Cornell Journal of Law and Public Policy

Volume 19
Issue 3 *Summer 2010*

Article 3

Making Sense of Drug Regulation: A Theory of Law for Drug Control Policy

Kimani Paul-Emile

Follow this and additional works at: http://scholarship.law.cornell.edu/cjlpp

 Part of the Law Commons

Recommended Citation

Paul-Emile, Kimani (2010) "Making Sense of Drug Regulation: A Theory of Law for Drug Control Policy," *Cornell Journal of Law and Public Policy*: Vol. 19: Iss. 3, Article 3.
Available at: http://scholarship.law.cornell.edu/cjlpp/vol19/iss3/3

This Article is brought to you for free and open access by the Journals at Scholarship@Cornell Law: A Digital Repository. It has been accepted for inclusion in Cornell Journal of Law and Public Policy by an authorized administrator of Scholarship@Cornell Law: A Digital Repository. For more information, please contact jmp8@cornell.edu.

ARTICLE

MAKING SENSE OF DRUG REGULATION: A THEORY OF LAW FOR DRUG CONTROL POLICY

*Kimani Paul-Emile**

This Article advances a new theory of drug regulation that addresses two previously unexamined questions: how law-makers are able to regulate drugs differently irrespective of the dangers the drugs may pose and independent of their health effects, and the process followed to achieve this phenomenon. For example, although tobacco products are the leading cause of preventable death in the United States, they can be bought and sold legally by adults, while marijuana, a substantially safer drug, is subject to the highest level of drug control. This Article posits a conceptual model for making sense of this dissonance and applies this model to the regulation of four common drugs: cocaine, marijuana, tobacco, and anabolic steroids. Although much has been written on the topic of licit and illicit drug regulation, none of the scholarship in this literature has attempted to explain through an examination of pharmaceutical, illicit, and over-the-counter drugs how the apparent inconsistencies and incoherence of the U.S. system of drug control have been achieved and sustained. This Article fills the gap in this literature by proposing an innovative and comprehensive theoretical model for understanding how drugs can become "medicalized," "criminalized" or deemed appropriate for recreational use, based upon little or no empirical evidence regarding the pharmacodynamics of the drug.

* Associate Professor of Law, Fordham University School of Law. I owe special thanks to Michelle Adams, Deborah Denno, Matthew Diller, Sheila Foster, Barry Furrow, David Garland, Myriam Gilles, Rachel Godsil, Risa Goluboff, Jennifer Gordon, Abner Greene, Douglas Husak, Olati Johnson, Dan Kahan, Sonia Katyal, Robin Lenhardt, Janai Nelson, Kevin Outterson, Terry Perlin, Aaron Saiger and Benjamin Zipursky, as well as participants at the 2009 Health Law Scholars Workshop, the 2009 Law & Society Association Junior Faculty Workshop, and the New York City Area Writing Colloquium for offering comments on prior versions of this article.

INTRODUCTION

The United States is a nation of drug users. The prevalence of drug use in the United States is astounding: from senior citizens who receive Medicare coverage, the largest group of drug users, to people convicted of drug offenses, who constitute a substantial portion of the state and federal prison populace. Today, drugs are consumed by members of nearly every segment of society and affect every aspect of modern life.[1] Due to the sheer ubiquity of drug use today, many Americans may feel confident that they have a reasonable understanding of how drugs are, or should be, regulated. Readers may imagine that in a liberal democratic society, drugs are regulated according to scientific or medical evidence regarding their dangers and benefits.

In fact, however, drug regulatory decision-making in the United States over the past 150 years has often borne very little relationship to science. Many drugs are regulated in ways that belie scientific or medical evidence regarding their pharmacological characteristics. Tobacco products, for example, are the leading cause of preventable death in the United States,[2] yet they can be bought and sold legally by adults, while marijuana—a significantly safer substance—is a Schedule I controlled drug and its use is therefore strictly prohibited.[3] Similarly, although all

---

[1] *See* SUBSTANCE ABUSE AND MENTAL HEALTH SERVS. ADMIN., DEP'T OF HEALTH & HUMAN SERVS., RESULTS FROM THE NATIONAL SURVEY ON DRUG USE AND HEALTH (2007), *available at* http://www.oas.samhsa.gov/p0000016.htm#Standard [hereinafter, RESULTS FROM THE 2007 NAT'L SURVEY ON DRUG USE AND HEALTH]. *See also* CLAYTON J. MOSHER & SCOTT AKINS, DRUGS AND DRUG POLICY: THE CONTROL OF CONSCIOUSNESS ALTERATION 147–168, 171–201 (Diana Breti ed., Sage Publications 2007).

[2] *See* B. Adhikari, Ph.D, et al., *Smoking-Attributable Mortality, Years of Potential Life Lost, and Productivity Losses - United States, 2000-2004*, 57 MORBIDITY & MORTALITY WKLY REP. 45, 1226–1228 (2005), *available at* http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5745a3.htm; CTRS. FOR DISEASE CONTROL & PREVENTION, TOBACCO USE: TARGETING THE NATION'S LEADING KILLER (2009), http://www.cdc.gov/nccdphp/publications/aag/osh.htm.

[3] *See* Comprehensive Drug Abuse Prevention and Control Act of 1970, 21 U.S.C. § 812(c)(Schedule I)(c)(10) (2002) (classifying marijuana Schedule I).

forms of cocaine share the same active ingredients and produce the same psychotropic effects, simple possession of one particular form of cocaine—crack—renders one subject to some of the most severe sanctions available for any drug.[4] Anabolic steroids are controlled substances; however, their distribution to some people seeking to enhance virility (particularly elderly men) is permissible, while sale to other healthy people seeking the same effects is not.[5]

The health effects of drug use do not appear to determine how a particular drug will be regulated. And this raises two questions: how are regulators able to treat drugs differently, irrespective of the dangers they may pose, and what processes do they follow to achieve this phenomenon? The state, at all levels of government, has at its disposal many regulatory mechanisms to control drug production, consumption and sale, including: drug scheduling by the U.S. Drug Enforcement Administration (DEA); imposition of state criminal and civil laws and penalties; market-based strategies, such as production subsidies and taxation; and the U.S. Food and Drug Administration (FDA) drug approval process and corresponding intellectual property laws, among others.[6] The choice among these various mechanisms, however, has often not been based on empirical evidence grounded in science or medicine. Although some drugs carry substantial health risks and others do not, the amount of risk posed is not accurately reflected in the regulatory processes selected to govern each drug. Equally confounding is the fact that the use of these divergent regulatory mechanisms does not appear to have arisen from

---

[4] *See* Knoll D. Lowney, *Smoked Not Snorted: Is Racism Inherent in Our Crack Cocaine Laws?*, WASH. U. J. URB. & CONTEMP. L. 121, 142 (1994) (explaining that "[i]n severe contrast to the harsh federal sentences for crack possession, a first-time offender possessing any other illicit drug is not subject to mandatory imprisonment, and faces a maximum sentence of 1 year"); Larry E. Walker, *Law and More Disorder! The Disparate Impact of Federal Mandatory Sentencing for Drug Related Offenses on the Black Community*, 10 J. SUFFOLK ACAD. L. 97, 118 (1995) (explaining that the Omnibus Anti-Drug Abuse Act of 1988 "specifically identifies one and only one controlled substance, i.e., crack, and attaches penalties in excess of those generally applied for simple possession"); Gary Fields, *Shorter Sentences Sought for Crack*, WALL ST. J., Apr. 30, 2009, http://online.wsj.com/article/SB124101257332168605.html (noting the imbalance between crack and powder cocaine sentences). *See generally* William Spade, Jr., *Beyond the 100:1 Ratio: Towards a Rational Cocaine Sentencing Policy*, 28 ARIZ. L. REV. 1233 (1996).

[5] Although nonmedical AAS distribution is a felony and many high profile professional athletes have, in recent years, been sanctioned for using the drug, AAS are also dispensed with little regulatory oversight at hundreds of "anti-aging clinics" across the country where older men go to enhance their virility through hormone replacement therapy. *See* Bruce Lambert, *Prominent Entertainers Cited in Steroids Inquiry*, N.Y. TIMES, Jan. 14, 2008, http://www.nytimes.com/2008/01/14/nyregion/14albany.html. An estimated one million men participate in physician-prescribed testosterone replacement therapy. *See* Leonard S. Marks, et al., *Effect of Testosterone Replacement Therapy on Prostate Tissue in Men with Late-Onset Hypogonadism: A Randomized Controlled Trial*, 296 JAMA 2351 (2006); Brian Vastag, *Many Questions, Few Answers for Testosterone Replacement Therapy*, 289 JAMA 971 (2003).

[6] *See infra* note 74.

one overarching goal; nor is it based upon universal principles of public health or even a unified moral or ethical ideal.

This Article posits a model for making sense of this dissonance. Although much has been written on the topic of licit and illicit drug regulation, none of the scholarship in this vast literature has attempted to explain through an examination of pharmaceutical, illicit, and over-the-counter drugs how the apparent inconsistencies and incoherence of the U.S. system of drug control have been achieved and sustained.[7] This Article fills the gap in this literature by proposing an innovative and comprehensive theoretical model for understanding how drugs become "medicalized," "criminalized," or deemed appropriate for recreational use, irrespective of any danger the drugs may pose.

The analytical framework this Article proposes, the "Regulatory Regime/ Norms" model, posits that drugs begin as blank slates onto which meaning is conferred. Prior to regulatory intervention, the way any particular drug is perceived or understood is indeterminate and amorphous. As a result, the project of regulating drugs is about allocating specific meaning and significance to a drug in order to prompt individuals to think about the drug in a way that allows for state intervention.[8] This is accomplished by regulatory regimes.

The Regulatory Regime/Norms model identifies three primary regulatory regimes used to control drug consumption and sale: the market regime, public health regime, and criminal regime. Each regime *creates and reinforces* specific norms with respect to the drugs it regulates: *moral* norms in the criminal regime, *disclosure* norms in the public health regime, and *assumption of risk* and *rational choice* norms in the market regime. These norms shape public understanding of drugs and the regulatory enterprise undertaken by the regime.

In order to have a drug placed in one regime over another, the corporate entities, private reformers, and government actors who compete in the drug placement process must successfully characterize the drug in a way that resonates with the norms of the regime that fits their goals.[9]

---

[7] *See infra* Part I.B.

[8] *See generally* Lawrence Lessig, *The Regulation of Social Meaning*, 62 U. CHI. L. REV. 943 (1995) (arguing that in some instances, government regulation constructs social meanings of the regulated entities).

[9] For examples of other scholarship employing frame analysis, see generally ERVING GOFFMAN, FRAME ANALYSIS: AN ESSAY ON THE ORGANIZATION OF EXPERIENCE (1974) (introducing frame analysis and describing its impact on societal understanding); JOSEPH R. GUSFIELD, SYMBOLIC CRUSADE: STATUS POLITICS AND THE AMERICAN TEMPERANCE MOVEMENT (1963) (invoking frame analysis in an examination of the American Temperance movement); JOSEPH R. GUSFIELD, THE CULTURE OF PUBLIC PROBLEMS: DRINKING-DRIVING AND THE SYMBOLIC ORDER (1981) (using perceptions of drinking-driving to address attitudes towards public problems); Michele A. Adams, *Framing Contests in Child Custody Disputes: Parental Alienation Syndrome, Child Abuse, Gender and Fathers' Rights*, 40 FAM. L. Q. 315 (2006) (using

The victor in this framing battle will see the drug regulated in its regime of choice, regardless of whether the drug poses a threat to health or safety and even if the regime placement decision flouts empirical evidence grounded in medicine or science. Once the drug has been placed, the regime will legitimate the regulators' characterization of the drug.

Regime placement, however, is not static. A drug will stay in a regime only so long as the characterization of the drug resonates with the norms of the regime. Therefore, if popular perception of the drug is no longer consonant with the norms of its regime, the drug can be moved out of that regime and into another. If, however, a drug in the criminal regime is persuasively characterized as being closely associated with socially maligned groups or racial minorities, it is significantly less likely that the drug will ever migrate out of the criminal regime.

As the Regulatory Regime/Norms model suggests, decisions that determine which regime a drug will be placed—that is to say, how it will be regulated—are only occasionally based on the pharmacological properties of each drug. Drug regulatory decision-making is much more accurately described as a high-stakes battle over how to persuasively frame a drug in a way that matches the norms of the regime that satisfies a particular group's preferences. This framing is the allocation of meaning that precedes the legal or legislative work of drafting laws and regulations. Thus, the act of framing certain drugs to fit in particular regimes is an inherently political endeavor with material consequences for those who are regulated and the corporate entities, private reformers and government actors who engage in the designation battles. Regime placement is determined by the winner in these struggles. Once these drug framing battles have ended and the victorious group has placed the drug in the regime of its choice, the norms that structure the regime work to mold popular understandings of the drug and legitimize the drug's placement in the regime.

In order to illustrate my Regulatory Regime/Norms model, this Article examines the regulation of four common drugs: tobacco, anabolic steroids, cocaine, and marijuana. These drugs span the spectrum of the U.S. system of drug control, both in terms of their pharmacological ef-

---

frame analysis to look at child custody disputes); Howard S. Becker, *Becoming A Marihuana Smoker*, 25 AM. J. SOC. 235 (1953) (looking at the reasons behind recreational marijuana use); Amy Kapczynski, *The Access to Knowledge Mobilization and the New Politics of Intellectual Property*, 117 YALE L.J. 804 (2008) (examining the effect of frame analysis on intellectual property law); Edward J. McCaffery et al., *Framing the Jury: Cognitive Perspectives on Pain and Suffering Awards*, 81 VA. L. REV. 1341 (1995) (discussing the impact of frames on compensation awards); Charlotte Ryan & Samuel Alexander, *"Reframing" the Presentation of Environmental Law and Policy*, 33 B.C. ENVTL. AFF. L. REV. 563 (2006) (invoking framing as a means to analyze and enhance environmental policy); Kathryn L. Tucker & Fred B. Steele, *Patient Choice at the End of Life: Getting the Language Right*, 28 J. LEGAL MED. 305 (2007) (arguing that negative framing used to describe end of life choices undercuts the issue).

fects and the regulatory mechanisms used to control their production, consumption and sale. Thus, they demonstrate the complex discontinuity of U.S. drug regulatory policy. Application of the Regulatory Regime/ Norms model to the regulation of these illicit, over-the-counter and pharmaceutical drugs provides valuable insight into the long and tortured history of U.S. drug regulation in a way that previous scholarship has not.

The remainder of this Article proceeds as follows. Part I provides a brief summary of the regulatory mechanisms used to control drugs in the United States and situates this Article within the academic literature on drug regulation. Part II presents my Regulatory Regime/Norms model, thus laying the foundation for subsequent analysis. This Part introduces the three primary regulatory regimes employed to control drug manufacture, distribution, and consumption: the criminal, public health, and market regimes. Part II also examines the specific norms and ideologies that are produced and reinforced within each regime (rational choice and assumption of risk, disclosure, and moral norms) and explains the way they enable regulators to structure particular drugs and drug users as governable, irrespective of whether the regulatory decision-making is based on scientific or medical evidence regarding the pharmacological effects of the drug.

Part III moves this model from the conceptual and theoretical to the concrete and verifiable by applying the model to the four drugs under consideration. This Part maps the regulatory battles that are waged over the regime into which a drug will be placed and explain how drugs are able to move from one regime to another. In so doing, this Part chronicles how marijuana became "dangerous" and tobacco the socially approved drug of choice; how one form of cocaine was distinguished from all others notwithstanding their similar pharmacodynamics; and how anabolic steroids were added to the list of scheduled drugs over the objections of the American Medical Association, FDA and the DEA. Thus, Part III identifies how each drug was initially understood as being in need of regulation and addresses the role of race and social class in the movement of drugs into and out of the criminal regulatory regime. Part IV, the final section of this Article, outlines the broader implications of my theory and suggests areas for future inquiry.

I. DRUG REGULATORY MECHANISMS & SCHOLARSHIP

A. *Overview of Drug Regulatory Mechanisms*

Broadly defined, a drug is a substance other than food that, when absorbed into the body of a living organism, affects the structure or func-

tion of the body.[10] Virtually every society and culture in human history has embraced the use of some sort of drug and developed norms governing its consumption.[11] Only the early inhabitants of arctic climates lacked indigenous drugs due to the inhospitable nature of their environment, which did not allow for the cultivation of such substances.[12] Once introduced by outside groups, however, drugs were readily adopted into these cultures.[13] The types of substances consumed and their effects are as varied as the cultures that use them.[14] Some drugs are taken to cure or ameliorate the symptoms of a disease or illness, while others, such as opiates and cannabis, are taken to relieve pain.[15] There are drugs like coffee, tobacco, coca, tea, and khat that are taken for their stimulant effects.[16] Still other drugs induce relaxation, provoke aggression, remove inhibitions, relieve tension, arouse or suppress the libido, or alter one's temporal experience.[17] While some drugs are taken to help people cope with depression, hardship or tragedy, others are consumed simply as recreational activity to ameliorate the monotony of daily life.[18] Psychotropic plants—organic substances that have the capacity to change the way one experiences time and space—are almost universally the most heavily regulated.[19]

In order to address the prevalence of drug use, government—at the federal, state and local levels—promulgates and enforces laws to control production, consumption, and sale. Thus, today, individuals of all income levels, from rural, suburban, and urban areas, and from virtually every age, racial, and ethnic group are subject to a dizzying array of drug

---

10 *See* Merriam Webster OnLine, http://www.merriam-webster.com/dictionary/drug (last visited Mar. 24, 2010) (defining "drug" as "a substance other than food intended to affect the structure or function of the body"). Most definitions of the term "drug" are imperfect. The Webster's dictionary, for example, also defines a drug as "a substance used for the diagnosis, cure, mitigation, treatment or prevention of disease" and as "an illegal substance that causes addiction, habituation or a marked change in consciousness." *Id.* The Food, Drug, and Cosmetic Act defines drugs as "articles (other than food) intended to affect the structure or any function of the body of man . . . ." 21 U.S.C. § 321(g)(1) (1994). Some drugs, however, could be considered food, such as mushrooms, and recently Cheerios cereal was threatened with classification as a drug by the FDA because the box label claimed that it helps to reduce cholesterol levels and the risk of coronary disease. *See* William La Jeunesse, *FDA Takes Cheerios to Task for Boastful Labels*, FOXNEWS.COM, June 19, 2009, http://www.foxnews.com/politics/2009/06/19/fda-takes-cheerios-task-boastful-labels/.

11 *See* MICHAEL POLLAN, BOTANY OF DESIRE: A PLANT'S EYE VIEW OF THE WORLD 139 (2001).

12 *See id.*

13 *See id.*

14 *See id.* at 140.

15 *See id.* at 142.

16 *See id.*

17 *See id.*

18 *See id.*

19 *See* RESULTS FROM THE 2007 NAT'L SURVEY ON DRUG USE AND HEALTH, *supra* note 1; *see generally* MOSHER & AKINS, *supra* note 1;

laws and regulations.[20] These drug control measures differ in many critical respects, as do their social and demographic effects; from the highly touted "war on drugs" and the increased policing of tobacco use in public spaces, to regulations that have allowed for the unprecedented proliferation of prescription drugs.[21]

The state justifies these laws as efforts to protect personal and public health, and to curb the social disorganization that may result from unregulated drug use.[22] The specific aims and regulatory mechanisms used by the policy-making bodies that are granted jurisdiction over drug use differ sharply; from the lofty stated goals of the FDA to the punitive powers of the DEA.[23] For example, one regulatory mechanism is drug scheduling.[24] Pursuant to the Controlled Substances Act, the DEA and FDA administer five categories or "schedules" established to classify controlled substances according to their potential for abuse, therapeutic value, and possible addictiveness.[25] Schedule I is the most restrictive classification and includes drugs such as heroin, LSD, and marijuana; while Schedule V is the least restrictive and includes codeine, a commonly prescribed painkiller.[26] The drug regulations enacted according to these schedules are enforced by the DEA.[27]

Another mechanism for drug control is the FDA drug approval process, which involves drug research, testing, and clinical trials undertaken by scientists,[28] including academic researchers who often work in concert with the pharmaceutical companies that will ultimately manufacture

---

20 *See id.*

21 *See id.*

22 *See* MOSHER & AKINS, *supra* note 1, at 203–37.

23 *See id.*

24 Comprehensive Drug Abuse Prevention and Control Act, 21 U.S.C. § 812 (2000).

25 *See id.* at §§ 801–971. Enforcement of the CSA is the responsibility of the Drug Enforcement Administration. *Id.* The FDA is charged with determining safe and effective medical use of drugs, and the National Institute of Drug Abuse has the authority to conduct scientific research. *Id.*

26 *See id.* § 812. Schedule I drugs are those that: (1) have a high potential for abuse, (2) have no therapeutic value, and (3) are not safe for medical use. Schedule II drugs are those that have a high potential for abuse, which may lead to severe psychological or physical dependence, but that have a currently accepted medical use with severe restrictions. Schedule II includes drugs such as cocaine, morphine and amphetamines. Schedule III drugs include anabolic steroids and marinol, while Schedule IV drugs include long-acting barbiturates, such as Phenobarbital and certain antidiarrheal drugs, including difenoxin. Finally, Schedule V drugs have a currently accepted medical use and the lowest potential for abuse relative to drugs in the other schedules. These drugs are typically available only for medicinal purposes, such as cough suppressants containing small amounts of codeine. *See id.*

27 *See id.* § 878. *See also* DEA Mission Statement, U.S. Drug Enforcement Agency, http://www.justice.gov/dea/agency/mission.htm (stating that "the DEA's primary responsibilities include . . . [e]nforcement of the provisions of the Controlled Substances Act").

28 The FDA has been charged with regulating pharmaceuticals since 1938. *See* Food, Drug, and Cosmetic Act of 1938, 21 U.S.C. §§ 301–95 (1994 & Supp. III 1998).

and market the drug.[29] Patent and intellectual property laws create financial incentives for innovation.[30]

Other regulatory mechanisms are: state criminal laws and penalties; production subsidies that allow government to encourage the cultivation of certain drugs; regulation that occurs at the point of sale, such as age restrictions on the sale of alcohol and nicotine; taxation that allows the government to discourage, or levy a cost on, certain types of drug use; and the dictates of private associations as with anabolic steroids.[31] An additional regulatory mechanism is litigation, which has increasingly become a dominant means by which drug use, production, and distribution are regulated, particularly when policy-makers are unwilling or unable to act legislatively.[32] Finally, there is the option to not regulate, thereby leaving the issue to be resolved by market forces.

B. *Overview of Drug Regulation Scholarship*

In the United States, drug regulation scholars have divided drugs roughly into three categories: illegal, over-the-counter, and prescription drugs.[33] This categorization is ostensibly based on the pharmacological effects of the drug. The rationale behind labeling one drug "medicine" and another "recreational," however, is not always so clear. This is because the inherent qualities of a particular drug or the effects it produces do not appear to determine whether the drug will be legalized or criminalized, or whether the user will be stigmatized, rehabilitated, marginalized, or left alone.[34]

As puzzling as this phenomenon is, perhaps equally puzzling from an academic perspective, is that very few scholars have, in fact, tried to figure out this conundrum. Although much has been written on the topic of drug regulation, the overwhelming majority of this work focuses on either illicit or licit drugs. Many scholars have produced work examin-

---

29 *See* Food and Drug Administration, Department of Health and Human Services, 21 C.F.R. §§ 1–1299 (2003).

30 *See* Trudo Lemmens, *Leopards in the Temple: Restoring Scientific Integrity to the Commercialized Research Scene*, 32 J.L. MED. & ETHICS 641, 654 (2004); A.K. Rai, *Regulating Scientific Research: Intellectual Property Rights and the Norms of Science*, 94 NW. U. L. REV. 77, 93–94 (1999).

31 *See generally* MOSHER & AKINS, *supra* note 1.

32 *See generally* Cipollone v. Liggett Group, Inc., 505 U.S. 504 (1992) (holding that the federal requirement that the surgeon general's warning appear on cigarette containers does not preempt state law damage claims against cigarette manufacturers); ROBERT KAGAN, ADVERSARIAL LEGALISM: THE AMERICAN WAY OF LAW (2001) (arguing that the "American way of law" uniquely privileges litigation as the chief method of policy making, implementation, and dispute resolution).

33 *See* MARGARET P. BATTIN, ET AL., DRUGS & JUSTICE: SEEKING A CONSISTENT, COHERENT, COMPREHENSIVE VIEW 8–9 (2008).

34 *See* discussion *infra* Part III.

ing the inconsistencies in the regulation of criminalized drugs,[35] while others have focused on tobacco[36] and pharmaceutical drug regulation.[37] This scholarship can be divided into three overlapping approaches: historical analysis, normative policy prescriptions, and critical analysis. The explanatory power of this work is limited by the fact that these scholars examine drugs in a category-specific way. In recent years, a few scholars have studied the regulatory inconsistencies that exist across

---

35 *See generally* RICHARD J. BONNIE & CHARLES H. WHITEBREAD II, THE MARIHUANA CONVICTION: A HISTORY OF MARIHUANA PROHIBITION IN THE UNITED STATES (1974) (exploring the inconsistent regulation of marihuana throughout the twentieth century); CRACK IN AMERICA: DEMON DRUGS AND SOCIAL JUSTICE (Craig Reinarman & Harry G. Levine eds., 1997) (analyzing the negative media treatment and policing of crack, which aided in creating an inflated sense of the crack epidemic); DRUGS IN AMERICA: A DOCUMENTARY HISTORY (David F. Musto ed., 2002) (examining the inconsistent treatment of various drugs throughout American history); TROY DUSTER, THE LEGISLATION OF MORALITY: LAW, DRUGS AND, MORAL JUDGMENT *passim* (1970) (focusing on how society forms moral opinions about and judgments of drugs and drug users); ROBERT J. MACCOUN & PETER REUTER, DRUG WAR HERESIES: LEARNING FROM OTHER VICES, TIMES, AND PLACES *passim* (2001) (comparing contemporary regulation and use of various drugs in an effort to foster reformulation of drug policing policies); DAVID F. MUSTO, THE AMERICAN DISEASE: ORIGINS OF NARCOTIC CONTROL (3d. ed. 1997); DAVID MUSTO & PAMELA KORSMEYER, THE QUEST FOR DRUG CONTROL: POLITICS AND FEDERAL POLICY IN A PERIOD OF INCREASING SUBSTANCE ABUSE, 1963–1981 (2002) (describing how political leaders grappled with the surges in drug use that occurred throughout the 1960s, 1970s, and 1980s); JOSEPH F. SPILLANE, COCAINE: FROM MEDICAL MARVEL TO MODERN MENACE IN THE UNITED STATES, 1884-1920 (2000) (examining the path of cocaine from a medically legitimate drug to a stigmatized and regulated illegal substance); Richard J. Bonnie & Charles H. Whitebread II, *The Forbidden Fruit and the Tree of Knowledge: An Inquiry into the Legal History of American Marijuana Prohibition*, 56 VA. L. REV. 971 (1970) (analyzing the inconsistent legal treatment of marijuana in the United States).

36 *See generally* Joseph R. Gusfield, *The Social Symbolism of Smoking and Health*, *in* SMOKING POLICY: LAW, POLITICS AND CULTURE 49, 49–68 (Robert L. Rabin & Stephen D. Sugarman eds., 1993) (addressing the seemingly contradictory attitudes towards smoking throughout the history of the United States); PETER D. JACOBSON & JEFFREY WASSERMAN, TOBACCO CONTROL LAWS: IMPLEMENTATION AND ENFORCEMENT (1997) (case studies of the effectiveness of state tobacco regulation); Robert A. Kagan & Jerome H. Skolnick, *Banning Smoking: Compliance Without Enforcement*, *in* SMOKING POLICY: LAW, POLITICS AND CULTURE 69, 69–94 (Robert L. Rabin & Stephen D. Sugarman eds., 1993) (examining effect of regulation on social norms and attitudes towards smoking); RICHARD KLUGER, ASHES TO ASHES: AMERICA'S HUNDRED-YEAR CIGARETTE WAR, THE PUBLIC HEALTH, AND THE UNABASHED TRIUMPH OF PHILIP MORRIS (1996) (study of the move to regulation and the efforts of the tobacco industry to overcome regulations); TARA PARKER-POPE, CIGARETTES: ANATOMY OF AN INDUSTRY FROM SEED TO SMOKE (2001) (discussing the tobacco industry's ability to overcome tobacco regulations); JACOB SULLUM, FOR YOUR OWN GOOD: THE ANTI-SMOKING CRUSADE AND THE TYRANNY OF PUBLIC HEALTH (1998); SUSAN WAGNER, CIGARETTE COUNTRY: TOBACCO IN AMERICAN HISTORY AND POLITICS (1971); ELIZABETH M. WHELAN, A SMOKING GUN: HOW THE TOBACCO INDUSTRY GETS AWAY WITH MURDER (1984).

37 *See generally* MARCIA ANGELL, THE TRUTH ABOUT THE DRUG COMPANIES (2004) (examining how drug companies use marketing campaigns to alter public perception and thwart regulation); DAVID HEALY, LET THEM EAT PROZAC: THE UNHEALTHY RELATIONSHIP BETWEEN THE PHARMACEUTICAL INDUSTRY AND DEPRESSION (2004) (examining the development of pharmaceutical regulation); JAMES HARVEY YOUNG, PURE FOOD: SECURING THE FEDERAL FOOD AND DRUG ACT OF 1906 (1989) [hereinafter YOUNG, PURE FOOD] (discussing the pure food movement and regulation of emerging technologies).

categories of licit and illicit drugs; however, this scholarship is more descriptive than theoretical, in that it notes the inconsistencies without seeking to fully explain them.[38] Indeed, neither this nor any of the other scholarship in this body of work on the regulation of drugs engages the fundamental questions motivating this Article: how regulators are able to treat drugs differently irrespective of the dangers they may pose and independent of their health effects, and the processes followed to achieve this phenomenon.

This Article can also be situated within two additional, important bodies of legal scholarship: law and social norms, and law and social meaning. Social norms scholarship emerged from the social sciences and was embraced by legal scholars—particularly Law and Economics theorists and criminal law scholars—who focused on norms of conduct in the analysis of legal issues.[39] The central tenets of the law and norms school, according to Robert Weisberg, are as follows:

> [S]ocial actors are governed less by formal laws than by patterns of behavior which have accrued normative, if not obligatory force; that norms often govern in a manner indifferent to legal rules, sometimes helping or impeding the enforcement of rules; that norms are immanent with social meaning which lawmakers would do well to heed, and which they can usefully exploit; and that people are susceptible to the conforming force of

---

38 *See generally* BATTIN, ET AL., *supra* note 33; CYNTHIA KUHN, ET AL. BUZZED: THE STRAIGHT FACTS ABOUT THE MOST USED AND ABUSED DRUGS FROM ALCOHOL TO ECSTASY (2003) (describing mental and physical effects of most drugs and the current status of drug regulation); Robert MacCoun, et al., *Assessing Alternative Drug Control Regimes*, 15 J. POL'Y ANALYSIS & MGMT. 330 (1996) (examining different regulatory regimes and their relative costs).

39 *See generally* ROBERT C. ELLICKSON, ORDER WITHOUT LAW: HOW NEIGHBORS SETTLE DISPUTES (1991) (examining how order is achieved without law through social norms); ERIC POSNER, LAW AND SOCIAL NORMS (2000) (analyzing ways in which the law and social norms interact); Katherine K. Baker, *Sex, Rape, and Shame*, 79 B.U. L. REV. 663 (1999) (analyzing how social norms affect the stigmatization and punishment of rapists); Robert Cooter, *Do Good Laws Make Good Citizens? An Economic Analysis of Internalized Norms*, 86 VA. L. REV. 1577 (2000) (discussing how states can use social norms to influence citizens to follow the law); Richard L. Hasen, *Voting Without Law?*, 144 U. PA. L. REV. 2135 (1996) (analyzing social norms and voting); Dan M. Kahan & Eric A. Posner, *Shaming White-Collar Criminals: A Proposal for Reform of the Federal Sentencing Guidelines*, 42 J.L. & ECON. 365 (1999) (exploring shaming punishments); Richard McAdams, *The Origin, Development, and Regulation of Norms*, 96 MICH. L. REV. 338, 340–46 (1997–1998); Symposium, *The Legal Construction of Norms*, 86 VA. L. REV. 1577 (2002) (exploring the development of social norms and the interplay between legality and social norms); Symposium, *Norms and Corporate Law*, 149 U. PA L. REV. 1607 (2001) (examining the role of social norms in the corporate law context).

> charismatic individuals or majoritarian patterns of behavior.[40]

Scholarship in the field of law and social meaning is both descriptive and prescriptive, and analyzes the construction of social meaning as a way of illuminating the salience and/or costs of particular behaviors in a given social context.[41] Those who write in this field address how social meaning is created and deployed by both governments and other actors to advance individual and collective ends.[42]

The distinction between these two fields of legal analysis, as Lawrence Lessig explains, is that "[n]orm talk accounts for behavior; it does not discipline itself to account for context."[43] "Meaning talk," on the other hand, focuses "on the relation of behavior to context and the differences that relation raises."[44] Thus, by examining the ways in which government and others work to create social meaning, scholars in this field seek to add depth to norms analysis.[45] Both law and norms, and law and meaning analyses have been used to explain numerous legally significant behaviors,[46] which makes it all the more surprising that none of the

---

[40] Robert Weisberg, *Norms and Criminal Law, and the Norms of Criminal Law Scholarship*, 93 J. CRIM. L. & CRIMINOLOGY 467, 468–69 (2003).

[41] *See* Robert Cooter, *Expressive Law and Economics*, 27 J. LEGAL STUD. 585 (1998); Dan M. Kahan, *Social Influence, Social Meaning, and Deterrence*, 83 VA. L. REV. 349 *passim* (1997) (examining the cost of upholding social norms); Dan M. Kahan, *What Do Alternative Sanctions Mean?*, 63 U. CHI. L. REV. 591 (1996) (exploring why society prefers imprisonment to alternative sanctions). *See also* Lawrence Lessig, *The Regulation of Social Meaning*, *supra* note 8; Richard McAdams, *A Focal Point Theory of Expressive Law*, 86 VA. L. REV. 1649 (2000); Cass Sunstein, *On the Expressive Function of Law*, 144 U. PA. L. REV. 2021 (1996); Symposium, *Social Norms, Social Meaning, and the Economic Analysis of Law*, 27 J. LEGAL STUD. 537 (1998).

[42] *See, e.g.*, Lessig, *supra* note 8, at 957 ("Meanings are used by collectives as well as by individuals, and most importantly for what follows, they are used by one kind of collective in particular—government. Governments trade on standing social meaning to advance state ends. If the nation suffers under a health craze, the government can use 'healthy styles of life' as arguments to fight drug usage. If the nation worships, then the government can use 'family values' to exclude homosexuals from social life. If a nation is trying to build national identity, then (tragically) it can use the constructed meaning of race and blood to carve up a nation.").

[43] Lawrence Lessig, *Social Meaning and Social Norms*, 144 U. PA. L. REV. 2181, 2183 (1996).

[44] *See id.* at 2183, 2185 ("Meaning talk reveals something more about the contours to the costs of the different behaviors; it imports a language that can understand discontinuities in the valuation of similar behavior.").

[45] *See* Lessig, *supra* note 8, at 948. *See also* Kahan, *Social Influence, Social Meaning, and Deterrence*, *supra* note 41, at 394 ("Laws shape individuals' perceptions of each other's beliefs and intentions in a variety of ways. The types of conduct that a community criminally punishes, as well as the manner and severity of the punishment it imposes, express shared valuations. Laws that regulate social norms determine the background against which private behavior conveys information about citizen's beliefs and intentions. These social meaning effects help determine whether social influence points toward or away from criminality.").

[46] *See generally* Symposium, *Norms and Corporate Law*, 149 U. PA L. REV. 1607 (2001) (highlighting the value of "norm governance" in corporate law); Symposium, *Social*

scholars in either field have engaged the critical questions posed in this Article.[47]

By investigating the role of social norms and meaning in the governance of a cross-section of drugs subject to diverse regulatory mechanisms—such as pharmaceutical, illicit, and over-the-counter drugs—this Article more clearly illuminates the subtle nuances of drug regulation and seeks to increase the analytical depth of academic and legal scholarship on drugs. The existing literature has not offered much insight into the confounding puzzle of why drugs are regulated as they are, and provides little guidance—whether descriptive, analytical, or normative—on how to move forward in this under-theorized area of academic and legal inquiry. This Article wades into this significant breach and examines an area of inquiry that has been left largely unexplored.

II. THE REGULATORY REGIME/NORMS MODEL

Before the government may regulate drugs or engage in any significant intervention into people's private affairs, it needs legitimating circumstances or a stated justification, such as a show of harm or a substantial state interest.[48] While the specific types of "threats" that drug regulators deem in need of remedy have differed over time, the most often stated justifications for intervention are harm to self, harm to others, and moral and ethical concerns.[49]

Norms, Social Meaning, and the Economic Analysis of Law, 27 J. LEGAL STUD. 537 (1998) (suggesting that heightened attention to social norms will signal a change in the field of law and economics).

47 Among legal scholars, Dan Kahan stands alone in having devised a theoretical model of norms and legal change that pays glancing attention to drugs. *See* Dan M. Kahan, *Gentle Nudges vs. Hard Shoves: Solving the Sticky Norms Problem*, 67 U. CHI. L. REV. 607, 631–33 (2000). Kahan argues that when lawmakers attempt to change contested social behaviors, such as smoking or illicit drug use, with a "hard shove," these lawmakers run the risk of triggering a self-defeating backlash. *See id.* If, however, lawmakers apply an incrementally escalating "gentle nudge," they can more effectively eliminate the contested behavior by shifting understanding of the behavior from general ambivalence to public condemnation, which then allows for more punitive legal action. *See id.* at 608. My Regulatory Regime/Norms model indicates, however, that it is not the incremental push alone that determines whether the behavior will one day be subject to regulation or harsh penal sanction, but rather, how that behavior is framed or characterized. It is the framing of the conduct in a way that is consistent with the specific norms of a regulatory regime that changes popular attitudes toward the contested behavior and allows for regulatory change, not simply the incremental nature of the regulatory enterprise. This norms-matching process drives drug regulatory decision-making to the exclusion of other factors, including empirical evidence.

48 *See* Comment, *Laetrile: Statutory and Constitutional Limitations on the Regulation of Ineffective Drugs*, 127 U. PA. L. REV. 233, 265 (noting that "[a] major governmental interest implicit in the establishment of the federal drug laws is the protection of both the general public and specific individuals from dangerous drugs").

49 *See* Elizabeth Weeks Leonard, *The Public's Right to Health: When Patient Rights Threaten the Commons*, 86 WASH. U. L. REV. 1335, 1348–49 (noting that "criminal prohibitions on . . . illicit drugs[ ] paternalistically aim to protect individuals from engaging in unsafe

These broad justifications tend to revolve around a few common themes, principally: ensuring the safety and efficacy of commercially manufactured pharmaceutical drugs; protecting children from the direct or indirect effects of drug use; fighting addiction; and reducing the secondary effects of drug use, such as criminal activity.[50] The underlying rationale is that the government can properly intervene when (1) vulnerable populations that may be limited in their ability to make independent, rational decisions about drug use are at risk, such as children; (2) individuals infringe upon the rights and freedoms of others, such as those who engage in secondary criminal activity, etc.; or (3) drug activity conflicts with state expectations about what constitutes appropriate, moral, responsible, and virtuous behavior.[51] Thus, the state must demonstrate whom it is protecting and why. Once the rationale has been stated, the issue then becomes which regulatory regime is the most suitable: the criminal regime, the public health regime, or the market regulatory regime.

Drug regulatory regimes, as operative today, did not exist a century ago.[52] They have taken shape over time and expanded their sphere of influence into areas of social life previously deemed "private" or beyond the proper reach of government.[53] In so doing, they developed specific areas of specialization that enabled them to establish their legitimacy and command authority.[54] Regulatory regimes have evolved into increas-

---

conduct, express moral condemnation, and aim to reduce 'neighborhood effects.'"). *See also* Randy E. Barnett, *The Harmful Side Effects of Drug Prohibition*, 2009 UTAH L. REV. 11 (2009) (arguing that other harms stem from the existence of drug laws).

50 *See* BATTIN ET AL., *supra* note 33, at 32–36.

51 *See id.* at 141–50; CLAYTON J. MOSHER & SCOTT AKINS, DRUGS AND DRUG POLICY: THE CONTROL OF CONSCIOUSNESS ALTERATION 6–22 (2007) (explaining the wide-ranging critiques that regulators levied against marijuana users during the twentieth century).

52 For an example of the way regulatory regimes evolve through an examination of the development of the public health regime in relation to passage of the Pure Food and Drug Act of 1906, see YOUNG, PURE FOOD, *supra* note 37.

53 *See* BATTIN ET AL., *supra* note 33, at 29–30.

54 *See* CHRISTOPHER HOOD ET AL., GOVERNMENT OF RISK: UNDERSTANDING RISK REGULATION REGIMES 9–11 (2001). The Regulatory regime concept emerged from the field of risk regulation, and was developed as an analytical construct to examine, compare and describe the different ways in which governing authorities manage risk. *See id.* Hood et al. adopt the risk regulatory regime as a framework for demonstrating the myriad ways risk regulation changes over time and differs across various domains. *See id.* In their analysis, the risk regulatory regime is a relatively bounded system of interacting parts that has some degree of continuity over time, and that can be examined at both broad and narrow levels of specificity. *See id.* The regulatory regime concept has been used since at least the 1970s by scholars from many disciplines. Economists have used it to compare policy instruments. *See* Stephen L. Elkin, *Regulation and Regime: A Comparative Analysis*, 6 J. PUB. POL'Y 49, 52–54 (1986). Legal scholars use the regime to examine different arrangements of rules, procedures and practices related to such topics as human rights or environmental protection. *See* Daniel L. Crane, *Technocracy and Antitrust*, 86 TEX. L. REV. 1159, 1162–63 (2008) (arguing that technocratic solutions to issues like environmental protection lead to overprotection against risk in administrative states); Daniel Gilman, *Oy Canada! Trade's Non-Solution to "The Problem of U.S. Drug Prices"*, 32 AM. J.L. & MED. 247, 264–70 (2006) (arguing that loosening drug regula-

ingly differentiated and autonomous systems.[55] Each is comprised of specific actors and institutions. And each regime is largely distinct from the others and maintains its own logic, training, and language.[56] Each is bound by its own rules, values, ethics, and culture; employs different regulatory methods; relies upon distinct forms of knowledge; embodies unique preferences, expectations, and commitments; and serves different, although occasionally overlapping, political, commercial, and governmental interests.[57] Each produces discourses that articulate regime norms, philosophies, and agendas. These discourses are deployed strategically and persuasively by the actors who administer and enforce the different regimes. For example, phrases such as "war on drugs," "harm reduction," and "personal responsibility" are not only constitutive parts of the criminal, public health, and market regimes, respectively, but they also work to influence public perceptions of drugs and drug users. The operation of this complex internal matrix allows each regime to erect its own institutional barriers. Thus, while drug regulatory regimes remain sensitive to outside norms and pressures, each regime exhibits a self-referential closure that enables it to reproduce itself as a distinct entity.[58]

Drug regulatory regimes are enforceable legal structures of regulation. They create and reinforce distinct belief systems, governing principles, ideologies, or what Lessig calls "orthodoxy," with respect to the

---

tions as between America and Canada would incur undue transaction costs); Thérèse Murphy & Noel Whitty, *Risk and Human Rights in U.K. Prison Governance*, 47 J. BRIT. CRIMINOLOGY 796, 806 (2007) (arguing that risk regulation should be more internationally focused, as human rights issues span across jurisdictional boundaries). *Cf.* MacCoun, et al., *supra* note 38, at 330–31 (normative objectives of drug enforcement policies should be weighed against the costs of implementing those objectives). Public policy theorists and political scientists use the regime to examine the nature of governance, relations between actors and their use of resources. *See* KEITH DOWDING, POWER 82–88 (1996) (using regime theory to explain the "systematic luck" of capitalists in light of the constrained options of other social groups); STEPHEN D. KRASNER, INTERNATIONAL REGIMES 235–39 (1983) (tying regime strength to international abilities and using the model to explain how American export/import rates fluctuate relative to the country's production of goods); Mark A. Kleiman & Aaron J. Saige, *Drug Legalization: The Importance of Asking the Right Question*, 18 HOFSTRA L. REV. 527, 565 (1990) (addressing drug control regimes with respect to such areas as legalization, criminalization, and regulated commerce). This is but a sampling of the numerous academic and practical uses of the regulatory regime analytic.

55 *See* HOOD ET AL., *supra* note 54, at 173–74.

56 *See id.* at 10–12 (noting that scholars in a number of different fields use the regulatory regime concept as an effective means of characterizing various forms of governing bodies as clusters of norms, rules, tactics, and procedures).

57 One example of this overlap is drug courts. Although these courts employ both criminal law and public health mechanisms, their underlying premise is primarily criminal. *See* JAMES A. INCIARDI ET AL., DRUG CONTROL AND THE COURTS 32 (1996). As a result, despite some slippage and overlap, these regimes are generally distinct entities. *Id.* at 85–88.

58 *See* BATTIN ET AL., *supra* note 33, at 7–9.

drugs placed within their sphere of influence.[59] These governing principles give each regime meaning, and operate as rules of the regime or instructions for how the regime organizes behavior and expectations about drugs.[60] The governing principles that structure each regime are *assumption of risk* and *rational choice* principles in the market regime, *disclosure* principles in the public health regime, and *moral* principles in the criminal regulatory regime.

A. *The Market Regulatory Regime*

Regulation through the market regime is the default position in a liberal, capitalist democratic society.[61] Within this regime, drugs are understood as consumer goods that are normalized through advertising and the respectability of their distribution through over-the-counter sales. The lack of stigma associated with drugs regulated through this regime allows the users to be deemed rational consumers who have assumed the risks attendant to their drug use. This risk allocation, according to the market ethos, promotes efficiency by ensuring that the costs and burdens of drug use are borne by those best able to take appropriate measures to reduce injury. Tobacco, alcohol, and caffeine are examples of drugs governed primarily by the market regime.

Corporations are the primary players in this regime. Drug companies (e.g., tobacco, alcohol, etc.) are driven by the self-reinforcing need to maximize profits by increasing their share of the market of potential drug users through the creation of consumers and the generation of sales.[62] Drug companies have become a formidable economic and political force, capable of thwarting most significant governmental attempts to

---

59 *See* Lessig, *supra* note 8, at 945–48. Lessig explains that the government "prescribes" orthodoxy when citizens ignore governmental construction of the social meanings that surround them. *Id.* at 946–47. In Lessig's view, social meanings "*are* what is orthodox. They constitute what is authority for a particular society, or particular culture." *Id.*

60 Lessig makes three assertions about social meanings. First, Lessig asserts the existence of social meanings; second, that social meanings are used by both individuals and groups to advance goals; and third, that the force of social meanings "hangs upon their resting upon a certain uncontested, or taken-for-granted, background of thought or expectation—alternatively, that though constructed, their force depends upon them not seeming constructed." *Id.* at 951.

61 *See* Robert A. Cooper, *Blinded by the Hype: Shifting the Burden When Manufacturers Engage in Direct to Consumer Advertising of Prescription Drugs*, 21 VT. L. REV. 1073, 1073 (1997) (noting that "[n]ow, consumers themselves are targeted by the pharmaceutical industry in both the print and electronic media with advertisements about everything from hair loss products and wrinkle creams to birth-control pills.").

62 *See* Julie M. Donohue, et al., *A Decade of Direct-to-Consumer Advertising of Prescription Drugs*, 357 NEW ENG. J. MED. 7, 673, 673–674 (2007). *See also* Jon D. Hanson & Douglas A. Kysar, *Taking Behavioralism Seriously: Some Evidence of Market Manipulation*, 112 HARV. L. REV. 1420, 1502 (1999) (describing a "coordinated . . . approach" by tobacco companies "to expanding the industry's reach and profitability.").

intervene in the market regime to regulate drugs.[63] This is due largely to the fact that the governing principles that structure the market regime reflect the orthodoxy of liberalism: the prevailing social arrangement of contemporary U.S. society.[64] These corporate actors, therefore, work hard to frame their drugs in ways that resonate with the dominant principles of the market regime: rational choice and assumption of risk. This is accomplished primarily through advertising, which normalizes drug consumption by shaping popular understanding of certain drug use as normal, healthy, pleasurable and, indeed, necessary.[65] Advertising is so critical to the operation of the market regulatory regime that corporations spend billions of dollars to carefully engineer advertisements for strategically targeted populations of potential consumers.[66]

The so-called "free market," however, is by no means unfettered by government interference.[67] Rather than reflecting a Hobbesian or natural state, the market is instead a socially conditioned and legally structured entity. It is the laissez-faire state that enforces liberal prescription in the market regime as government plays a much smaller role in this regime than in the others.[68] Thus, many drugs in the market regime are subject to some, albeit minimal, regulation (e.g., alcohol and tobacco as opposed to caffeine or salvia divinorum, a powerful yet unregulated hallucinogen). Because the market regime is the original position in a liberal,

---

63 *See* MELODY PETERSEN, OUR DAILY MEDS 9–11 (2008).

64 *See* Allan C. Hutchinson, 73 CAL. L. REV. 755, 760 (1985) (explaining that "[i]n all its forms, liberalism begins and ends with the individual," and "maintains that the self-interested actions of individuals represent the most appropriate and effective principled basis for society's economic and political organization).

65 *See generally* DAVID HEALY, LET THEM EAT PROZAC: THE UNHEALTHY RELATIONSHIP BETWEEN THE PHARMACEUTICAL INDUSTRY AND DEPRESSION (2004); YOUNG, PURE FOOD, *supra* note 37; MARCIA ANGELL, THE TRUTH ABOUT THE DRUG COMPANIES (2004).

66 *See* ANGELL, *supra* note 37, at 136 (noting that drug companies masquerade marketing as education about their drugs, which is directed mostly at doctors); PETERSEN, *supra* note 63, at 140–45 (explaining that drug companies target remedies for chronic illnesses as "blockbuster drugs" that bring in high revenue); Josef Winkler, *You Wanted the Best, You Got the Best! The Current Direct-to-Consumer Prescription Drug Advertisement Dilemma*, 26 BIOTECH. L. REP. 331, 332–333 (2007) (discussing the billions of dollars spent for direct-to-consumer advertising).

67 *See* Robert Hessen, *Capitalism*, CONCISE ENCYCLOPEDIA ECON., http://www.econlib.org/library/Enc/Capitalism.html ("A fully free economy . . . never has existed, but governmental authority over economic activity has sharply increased since the eighteenth century, and especially since the Great Depression.").

68 *See* Dennis Chong et al., *Patterns of Support for Democratic and Capitalist Values in the United States*, 13 BRIT. J. POL. SCI. 401, 401, 404, 434 (1983) (contrasting interpretations of capitalism along with principles of democracy, ranging from welfare state capitalism to laissez-faire capitalism. The welfare-state pattern is high on democracy and low on capitalism, whereas the liberal pattern is high on both capitalism and democracy. Conservatives favor a pattern of high capitalism and low democracy.).

capitalist, democratic society, regulators must justify their decisions to intervene in this regime.[69]

B. *The Public Health Regulatory Regime*

The public health regulatory regime governs through science, which is more than just a metaphor; it is, rather, a specific and penetrating form of governance.[70] From the FDA and National Institute on Drug Abuse to the Office of National Drug Control Policy and the National Institutes of Health, the missions of public health institutions and agencies with respect to drug regulation are vast, encompassing, broad-based efforts to: evaluate population health; prevent addiction, reduce the harms attendant to drug use (e.g., diseases passed through shared needles, etc.), assure the safety and efficacy of commercially manufactured drugs, evaluate the quality of and ensure access to drug treatment services, oversee and finance research, and encourage healthy behavior.[71]

The institutes and actors that constitute the public health regime operate under principles of disclosure.[72] These principles have emerged from the creation, evaluation, and dissemination of scientific knowledge, which requires an open, collaborative process, where transparency is paramount, and data is shared freely among those engaged in its research and evaluation. Disclosure, therefore, is essential to the fundamental authority of regulatory decision-making in the public health regime as this authority is based entirely upon the independence, accuracy, and integrity of the procedures and protocols used to arrive at medical, scientific, and public health policy conclusions.[73]

Disclosure principles also enable the FDA to effectively evaluate drug safety and efficacy during all phases of the drug approval process

---

[69] *See* discussion *infra* Part III.

[70] *See* PUBLIC HEALTH LAW & ETHICS: A READER 226–63 (Lawrence O. Gostin ed., 2003) (arguing that where capital markets neglect public health, the government should be allowed to regulate).

[71] *See* GLEN HANSON ET AL., DRUGS AND SOCIETY 95–98 (2005); LAWRENCE O. GOSTIN, PUBLIC HEALTH LAW: POWER, DUTY, RESTRAINT, 44–46 (2003); U.S. Department of Health and Human Services, Organizational Chart, http://www.hhs.gov/about/orgchart/index.html (last visited Mar. 24, 2010); U.S. Food and Drug Administration, About the FDA Organization Charts, http://www.fda.gov/AboutFDA/CentersOffices/OrganizationCharts/default.htm (last visited Mar. 24, 2010) (showing that Department of Health and Human Services includes the following agencies: Food and Drug Administration, Centers for Disease Control, National Institutes of Health, Agency for Healthcare Research and Quality; Agency for Toxic Substances and Disease Registry, Substance Abuse & Mental Health Services Administration. Within the FDA, the Center for Drug Evaluation and Research division reviews and monitors medical drug safety. The Center for Veterinary Medicine assumes the role for animals. Biologics Evaluations and Research governs vaccine safety).

[72] *See* William M. Sage, *Regulating Through Information: Disclosure Laws and American Health Care*, 99 COLUM. L. REV. 1701, 1773–74 (1999) (noting that failure to incorporate direct government action in health care regulation has given rise to disclosure requirements).

[73] *See id.*

including requiring commercial drug manufacturers to release research data on drug properties and possible negative side effects, in order to ensure that drugs function according to manufacturers' claims.[74] The disclosure of such health data from drug makers is essential to enabling medical practitioners to make informed professional decisions affecting patient care and for consumers to select the appropriate drugs to address their health needs.

C. *The Criminal Regulatory Regime*

The criminal drug regulatory regime focuses on the investigation, interdiction, arrest, prosecution and incarceration of those involved with illicit drug consumption, distribution, trafficking, and manufacture with the goal of punishing those who have transgressed the boundaries of civilized society. In the criminal regulatory regime, drug regulation is not only a practice of government, a means of shaping conduct, and an exercise of power and authority; it is also an aspirational endeavor to the extent that it seeks to forge notions of whom and what we should be individually and collectively. Thus, for a drug to be moved from the market or public health regimes to the criminal regulatory regime, it must

---

[74] *See* W. Kip Viscusi, *Corporate Risk Analysis: A Reckless Act?*, 52 STAN. L. REV. 547, 579–80 (2000). *See also* Federal Food, Drug, and Cosmetic Act of 1938, 21 U.S.C. §§ 301-95 (1994 & Supp. III 1998); JAMES ROBERT NIELSON, HANDBOOK OF FEDERAL DRUG LAW (2d ed. 1992) (noting that the FDA drug approval process begins when a manufacturer files an Investigational New Drug Application (INDA) with the FDA, which includes "pre-clinical studies," such as chemical analyses, animal studies, and proposed methods for human trials. The FDA then determines whether the drug can be used safely in human studies, whether protocols adequately protect human subjects, and whether the studies are designed to effectively evaluate the drug's safety and efficacy. Human clinical trials typically occur in three phases, which usually takes four to six years to complete. Phase I is conducted on a relatively small number (50-100) of healthy subjects, in order to determine the safety and possible side effects of the drug. Phase II studies tend to be larger (50-200 people), randomized, controlled studies on participants who have the disease or condition the drug is meant to treat. Phase III trials include hundreds and possibly thousands of subjects, and, are aimed at providing additional information on safety and efficacy, necessary to evaluate the drug's overall risk-benefit value. Upon completion of these phases, the drug manufacturer can submit a New Drug Application (NDA) to the FDA, which mandates the disclosure of detailed safety and efficacy data and analysis. The NDA must include: dosage instructions for use, known precautions, warnings, contraindications, and proposed labeling for the new drug that describes the conditions it is intended to treat. Generally, only data collected by one out of ten manufacturers culminates in an NDA filing. In making its evaluation, the FDA conducts a risk-benefit analysis, examining the severity of the health condition targeted and the availability of alternate therapies. Thus, if the drug treats a life-threatening ailment or is the only drug on the market for a particular condition, the chance of its approval increases substantially. This creates an incentive for researchers to create beneficial and often life-saving medications. It also encourages and expedites the drug approval process so that those in dire need can get their drugs quickly. The FDA evaluation and approval process can take from two to three years and the entire process can last from seven to thirteen years. All prescription drugs are controlled through this regulatory system, with the exception of drugs used by pediatric patients, which have historically undergone little regulation).

do more than pose an ostensible threat to public health or safety; use of the drug must be perceived to violate fundamental moral values.[75]

The criminal regime creates and reinforces principles derived from moral prescriptives.[76] In addition to its regulatory and juridical functions, the criminal regulatory regime creates and reaffirms the moral principles of the collective consciousness *writ large*.[77] Understood as such, this type of regulation is preconditioned upon notions of morality; both in terms of how regulators influence values, behavior, and beliefs with regard to that which constitutes good, just, appropriate, and responsible behavior; as well as how individuals perceive and respond to government.

D. *Norms and the Regulatory Regime/Norms Model*

The public and private entities that operate in each drug regulatory regime produce and reinforce social norms. Social norms are customary rules of behavior that people in a society or group follow for reasons other than fear of legal sanction.[78] Although norms are abstract to the extent that they can exist anywhere, they must be contextualized in order to convey meaning and be understood. In my model, the regimes provide that context.[79] The norms that emerge from each regulatory regime are manifestations of the regime's governing principles: rational choice and assumption of risk, disclosure, or moral norms.[80] These norms make sense in relation to the particular regulatory regime they reflect and embody regime principles as taken-for-granted and uncontested in meaning.[81] Thus, the power of these norms is that within the appropriate context, the meanings they convey seem natural and not constructed.[82]

According to the Regulatory Regime/Norms model, the project of regulating drugs is about allocating specific meaning to drug use in relation to the norms of a particular regime in order to shape public understanding of the drug in a way that allows for state intervention. As I will

---

75 *See* discussion *infra* Parts III and IV.

76 *See* Weisberg, *supra* note 40, at 468.

77 *See* Duster, *supra* note 35, at 219–20.

78 *See, e.g.*, Lynn A. Stout, *Social Norms and Other-Regarding Preferences*, *in* NORMS AND THE LAW 15 (John N. Drobak ed., 2006) (noting that although there is considerable disagreement in relevant legal literature about the definition of norms and how they operate, most scholars define norms as established or customary rules of behavior that people in a society or group follow for reasons other than fear of legal sanction). *See also* McAdams, *The Origin, Development, and Regulation of Norms*, *supra* note 39, at 340 ("[Norms are] informal social regularities that individuals feel obligated to follow because of an internalized sense of duty, because of a fear of external non-legal sanctions, or both.").

79 *See* Lessig, *Social Meaning and Social Norms*, *supra* note 43, at 2183–84.

80 *See* Weisberg, *supra* note 40, at 468–69.

81 *See* Lessig, *The Regulation of Social Meaning*, *supra* note 8, at 951.

82 *See id.*

demonstrate in the following section, how a drug will be regulated is determined by the victor in a contest to characterize the drug in a way that is consistent with the norms of a specific regulatory regime. If the characterization is persuasive, then the drug may be placed in the regime regardless of whether the veracity of the victor's claims can be verified scientifically. Therefore, if the corporate entities, private reformers, and government actors who engage in drug designation decisions are able to successfully shape public perception of a drug in a way that matches the norms of a particular regime, then the drug may be regulated in that regime, regardless of whether the drug presents a threat to safety or health and even if the regime placement decision is not supported by scientific or medical evidence regarding the drug's pharmacological properties. Once the drug has been placed, the regime will legitimate the regulators' characterization of the drug.

The drug will stay in the regime until its characterization no longer resonates with the norms of the regime. Hence, once popular understanding of a drug is no longer consistent with the norms of the regime, the drug can be moved out of that regime and into another. However, if a criminalized drug has also been linked to a racialized or socially maligned group, it will be significantly more difficult for the drug to one day migrate into another regime. Therefore, even if one is able to successfully undermine the morally charged meaning attached to a drug regulated in the criminal regime, the extent to which the drug is identified with racial minorities or other marginalized groups will determine whether the drug will ultimately ever move from the regime.

The following section applies the Regulatory Regime/Norms model to the regulation of tobacco, marijuana, anabolic steroids and cocaine in order to demonstrate the model's explanatory force and empirical grounding.

III. ANIMATING THE MODEL: A TALE OF FOUR DRUGS

A. *A Contest of Characterizations: Moving a Drug from One Regulatory Regime to Another*

This section animates the Regulatory Regime/Norms model by illustrating how drugs move among regulatory regimes. Part A applies the model to the regulation of tobacco, cocaine, marijuana, anabolic steroids, and passage of the Pure Food & Drug Act of 1906. Part B provides a more detailed look at the model by closely analyzing the regulation of tobacco. Part C examines the movement of drugs out of the criminal regime and addresses the roles of race and class in this process.

If a group is able to persuasively frame a drug in a way that is consonant with the norms of the regime that suits the group's preferences, then the drug may be placed in that regime, regardless of whether

the designation decision is supported by empirical evidence grounded in science or medicine. For example, tobacco was regulated for over a century in the market regime because its manufacturers successfully used advertising to painstakingly shape the meaning of smoking to reflect the prevailing norms of the market regulatory regime: rational choice and assumption of risk.[83]

Despite tobacco's undisputed negative health effects and staggeringly high mortality rate, the tobacco industry has effectively used advertising to portray tobacco consumption as synonymous with freedom, independence, masculinity, sophistication, and cosmopolitanism.[84] This characterization shaped public opinion and drove public acceptance, which was reflected back and popularized through positive media representations of smokers as young, healthy, and attractive.[85] The tobacco industry's success in framing the drug in a way that is consistent with market regime norms has enabled it to not only defeat numerous attempts to shift tobacco into the public health regime, but has made it the second most popular recreational drug in the United States after alcohol.[86]

In the case of marijuana, by contrast, no corporation bankrolled the fight to keep the drug in the market regime, where marijuana had been widely available as a commonly used appetite stimulant, muscle relaxant,

---

[83] *See* Helmut Wakeham, *Why One Smokes* (1969), *available at* http://legacy.library.ucsf.edu/tid/pds74e00 (first draft of a memorandum from Vice President of Research and Development at Philip Morris). *See also* FEDERAL TRADE COMM'N, REPORT TO CONGRESS FOR 1995, PURSUANT TO THE FEDERAL CIGARETTE AND ADVERTISING ACT 17 tbl.3D (1997) (showing that in 1993, for example, tobacco companies spent over 6 billion dollars on advertising and promotion); FEDERAL TRADE COMM'N, REPORT TO CONGRESS FOR 1996, PURSUANT TO THE FEDERAL CIGARETTE LABELING AND ADVERTISING ACT 18 tbl.3E (1998) (showing that the tobacco industry spent five billion dollars on advertising and promotion in 1994).

[84] *See* Wakeham, *supra* note 83 ("'Smoking a cigarette for the beginner is a symbolic act. The smoker is telling the world, this is the kind of person I am.' Surely, that there are many variants of the theme, 'I am no longer my mother's child, I'm tough, I am an adventuress, I'm not square.' Whatever the individual intent, the act of smoking remains a symbolic declaration of personal identity . . . . As the force from the psychological symbolism subsides, the pharmacological effect takes over to sustain the habit, augmented by the secondary gratifications.").

[85] *See id.*

[86] *See* Elizabeth Brown Alphin, Note, *Federal Tobacco Regulation: The Failure of the FDA Jurisdiction over Tobacco and the Possibility of Compromise Through a Congressional Regulatory Scheme*, 40 BRANDEIS L.J. 121, 123–24 (2001) (chronicling the history of tobacco regulation and the responses of the tobacco industry); Sylvia A. Law, *Addiction, Autonomy, and Advertising*, 77 IOWA L. REV. 909, 920–21 (1992) (comparing advertising in the alcohol and tobacco industries); Steven Jonas, *The Drug Problem: A Public Health Approach to the Reduction of the Use and Abuse of Both Legal and Illegal Recreational Drugs*, 18 HOFSTRA L. REV. 751, 792 (1990) (providing a population estimate of nonmedical drug use; the highest use percentage is seen for alcohol, and the second for tobacco); Cynthia S. Duncan, Note, *The Need for Change: An Economic Analysis of Marijuana Policy*, 41 CONN. L. REV. 1701, 1705 (2009) (noting that alcohol and tobacco lead marijuana in recreational drug use).

analgesic, hypnotic, and anticonvulsant.[87] Instead, marijuana was moved to the criminal regulatory regime due to the success of a grassroots movement in the Southwestern United States to frame marijuana use in a way that resonated with the moral norms of the criminal regime.[88] This movement, later joined by the Federal Bureau of Narcotics, and assisted by the media, successfully labeled marijuana in the public mind as "Mexican opium," a drug that turned Mexican field hands violent and high school students insane.[89] Indeed, at the turn of the twentieth century, marijuana consumption in southwestern states was limited almost exclusively to the Mexican population, which was perceived by many in the region as posing an economic threat to the domestic labor force.[90] Before long, racist and xenophobic fears about Mexican immigrants, fueled by claims of a causal relationship between marijuana and criminality, prompted southwestern states with large Mexican populations to begin passing legislation outlawing the drug. By 1937, forty-six states had passed such legislation, often with little debate.[91]

Similarly, cocaine was a popular recreational and therapeutic drug found in everything from alcoholic beverages, cigarettes, cough suppres-

---

87 *See* JEROME L. HIMMELSTEIN, THE STRANGE CAREER OF MARIHUANA: POLITICS AND IDEOLOGY OF DRUG CONTROL IN AMERICA 21–22 (1983).

88 *See* Kathleen Auerhahn, *The Split Labor Market and the Origins of Antidrug Legislation in the United States*, 24 LAW & SOC. INQUIRY 411, 432 (1999).

89 *See id.* at 59-71 (noting that tabloid newspapers across the country reported graphic stories of alleged marijuana-induced madness, violence, sexual deviance, and criminal activity, typically perpetrated by immigrants intoxicated by the drug). *See also* LESTER GRINSPOON, M.D. & JAMES BAKALAR, MARIHUANA: THE FORBIDDEN MEDICINE 195 (2d ed. 1997) (noting that the supposed dangers posed by marijuana were even addressed in popular movies, such as the 1936 film, *Reefer Madness*, which depicted a killing, suicide, rape, and subsequent descent into insanity among high school students lured into smoking marijuana).

90 *See* Auerhahn, *supra* note 88, at 432. *See also* JOHN HELMER, DRUGS AND MINORITY OPPRESSION 55, 75 (1975) ("[Anti-Mexican sentiment rose from the] struggle for a diminishing number of jobs in the unskilled sector . . . ."); JOHN HELMER & THOMAS VIETORISZ, THE DRUG ABUSE COUNCIL, DRUG USE, THE LABOR MARKET, AND CLASS CONFLICT (1974) ("[A] theory of the evils of [marijuana], which linked its use and supply to being Mexican, made hostility toward these people seem slightly more reasonable, and public policy to remove them that much more acceptable.").

91 *See* EDWARD M. BRECHER, CONSUMERS UNION, LICIT AND ILLICIT DRUGS 413 (1972) ("By 1937, forty-six of the forty-eight states as well as the District of Columbia had laws against marijuana."). *See also* BONNIE & WHITEBREAD, THE MARIHUANA CONVICTION, *supra* note 35, at 51–52 (mapping all anti-Marijuana legislation enacted between 1915-1933: Alabama (1932); Arizona (1931); Arkansas (1923); California (1915); Colorado (1917); Delaware (1933); Idaho (1927); Illinois (1931); Indiana (1929); Iowa (1929); Kansas (1927); Louisiana (1914); Maine (1914); Massachusetts (1914); Michigan (1929); Mississippi (1930); Montana (1927); Nebraska (1927); Nevada (1923); New Mexico (1923); New York (1927); North Dakota (1933); Ohio (1927); Oklahoma (1933); Oregon (1923); Pennsylvania (1933); Rhode Island (1918); South Dakota (1931); Texas (1919); Utah (1915); Vermont (1915); and Wyoming (1929)); Bonnie & Whitebread, *The Forbidden Fruit and the Tree of Knowledge*, *supra* note 35, at 1010-20 ("We conclude that the legislative action and judicial approval were essentially kneejerk responses uninformed by scientific study or public debate and colored instead by racial bias and sensationalistic myths.").

sants, baby elixirs and, most famously, Coca-Cola,[92] until Southern whites, during the early twentieth century, successfully characterized cocaine as a drug that incited criminality, sexual deviance, and defiant behavior in African-Americans.[93] This framing of cocaine in moral terms prompted its movement from the market regime to the criminal regulatory regime.[94] So persuasive was this characterization of cocaine that in the ensuing hysteria, Southern police departments switched from .32 to .38 caliber bullets due to widespread reports that cocaine-endowed African-Americans with extraordinary cunning and strength thus rendering them virtually invincible to conventional weaponry.[95] Despite whites' fears that cocaine would provoke an African-American-led revolt and crime spree, none ever materialized.[96] Nevertheless, the fear that these myths and fantasies evoked was enough to ease the passage of several laws restricting cocaine use, including the nation's first criminal drug control law, the Harrison Act of 1914.[97]

The regulation of anabolic androgenic steroids (AAS), a commercially manufactured pharmaceutical drug, is also illustrative of the Regu-

---

92 *See* MUSTO, THE AMERICAN DISEASE, *supra* note 35, at 7. Cocaine was legal and widely used recreationally during the 1800s. CRACK IN AMERICA, *supra* note 35 at 132. Its ability to constrict blood vessels and limit bleeding made it an effective local anesthetic for eye, nose, and throat surgeries. *Id.* at 131–32. It was also used to treat ailments, such as sinusitis and hay fever as well as opium, morphine, and alcohol addiction. MUSTO, THE AMERICAN DISEASE, *supra* note 35, at 7.

93 *See id. See also* Edward H. Williams, *The Drug-Habit Menacing in the South, in* DRUGS IN AMERICA: A DOCUMENTARY HISTORY, *supra* note 35, at 360, 363 (alleging increased sexuality in African-American cocaine users).

94 *See* MUSTO, THE AMERICAN DISEASE, *supra* note 35, at 8.

95 *See id.* at 7; Williams, *supra* note 93, at 361.

96 David T. Courtwright, *The Hidden Epidemic: Opiate Addiction and Cocaine Use in the South, 1860-1920*, 49 J. S. HIST. 57, 71 (1983) (hypothesizing that few cocaine induced criminal acts spurred irrational fears in Southern whites similar to white's fears of slave uprisings in the antebellum South).

97 One of the primary forces behind passage of the Harrison Act was Dr. Hamilton Wright, the State Department's Opium Commissioner during Theodore Roosevelt's administration, who wrote that cocaine was "a potent incentive in driving humbler Negroes all over the country to abnormal crimes." JOHN HELMER, DRUGS AND MINORITY OPPRESSION *supra* note 90 at 53. Dr. Wright alleged that:

> Once the negro has reached the state of being a 'dope taker'— and a very few experimental sniffs of the drug make him an habitué—he is a constant menace to his community until he is eliminated. For his whole nature is changed for the worse by the habit. Sexual desires are increased and perverted, peaceful negroes become quarrelsome, and timid negroes develop a degree of 'Dutch courage' that is sometimes almost incredible. A large proportion of the wholesale killings in the South during recent years have been the direct result of cocaine and frequently the perpetrators of these crimes have been hitherto inoffensive, law-abiding negroes. Moreover, the negro who has once formed the habit seems absolutely beyond redemption. Imprisonment 'cures' him temporarily: but when released he returns to the drug almost invariably.

Williams, *supra* note 93, at 360–63. Wright would later maintain that "the negro drug-taker" should be incarcerated rather than treated for his addiction. *Id.* at 3

latory Regime/Norms Model.[98] For nearly half a century, AAS had been classified as prescription drugs and the FDA had regulated them in the public health regime.[99] The sale of AAS for other than medicinal purposes, however, was criminalized with passage of the Anabolic Steroid Control Act of 1990, which added the drug to Schedule III of the Controlled Substances Act.[100] AAS were not relegated to the criminal regime because of their alleged health effects or concerns about illicit trafficking.[101] Rather, AAS were criminalized because of their place at the center of a cheating scandal at the 1988 Seoul Summer Olympic Games and the subsequent dramatic coverage of AAS use in a series of articles published in *Sports Illustrated*.[102]

On November 18, 1988, scarcely a month after Canadian sprinter Ben Johnson was stripped of his Olympic gold medal having tested positive for AAS after beating American rival Carl Lewis in a world record setting race, President Ronald Reagan signed into law the Anti-Drug Abuse Act of 1988.[103] This law amended the Food, Drug, and Cosmetics

---

98 AAS, synthetic derivatives of the naturally occurring hormone testosterone, were devised to maximize testosterone's anabolic, or tissue-building capacity, while minimizing many of its androgenic, or masculinizing effects. *See* Charles E. Yesalis, *Introduction*, *in* ANABOLIC STEROIDS IN SPORT AND EXERCISE 1, 1 (Charles E. Yesalis ed., 2d ed. 2000). *See also* Cynthia M. Kuhn, *Anabolic Steroids*, 57 RECENT PROGRESS IN HORMONE RES. 411, 412 (2002) (describing anabolic steroid characteristics). AAS have therapeutic and non-therapeutic uses unlike narcotics, which are taken for their consciousness altering effects. *See* Charles D. Kochakian & Charles E. Yesalis, *Anabolic-Androgenic Steroids: A Historical Perspective and Definition*, *in* ANABOLIC STEROIDS IN SPORT AND EXERCISE 17, 35–40 (Charles E. Yesalis ed., 2d ed. 2000).

99 Since the 1938 passage of the Federal Food, Drug, and Cosmetic Act (FDCA), the FDA has regulated AAS. *See* Adrian Wilairat, Comment, *Faster, Higher, Stronger? Federal Efforts to Criminalize Anabolic Steroids and Steroid Precursors*, 8 J. HEALTH CARE L. & POL'Y 377, 387 (2005). The FDCA sets criteria to classify prescription drugs and limit access to particular drugs to people who demonstrate a legitimate medical need. *See* Federal Food, Drug, and Cosmetic Act of 1938, Pub. L. No. 75-717, 52 Stat. 1040 (codified as 21 U.S.C. §§ 301–99 (2006)). Thus, the FDA determines whether a substance will be classified as prescription or over-the-counter. *Id.*

100 *See* Crime Control Act of 1990, Pub. L. No. 101-647, 104 Stat. 4789 (classifying AAS within Schedule III(e) in 21 U.S.C. § 812(c)).

101 *See Anabolic Steroids Control Act: Hearing on H.R. 4658 Before the Subcomm. on Crime of the H. Comm. on the Judiciary*, 101st Cong. 21 (1990) [hereinafter *Anabolic Steroids Control Act Hearing*] (statement of Leslie Southwick, Deputy Assistant Attorney General, Civil Division, U.S. Department of Justice).

102 *Sports Illustrated* published an issue the week after Ben Johnson was disqualified featuring him on the cover emblazoned with the heading "Busted!" William O. Johnson & Kenny Moore, *The Loser*, SPORTS ILLUSTRATED, Oct. 3, 1988, at 32–39. The article, about Johnson's fall from grace, recounted the events leading to disqualification and discussed the perceived ease with which athletes evade AAS detection. *Id. See also* Tommy Chaikin & Rick Telander, *The Nightmare of Steroids*, SPORTS ILLUSTRATED, Oct. 24, 1988, at 82–102 (explaining college linebacker Tommy Chaikin's steroid induced transformations and suicide attempt).

103 Anti-Drug Abuse Act of 1988, P. L. No. 100-690, § 2403, 102 Stat. 4203 (1988).

Act by establishing a new criminal provision that significantly increased the penalties for AAS distribution.[104]

Within months, Congress held a series of hearings on whether to add AAS to the schedule of controlled substances.[105] At these hearings, scant evidence was presented that AAS use posed a significant threat to healthy adult men.[106] Furthermore, just months before the 1988 Olympics, the Drug Enforcement Agency (DEA) and the U.S. Department of Health and Human Services (HHS) recommended against scheduling AAS.[107] Legislators, nevertheless, emerged victorious in their efforts to frame AAS to fit the moral norms of the criminal regime.[108] The morally charged issue of cheating in sports had specific resonance in the

---

104 The Anti-Drug Abuse Act of 1988 made the distribution or possession of AAS with the intent to distribute without a valid prescription a felony subject to up to three years imprisonment and a fine. *See* 21 U.S.C. § 333(e)(1) (2006). Distribution or possession with intent to distribute to persons under eighteen years of age would result in up to six years imprisonment and a fine. Pub. L. 100-690 (1988) (current version codified as The Anabolic Steroids Control Act of 1990). In addition, the law subjected AAS traffickers to criminal forfeiture. *See* § 333(a). The law also increased the penalties for the distribution of Human Growth Hormone to a maximum of five years for possession with intent to distribute, and ten years if the offense involved a minor. *See* § 333(e)(2).

105 *See Anabolic Steroids Control Act of 1990: Hearing on H.R. 4658 Before the Subcomm. on Crime of the House Comm. on the Judiciary,* 101st Cong., 2d Sess. (1990); *Abuse of Steroids in Amateur and Professional Athletics: Hearing Before the Subcomm. on Crime of the House Comm. on the Judiciary,* 101st Cong., 2d Sess. (1990); *Steroids in Amateur and Professional Sports: The Medical and Social Costs of Steroid Abuse: Hearings Before the S. Comm. on the Judiciary,* 101st Cong., 1st & 2d Sess. (1989); *Anabolic Steroid Restriction Act of 1989: Hearing on H.R. 995 Before the House Comm. on the Judiciary,* 101st Cong., 1st Sess. (1989).

106 The Senate Judiciary Committee's Report on the Steroid Trafficking Act focused primarily on the most inflammatory testimony presented during the hearings, despite the fact that there was little scientific or medical evidence to support these claims and that most of these allegations were based on anecdotal accounts, surveys, and self-reports. *See* S. REP. NO. 101-433 (1989). The report presented few dissenting opinions and did not mention the American Medical Association's opposition to drug scheduling. *See* S. REP. NO. 101-433, at 5–8 (1989).

107 In 1987, the Department of Justice solicited the opinions of the DEA and the HHS on whether to schedule AAS under the CSA. *Anabolic Steroids Control Act Hearing, supra* note 101, at 21. The DEA recommended against scheduling and the HHS concurred after finding that "the available evidentiary base concerning steroids, although growing, is not comprehensive. The data available do not establish that steroids possess psychoactive effects comparable to those substances currently scheduled." See *id.*

108 In his opening remarks during one of the legislative hearings, then Delaware Senator, Joseph R. Biden, who presided over the hearing, recounted the events of the 1988 Seoul Olympics and noted that one of the most troubling aspects of AAS use was that it undermined "our value system, the so-called American way." *Steroids in Amateur and Professional Sports, supra* note 105. When asked why Congress was focusing on AAS as opposed to other drugs, Biden explained, "the thing that disturbs me most about this issue beyond the health effects, as bad as they are, is this notion that we are undermining the very *raison d'etre*, the very reason that sports play such a major role in America, particularly among our young." *Id.* at 102. Biden emphasized, "we need to consider adding steroids to the list of 'controlled substances,' treating them the same way we treat other dangerous drugs such as cocaine and heroin." *Id.* at 4. Biden's remarks are representative of tenor of the testimony presented at the hearings. See *id.*

criminal regulatory regime that was not present in the public health or market regimes. This enabled Congress to criminalize nonmedical AAS sales legislatively, over objections from the American Medical Association, FDA, and DEA.[109] In so doing, Congress circumvented the forty-year-old administrative drug scheduling process and thereby set a drug regulatory precedent.

The Regulatory Regime/Norms model also explains passage of the historic Pure Food and Drug Act of 1906.[110] Drugs sold prior to 1906 ran the gamut from well-intentioned but ineffective medicines to patently phony nostrums.[111] The quality of these drugs was generally unreliable and of questionable purity because many drugs, including "soothing syrups" for infants, contained inert substances and often some quantity of cocaine, opium, alcohol, arsenic, mercury, or other narcotic, addictive, or lethal drug.[112] Estimations at the time put the death toll from such drugs in the tens of thousands.[113] Despite the obvious need for regulation, the ethos of the market regime was that it was up to the consumer to take appropriate precautions against adulterated and fake drugs.[114] Thus, there was little protection for drug consumers because assumption of risk and rational choice principles dominated the market regime.

In 1905, however, those who championed drug control legislation—primarily women and physicians—successfully characterized the issue in a way that resonated with the norms of the public health regime. Rather

---

109 AAS were added to Schedule III of the CSA, when President Bush signed into law the Crime Control Act of 1990, on November 29, 1990. *See* 18 U.S.C. § 1 (1990).

110 Pure Food and Drug Act, 34 Stat. 768 (1906) (amended 1907).

111 *See* JAMES HARVEY YOUNG, THE TOADSTOOL MILLIONAIRES: A SOCIAL HISTORY OF PATENT MEDICINES IN AMERICA BEFORE FEDERAL REGULATION 16–17 (1961) [hereinafter TOADSTOOL MILLIONAIRES]. One drug, for example, an alleged "brain tonic" created to alleviate headaches and aptly named, Cuforhedake Brane-Fude, contained a potentially lethal mixture of alcohol, caffeine and acetanilid, among other drugs. *See* JAMES HARVEY YOUNG, THE MEDICAL MESSIAHS: A SOCIAL HISTORY OF HEALTH QUACKERY IN TWENTIETH-CENTURY AMERICA 4–6 (1967) [hereinafter MEDICAL MESSIAHS]. *See also* PHILIP J. HILTS, PROTECTING AMERICAN'S HEALTH: THE FDA, BUSINESS, AND ONE HUNDRED YEARS OF REGULATION 48 (2003) ("Peruna, an industry leader, was a remedy sold for a variety of illnesses, from colds and congestion . . . to tuberculosis, inflamed appendix, the mumps, and 'female complaints.' The main secret ingredients in the bottle were alcohol and water, with 28 percent of the mixture pure alcohol.").

112 *See* YOUNG, PURE FOOD, *supra* note 37, at 29, 258 (discussing often fatal soothing syrups for infants). *See also* HILTS, *supra* note 111, at 48; YOUNG, MEDICAL MESSIAHS, *supra* note 111, at 4–6.

113 *See* HILTS, *supra* note 111, at 46.

114 *See id.* at 29. For example, echoing the dominant sentiment of the time, Dr. John H. Griscom of the New York Academy of Medicine suggested that the problem "lies rather with the public which patronizes, and not so much with the tradesman who profits by" the sale of patent drugs. *Id.* Similarly, U.S. Representative William Adamson of Georgia dubbed the proposed Pure Food and Drug Act, "pure foolishness," and objected to its passage by arguing that "the Federal Government was not created for the purpose of cutting your toe nails or corns." *See* YOUNG, PURE FOOD, *supra* note 37, at 253 (citation omitted).

than highlight the immorality of selling toxic, addictive, or lethal drugs—which would have moved dangerous drugs into the criminal regulatory regime—these reformers instead argued that the contents of hazardous drugs should be disclosed because individuals cannot make safe decisions about drug consumption if they are unaware of what is in their drugs.[115] Pointing to high profile exposés of the drug industry to advance their claims,[116] these reformers persuasively characterized the problem in a way that resonated with the disclosure norms of the nascent public health regime and, in so doing, forced passage of the Pure Food and Drug Act of 1906.[117] The unprecedented legislation did not criminalize or ban the manufacture or sale of dangerous drugs, but rather centered public health concerns.[118] The Act prohibited misrepresentation in drug labeling and mandated that manufacturers disclose the presence and amount of certain drugs, including alcohol, opium, cocaine, heroin, morphine, chloroform, or acetanilide, although it did not prohibit inclusion of such substances.[119] Thus, although the Pure Food and Drug Act predated regulatory regimes as we know them today, by disrupting the

---

115 *See* YOUNG, PURE FOOD, *supra* note 37, at 258. U.S. Representative James Robert Mann of Illinois, who was instrumental in passing the Pure Food and Drug Act, argued, to great applause from his colleagues in the House, that "[w]e can not undertake to prevent the man who is an opium fiend from obtaining opium, but we can undertake to prevent the man who never wishes to take opium from taking it without knowing he is taking it." *Id.* During hearings on the bill, Mann cited case histories of those unwittingly addicted to or killed by drugs, particularly infants poisoned by lethal doses of morphine in soothing syrups. *Id.* According to these reformers, disclosure was the only way for the public to protect against the danger and deception posed by drugs. *See id.* at 258–59.

116 *See* YOUNG, TOADSTOOL MILLIONAIRES, *supra* note 111, at 234, 239–40. The publication of Upton Sinclair's best-selling novel, *The Jungle*, which described in graphic detail the unsanitary condition of Chicago meat packinghouses, was instrumental in fueling public support for food and drug regulations. *See id.* at 239. The effects of *The Jungle* were compounded by articles highlighting the fraud and malfeasance on the part of patent medicine manufacturers, which appeared in such magazines as *Ladies' Home Journal*. *See id.* at 212–13, 234. A damning series of articles by Samuel Hopkins Adams in *Collier's* magazine revealed that many well-known patent medicines were little more than narcotics mixed with inert substances, and this included patent drugs intended for use by children. *Id.* at 219–25, 275 (citing Samuel Hopkins Adams' collection of articles, *The Great American Fraud*, originally published in *Collier's* magazine from 1905 to 1907).

117 *See* YOUNG, PURE FOOD, *supra* note 37, at 208 (noting the AMA's pressure on the Senate to control "worthless, dangerous and enslaving drugs").

118 *See id.* at 264 (highlighting that the Food and Drug Act rested on the idea that "if the consumer was adequately informed, he could protect himself against deception, even against danger").

119 *See id.* at 267. The law prohibited labels that had "any statement, design or device regarding such article, or the ingredients or substances contained therein which shall be false or misleading in any particular." *Id.* The law did not require that other substances be listed, however, if the manufacturer advertised that the product contained a particular drug, this representation, and the amount claimed, had to be accurate. *Id.* Violation of the act was a misdemeanor offense that could render one subject to a fine not to exceed $200 for a first offense or $300 for each subsequent offense and/or imprisonment not to exceed a year. *Id.* at 268. Adulterated or misbranded drugs were also subject to seizure. *Id.*

norms of the market regime and characterizing drugs in a way that was consistent with the disclosure norms of the burgeoning public health regime, reformers were able to pave the way for passage of the first federal law to regulate drugs in the name of public health.[120]

As we have seen with marijuana, cocaine, AAS, and the passage of the Pure Food and Drug Act, specific social events can create opportunities for those who engage in drug designation contests to succeed in characterizing a drug in a way that penetrates public thinking and makes regulatory regime changes possible. As the Regulatory Regime/Norms model makes clear, there is a contingency as to how a drug becomes vulnerable to the framing contests that lead to drug regulatory regime change. Anabolic steroids demonstrate this contingency. It is quite conceivable that had it not been for the Olympic cheating scandal, anabolic steroids could have become over-the-counter drugs regulated with age restrictions, much like tobacco and alcohol. Likewise, based on its broad social appeal, if marijuana were discovered today it might not be criminalized. Similarly, widely published exposés of the drug industry allowed drug regulation advocates, at the turn of the century, to focus public attention on their argument that drug makers should be required to disclose the contents of their drugs.[121] However, these contingencies of historical context and physical place do not drive regulatory outcomes, but simply create opportunities for interested parties to characterize a drug in a way that shapes its popular understanding.

The Regulatory Regime/Norms model posits that the way a drug will be regulated is not a path-dependent story.[122] How a drug is presently regulated is relevant to how it will be regulated in the future, but it

---

120 See Food and Drug Administration, Legislation, http://www.fda.gov/RegulatoryInformation/Legislation/default.htm (last visited Mar. 14, 2010) ("The Food and Drugs Act of 1906 was the first of more than 200 laws that constitute one of the world's most comprehensive and effective networks of public health and consumer protections.").

121 *See* Brian Rubens, *Common Law versus Regulatory Fraud: Parsing the Internet Requirement of the Felony Penalty Provision of the Food and Drug, and Cosmetic Act*, 72 U. CHI. L. REV. 1501, 1506 (2005) (noting a manufactured drug that "killed hundreds of people after a manufacturer distributed a drug that it failed to test for safety").

122 Lockhart defines path dependence as follows: "[O]nce a society starts building particular public institutions (e.g., a presidential as opposed to parliamentary democracy) or policies (e.g., the financing of medical care), it becomes increasingly difficult across time to effect institutional or policy change which breaks free of the initial path's confining influence." CHARLES LOCKHART, THE ROOTS OF AMERICAN EXCEPTIONALISM: INSTITUTIONS, CULTURE AND POLICIES 7 (2003). Klein and Marmor write that path dependency:

> is simply another way of describing the incremental, adaptive nature of much policy making . . . . The fact that policy makers faced with a new problem tend to draw on an established repertory of tools reinforces the bias of public policy against radical innovation, as does dependence on existing organizations for delivery . . . . More narrowly and rigorously, path dependency is seen as flowing from the structure of interests created by policy . . . . Decisions taken at point A in time entrench—sometimes indeed create—interests that come to constrain decisions at point B."

is not dispositive. The critical factor in this determination is how successfully the drug is framed. For example, a drug that has already been criminalized or one that is mass-consumed may be more difficult to shift into another regime than a newly discovered drug. The Regime/Norms model indicates that this is because, unlike newly discovered drugs, the social meaning of which is indeterminate and ambiguous, those drugs that are well-established in a regime already have meaning conferred in them. As a result, in order to move these drugs one must destabilize the existing meaning of the drug in relation to its current regime. Then the framing process can be used to signify the drug in relation to the norms of a different regime, and in so doing, prompt individuals to think and feel differently about the drug so as to allow for a regime re-designation. The recent shift of tobacco from the market regime to the public health regime provides a more in-depth example of this phenomenon.

B. *A Closer Look at the Model: Tobacco*

Although tobacco products are the leading cause of preventable death in the United States,[123] killing over 440,000 people annually[124]

Rudolf Klein & Theodore Marmor, *Reflections on Policy Analysis: Putting It Together Again, in* OXFORD HANDBOOK OF PUBLIC POLICY 890, 900–01 (Michael Moran, Martin Rein, & Robert E. Goodin eds., 2006). As Richard Pildes puts it: "[O]ne of the iron laws of democratic institutions is that institutional structures, once created, become refractory to change. Identities and interests coalesce around existing institutional arrangements." Richard H. Pildes, *The Constitutionalization of Democratic Politics*, 118 HARV. L. REV. 29, 84 (2004).

123 *See* Ctrs. for Disease Control & Prevention, Targeting the Nation's Leading Killer: At a Glance 2010, http://www.cdc.gov/nccdphp/publications/aag/osh.htm (last visited Mar. 24, 2010).

124 *See* Ctrs. for Disease Control & Prevention, *Smoking-Attributable Mortality, Years of Potential Life Lost, and Productivity Losses - United States, 2000-2004*, 57 MORBIDITY & MORTALITY WKLY REP. 45, 1226-28 (2005), *available at* http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5745a3.htm. Smoking has been definitively linked to the development of heart diseases, strokes, bronchitis, emphysema, cardiovascular disease (atherosclerosis and abdominal aortic aneurysm), respiratory disease (impaired lung function, chronic obstructive pulmonary disease, asthma, and pneumonia), brain aneurisms, acute myeloid leukemia, and cancer of the throat, mouth, tongue, lip, larynx, colon, esophagus, pharynx, lungs, bladder, kidneys, pancreas, stomach, breast and cervix. *See* CTRS. FOR DISEASE CONTROL & PREVENTION, THE HEALTH CONSEQUENCES OF SMOKING: A REPORT OF THE SURGEON GENERAL (2004), *available at* http://www.surgeongeneral.gov/library/smokingconsequences/. Among women, tobacco consumption contributes to low bone density, osteoporosis and pregnancy complications including low birthweight babies, preterm delivery, stillbirth and fetal death. *Id.* Researchers have recently isolated a chemical in tobacco that may contribute to the development of diabetes, cancer, Alzheimer's disease and accelerate the ageing process. *See Tobacco Chemical Blamed for Disease*, BBC NEWS WORLD EDITION, Oct. 29, 2002, *available at* http://news.bbc.co.uk/2/hi/health/2361167.stm (citing study by Scripps Research Institute). Today, approximately 8.6 million people in the United States suffer from smoking related illnesses. American Cancer Society, Study: 8.6 Million Americans Sick With Tobacco-Related Illnesses, Nov. 5, 2003, http://www.cancer.org/docroot/NWS/content/NWS_2_1x_Study_86_Million_Americans_Sick_With_Tobacco-related_Illnesses.asp. There are at least sixty-four carcinogens in cigarette smoke; of these, the International Agency for Research on Cancer (IARC) has classi-

(more than the combined number of those killed by AIDS, alcohol, car accidents, illicit drugs, homicide, and suicides),[125] tobacco has been regulated, for over a century, in the market regime, and tobacco manufacturers have been extremely resilient and resourceful in staving off meaningful public health regulation. Manufacturers have accomplished this by effectively using advertising to shape popular conceptions of tobacco and drive acceptance.[126]

While one might assume that tobacco's ability to avoid regulation is due to its historical popularity and prevalence of use, the Regulatory Regime/Norms model suggests otherwise. A comparison with alcohol, an equally popular drug, provides an instructive example. During the late nineteenth century, the temperance movement identified smoking as a "dirty habit" responsible for many social ills.[127] Drawing no distinction between alcohol and tobacco,[128] these prohibitionists framed the use of these drugs as a moral threat that undermined not only individual and public health, but also Victorian notions of self-discipline and control.[129] Unlike alcohol, which would be relegated to the criminal regime after the

---

fied eleven as proven human carcinogens, six as probable human carcinogens, and forty-six as possible human carcinogens. *See* Dietrich Hoffmann & Ilse Hoffmann, *The Changing Cigarette, 1950-1995*, 307 J. TOXICOLOGY & ENVTL. HEALTH 316 (1997) (citing INTERNATIONAL AGENCY FOR RESEARCH ON CANCER, MONOGRAPHS ON THE EVALUATION OF CARCINOGENIC RISKS TO HUMANS UPDATE (Supp. 7, 1987), vols. 43–66 (1988-1996)). Tobacco smoke contains over 4,000 chemical compounds, including: particles and gases, such as nicotine, tar, benzine, carbon monoxide, ammonia, dimethylnitrosamine, hydrogen, cyanide, acrolein and formaldehyde. *See Q & A: Passive Smoking*, BBC NEWS, Oct. 18, 2004, http://news.bbc.co.uk/2/hi/health/medical_notes/3235820.stm (citing findings of the Scientific Committee on Tobacco and Health).

125 ERIC LINDBLOM, CAMPAIGN FOR TOBACCO FREE KIDS 1 (2009), *available at* http://www.tobaccofreekids.org/research/factsheets/pdf.

126 *See* ALLAN M. BRANDT, THE CIGARETTE CENTURY: THE RISE, FALL, AND DEADLY PERSISTENCE OF THE PRODUCT THAT DEFINED AMERICA 31–33, 54–55, 313–14 (2007). *See also* NEIL H. BORDEN, THE ECONOMIC EFFECTS OF ADVERTISING, 207–49 (1944); Patrick Porter, *Advertising in the Early Cigarette Industry: W. Duke, Sons & Company of Durham*, 69 N.C. HIST. REV. 1, 41 (1971).

127 *See* BRANDT, *supra* note 126, at 45–46.

128 *See id.* ("Temperance reformers drew no distinction between tobacco and alcohol: in their view, immorality led to bad health and unhealthful living to immoral life.").

129 *See id.* at 46–47 ("'The anti-tobacco crusade is a moral one, just as was the struggle for temperance,' wrote the social reformer Vida Milholland. 'It is a fight to free our beloved nation from a form of mental slavery, to which she is submitting, as long as she permits the poisoned drug, tobacco, to spread its fumes, like a pall over the land."; "An 1884 New York Times editorial stated the national crisis in no uncertain terms: 'The decadence of Spain began when the Spaniards adopted cigarettes, and if this pernicious practice obtains among adults Americans the ruin of the Republic is close at hand.'"; "In 1916, [Henry Ford] published a widely circulated compendium of anti-tobacco materials under the title *The Case Against the Little White Slaver* and vowed not to hire smokers: 'Boys who smoke cigarettes we do not care to keep in our employ. In the future we will not hire anyone whom we know to be addicted to this habit. . . . We made a study of the effect upon the morals and efficiency of men in our employ addicted to this habit and found that cigarette smokers were loose in their morals, very apt to be untruthful . . . .'").

1919 ratification of the Eighteenth Amendment, tobacco remained in the market regime due to the industry's dramatic increase in advertising spending.[130] Between 1910 and 1913, during the height of the temperance movement's prominence, tobacco manufacturers increased expenditures on cigarette advertising by nearly 200 percent, which precipitated a seismic shift in public understanding of their drug.[131]

In order to create public acceptance of tobacco, cigarette companies spent the remainder of the twentieth century, using advertising to frame tobacco in a way that was consistent with the rational choice and assumption of risk norms of the market regime. In so doing, the cigarette industry succeeded in transforming common perceptions of tobacco consumption; the public came to view tobacco as being no different from other hazardous but enjoyable products that were generally tolerated and regulated with moderation, such as knives, chainsaws, and snowmobiles.[132] Therefore, according to the industry, tobacco consumption, like other potentially dangerous activities, such as skiing, parachuting or whitewater rafting, should be permitted so long as the person engaged in the activity has a good, if not perfect, understanding of the risks involved.

Even the U.S. Surgeon General's 1964 declaration that cigarettes posed a significant health hazard and contributed to many life-threatening diseases, including lung cancer, did not weaken the tobacco industry's foothold in the market regime.[133] Shortly after the release of the Surgeon General's report, the Federal Trade Commission (FTC)—the regulatory agency with primary control over the advertising of tobacco products—promulgated regulations requiring that tobacco products contain warnings,[134] and Congress enacted legislation prohibiting tobacco companies from advertising on television or radio.[135] Although cigarette sales dropped immediately after publication of the Surgeon General's report, by 1966, sales had reached record levels, and by June of 1967, the

---

130 *See id.* at 54. In 1910, the tobacco industry spent an estimated $13 million on advertising, with cigarettes accounting for nearly one-third of this sum. *Id.* By 1913, expenditures on cigarette advertising alone would account for $13 million. *Id.*

131 *See id.*

132 *See* BRANDT, *supra* note 126, at 280.

133 *See* THE SURGEON GENERAL'S ADVISORY COMMITTEE ON SMOKING AND HEALTH, U.S. DEP'T OF HEALTH, EDUCATION AND WELFARE, SMOKING AND HEALTH, 31–32 (1964). The U.S. Surgeon General declared that "cigarette smoking is a health hazard of sufficient importance in the U.S. to warrant appropriate remedial action." *Id.* at 33.

134 Unfair or Deceptive Advertising and Labeling of Cigarettes in Relation to the Health Hazards of Smoking, 29 Fed. Reg. 8324, 8325 (1964).

135 Public Health Cigarette Smoking Act of 1969, Pub. L. No. 91-222, § 6, 84 Stat. 87, 89 (1969) (codified as amended at 15 U.S.C. § 1335 (2000)).

FTC could find "virtually no evidence that the warning statements on cigarette packages had any significant effect."[136]

Tobacco manufacturers' ability to survive this seemingly inevitable redesignation of their drugs to the public health regime was due to their success at using government-mandated warning labels to frame the act of smoking in a way that was consonant with the dominant market regime norms of assumption of risk and rational choice. According to their logic, as long as rational people in a free society are aware of the risks involved in smoking, they should have a right to engage in the activity.[137] Thus, the industry was able to promote cigarette use as an act of independence and rebellion, while at the same time transforming the warning labels into disclaimers that would eventually shield cigarette manufacturers from future liability.[138]

The regulatory landscape began to change for tobacco when, during the early 1970s, the first of two events allowed public health reformers to undermine the tobacco industry's characterization of its drug in relation to the norms of the market regime and frame the drug in a way that was resonant with the norms of the public health regime, where the drug would ultimately be reassigned. In 1972, a report of the U.S. Surgeon General concluded that cigarette smoking was not only harmful to smokers but also to those around them.[139] So called "second-hand smoke" presented a health hazard to *non-smokers*, and as such, undermined the *assumption of risk* norms upon which the market regime is premised. When smoking was understood as an individual behavior that posed little risk to others, tobacco manufacturers were able to remain in the market regime by arguing successfully that government regulation raised the specter of "Big Brother" and represented paternalistic overreaching by the state. Thus, for decades, smokers were allowed to *assume* the often fatal risks attendant to their own behavior. These risks, however, were not assumed by nonsmokers but were rather *imposed* upon them, essen-

---

136 *See* BRANDT, *supra* note 126, at 257. In 1974, per capital consumption of tobacco products was approximately 4,100 cigarettes per year—virtually the same as it had been a decade earlier. *See id.* at 280.

137 *See* Richard C. Ausness, *Cigarette Company Liability: Preemption, Public Policy, and Alternative Compensation Systems*, 39 SYRACUSE L. REV. 897, 953 (criticizing cigarette manufacturers' position that smokers assume the risk of their behavior); Ellen Wertheimer, *Pandora's Humidor: Tobacco Producer Liability in Tort*, 24 N. KY. L. REV. 397, 417 & n.48 (noting that a position often asserted by tobacco manufacturers in litigation is that "smokers assume all dangers that [cigarettes] involve").

138 This strategy would ultimately protect the company from liability years later during a wave of tobacco litigation. *See Cipollone v. Liggett Group, Inc.*, 505 U.S. 504 (1992) (holding that federal law preempts state failure to warn claims against cigarette manufacturers).

139 *See* U.S. DEP'T OF HEALTH, EDUC. & WELFARE, THE HEALTH CONSEQUENCES OF SMOKING, SURGEON GEN. REP., 121–35 (1972). The Surgeon General reiterated this finding in subsequent reports published in 1979 and 1984. *See, e.g.*, U.S. DEP'T OF HEALTH, EDUC. & WELFARE, SMOKING AND HEALTH, SURGEON GEN. REP., 1–25, 21–17 (1979).

tially transforming these individuals into involuntary smokers. This introduction of the "innocent victim" dramatically changed the equation in favor of regulation.[140] In 1973, just one year after the release of the Surgeon General's report on second hand smoke, Arizona became the first state to restrict smoking in public places, and by 1981 no fewer than thirty-six states had passed legislation limiting when and where people could smoke.[141]

The damage to the tobacco industry prompted by the discovery that smoking caused illness in nonsmokers was compounded by the subse-

---

140 Tobacco smoke presents a health hazard even for those who are not actively smoking. So called, "second-hand smoke" can cause headaches, sore throat, eye irritation, dizziness and nausea. *Q & A: Passive Smoking*, *supra* note 124. Exposure for only 30 minutes can reduce coronary blood flow. *Id.* (citing findings of the Scientific Committee on Tobacco and Health). A team of researchers from the National Cancer Institute found that tobacco smoke produces substantially more fine particulate matter—the most dangerous component of air pollution—than diesel exhaust. *Smoking More Toxic than Car Fumes*, BBC NEWS, Aug. 24, 2004, *available at* http://news.bbc.co.uk/2/hi/health/3590578.stm (citing studies conducted by the National Cancer Institute and the Tobacco Control Unit). Thus, the Environmental Protection Agency (EPA) has classified environmental tobacco smoke as a class A carcinogen, along with asbestos and arsenic. *Q & A: Passive Smoking*, *supra* note 124. Studies have shown that nonsmokers exposed to second-hand smoke for long periods of time increase their risk of heart disease and lung cancer by 25%. *Id.* Even low levels of exposure to tobacco smoke in the home have been linked to reduced test results in reading and math among children. *See Tobacco Smoke Dulls Child Brains*, BBC NEWS, Jan. 4, 2004, *available at* http://news.bbc.co.uk/2/hi/health/4145645.stm (citing study of 4,400 children by the U.S. Children's Environmental Health Center). The greater the exposure to second-hand smoke, the more pronounced the decline in mathematical and reading abilities. In homes where both parents smoke, young children have a 72% increased risk of respiratory illness, including bronchitis and pneumonia. *See Q & A: Passive Smoking*, *supra* note 124. Researchers have found that children exposed to cigarette smoke may harbor other harmful organisms, such as streptococcus pneumonia, because the smoke interferes with the 'healthy' bacteria normally found in the nose and throat. *See* Nicholas Bakalar, *In Children, Rise in Bacteria is Linked to Smoke*, N.Y. TIMES, Mar. 21, 2006, *available at* http://query.nytimes.com/gst/fullpage.html?res=9C03E6D91F31F932A15750C0A9609C8B63. Additional studies have concluded that tobacco trapped in household dust can expose children to the equivalent of several hours of smoking. *Smoke in Dust Poses Health Risk*, BBC NEWS, Feb. 24, 2004, *available at* http://news.bbc.co.uk/2/hi/health/3508035.stm (citing study of 49 homes with infants aged between two and twelve months conducted by researchers at San Diego State University). Even in homes where adults smoked outside, the levels of tobacco contaminants were seven times higher than in smoke-free homes. *Id.* Tobacco toxicity levels were up to eight times higher in homes where adults smoked inside than in homes where no adults smoked. *Id.* Residual smoke particles have been linked to increased risk of asthma and sudden infant death. *Id.* An infant's exposure to these toxins continues even months after the smoking has ceased. *Id.* Researchers contend that infants and children are particularly susceptible to inhaling this type of second-hand smoke because of the amount of time they spend indoors, their close physical proximity to the smoker(s), and their breathing rates being higher than that of adults, allowing them to inhale more contaminants. *Id.*

141 *See* BRANDT, *supra* note 126, at 288–89. Arizona prohibited smoking in elevators, theaters, museums, libraries, and buses, and designated smoking areas in government buildings, healthcare facilities, and other public spaces. *Id.* at 288. Minnesota became the first state to pass comprehensive anti-smoking legislation, when, in 1975, the state enacted the Clean Indoor Air Act, which banned smoking in most public offices, stores and banks. *Id.*

quent revelation that tobacco manufacturers had withheld their knowledge that nicotine in tobacco products caused addiction.[142] This discovery first came to light shortly after the April 14, 1994 joint appearance before Congress of top executives from several major tobacco companies, who testified that the nicotine in their products was not addictive and that they did not adjust nicotine levels in tobacco.[143] Despite high-level tobacco industry executives' public disavowal of tobacco's addictiveness, later that year, two former Philip Morris scientists testified before Congress that a series of studies commissioned by the company on the pharmacodynamics and neurological effects of nicotine determined that tobacco was, indeed, a highly addictive drug.[144] Additional leaked documents provided incontrovertible proof that tobacco manufacturers knew that nicotine was addictive many years before it was commonly known.[145] Evidence showed that tobacco companies intentionally

---

142 Nicotine, one of the powerful alkaloids found in tobacco products, is highly addictive. Studies have demonstrated that nicotine is as addictive as cocaine, morphine and other opiates. *See* U.S. DEP'T OF HEALTH & HUMAN SERVS., THE HEALTH CONSEQUENCES OF SMOKING: NICOTINE ADDICTION, SURGEON GEN. REP. NO. 88-8406, i (1988).

143 *See* BRANDT, *supra* note 126, at 365–66. According to one industry executive, James Johnston of R. J. Reynolds Tobacco Co., "[w]e do not do anything to hook smokers or keep them hooked." He continued, "we no more manipulate nicotine in cigarettes than coffee makers manipulate caffeine." Jill Zuckman, *Tobacco Executives at Hearing; Nicotine Focus of House Unit*, BOSTON GLOBE, Apr. 15, 1994, at A3.

144 *Regulation of Tobacco Products (Part 2): Hearings Before the Subcomm. on Health and the Environment of the H. Comm. on Energy and Commerce*, 103d Cong., 2d Sess. at 17–18, (1995) (statements of former Philip Morris scientists, Victor DeNoble and Paul Mele). The researchers testified that the tobacco company used "exactly the same tests" that the National Institute on Drug Abuse used to determine whether a drug has a potential for abuse. *Id.* at 17.

145 Industry documents showed that tobacco firms knew for decades about nicotine's powerful pharmacological effects. *See* David A. Kessler et al., *The Food and Drug Administration's Regulation of Tobacco Products*, 335 NEW ENG. J. MED. 988 (1996). In an internal memo, the general counsel to Brown and Williamson, a tobacco company, stated: "[N]icotine is addictive . . . . We are, then, in the business of selling nicotine, an addictive drug." Analysis Regarding The Food and Drug Administration's Jurisdiction Over Nicotine-Containing Cigarettes and Smokeless Tobacco Products, 60 Fed. Reg. 41,453, 41,611 (Aug. 11, 1995) (citing a 1963 internal tobacco industry document); *see also* John Slade et al., *Nicotine Addiction: The Brown and Williamson Documents*, 274 JAMA 225, 228 (1995). Another memo from 1972 written by an R. J. Reynolds research scientist averred: "Thus, a tobacco product is, in essence, a vehicle for the delivery of nicotine, designed to deliver the nicotine in a generally acceptable and attractive form. Our industry is then based upon design, manufacture and sales of attractive dosage forms of nicotine which have more overall value, tangible or intangible, to the consumer than those of our competitors." BRANDT, *supra* note 126, at 318. Other memos indicated that Philip Morris considered suppressing evidence that withdrawal from nicotine was similar to that of other highly addictive drugs, including morphine. *See* John Schwartz, *Tobacco Officials Discussed Hiding Data, Memos Indicate*, WASH. POST, Sept. 18, 1996, at A3. These documents also demonstrated that the companies intended their products to be nicotine delivery devices. In 1972, a Philip Morris executive remarked: "Think of the cigarette pack as a storage container for a day's supply of nicotine. . . . Think of the cigarette as a dispenser for a dose unit of nicotine. . . . Think of a puff of smoke as the vehicle of nicotine. . . . Smoke is beyond question the most optimized vehicle of nicotine and the cigarette the

engineered cigarettes to provide carefully calibrated doses of nicotine to smokers in order to manipulate cigarettes' addictiveness and control the rate at which nicotine is delivered to and absorbed into the bloodstream.[146] Although tobacco manufacturers tried to frame this information as proprietary and properly protected as trade secrets, public health reformers successfully framed this withholding of information as a *disclosure failure*, which opened the door to public health regulation the following year.[147] Reversing nearly a century of policy, President Clinton, on August 10, 1995, announced that he would seek to use his executive authority to grant the FDA jurisdiction over tobacco.[148]

It is important to note that despite the fact that the Surgeon General had issued a report in 1988 concluding that nicotine in cigarettes was an addictive drug, it was not until public health reformers framed the tobacco industry's actions as a disclosure failure that they were able to penetrate the market regime by framing the drug in relation to public health regime norms.

Drug makers often justify the withholding of information by arguing that competitive pressure to protect corporate interests and maximize profits discourage them from releasing medical and scientific data on the health impact of the drugs they manufacture.[149] These arguments reso-

---

most optimized dispenser of smoke." Analysis Regarding the Food and Drug Administration's Jurisdiction Over Nicotine-Containing Cigarettes and Smokeless Tobacco Products, 60 Fed. Reg. 41,453, 41,617 (Aug. 11, 1995) (citing a 1972 Philip Morris internal memorandum). Similarly, in another industry document an R. J. Reynolds executive maintained that "[i]n a sense, the tobacco industry may be thought of as being a specialized, highly ritualized, and stylized segment of the pharmaceutical industry. Tobacco products uniquely contain and deliver nicotine, a potent drug with a variety of physiological effects." *Id.* at 41, 617–18 (citing Philip J. Hilts, *U.S. Convenes Grand Jury to Look at Tobacco Industry*, N.Y. TIMES, July 26, 1995, at A1).

146 *See, e.g.*, Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents, 61 Fed. Reg. 44,396, 45,110–11, 45,127 (Aug. 28, 1995). *See also* Analysis Regarding the Food and Drug Administration's Jurisdiction Over Nicotine-Containing Cigarettes and Smokeless Tobacco Products, 60 Fed. Reg. 41,453, 41,710 (Aug. 11, 1995).

147 *See* David M. Forman, Note, *Big Tobacco: An Impenetrable Industry Regulators Can Only Hope to Contain*, 31 SUFFOLK U. L. REV. 125, 147, & n.132 (1997). *See also* U.S. Tobacco Co. v. Harshbarger, 1997 WL 137200 at *1, *2 (noting that U.S. Tobacco Co.'s "real grievance [with a Massachusetts law requiring them to disclose ingredient information] is that they will suffer serious harm from . . . public disclosure of their confidential information.").

148 *See President's News Conference*, 31 WKLY COMP. PRES. DOC., 1415 (Aug. 10, 1995). *See also* Analysis Regarding the Food and Drug Administration's Jurisdiction Over Nicotine-Containing Cigarettes and Smokeless Tobacco Products, 60 Fed. Reg. 41,453, 41,426 (Aug. 11, 1995).

149 *See* Alex Berenson, *Despite Vow, Drug Makers Still Withhold Data*, N.Y. TIMES, May 31, 2005, at A1; Editorial, *Drugs and Disclosure*, N.Y. TIMES, Oct. 10, 2008, at A22; Barry Meier, *For Drug Makers, a Downside to Full Disclosure*, N.Y. TIMES, May 23, 2007, http://www.nytimes.com/2007/05/23/business/23drug.html. The pharmaceutical industry, for example, has consistently opposed government-mandated disclosure. *See* Berenson, *supra* at A1. Pharmaceutical companies test their products in thousands of clinical trials each year and the

nate in the market regime. As we have seen, however, if public health reformers can frame this withholding of information as a disclosure failure, as opposed to an assumed risk, they may succeed in changing public understanding of the drug in relation to the market regime, and shift the drug into the public health regime where disclosure norms resonate.

Market regime norms were further disrupted when reformers argued successfully that, as an addictive drug, tobacco is fundamentally incompatible with the norms of rational choice.[150] Reformers revealed that tobacco industry executives, in direct contravention of their testimony before Congress, had spent decades surreptitiously marketing tobacco products to minors, a group defined as unable to assume certain risks.[151]

Armed with this powerful evidence, the FDA, in accordance with its authority enumerated under the FDCA, asserted its power to regulate cigarettes as combined drugs and drug delivery devices, and promulgated a regulation aimed at reducing smoking in young people.[152] Although the U.S. Supreme Court rejected the FDA's attempt to claim jurisdiction over tobacco products by ruling that the regulatory authority the FDA sought to exercise must be delegated by Congress, on June 10, 2009, Congress responded by passing the Family Smoking Prevention and Tobacco Control Act.[153] The Act grants the FDA explicit authority over tobacco products and the power to regulate their manufacture, sale, distribution, and promotion.[154]

The tobacco industry successfully resisted meaningful regulation by using advertising to shape norms of conduct and consumption with re-

---

companies are very protective of their data. *Id.* While often too complicated for general public consumption, clinical trial data is useful to medical practitioners and academic scientists who use it to compare drugs and determine possible side effects. *Id.* The industry, through its lobbying trade group, the Pharmaceutical Research and Manufacturers of America (PhRma), has nevertheless advocated against the creation and enforcement of a federal registry for clinical trial data.

150 *See* KLUGER, *supra* note 36, at 213.

151 *See* John P. Pierce et al., *Smoking Initiative by Adolescent Girls, 1944 Through 1988*, 271 JAMA 608 (1994) (reporting that the advent of Virginia Slims and other brands targeting female smokers coincided with the sharp increase in teen girls smoking); Associated Press, *Tobacco Firm Targeted Teens*, BALTIMORE SUN, Jan. 15, 1998, at A1 (reporting that according to industry documents, R. J. Reynolds targeted adolescents as young as 13 and created a brand designed to entice boys to smoke); Barry Meier, *Painting a Target on Teen Smokers*, SACRAMENTO BEE, Jan. 15, 1998, at A1 (reporting that in 1988, R. J. Reynolds sought to advertise heavily in places where teenagers congregate, including video game arcades, fast food restaurants, and outdoor sports venues); John Schwartz, *Philip Morris Memos Detail Teen Habits*, WASH. POST, Jan. 30, 1998, at A15.

152 *See* Nicotine in Cigarettes and Smokeless Tobacco Products is a Drug and These Products are Nicotine Delivery Devices Under the Federal Food, Drug and Cosmetic Act, 60 FED. REG. 41,314, 41,454, 41,787 (Aug. 11, 1995).

153 *See* Brown & Williamson Tobacco Corp. v. Food & Drug Admin., 153 F.3d 155 (4th Cir. 1998), *aff'd*, 529 U.S. 120 (2000).

154 *See* The Family Smoking Prevention and Tobacco Control Act, H.R. 1256, 111th Cong. (2009).

spect to smoking, until public health reformers effectively undermined the norms of the market regime that had held the drug ensconced there.[155] These reformers then reframed the drug in a way that resonated with the disclosure norms of the public health regime, and have succeeded in shifting the drug into that regime. Today, cigarettes, once the popular and socially approved drug of choice, are increasingly demonized, and public smoking is anathema.[156] Many states and local governments have enacted laws and ordinances regulating when and where people can smoke, and at least one city—Calabasas, California—has banned smoking in all public places, both indoor and outdoor, where anyone might be exposed to second-hand smoke.[157] Smoking is becoming a marginalized practice, increasingly associated with lower educational and socioeconomic status.[158] And, as the Regulatory Regime/ Norms model makes clear, to the extent that tobacco is consumed primarily by low-income and marginalized communities, if current trends con-

---

155 Virtually all of the bills introduced by federal legislators aimed at granting the FDA explicit jurisdiction over tobacco products have been defeated. *See* H.R. 2147 & S. 672, 104th Cong. (1993); H.R. 4350 & S. 2298, 103d Cong. (1992); H.R. 1494 & S. 769, 101st Cong. (1989); H.R. 3294, 100th Cong. (1987); H.R. 279, 96th Cong. (1979); S. 3317, 95th Cong. (1978); H.R. 7168, 95th Cong. (1977); H.R. 3879, 95th Cong. (1977); H.R. 2419, 95th Cong. (1977); S. 1682, 88th Cong. (1963); H.R. 5973, 88th Cong. (1963); H.R. 11280, 84th Cong. (1956). In 1984, Congress amended the FCLAA to include the Comprehensive Smoking Education Act. *See* Comprehensive Smoking Education Act of 1984, Pub. L. No. 98-474, 98 Stat. 2200 (1984). In 1986, Congress passed the Comprehensive Smokeless Tobacco Health Education Act (CSTHEA) to regulate the manufacture, packaging and distribution of smokeless tobacco products. *See* Pub. L. No. 99-252, § 2, 100 Stat. 30, 30–31 (codified at 15 U.S.C. §§ 4401–4408 (2001)). This law, however, did not provide the FDA with regulatory jurisdiction over smokeless tobacco products. *Id.*

156 *See* Joseph R. Gusfield, *The Social Symbolism of Smoking and Health*, *in* SMOKING POLICY: LAW, POLITICS AND CULTURE 49 (Robert L. Rabin & Stephen D. Sugarman eds., 1993).

157 *See* Calabasas, Cal., Ordinance No. 2006-217, (Feb. 15, 2006), *available at* http://www.cityofcalabasas.com/pdf/agendas/council/2006/021506/item2-O2006-217.pdf. The city council in Calabasas, California unanimously enacted this anti-smoking ordinance in February 2006. *Id.* This ordinance permits fines of up to $5,000 for misdemeanor smoking violations, making it the most stringent anti-smoking law in the country. *See id. See also* John M. Broder, *Smoking Ban Takes Effect, Indoors and Out*, N.Y. TIMES, Mar. 19, 2006, http://www.nytimes.com/2006/03/19/national/19smoke.html; Jordan Raphael, Note, *The Calabasa Smoking Ban: A Local Ordinance Points the Way for the Future of Environmental Tobacco Smoke Regulation*, 80 S. CAL. L. REV. 393 (2007).

158 *See* BRANDT, *supra* note 126, at 308 ("Data from the Centers for Disease Control showed smoking declining with levels of education: more than 40 percent of people who dropped out of high school were smokers, compared to fifteen percent of those with college degrees. On seeing these numbers, University of Michigan economist Kenneth Warner remarked that 'smoking related disease will increasingly become a class-based phenomenon.'"). *See also* Centers for Disease Control and Prevention, *Cigarette Smoking Among Adults – United States 2007*, 54 MORBIDITY & MORTALITY WKLY REP., 45, 1221–26 (2008), *available at* http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5745a2.htm; Trish Hall, *Smoking of Cigarettes Seems to be Becoming a Lower-Class Habit*, WALL ST. J., June 25, 1985, at A1.

tinue, it is quite conceivable that tobacco may be criminalized one day in the not too distant future.[159]

C. *Moving a Drug out of the Criminal Regime*

Once a drug is assigned to and framed within a particular regime, it is very difficult to reassign it to another regime because its social meaning is quickly reinforced and consolidated. Yet, while regulatory regimes exhibit a degree of continuity over time, drug placement in a particular regime is rarely, if ever, fixed, stable, or uncontested. As the Regulatory Regime/Norms model suggests, once the norms associated with a drug and those of its regime no longer mesh, outward movement of the drug from the regime becomes possible.

Thus, with respect to drugs that originate in the market regime - such as tobacco, marijuana, and cocaine - reformers or government actors can overcome the liberal presumption against state intervention into people's private affairs (the market default position) by successfully characterizing the drug in a way that matches the norms of another regulatory regime. The case of AAS shows that the Regulatory Regime/ Norms model also explains the movement of commercially manufactured pharmaceutical drugs out of the public health regime. But what about drugs moving out of the criminal regulatory regime?

Unlike efforts to move a drug out of the market or public health regime, whether a drug may move out of the criminal regulatory regime is determined by moral norms and the social status of the drug's users. As a result, if a drug is closely associated with a racialized or socially maligned group, movement out of the criminal regulatory regime becomes significantly less likely to occur. Therefore, even if one is able to successfully undermine the morally charged meaning attached to a drug regulated in the criminal regime, the extent to which the drug is identified with racial minorities or other marginalized groups will determine whether the drug will ultimately ever move from the regime.

The unique susceptibility of the criminal regime to moral norms based on fear and blame renders its institutional boundaries porous with respect to the in-migration of drugs associated with presumed deviations from popularly accepted modes of moral conduct. If the drug, however, is also identified with marginalized or racialized groups then this becomes a one-way porosity as this identification makes it not only more likely that the drug will be criminalized, but also less likely that the drug will be moved out of the criminal regime and into another regulatory regime. For example, AAS are used primarily by professional and amateur athletes, body builders, and teenagers who seek to enhance their ath-

159 *See id.*

letic performance and physical appearance.[160] The fact that AAS are used predominantly by these mainstream groups is the likely reason that only unauthorized *sale* of AAS are illegal, while *possession* and consumption are not. The Regulatory Regime/Norms theory suggests that this is due to the social status of the users. That AAS possession was not criminalized reflects the demographics of those who use the drug, while the fact that distribution was criminalized is a function of the morally charged context in which the substance was framed as a social problem.

Unlike the regulation of AAS, possession and distribution of cocaine and marijuana were relegated squarely to the criminal regulatory regime. Marijuana and cocaine were initially assigned to the criminal regime because of allegations of crime and immorality associated with the consumption of each drug. This, coupled with the fact that the users were of low social status, ensured that possession as well as distribution would be criminalized. Marijuana and cocaine enjoyed broad social appeal and were widely consumed for both therapeutic and recreational purposes until the early twentieth century.[161] Despite marijuana's 5,000 year medical history[162] and the fact that cocaine could be found in everything from medical elixirs to soft-drinks, once these drugs became associated with presumed morally deviant behavior by maligned racial groups such as Mexicans and African-Americans, they were abruptly criminalized.[163] Regulators argued that cocaine use by African-Americans and marijuana consumption by Mexicans caused members of these groups to engage in deviant behavior and lawlessness. These claims were readily accepted by the general public to the extent that they were consistent with the morally charged, popular-political construction of these groups.

Beginning in the 1960s and through the 1970s, it appeared that marijuana would move out of the criminal regime and into the market regime due to two factors: (1) the efforts of a peaceful countercultural movement and of marijuana legalization advocates to characterize the drug in a way that was consonant with the norms of the market regime,[164] and (2) the fact that these groups were comprised primarily of

---

160 *See, e.g.*, Jarred R. Tynes, Comment, *Performance Enhancing Substances*, 27 J. LEGAL MED. 493, 493–94 (2006).

161 *See generally supra* Part III.A (detailing the history of marijuana and cocaine in medicine and recreation before the American government criminalized these drugs).

162 *See* LESTER GRINSPOON, M.D., & JAMES B. BAKALAR, MARIJUANA: THE FORBIDDEN MEDICINE 3 (2d ed. 1997).

163 *See generally supra* part III.A.

164 *See* HIMMELSTEIN, *supra* note 87, at 105–13, 122, 130–34; MYRON A. MARTY, DAILY LIFE IN THE UNITED STATES, 1960-1990: DECADES OF DISCORD 300–01 (1997). One of the most notable drug legalization organization of the period was NORML (National Organization to Reform Marijuana Laws). *See* ROBERT DEITCH, HEMP: AMERICAN HISTORY REVISITED: THE PLANT WITH A DIVIDED HISTORY 179 (2003).

white middle-class individuals.[165] During those decades, increasingly prominent libertarian attitudes about the appropriate role of the state with respect to individual conduct, increased social freedoms, and the general permissiveness that became synonymous with that period, allowed these groups to frame marijuana use as an expression of individual liberty and personal choice, which resonated with the assumption of risk and rational choice norms of the market regime.[166] Those groups were so successful in framing marijuana use as an expression of personal liberty and the drug itself as a substance responsible for little more than lethargy and lassitude, that in 1973, Oregon became the first state to decriminalize certain uses of marijuana,[167] and in 1977, President Jimmy Carter publicly supported relaxing federal marijuana laws.[168]

Although it seemed that public perception of marijuana was shifting from condemnation to general tolerance, by the end of the decade the drug would be pulled back from the brink of acceptance in a dramatic shift in public and regulatory perception. The shift was primarily driven by social conservative activists and "concerned parents" groups who succeeded in characterizing the drug as an integral part of a subversive and socially deviant "hippie"/"drop-out" subculture responsible for the degradation of main-stream cultural values, traditional sexual mores, and prevailing gender roles.[169] At the time, scientists and others who offered evidence that marijuana's medical risks were minimal and its effects on users benign were unable to make their voices heard over the din of fear-mongering, amplified by moral condemnation.[170] Such sentiments would eventually help propel Ronald Reagan into the White House and

---

165 *See* HIMMELSTEIN, *supra* note 87, at 99–100, 106–11.

166 *See* MUSTO, *supra* note 35, at 247–50.

167 *See* Albert DiChiara & John F. Galliher, *Dissonance and Contradictions in the Origins of Marihuana Decriminalization*, 28 LAW & SOC'Y REV. 1, 41 (1994).

168 President Jimmy Carter, Message to Congress (Aug. 2, 1977) ("Penalties against possession of a drug should not be more damaging to an individual than the use of the drug itself. . . . Nowhere is this more clear than in the laws against the possession of marijuana in private for personal use."). *See also* DiChiara & Galliher, *supra* note 167, at 46.

169 *See* HIMMELSTEIN, *supra* note 87, at 4; MARTY, *supra* note 164, at 125; DiChiara & Galliher, *supra* note 167, at 68. *See also* HIMMELSTEIN, *supra* note 87, at 121–22, 144–45; *Youth: The Hippies*, TIME, July 7, 1967, http://www.time.com/time/magazine/article/0,9171,899555,00.html (describing, if it were to exist, the Hippie code as "[d]o your own thing, wherever you have to do it and whenever you want. Drop out. Leave society as you have known it. Leave it utterly. Blow the mind of every straight person you can reach. Turn them on, if not to drugs, then to beauty, love, honesty, fun."). The parents' movement against marijuana was emboldened by the publication of the parent's handbook *Parents, Peers, and Pot* in 1979, which claimed that marijuana caused numerous outlandish side effects (including sterility and the transposing of the right and left sides of the brain) and was a "gateway" drug that leads to hard drug use. *See* RUDOLPH J. GERBER, LEGALIZING MARIJUANA: DRUG POLICY REFORM AND PROHIBITION POLITICS 31–32 (2004).

170 *See* U.S. NAT'L COMM'N ON MARIJUANA & DRUG ABUSE, MARIHUANA: A SIGNAL OF MISUNDERSTANDING 152, 176 (1972). *See generally* Laura M. Rojas, *California's Compassionate Use Act and the Federal Government's Medical Marijuana Policy: Can California*

fuel his and subsequent administrations' protracted, morally-charged "war on drugs" and "zero-tolerance" anti-marijuana campaigns.[171] Since 1996, the number of arrests for possessing marijuana has exceeded that for any other type of drug.[172]

Today, however, there is a concurrent tension between the emergent medicalization of marijuana and the ongoing criminalization of the drug.[173] According to the Regulatory Regime/Norms model, this is due to the fact that marijuana is no longer associated in the public imagination with "dope fiend" Mexicans or "sexually deviant" hippies, but instead with severely ill, middle class, white people. Since the 1990s, this association has intensified interest in marijuana as medicine[174] and helped the drug begin the process of migrating from the criminal regulatory regime into the public health regime. Indeed, several states have enacted their own laws allowing legal access to the drug, particularly for medicinal purposes.[175]

Physicians Recommend Marijuana to Their Patients Without Subjecting Themselves to Sanctions?, 30 MCGEORGE L. REV. 1373, 1380-81 (1999).

171 *See* DiChiara & Galliher, *supra* note 167, at 68; Rojas, *supra* note 170, at 1380.

172 *See* U.S. Dep't of Justice, Office of Justice Programs, Bureau of Justice Statistics, http://www.ojp.usdoj.gov/bjs/dcf/tables/drugtype.htm (last viewed Nov. 9, 2009). *See also* Symposium, *Will Money Talk?:The Case for a Comprehensive Cost-Benefit Analysis of the War on Drugs*, 20 STAN. L. & POL'Y REV. 229, 230 (noting an increase in marijuana arrests since 1980); Drug Enforcement Administration, Federal Trafficking Penalties, http://www.justice.gov/dea/agency/penalties.htm.

173 An October 2009 Gallup poll revealed that while 44% of Americans favored marijuana legalization, 54% were opposed the idea. *See* Lydia Saad, *U.S. Support for Legalizing Marijuana Reaches New High*, GALLUP, Oct. 19 2009, http://www.gallup.com/poll/123728/u.s.-support-legalizing-marijuana-reaches-new-high.aspx. Nevertheless, a 2005 nation-wide Gallup poll showed 78% of people in the United States "supported making marijuana legally available for doctors to prescribe in order to reduce pain and suffering." Joseph Carroll, *Who Supports Marijuana Legalization*, GALLUP, Nov. 1, 2005, http://www.gallup.com/poll/19561/Who-Supports-Marijuana-Legalization.aspx.

174 Studies have demonstrated marijuana to be an effective treatment for chronic pain, nausea, appetite loss, and other ailments experienced by people suffering from AIDS and the effects of chemotherapy for the treatment of cancer. *See* GRINSPOON & BAKALAR, *supra* note 89, at 1875–76. Anecdotal evidence suggests that marijuana can provide relief for other conditions, including glaucoma, epilepsy, neuralgia, asthma, cramps, migraine headaches, insomnia, phantom limb pain and depression. *See id.* at 1875. Marijuana is nontoxic, does not appear to be addictive, and does not cause death by overdose, unlike alcohol, cocaine or heroin. *See id.* at 1876. Alcohol is more than 100 times more lethal than marijuana. *Id.* Delta-9-tetrahydrocannabinol (THC), the active ingredient in cannabis, is available as the Schedule II synthetic drug, Marinol, which is a legally prescribed pill used to treat chronic pain and nausea. *Id.* Many people suffering from AIDS, cancer, multiple sclerosis and chronic pain, however, contend that Marinol does not provide effective symptomatic relief for their conditions. *See id.*

175 Thirteen states—Alaska, California, Colorado, Maine, Massachusetts, Minnesota, Mississippi, Nebraska, Nevada, New York, North Carolina, Ohio and Oregon—have decriminalized possession of small amounts of marijuana for personal use, while keeping cultivation and distribution criminal offenses. *See* Eric Blumenson & Eva Nilsen, *No Rational Basis: The Pragmatic Case for Marijuana Law Reform*, 17 VA. J. SOC. POL'Y & L. 43, 73 n.119 (2009) (noting that "[t]hirteen states allow the simple possession of a small quantity of

Unlike marijuana, however, the status of cocaine remains unchanged, and the form of cocaine most closely associated with African-Americans—crack cocaine—appears the least likely of any drug to move out of the criminal regime. Crack offenses are punished much more harshly than offenses involving any other drug, and are, in fact, punished 100 times more severely than offenses involving crack's pharmacological twin, powder cocaine.[176] African-Americans have borne a disproportionate share of these severe penalties. This sentencing differential is the result of the Anti-Drug Abuse Act of 1986 (1986 ADAA), which established mandatory minimum penalties for individuals convicted of trafficking in a variety of controlled substances based on the weight of the drug used in the offense.[177]

The 1986 ADAA mandatory minimum sentence guidelines dramatically increased the length of time served by federal drug offenders and apply to all scheduled narcotics.[178] Crack cocaine offenses, however, received the most severe penalties. In fact, the quantity threshold for crack cocaine that triggered a 5 and 10-year mandatory minimum sentence was substantially lower than for even powder cocaine.[179] This is so notwithstanding that there is no difference between crack and powder cocaine other than the way each drug is administered.[180] According to the notorious 100:1 ratio between powder and crack cocaine sentencing,

---

marijuana for personal use to be treated as a civil infraction resulting in no arrest and no criminal record); *see also* National Organization for Reform of Marijuana Laws, Marijuana Decriminalization & Its Impact on Use, Feb. 27, 2010, http://norml.org/index.cfm?Group_ID=3383. Thirteen states — Alaska, California, Colorado, Hawaii, Maine, Maryland, Montana, Nevada, New Mexico, Oregon, Rhode Island, Vermont and Washington—have legalized marijuana for medicinal purposes with a physician's approval. *See* COLO. CONST. art. XVIII § 14 (2001); NEV. CONST. art. IV, § 38 (West 2001); ALASKA STAT. §§ 11.71.010–17.37.090 (2000); CAL. HEALTH & SAFETY CODE § 11362.5 (West 2005); HAW. REV. STAT. §§ 329-121–329-127 (2003); ME. REV. STAT. ANN. tit. 22, § 2383-B (2003); MD. CODE ANN., CRIM. LAW § 5-601(c)(3)(i) (West 2002); ORE. REV. STAT. § 475.300 (2001); VT. STAT. ANN. tit. 18, § 4473(a); WASH. REV. CODE ANN. §§ 69.51.010–69.51.080 (West 2003); THE DRUG POLICY FORUM OF HAWAII, THE MEDICAL USE OF MARIJUANA: A GUIDE TO HAWAII'S LAW FOR PHYSICIANS, PATIENTS AND CAREGIVERS, 1, 1 (2001), *available at* http://dpfhi.org/docs/mmjbooklet.pdf; Drug Policy Alliance Network, Medical Marijuana, http://www.drugpolicy.org/marijuana/medical/ (last visited Mar. 24, 2010). However, in a pair of decisions addressing California's medical marijuana law, the U.S. Supreme Court ruled that the Controlled Substances Act preempts state marijuana laws regarding manufacture and distribution by cannabis clubs and local cultivation and use. *See* Gonzalez v. Raich, 545 U.S. 1, 30-33 (2005); United States v. Oakland Cannabis Buyers' Cooperative, 532 U.S. 483, 490 (2001).

176 *See generally* note 4 and accompanying text (discussing disparate penalties between crack and other forms of cocaine).

177 *See* Anti-Drug Abuse Act of 1986, Pub. L. No. 99-570, 100 Stat. 3207 (1986).

178 *See id.*

179 *Id.*

180 *See* U.S. SENTENCING COMM'N, SPECIAL REPORT TO THE CONGRESS: COCAINE AND FEDERAL SENTENCING POLICY viii (2002) [hereinafter COCAINE AND FEDERAL SENTENCING POLICY].

in order for a powder cocaine dealer to receive the same prison sentence as someone who sold small quantities of crack cocaine, the powder cocaine dealer would have to sell 100 times what the crack dealer sold. As a result, in order to receive the mandatory ten-year trafficking sentence, one would have to sell either fifty grams of crack or over 5,000 grams of powder cocaine. Congress further expanded the disparity between powder and crack cocaine when it passed the Controlled Substances Act, which created mandatory minimum penalties for simple possession of a controlled substance and, once again, distinguished crack from powder cocaine and other narcotics.[181]

Congress imposed the 100:1 ratio for crack *vis à vis* powder cocaine during a period of pervasive, racially-tinged media reports linking crack with gang violence, high rates of addiction, prostitution, child neglect and "crack babies" flooding urban hospitals.[182] Such allegations captured the public's attention and inspired a moral panic, which allowed legislators to substantiate the incendiary media reports conflating issues of poverty, race, drugs, and crime by passing legislation based on little scientific or medical evidence.[183] Indeed, the 1986 ADAA bypassed committee and sped through Congress, which relied upon little empirical data on cocaine in promulgating the Act and engaged in virtually no debate.[184]

Although the media frenzy has quieted and the crime and alleged moral decay once attributed to crack has subsided, regulators remain unable to summon the political will to reduce the penalties attendant to a

---

181 *See* Controlled Substances Act, 21 U.S.C. § 844 (1994). According to the Controlled Substances Act, simple possession of more than five grams of crack is punishable by a minimum of five years in prison, while simple possession of any quantity of powder cocaine by a first time offender is a misdemeanor punishable by no more than one year in prison. *See id.*

182 *See* BONNIE & WHITEBREAD, THE MARIHUANA CONVICTION *supra* note 35 at 1–4.

183 *See* William Spade, Jr., *Beyond the 100:1 Ratio: Towards a Rational Cocaine Sentencing Policy*, 38 ARIZ. L. REV. 1233, 1249–50 (1996). Some legislators involved in the enactment of the 1986 ADAA have suggested that the swift passage of the little-debated Act was facilitated by the intensely strident and racially inflammatory tone of the media coverage of crack cocaine and its link to urban crime. *See id.* at 1249–50. The Sentencing Commission majority in 1995 wrote, "when the Commission began studying cocaine sentencing policy, it found that the picture of crack painted by the media bore little resemblance to the reality portrayed by scientific research on the subject." U.S. Sentencing Comm'n, Statement of the Comm'n Majority in Support of Recommended Changes in Cocaine and Federal Sentencing Policy, 7 FED. SENTENCING REP. 312 (June 1, 1995) [hereinafter 1995 Comm'n Statement].

184 At least one senator was disturbed by the rush to pass the bill. According to Senator Evans, passage of the 1986 ADAA represented "the sanctimonious election stampede of the House of Representatives, a stampede that trampled on the Constitution. In fact, at times the action over there resembled a congressional lynch mob more than it did careful legislation." 132 CONG. REC. S13741-01 (daily ed. Sept. 26, 1986) (statement of Sen. Evans). There were few hearings held in the House on increasing the penalties for crack offenses and the Senate held only one hearing on the issue, which lasted less than four hours. U.S. SENTENCING COMM'N, SPECIAL REPORT TO THE CONGRESS: COCAINE AND FEDERAL SENTENCING POLICY 9-14 (1995) [hereinafter 1995 COMM'N REPORT].

crack cocaine conviction.[185] The Regulatory Regime/Norms model indicates that this is because black people are closely associated with crack cocaine use and sale in the public imagination.[186] In 1992, at the height of the crack and powder cocaine sentencing guidelines battle, 92.6% of those convicted for federal crack cocaine offenses were black, while only 4.7% were white.[187] In comparison, during the same year, 45.2% of those sentenced for powder cocaine offenses were white, while 20.7% were black.[188] Although more whites ingest and sell crack than blacks, fewer whites are arrested, prosecuted, convicted, and incarcerated for crack cocaine offenses.[189] Indeed, in 2006, of all the federal crack cocaine defendants, 81.8% were black.[190] The race differential between crack and powder cocaine pervades every aspect of the criminal regula-

185 *See* COCAINE AND FEDERAL SENTENCING POLICY *supra* note 180, at viii. This report also notes, *inter alia*: (1) there is no difference between crack and powder cocaine other than the way they are administered; (2) the negative effects of prenatal crack cocaine exposure are identical to the negative effects of prenatal powder cocaine exposure, both of which are "significantly less severe than previously believed" and are, in fact, less damaging that the effects of prenatal tobacco or alcohol exposure; (3) the "epidemic of crack use by youth never materialized to the extent feared;" (4) crack cocaine use among students and young adults "historically has been low, particularly in relation to powder cocaine;" (5) the penalty system that associated crack with violent crime was no longer accurate and therefore lacked adequate sentencing proportionality. *See id.* at v-vii. *See also* Michael B. Cassidy, *Examining Crack Cocaine Sentence in a Post-Kimbrough World*, 42 AKRON L. REV. 105, 132–33 (2009) (discussing Congress' reluctance to fix the disparity; and that "[d]uring the 2007-2008 legislative session, six crack cocaine reform bills were introduced," but that "most of the proposed legislation appears to be at a standstill.").

186 *See* BONNIE & WHITEBREAD, *supra* note 35, at 12–13, 231, 241. *See also* Spade, *supra* note 183, at 1255.

187 *See* United States v. Clary, 846 F. Supp. 768, 786 (E.D. Mo. 1994) (citing U.S. Sentencing Commission representative sample of all drug cases received for fiscal year 1993), *rev'd*, 34 F.3d 709 (8th Cir. 1994), *cert. denied*, 513 U.S. 1182 (1995).

188 *Id.*

189 According to government data, overall drug use, abuse, and dependency rates are similar between all racial groups—with little variation between blacks and whites especially. *See* RESULTS FROM THE 2007 NAT'L SURVEY ON DRUG USE AND HEALTH, *supra* note 1, at 75. With regard to crack cocaine, however, white users significantly outnumber blacks in the latest available data. *See* Office of Applied Studies, U.S. Dep't of Health and Human Servs., 2003 Nat'l Survey on Drug Use & Health: Table 1.42a: Crack Use By Demographics (2003), http://www.oas.samhsa.gov/Nhsda/2k3tabs/Sect1peTabs1to66.htm#tab1.43a. Nevertheless, in 2006, 81.8% of federal crack cocaine offenders were black. *See* UNITED STATES SENTENCING COMM'N, REPORT TO CONGRESS: COCAINE AND FEDERAL SENTENCING POLICY 15 (2007), *available at* http://www.ussc.gov/r_congress/cocaine2007.pdf [hereinafter 2007 COMM'N REPORT]. According to another recent federal study, blacks outnumbered whites by more than four to one as suspects arrested by Drug Enforcement Administration agents on crack cocaine charges. *See* Bureau of Justice Statistics, U.S. Dep't of Justice, Federal Justice Statistics 2006–Statistical Tables: Table 1.4 (2006), http://www.ojp.usdoj.gov/bjs/pub/html/fjsst/2006/tables/fjs06st104.pdf. Black male drug offenders also have a 20% greater chance of being imprisoned than white male offenders. *See* UNITED STATES SENTENCING COMM'N, FIFTEEN YEARS OF GUIDELINES SENTENCING 122 (2004), *available at* http://www.ussc.gov/15_year/15_year_study_full.pdf.

190 *See* 2007 COMM'N REPORT, *supra* note 189, at 15.

tory regime, from arrest and prosecution to sentencing and incarceration.[191] For example, although the DEA in 2003 made almost double the number of arrests for powder cocaine as for crack cocaine, the number of defendants ultimately sentenced was nearly equal.[192]

In 1995, the U.S. Sentencing Commission—an independent bipartisan body endowed with a mandate to promulgate a system of mandatory sentencing guidelines on the appropriate form and degree of punishment for those convicted of federal crimes—concluded that "fundamental fairness" dictates that crack and powder be treated equally.[193] The Commission reiterated this determination in several subsequent reports and "strongly" recommended changing the sentencing guidelines to eliminate the sentencing differential between the drugs by raising the threshold for crack.[194] Congress responded by rejecting the Commission's propos-

---

191 *See id.* at 15–16.

192 *See* INDIANA STATE EPIDEMIOLOGY AND OUTCOMES WORKGROUP, THE CONSUMPTION AND CONSEQUENCES OF ALCOHOL, TOBACCO, AND DRUGS IN INDIANA: A STATE EPIDEMIOLOGICAL PROFILE 89 (2006), *available at* http://www.policyarchive.org/handle/10207/bitstreams/120.pdf. Moreover, between October 1, 2001 and September 30, 2002, there were 7,261 arrests for powder cocaine and 4,400 arrests for crack cocaine. BUREAU OF JUSTICE STATISTICS, U.S. DEP'T OF JUSTICE, COMPENDIUM OF FEDERAL JUSTICE STATISTICS 18 (2002), *available at* http://www.ojp.usdoj.gov/bjs/pub/pdf/cfjs0201.pdf.

193 *See* 1995 COMM'N REPORT, *supra* note 184, at xiv ("Given the Sentencing Reform Act of 1984, the most efficient and effective way for Congress to direct cocaine sentencing policy is through the established process of sentencing guidelines, rather than relying solely on statutory distinction between the two forms of the same drug."). The Commission concluded, "we were unable to establish that these social problems [attendant to crack use] result from the drug itself rather than from the disadvantaged social and economic environment in which the drug often is used. We note that these problems are not unique to crack cocaine, but are associated to some extent with abuse of any drug or alcohol." 1995 Comm'n Statement, *supra* note 183, at 316. The Commission stated further that it did not believe "that longer punishment can be justified solely because a particular form of a drug is more likely to be used by a disadvantaged population." *Id.* Thus, in 1995, the Commission approved amendments to the guidelines equalizing the guideline's treatment of powder and crack cocaine and recommended that Congress do the same with the statutory minimum. *Id.* at 317.

194 *See* 1995 COMM'N REPORT, *supra* note 184, at 198 ("The commission strongly recommends against a 100-to-1 quantity ratio."). *See also* 2002 COMM'N REPORT, *supra* note 180, at viii ("[T]he Commission again unanimously and firmly concludes that the various congressional objectives can be achieved more effectively by decreasing substantially the 100-to-1 drug quantity ratio."). In its April 1997 report, the Commission concluded that the 100:1 ratio was unjustifiable, noting that all cocaine is initially distributed in powder form and is only later processed into crack. U.S. SENTENCING COMM'N, SPECIAL REPORT TO THE CONGRESS: COCAINE AND FEDERAL SENTENCING POLICY 5 (1997) [hereinafter 1997 COMM'N REPORT]. The Commission proposed equalizing the penalties for simple possession of crack and powder cocaine. *Id.* at 10. It also recommended that the five-year mandatory minimum sentence threshold be raised for crack and lowered for cocaine. *Id.* at 2. Citing evidence that the current five gram threshold disproportionately targeted low-level street dealers, *id.* at 5, the Commission proposed raising the five-year mandatory minimum sentence threshold for crack from five grams to 25–75 grams and recommended lowering the threshold for powder cocaine from 500 grams to 125–375 grams. *Id.* at 2. Thus, the 100:1 ratio between powder and crack cocaine would approximately be replaced with a 5:1 ratio. The Commission reasoned that: (1) the sentencing guidelines already provide substantial penalties for aggravating factors attend-

als—for the first time since the guidelines were enacted—and stipulated that any future proposal to modify the sentencing guidelines must not give equal treatment to offenses involving equal quantities of crack and powder cocaine.[195]

Despite recent moves by the U.S. Supreme Court and the federal Sentencing Commission to equalize the treatment of crack and powder cocaine, Congress has yet to act.[196] Only Congress has the ultimate authority to amend the sentencing disparity in the 1986 ADAA, which mandates punishing crack cocaine offenses 100 times more severely than those for powder cocaine, and so far, it has refused to do so.[197] The Regulatory Regime/Norms model makes clear that so long as the sale and use of crack cocaine remain popularly associated with poor African-Americans, the drug will stay in the criminal regime.

CONCLUSION: MOVING FORWARD

This Article addresses fundamental questions that previous scholarship has neglected: how regulators are able to treat drugs differently irrespective of the dangers they may pose, and the processes followed to

---

ant to trafficking in powder cocaine, *id.* at 6; (2) crack and powder cocaine have the same active ingredient and produce the same physiological and psychotropic effect, 2002 COMM'N REPORT, *supra* note 180, at v; (3) the addictive potential of the various forms of cocaine were based on the methods of administration and not anything intrinsic to the drug, 1997 COMM'N REPORT, *supra*, at 4; and (4) that punishing low-level crack dealers as opposed to the more sophisticated and powerful wholesale distributors of powder cocaine from which crack is derived was unfair and inconsistent with the underlying goals of the criminal justice system, *id.* at 5. The Commission further noted that most drug dealers traffic in multiple drugs and that crack cocaine distributions frequently involve powder cocaine as well. 1995 Comm'n Statement, *supra* note 183, at 317. The Commission suggested that imposing higher penalties for crack "ignores the realty of these polydrug distributions and the risks associated with the other drugs present in a 'crack cocaine' distribution." *Id.*

195 *See* Steven L. Chanenson & Douglas A. Berman, *Federal Cocaine Sentencing in Transition*, 19 FED. SENTENCING REP. 291, 292 (2007), *available at* http://sentencing.typepad.com/sentencing_law_and_policy/files/crack_ed_obs_fsr19.5.pdf. *See also Sentencing Comm'n Again Seeks Input on Sentences for Crack, Money Laundering*, 58 CRIM. L. REP. 1319, 1320 (1996).

196 *See* 2007 COMM'N REPORT, *supra* note 189, at 1. In two 2007 decisions, the U.S. Supreme Court ruled that federal judges have broad discretion to set aside the federal sentencing guidelines to impose sentences based on their assessment of a particular offense and defendant. Harry Sandick, Gall *and* Kimbrough *and Their Relevance to Sentencing in White-Collar Cases*, 20 FED. SENTENCING REP. 159, 159 (2008) (citing Gall v. United States, 552 U.S. 38 (2007) and Kimbrough v. United States, 552 U.S. 85 (2007)). Both cases involved trial court judges whose decisions were overturned on appeal after they imposed sentences lighter than those recommended by the guidelines. *See* Kimbrough v. United States, 552 U.S. 85, 110-11 (2007); Gall v. United States, 552 U.S. 38, 59-60 (2007). The following day, the Sentencing Commission voted unanimously to decrease, retroactively, the sentences for crack cocaine offenses, thereby reducing the 100:1 ratio. Press Release, U.S. Sentencing Comm'n, U.S. Sentencing Comm'n Votes Unanimously to Apply Amendment Retroactively for Crack Cocaine Offenses (Dec. 11, 2007), *available at* http://www.ussc.gov/PRESS/rel121107.htm.

197 *See* Cassidy, *supra* note 185, at 132.

achieve this phenomenon. It offers a conceptual framework that explains how drug regulators segue from the default position of deferring to personal choice and market forces, to regulation, criminalization and prohibition, without relying upon scientific or medical evidence regarding the pharmacological properties of the drug. This framework is then applied to the regulation of four common pharmaceutical, illicit, and over-the-counter drugs: cocaine, marijuana, tobacco, and anabolic steroids.

As this Article demonstrates, the pharmacological effect of a drug does not necessarily determine how it will be governed. Rather, it is the way a drug is framed that determines how the drug will be popularly understood and ultimately regulated. According to the Regulatory Regime/Norms model, the meaning of any drug (how it is perceived or understood) is initially ambiguous and indeterminate. As a result, the project of getting a drug into a particular regulatory regime is about allocating specific meaning and significance to the drug in order to prompt individuals to think and feel about the drug in a way that allows for regime placement. This is accomplished by framing a drug to match the norms of a particular regime. Thus, the critical work at the level of regulation is in the framing.

Framing battles are ongoing since the meaning of a drug is always open to contest and debate. This study demonstrates, for example, that it is not uncommon for the same drug to be signified over time in many, often conflicting, ways. "Reefer-madness," "killer-weed," and "medical-marijuana," all refer to the same drug—marijuana, but it has been framed differently to conform to the specific norms of two distinct regimes. Similarly, tobacco began as a drug with little significance and was subsequently framed unsuccessfully as a moral hazard, then, quite persuasively, as a symbol of freedom and independence, and is now characterized as a public health menace.

Once a group has convincingly framed a drug in a way that resonates with the norms of its regime of choice, then the drug may be placed in that regime, regardless of whether the designation decision is supported by scientific or medical evidence. As we have seen with cocaine, marijuana, and anabolic steroids, however, if a drug in the criminal regulatory regime is closely associated with socially maligned groups or racial minorities, then it is substantially more difficult for the drug to eventually migrate out of the regime.

The framing process is not always straight-forward and uncomplicated. This is particularly evident when we look at the role of the individual within the groups that engage in these framing battles. I posit that most, if not all, individuals within the groups that compete to control the meaning of drugs know in advance what they would like the drug to mean, which is to say, how they would like the drug to be regulated.

Indeed, their common understanding of the drug's meaning is what drew them to the group in the first instance and what motivates them to coordinate and endeavor to shape the meaning of the drug. These individuals, however, may or may not be fully aware of the framing process: the explicit framing of a particular drug to match the norms of a particular regime. For example, as I have demonstrated, corporate actors realize the power and efficacy of framing a drug to fit the norms of the market regime and know all too well how to achieve that regime placement.[198] The same may be said of at least some individuals who join groups that aim to criminalize drugs or that seek to ensure public health regulation of drugs.[199]

Other individuals, however, may not be explicitly aware of an individual regime's norms or governing principles. For instance, some advocates who oppose either the legalization or criminalization of a certain drug may not realize that stressing disclosure principles will significantly increase the likelihood that the drug will be subject to public health regulation. While these same individuals most likely expect disclosure from public health entities and understand that moral norms play a significant role in the criminal regime, they may be unable able to explicitly articulate those norms or governing principles in relation to the role they play in drug regulation. In this way, the framing process can be messy and chaotic, but this dynamic is what also allows the efforts of those who consciously participate in the framing process to often go unnoticed on a broader social level.

The Regulatory Regime/Norms theory is a testable model that has important normative implications for policymakers and lawmakers. By revealing the way drugs are placed in regulatory regimes, this model helps us see clearly how and why the current U.S. system of drug regulation is so inconsistent and seemingly incoherent, which is the first step towards devising appropriate policy solutions and a more transparent and principled system of drug control. Indeed, although drug regulatory processes are not value-neutral and therefore cannot be completely insulated from politics, an understanding of the role of framing in these processes can help guard against the distortion of drug regulation by misinformation, bad science, or racial prejudice.

This Article exposes and explains the process through which drug regulatory decisions are made, which is critically important as the ultimate placement of a drug in a regime has wide-reaching material consequences for those who are regulated and the corporate entities, private reformers and government actors who compete to have a drug assigned to one regime over another. For example, billions of dollars were at

198 See *infra* Part III.B.

199 See *infra* Part III.A.

stake for tobacco manufacturers as they struggled to characterize their drug in a way that would keep it from shifting from the market regime into the public health regime. Similarly, even though many drugs are relegated to the criminal regime based on little or no empirical evidence, this regime placement has substantial, real-world ramifications for those convicted of a felony drug offense, who face not only the possibility of a long prison term, but may be denied the right to vote, removed from public housing and denied eligibility for federal entitlements, such as public assistance benefits, student loans and food stamps.

The theory advanced in this Article also has implications for activists seeking to effect legal change with respect to drugs. To the extent that framing influences popular attitudes towards drugs and drug use, activists would be wise to place less emphasis on lobbying legislators and policymakers by relying upon scientific data on drugs, and instead place greater emphasis on framing the issue in a way that matches the norms of the regime they prefer, and then spreading their message directly to citizens in order to shape public understanding of the drug. Indeed, according to the Regulatory Regime/Norms model, science can be brought to bear on the meaning of drugs and it can influence how the drug will be regulated, but its influence is not dispositive. Science is but one resource in the commercial, cultural, and political battle over meaning. Thus, those who seek to change the regulatory status of a particular drug should focus on the framing in conjunction with proving the validity of their scientific evidence.

The Regulatory Regime/Norms model also holds substantial significance for the study of drug regulation. By identifying the framing process and the specific norms and principles that structure each regime, the Regulatory Regime/Norms model suggests not only how different substances are conceived of and structured as open to regulation, but it also helps us see more clearly the aims and concerns of the public and private entities that engage in these drug placement contests. Thus, the model provides a useful analytical lens with which to investigate the fluidity, multidimensionality, and ubiquity of state and private efforts to govern drug use, and it illuminates the operation of power in contemporary drug regulation.

This Article is but a point of departure as I intend to continue investigating regulatory regimes generally, and drug regulatory regimes specifically, including applying the Regulatory Regime/Norms model to additional drugs. Through the Regulatory Regime/Norms framework, I seek to inspire a re-imagining of the way social, political, and economic power can and should be exercised in and through regulatory regimes. It is my hope that this Article invites further research into drug regulation as a specific and penetrating mode of governance.