use by AIDS patients or people suffering from glaucoma would clearly be making a health claim and falls under 21U.S.C.201(g~1)(B). Marijuana intended as medicine is more problematic. Should the lengthy NDA process be required? Should it be sold over the counter? It seems desirable to have patients with glaucoma or AIDS taking medicine under medical supervision. However, one could argue that patients with these conditions need help right away and should not have to wait out a long approval process. One could argue that marijuana falls under the GRAS exception by virtue of its track record of safety. This is a difficult choice, but because this product is making a claim of efficacy (unlike recreational marijuana) in disease treatment and because all new drugs today start as prescription drugs, there should not be an exception made for marijuana. The NDA process could resolve once and for all any uncertainties about safety and efficacy and publicity could help change public bias against marijuana. Patients who need immediate access could use synthetic THC which has been approved for limited medical use by FDA and DEA.³²

³²51 FedReg. 17476 (May 13, 1986)

III. Conclusion

It is at times frustrating to consider the circumstances of marijuana regulation in the United States today. After reading about the long and safe history of marijuana use and the anti-marijuana propaganda developed in this century, it is difficult to see the prohibition of marijuana as anything but irrational. While it is difficult to see immediate reformation, we can keep our eyes on certain goals. We should not continue to feed new generations of Americans misinformation about marijuana while we condone the use of more dangerous drugs like cigarettes and alcohol. We should not continue to wage a costly and interminable war against drugs while deeper social problems go unaddressed. We should not create a breeding ground for organized crime that allows the criminal underworld to grow rich off the demand for marijuana that is not met by the licit free market. We cannot let patients suffering from glaucoma and AIDS to be denied relief for decades to come. We must learn the lessons of the history of alcohol prohibition. We must not enter a new century weighed down by myths of the past.