

# A DEMOCRACY DEFICIT WITHIN AMERICAN DRUG POLICY

O. HAYDEN GRIFFIN, III\*

## ABSTRACT

Democracy deficits exist when citizens are not effectively allowed input or cannot help create legislation or policy. As societies have modernized, the concept of democratic deficits has become more important due to the growing influence of administrative law. Traditionally, within American society, legislation is not created unless a legislature passes a law and an executive signs that law. However, the increasing complexities of society have caused legislatures to empower various bureaucratic agencies with the continually growing ability to make binding administrative law. Typically, administrative laws are decisions that should be made by experts within a respective issue area, and violations of these rules are usually monetary fines or orders to cease a certain activity. Within American drug policy, while regulatory agencies are not only allowed to make administrative law, these agencies are also able to make rulings that carry criminal penalties. It is argued that these actions represent democracy deficits.

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\* O. Hayden Griffin, III, Assistant Professor of Criminal Justice, University of Alabama at Birmingham. PhD. Criminology, Law & Society, 2011, University of Florida. JD, 2001, The T.C. Williams School of Law, University of Richmond.

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I. INTRODUCTION

In the American legal system, law is typically divided into four categories: administrative law, common law, procedural law, and statutory law. These different types of law are important for the formation and maintenance of the American legal system. Based on the principles of legality and due process, before a person can be convicted of a crime in the United States, there must be a valid law, which states both the offense to be regulated and the punishment for that crime if a person is found guilty.<sup>1</sup> In early America, many criminal offenses came from the common law and over the years, have mostly been codified into criminal statutes.<sup>2</sup> After the decision in *Marbury v. Madison*, the Supreme Court empowered itself with the ability to engage in judicial review, which definitively established the ability of the judicial system to develop procedural law (some refer to procedural law as case law).<sup>3</sup>

Administrative law, also known as agency law, has not traditionally been a substantial part of American criminal law.<sup>4</sup> Generally, administrative law has been created by government agencies when establishing legal standards that require a great deal of expertise, such as what levels factories are allowed to pollute the air or the proper disposal standards for industrial waste.<sup>5</sup> Penalties for corporations or people who violate these administrative provisions are almost exclusively civil in nature and typically result in punishments of monetary fines, shutting down the corporation, or prohibiting corporations or people from engaging in these noxious behaviors.<sup>6</sup> Perhaps the major reason that administrative law, unlike criminal law, does not usually include the punishment of

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<sup>1</sup> Edward L. Rubin, *Due Process and the Administrative State*, 72 CALIF. L. REV. 1044 (1984).

<sup>2</sup> Paul H. Robinson & Jane A. Grall, *Element Analysis in Defining Criminal Liability: The Model Penal Code and Beyond*, 35 STAN. L. REV. 681 (1983).

<sup>3</sup> *Marbury v. Madison*, 5 U.S. 137 (1803).

<sup>4</sup> See Dean John Champion, Richard D. Hartley, Gary A. Rabe, *CRIMINAL COURTS: STRUCTURE, PROCESS, AND ISSUES* 10 (2006).

<sup>5</sup> *Id.*

<sup>6</sup> *Id.*

incarceration is that the legal standards are not created through a democratic process that would comply with traditional notions of the principles of legality and due process.

While most areas of policy seem to follow this model, within drug policy, the distinction between criminal law and administrative law seems to have become blurred. In particular, with the passage of the Controlled Substances Act of 1970 (“CSA”)<sup>7</sup> and several amendments to this omnibus bill, the ultimate authority for many aspects of American federal drug policy have become vested within the Drug Enforcement Administration (“DEA”).<sup>8</sup> In many instances, the authority comes with little practical oversight.<sup>9</sup> Some scholars have argued that the increasing bureaucratization of governments, as well as other factors, has led to democratic deficits, where citizens are either disengaged from the political process, or in some instances, effectively blocked from participation in creating or voting on policy.<sup>10</sup> Many aspects of the current federal regulation of drug policy constitute a democratic deficit. This is important not only because the democratic process is not being honored, but also because it hinders the ability of state governments to consider various reforms to drug policies. This in turn minimizes the ability of states to serve as “laboratories of democracy” in which new policies and policy changes can be implemented.

## II. DEMOCRACY DEFICITS

How much power any one person has in shaping law and governance is an omnipresent issue within society. For instance, even though the United States is often referred to as a democracy, the nation is actually governed as a republic. Voters elect legislators who create legislative bills, and then a chief executive has some degree of oversight as to whether these legislative bills become law. As Maddox notes, to many people, a republic is a better form of government than democracy, due to the hope that pragmatic legislators (at least compared to the general citizenry) will not govern according to kneejerk reactions or otherwise confirm Plato’s

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<sup>7</sup> Comprehensive Drug Abuse Prevention and Control Act of 1970, ch. 91-513, 84 Stat. 1242 (1970).

<sup>8</sup> See Michael M. O’Hear, *Federalism and Drug Control*, 57 VAND. L. REV. 783 (2004).

<sup>9</sup> *Id.*

<sup>10</sup> See generally Tina Nabatchi, *Addressing the Citizenship and Democratic Deficits: The Potential of Deliberative Democracy for Public Administration*, 40 AM. REV. PUB. ADMIN. 376 (2010); Andreas Follesdal & Simon Hix, *Why There is a Democratic Deficit in the EU: A Response to Majone and Moravcsik*, 44 JCMS: J. COMMON MARKET STUD. 533 (2006).

assessment of direct democracy as “mob rule.”<sup>11</sup> One exception to the traditional legislative process, which perhaps illustrates a yearning from some Americans to have a form of government more akin to direct democracy, is the ballot initiative process through which citizens can vote on legislation directly.<sup>12</sup> In some instances, controversial legislation is more likely to be passed by ballot initiative, since legislators may be less willing to support controversial proposals, fearing that their vote on a controversial bill might come back to haunt them when they later run for reelection.<sup>13</sup> It seems more than a coincidence that all eight states that have so far voted to legalize the recreational sale of marijuana (California, Colorado, Nevada, Maine, Massachusetts, Washington, Alaska, and Oregon) did so by ballot initiative.<sup>14</sup>

One recurring criticism within the United States is a lack of participation among citizens in the democratic process, particularly, low rates of voter turnout. While some people might chalk up low rates of voter turnout to simple apathy, some scholars see a bigger problem and believe this might be a harbinger of something worse, perhaps even the eroding of American society itself. One term that was developed to describe this process is “citizenship deficit.”<sup>15</sup> A similar concept to a citizenship deficit is a “democratic deficit.”<sup>16</sup> Essentially, a democratic deficit occurs when democratic governments and institutions within those governments fail to live up to the principles and practices of democracy.<sup>17</sup> At a basic level, a democracy deficit can occur if citizens believe they have no effect or say in the democratic process.<sup>18</sup>

A democracy deficit can manifest in various ways. Some scholars have argued that the European Union has usurped the sovereignty of

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<sup>11</sup> See Graham Maddox, *Republic or Democracy?*, 28 *POLITICS* 9, 15 (1993).

<sup>12</sup> See generally Mark A. Smith, *The Contingent Effects of Ballot Initiatives and Candidate Races on Turnout*, 45 *AM. J. OF POL. SCI.* 700 (2001); Mark A. Smith, *Ballot Initiatives and the Democratic Citizen*, 64 *J. OF POL.* 892 (2002); Caroline J. Tolbert, et al., *The Effects of Ballot Initiatives on Voter Turnout in the American States*, 29 *AM. POL. RESEARCH* 625 (2001).

<sup>13</sup> See generally Shaun Bowler, et al., *Ballot Propositions and Information Costs: Direct Democracy and the Fatigued Voter*, 45 *W. POL. Q.* 559 (1992); Daniel A. Smith & Caroline J. Tolbert, *The Initiative to Party Partisanship and Ballot Initiatives in California*, 7 *PARTY POL.* 739 (2001).

<sup>14</sup> Melia Robinson, *It's 2017: Here's Where You Can Legally Smoke Weed Now*, *Business Insider*, (Jan. 8, 2017), <http://www.businessinsider.com/where-can-you-legally-smoke-weed-2017-1>.

<sup>15</sup> Nabatchi, *supra* note 10, at 378.

<sup>16</sup> *Id.*

<sup>17</sup> *Id.*

<sup>18</sup> *Id.*

member countries so that individual countries have no effective say in how they are being governed.<sup>19</sup> Some comparison can be made between the situation with the European Union and the United States, either due to the Supremacy Clause of the United States Constitution, which often makes the individual states subservient to the federal government or the actual republican form of government itself.<sup>20</sup> However, perhaps the best example is the growing authority of administrative bureaucracies within the United States. For instance, Durant describes how the disconnect between average lay citizens and the Environmental Protection Agency (EPA) is best illustrative of a democracy deficit in the United States. Environmental activists often argue that the EPA is too slow to act when environmental harms or disasters occur, and that the agency often waits until there is overwhelming proof of such incidents.<sup>21</sup> As Nabatchi argues, citizenship deficits are not only damaging due to the lack of participation in the democratic process, but those who chose not to participate (and others) may consider high levels of voter apathy as a sign that the democratic process is illegitimate.<sup>22</sup> In the case of democratic deficits, if people do not believe they have either an effective say in government or a way to affect the process, this can lead citizens to cease participating in the process.<sup>23</sup> Essentially, citizenship and democratic deficits can be self-reinforcing.<sup>24</sup>

While low voter turnout and citizen dissatisfaction are reasons enough to be concerned with citizenship and democracy deficits, one issue perhaps looms larger. Many scholars have noted that the legitimacy of the law is important, not just so citizens believe that law is valid, but also because research has consistently found that people who either believe that a law or its process of enforcement is illegitimate are more likely to criminally offend. For instance, Tom Tyler has repeatedly argued that the legitimacy of the law is more important than the feared punishment that corresponds with violating a criminal statute.<sup>25</sup> Likewise, criminal laws must be passed legitimately and democratically not only to fulfill technical and legal requirements and the demands of due process, but also to ensure

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<sup>19</sup> See generally Follesdal, *supra* note 10.

<sup>20</sup> *Id.*

<sup>21</sup> Robert F. Durant, *The Democratic Deficit in America*, 100 POL. SCI. Q. 25, 30 (1995).

<sup>22</sup> Nabatchi, *supra* note 15, at 380.

<sup>23</sup> *Id.*

<sup>24</sup> *Id.*

<sup>25</sup> See generally TOM R. TYLER, *WHY PEOPLE OBEY THE LAW* (2006) (arguing that lawmakers are better off creating legitimate criminal systems worthy of respect rather than laws focused solely on deterrence through fear.).

that citizens perceive laws as being legitimate.<sup>26</sup>

### III. THE CREATION OF FEDERAL DRUG POLICY

Despite the continual growth and breadth of federal legislation, even today, most criminal prosecutions occur at the state level and involve the violations of state laws.<sup>27</sup> While the Supremacy Clause of the United States Constitution has always placed the Constitution and federal legislation superior state law, until the twentieth century, this typically only involved decisions surrounding the constitutionality of state legislation.<sup>28</sup> However, beginning in the twentieth century, the federal government began to more heavily involve itself in the creation of criminal statutes and the enforcement of criminal law.<sup>29</sup> For the most part, the federal government has left the prosecution of more traditional common law and statutory crimes to the states, such as criminal homicide, various forms of theft, and sexual assault.<sup>30</sup> However, the federal government has created a significantly growing number of federal crimes involving federal taxation, securities fraud, a plethora of regulatory crimes, and drug policy.<sup>31</sup>

### IV. DRUG SAFETY

The first federal drug statute was the Drug Importation Act of 1848.<sup>32</sup> During the Mexican-American War (1846-1848), disease ran rampant among American soldiers and was responsible for more deaths than combat.<sup>33</sup> Few effective medicinal treatments existed for the ailments that the afflicted soldiers suffered, and the few medications that were available were mostly diluted or impure.<sup>34</sup> After the ensuing scandal, Congress passed the Drug Importation Act, which required that all drugs that were imported into the United States be inspected for both purity and quality.<sup>35</sup> Ultimately, the law was not effective due to a failure to establish standards

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<sup>26</sup> *Id.*

<sup>27</sup> LAWRENCE FRIEDMAN, CRIME AND PUNISHMENT IN AMERICAN HISTORY 261 (1994).

<sup>28</sup> *Id.*

<sup>29</sup> *Id.*

<sup>30</sup> *Id.*

<sup>31</sup> *Id.*

<sup>32</sup> FRAN HAWTHORNE, INSIDE THE FDA: THE BUSINESS AND POLITICS BEHIND THE DRUGS WE TAKE AND THE FOOD WE EAT 37-38 (2010).

<sup>33</sup> *Id.*

<sup>34</sup> *Id.*

<sup>35</sup> *Id.*

for each criterion (dilution or impurities) and customs officials, who were supposed to enforce the law, were not provided training to conduct these inspections.<sup>36</sup> To some, the legislation might not be worth mentioning; however, the 1848 Drug Importation Act was important for two reasons.<sup>37</sup> First, it was a typical use of federal power at the time—Congress passed a law in support of its customary federal duty in regulating the borders of the United States.<sup>38</sup> Second, the ultimate failure of the legislation was due to Congress lacking the sufficient technical knowledge to set applicable standards regarding the regulation of drugs.<sup>39</sup> This failure became one of the primary motivations in the creation of future federal regulatory statutes involving drug regulation.

In general, the federal government has regulated drugs for two reasons: public safety and potential for abuse. The first purpose is indicative of the rationale for the creation of the Drug Importation Act of 1848, but would not be addressed again until the Pure Food and Drug Act of 1906.<sup>40</sup> Although the Pure Food and Drug Act of 1906 targeted many of the horrors of American food processing, which had been documented by Upton Sinclair in *The Jungle*, the Act was also targeted at the patent medicine industry.<sup>41</sup> Patent medicines were drug products that included written promises to a variety of curative effects and were referred to as “patent” so that the manufacturers of these products could keep their formulations a secret.<sup>42</sup> While there may not seem anything especially nefarious about a company wanting to protect trade secrets, this was not the motivation behind the secrecy of the formulations of patent medicines.<sup>43</sup> For the most part, these medicines did nothing to combat the symptoms of most illnesses because patent medicines routinely contained various combinations of alcohol, cocaine, and opiates.<sup>44</sup> If people had known that they were ingesting these types of substances, they would have perhaps been less likely to have purchased or used these “medicines.” The Pure

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<sup>36</sup> *Id.*

<sup>37</sup> *Id.*

<sup>38</sup> HAWTHORNE, *supra* note 32.

<sup>39</sup> *Id.*

<sup>40</sup> PAUL M GAHLINGER, *ILLEGAL DRUGS: A COMPLETE GUIDE TO THEIR HISTORY, CHEMISTRY, USE AND ABUSE* 58 (2004).

<sup>41</sup> *Id.*

<sup>42</sup> See generally Robert P Fischelis, *What is a Patent or Proprietary Medicine?*, 46 SCI. MONTHLY 25 (1938).

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

<sup>44</sup> *Id.*

Food and Drug Act did not actually outlaw any product; rather, the legislation merely required that foods and drugs have their ingredients labeled.<sup>45</sup> This became clear in *United States v. Johnson*, when the Supreme Court ruled that selling bottles of medicine that falsely claimed the product was effective in curing cancer did not violate the Pure Food and Drug Act.<sup>46</sup> According to the Court, to avoid a charge of “mislabeling” a product under the Act, a manufacturer was only required to ensure that all ingredients were labeled.<sup>47</sup> The law did not address claims of effectiveness.<sup>48</sup> However, only one year later, Congress passed the Sherley Amendment to the Pure Food and Drug Act, which expanded the definition of misbranding to include false promises regarding the curative effects or therapeutic benefits of medications.<sup>49</sup>

While today’s society might take for granted that laws require manufacturers to tell consumers exactly what they are ingesting, the Pure Food and Drug Act was not passed on a whim.<sup>50</sup> As Edwin Sutherland noted, 140 pure food and drug bills had been introduced in the thirty years before the ultimate passage of the legislation in 1906.<sup>51</sup> The failure of these bills was largely a testament to the lobbying power of the pharmaceutical industry.<sup>52</sup> However, merely advising people what they are taking is a minor step compared to actually informing the public as to whether what they are taking is actually safe. As much as the pharmaceutical industry fought the Pure Food and Drug Act, the industry was not eager for new regulatory restrictions or obligations. It would take two tragedies before a regulatory system would emerge that added new protections for consumers.

## V. THE TRAGEDIES

The drug Sulfanilamide was first synthesized in 1908 and had been proven beneficial to treat bacterial infections.<sup>53</sup> The common route of

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<sup>45</sup> ERICH GOODE, *DRUGS IN AMERICAN SOCIETY* (8th 2011).

<sup>46</sup> *United States v. Johnson*, 221 U.S. 488 (1911).

<sup>47</sup> *Id.*

<sup>48</sup> GOODE, *supra* note 45.

<sup>49</sup> O. Hayden Griffin, III, *The Role of the United States Supreme Court in Shaping Federal Drug Policy*, 39 AM. J. CRIM. JUST. 660, 661-62 (2014).

<sup>50</sup> See Edwin H Sutherland, *White-Collar Criminality*, 5 AM. SOCIOLOGICAL REV. 1, 8 (1940).

<sup>51</sup> *Id.*

<sup>52</sup> *Id.*

<sup>53</sup> Carol Ballentine, *Taste of Raspberries, Taste of Death: The 1937 Elixir Sulfanilamide Incident*, 15 FDA CONSUMER MAGAZINE 18, 18-19 (1981).



administration for the medication was by either capsule or tablet form.<sup>54</sup> However, S.E. Massengill, the manufacturer of the medication, wanted to manufacture Sulfanilamide in a liquid form as well.<sup>55</sup> To create a liquid form of Sulfanilamide, diethylene glycol was added since the compound was a useful solvent and moistening agent.<sup>56</sup> This seemed a somewhat odd choice for human consumption considering diethylene glycol was used for the production of resins, explosives, and antifreeze.<sup>57</sup> As a means to offset the unappealing taste of the new concoction, which was called Elixir Sulfanilamide, raspberry extract was added to improve the flavor of the new medication.<sup>58</sup> Diethylene glycol had never been proven safe for human consumption and up to that time, had not been permitted in food production.<sup>59</sup> Within the mere four weeks that Elixir Sulfanilamide was available, it became clear why diethylene glycol had been unavailable for human consumption; of the 353 patients who received the medication, 105 died and thirty-four of those were children.<sup>60</sup>

In the wake of the Elixir Sulfanilamide debacle, Congress passed the Food, Drug and Cosmetic Act of 1938.<sup>61</sup> Afterwards, before a pharmaceutical company could sell drugs to American consumers, the company had to file a new drug application (“NDA”) with the newly created government agency the Food and Drug Administration (“FDA”).<sup>62</sup> Within the application, the pharmaceutical company was required to demonstrate that the drug was safe for human consumption.<sup>63</sup> Congress based its authority to pass the law on its constitutional authority to regulate interstate commerce.<sup>64</sup> The Kefauver-Harris Amendments, enacted in 1962, required that drugs be safe for human consumption and that the drugs be proven effective in human clinical trials for the treatment of the specific ailments that the pharmaceutical companies advertised.<sup>65</sup> Additionally,

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<sup>54</sup> *Id.*

<sup>55</sup> *Id.*

<sup>56</sup> *Id.*

<sup>57</sup> *Id.*

<sup>58</sup> *Id.*

<sup>59</sup> Ballentine, *supra* note 59.

<sup>60</sup> Paul M. Wax, *Elixirs, Diluents, and the Passage of the 1938 Federal Food, Drug and Cosmetic Act*, 122 ANNALS INTERNAL MED. 456, 456 (1995).

<sup>61</sup> David F. Cavers, *The Food, Drug, and Cosmetic Act of 1938: Its Legislative History and its Substantive Provisions*, 6 L. CONTEMP. PROBS. 2, 20 (1939).

<sup>62</sup> *Id.*

<sup>63</sup> *Id.*

<sup>64</sup> *Id.*

<sup>65</sup> Wax, *supra* note 60, at 459.

the Amendments provided guidelines for animal and human trials upon which the safety and efficacy of drugs were primarily based.<sup>66</sup> Although long overdue, these new regulations were passed primarily as a response to both the high rates of birth defects in women that used the drug Thalidomide to treat their pregnancy morning sickness, as well as to the reports that Thalidomide caused peripheral neuritis.<sup>67</sup> Since Thalidomide never received FDA approval, only a few children in the United States were born with Thalidomide induced birth defects.<sup>68</sup> However, there were over 8,000 cases of children born with Thalidomide induced birth defects in other countries where there was no government approval agency.<sup>69</sup> Furthermore, the drug most likely caused countless miscarriages, but went undiagnosed due to the lack of awareness that Thalidomide could cause miscarriages.<sup>70</sup>

The current drug regulatory system within the United States is not without problems. Many people have noted the presence of drug recalls and question whether the FDA exercises enough oversight on drug approval for the American pharmaceutical market.<sup>71</sup> One of the problems that is often cited is that the FDA does not actually perform safety and efficacy testing.<sup>72</sup> Instead, pharmaceutical companies conduct clinical trials and present the relevant data to the FDA. The FDA has to consistently wonder if pharmaceutical companies provide all relevant data, or if in some cases, companies do not disclose all the known facts about a drug.<sup>73</sup> Yet, at the same time, some people criticize the FDA for being too cautious and not approving new drugs in a timely manner. In particular, people who are suffering from terminal illnesses have sought access to experimental medications.<sup>74</sup> Regardless, it seems that the FDA's regulatory powers to approve drugs are a legitimate vesting of power within a bureaucratic agency, and are indicative of why administrative law has been created.<sup>75</sup> While ultimately some people might bemoan the sole use of federal

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<sup>66</sup> *Id.*

<sup>67</sup> *Id.*

<sup>68</sup> *Id.*

<sup>69</sup> *Id.*

<sup>70</sup> Griffin, *supra* note 49, at 662.

<sup>71</sup> See Richard A. Deyo, *Gaps, Tensions, and Conflicts in the FDA Approval Process: Implications for Clinical Practice*, 17 J. AM. BOARD FAM. PRAC. 142 (2004).

<sup>72</sup> *Id.*

<sup>73</sup> *Id.*

<sup>74</sup> Griffin, *supra* note 49, at 663-64.

<sup>75</sup> *Id.*

authority to make these decisions, it seems like a delegation of powers by Congress that does not fit within the definition of a democratic deficit. However, the questions of what constitutes the acceptable use of drugs and whether drugs have a legitimate medical purpose after receiving FDA approval are still left unanswered.

## VI. ACCEPTABLE USE OF DRUGS

Around the same time that the United States was dealing with issues surrounding the safety of drugs, the country was also concerned with who should be permitted access to drugs. Regarding drug use in America in the 1700s and 1800s, Edward Brecher referred to the country as a “dope fiend’s paradise” where any and all substances were available without restriction.<sup>76</sup> While Brecher made a valid point, since there were no federal laws governing the use of drugs, and only a few state regulations existed, his point seems hyperbolic.<sup>77</sup> For instance, morphine was first synthesized in the early 1800s, but it was not until 1853, after the hypodermic syringe was invented, that morphine abuse really began.<sup>78</sup> Additionally, it was not until later in the century that cocaine and heroin were synthesized.<sup>79</sup> Marijuana was available in the United States, but smoking of the plant was rare until the 1900s.<sup>80</sup> Lastly, the synthetic era of medications, which saw the advent of drugs such as barbiturates and amphetamines, did not begin until the early 1900s.<sup>81</sup> Thus, while Brecher’s argument is true regarding a lack of drug regulation in America at the time, the only drugs available for most of that time were alcohol, tobacco, and opium.<sup>82</sup> While these three substances have habit-forming properties and can potentially cause great harm, this limited menu of available substances is quite different from the seemingly endless choices a drug user has today.

By the turn of the twentieth century, several states and localities enacted provisions that regulated or banned opium.<sup>83</sup> Furthermore,

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<sup>76</sup> EDWARD M. BRECHER, *LICIT AND ILLICIT DRUGS: THE CONSUMERS UNION REPORT ON NARCOTICS, STIMULANTS, DEPRESSANTS, INHALANTS, HALLUCINOGENICS, AND MARIJUANA – INCLUDING CAFFEINE, NICOTINE AND ALCOHOL* 17 (1972).

<sup>77</sup> *Id.*

<sup>78</sup> *Id.*

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

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

<sup>81</sup> GOODE, *supra* note 45, at 16.

<sup>82</sup> *Id.*

<sup>83</sup> DAVID F. MUSTO, *THE AMERICAN DISEASE: ORIGINS OF NARCOTIC CONTROL* 91 (1999).

America's continued alcohol problem resulted in alcohol prohibition in many states during the 1800s and the ultimate failed federal experiment of national alcohol prohibition that took place from 1920-1933.<sup>84</sup> Yet, it was geopolitics rather than a concern for the health and wellbeing of Americans that led to the first federal law that either regulated or prohibited the use of any drug in the United States.<sup>85</sup>

Following the Spanish-American War of 1898, America's goals of becoming a bigger global player and colonial master received some sustenance.<sup>86</sup> As part of the spoils of a victorious war, the United States gained the colony of the Philippines from Spain. After taking control of the Philippines, colonial administrators from the United States discovered that opium abuse was rampant within the colony, as well as within neighboring China.<sup>87</sup> China had sought to prohibit opium use within its border and fought two unsuccessful wars with the United Kingdom for this purpose.<sup>88</sup> In addition to aspirations of global power, the United States wanted commercial access to the Chinese market; however, the United States was not on the best of terms with China due to the frequent discrimination and persecution against Chinese immigrants in the United States.<sup>89</sup> Relationships between the two countries became so acrimonious that Chinese merchants boycotted American goods.<sup>90</sup>

In 1909, the first International Opium Commission took place in Shanghai ("Shanghai Conference"), China.<sup>91</sup> The United States hoped to lessen the animosity between China and the United States supporting restriction of the opium trade.<sup>92</sup> However, at the Shanghai Conference, the hypocrisy of the United States did not go unnoticed.<sup>93</sup> While the United States seemed vigorous in its support of regulating opium on a global scale, no American federal law existed that regulated opium.<sup>94</sup> To placate these criticisms, the United States sought quickly to enact a law regulating opium.

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<sup>84</sup> GAHLINGER, *supra* note 40, at 60-61.

<sup>85</sup> *Id.*

<sup>86</sup> GOODE, *supra* note 45, at 328-29.

<sup>87</sup> *Id.*

<sup>88</sup> *Id.*

<sup>89</sup> *Id.*

<sup>90</sup> *Id.*

<sup>91</sup> *Id.*

<sup>92</sup> GOODE, *supra* note 45, at 328-29.

<sup>93</sup> *Id.*

<sup>94</sup> *Id.*

<sup>95</sup> The barrier to creating such a regulation was that pharmaceutical lobbyists in the United States would fight any new legislation regulating drugs.<sup>96</sup> Thus, it was imperative that any proposed law avoid being overtly controversial, to appease the lobbyists, while also maintaining some sense of regulation.<sup>97</sup> As a result, in the same year of the Shanghai Conference, the United States enacted the Smoking Opium Exclusion Act.<sup>98</sup> This legislation had the sole purpose of banning only the importation of smokeable opium into the United States; it did nothing to regulate other forms of opium, which were far more habit-forming.<sup>99</sup> Additionally, it was ironic that the United States passed a law that seemed to target Chinese immigrants, who were inordinately scapegoated as smokers of opium, in their attempt to appease claims of prejudice against Chinese immigrants.<sup>100</sup> In 1910, in an effort to create a more comprehensive regulatory system, Representative David Foster of Vermont introduced the eponymous Foster Bill.<sup>101</sup> Based upon the taxing powers of the federal government, the bill would have required all distributors of opiates, cocaine, chloral hydrate, and marijuana to pay taxes and keep records of those transactions.<sup>102</sup> Ultimately, the Foster Bill was defeated in 1911 due to the pharmaceutical industry's intense lobbying efforts.<sup>103</sup>

Two years after the Shanghai Conference, the International Opium Commission reconvened in Hague, Netherlands.<sup>104</sup> Much like the Shanghai Conference, representatives from the United States again attempted to not only advocate for international controls of opium, but also for other drugs, such as heroin and cocaine.<sup>105</sup> In a seeming case of *déjà vu*, the representatives of other nations again criticized the United States for failing to have any meaningful legislation that regulated or controlled drugs within America.<sup>106</sup> In the wake of the conference at Hague, United States' efforts began anew to have a more comprehensive regulatory system of

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<sup>95</sup> *Id.*

<sup>96</sup> *Id.*

<sup>97</sup> *See id.*

<sup>98</sup> *Id.*

<sup>99</sup> GOODE, *supra* note 45, at 328-29.

<sup>100</sup> *Id.*

<sup>101</sup> MUSTO, *supra* note 83, at 40-41.

<sup>102</sup> *Id.* at 41-42.

<sup>103</sup> *Id.* at 52-53.

<sup>104</sup> *Id.*

<sup>105</sup> *Id.*

<sup>106</sup> *Id.*

drugs.<sup>107</sup> In 1912, the Foster Bill was essentially resurrected as the Harrison Bill, this time named after Representative Francis Burton Harrison of New York.<sup>108</sup> The pharmaceutical lobby still opposed the Harrison Bill, as did Southern legislators due to concerns that the legislation would usurp state rights.<sup>109</sup> Ultimately, the Harrison Narcotic Act of 1914 was passed, despite the objections of the pharmaceutical lobby, but with the temporary approval of the American Medical Association.<sup>110</sup> The final bill only regulated cocaine and opiates.<sup>111</sup> Marijuana was omitted, largely due to the perception at the time that marijuana use was not a significant problem.<sup>112</sup>

The Harrison Narcotic Act was novel for three primary reasons. First, it established a basic regulatory framework for drugs. Second, it firmly established a medical criterion for the legal use of drugs: a medical prescription was required for legal consumption of opiates or cocaine. Third, its implementation essentially began the war on drugs.

Although initially based on the taxing power of the United States, the Supreme Court ruled in 1919 that drug users, physicians, or anyone else who illegally dispensed drugs could be criminally prosecuted under the Harrison Narcotic Act.<sup>113</sup> Furthermore, the Supreme Court also ruled that physicians could not prescribe opiates or cocaine to patients to maintain their addiction.<sup>114</sup> Thus, anyone who suffered from substance abuse had to obtain drugs illegally.<sup>115</sup>

Initially excluded from the Harrison Narcotic Act, marijuana began to garner the American public's attention during the 1930s.<sup>116</sup> Hyperbolic claims that marijuana use led to violence, insanity, or both began to appear in print media.<sup>117</sup> Around the time of the passage of the Harrison Narcotic Act, several states began to regulate marijuana, beginning in the

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<sup>107</sup> *Id.*

<sup>108</sup> MUSTO, *supra* note 83, at 40-41.

<sup>109</sup> *Id.*

<sup>110</sup> *Id.*

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

<sup>112</sup> MUSTO, *supra* note 83, at 54-61.

<sup>113</sup> Griffin, *supra* note 49, at 666-68.

<sup>114</sup> *Id.*

<sup>115</sup> *Id.*

<sup>116</sup> RICHARD J. BONNIE & CHARLES H. WHITEBREARD II, *THE MARIJUANA CONVICTION: A HISTORY OF MARIJUANA PROHIBITION IN THE UNITED STATES* 141-43 (The Lindesmith Center, 1999) (1974).

<sup>117</sup> *Id.*

northeastern and southwestern United States.<sup>118</sup> By the 1930s, a majority of the states regulated marijuana.<sup>119</sup> Federal regulators began to show an interest in regulating marijuana, but they had a problem. The most obvious way to regulate marijuana was to simply amend the Harrison Narcotic Act and add marijuana to the regulatory framework.<sup>120</sup> Indeed, that was the original plan for the legislation, but ultimately, marijuana was omitted from the final law.<sup>121</sup> However, in somewhat of a harbinger of contemporary attitudes about marijuana, many lawmakers did not want to list marijuana within the Harrison Narcotic Act.<sup>122</sup> They believed, if marijuana was included in a law that regulated drugs with medical utility, some people would argue that meant that marijuana had medical utility as well.<sup>123</sup> Ultimately, the Marijuana Tax Act was passed in 1937, which required registered marijuana sellers and purchasers to obtain tax stamps for marijuana.<sup>124</sup> If a person was allowed to register under the Act, purchasing a tax stamp was \$1; however, if a person was not allowed to register under the Act, purchasing a tax stamp was \$100.<sup>125</sup> The law was based on the National Firearms Act of 1934 and essentially sought to tax marijuana out of legal existence.<sup>126</sup>

The regulatory dilemma that Congress faced regarding marijuana exposed many of the flaws of the drug regulatory system and the changes that needed to be made. Legislators seemed to be unconvinced of the medical utility of marijuana; however, at that time, did not want to take the more extreme action of completely prohibiting marijuana under all circumstances (similar to what Congress did when heroin was prohibited from all medical use in 1924).<sup>127</sup> Furthermore, as Joseph Spillane noted, with the rapid increase in the use of synthetic drugs, such as barbiturates and amphetamines, and the rapidly increasing pharmacopeia of new drugs, a new regulatory framework was badly needed.<sup>128</sup> With the potential

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<sup>118</sup> *Id.*

<sup>119</sup> *Id.*

<sup>120</sup> *Id.*

<sup>121</sup> *Id.*

<sup>122</sup> BONNIE & WHITEBREAD, *supra* note 116.

<sup>123</sup> *See id.*

<sup>124</sup> *Id.*

<sup>125</sup> *Id.* at 119-24.

<sup>126</sup> *Id.*

<sup>127</sup> Joseph F. Spillane, *Debating the Controlled Substances Act*, 76 DRUG AND ALCOHOL DEPENDENCE 17, 20-21 (2004).

<sup>128</sup> *Id.*

addition of hundreds if not thousands of new drugs and only the FDA empowered to decide whether drugs simply met the standard of not being toxic and having some medical benefit, there was not any meaningful method to regulate these new substances without having to constantly amend the Harrison Narcotic Act.<sup>129</sup> This was impractical for a host of reasons, of which the most significant was that passing new legislation *takes time*. As previously noted, new drug legislation often took years. Something new needed to be done to bring expediency to the drug regulation process. Likewise, administrative law addresses many of Congress' issues with the drug regulation process since administrative agencies can more efficiently oversee technical and specific laws.

Congress first tried to create a new system of evaluating existing and new drugs by amending the Pure Food, Drug and Cosmetic Act. Members of Congress considered the FDA's approval process of new drugs a promising way forward, despite the process' aforementioned flaws.<sup>130</sup> In addition to tasking the FDA with the approval of drugs, in 1951, Congress passed the Durham-Humphrey Amendment.<sup>131</sup> Under the Durham-Humphrey Amendment, the FDA was empowered to approve new drugs and decide if a drug should only be available on a prescription basis.<sup>132</sup> To make this determination, the FDA's role is to require a prescription for any drug that was habit-forming, toxic, or harmful.<sup>133</sup> Certainly, these criteria seem vague and provide very little clarification beyond what already existed. Even today, one of the most common continuing problems is predicting which drugs will be most popular among those who are likely to engage in illicit substance use. Balster and Bigelow argue that this is one of the most difficult predictions in the drug abuse liability assessment process.<sup>134</sup> As a result, the only meaningful contribution of the Durham-Humphrey Amendment was the clarification that the FDA must, in addition to drug approval, decide whether a new drug should be made available via prescription or over-the-counter.<sup>135</sup>

In 1965, Congress tried again to create a more comprehensive

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<sup>129</sup> *Id.*

<sup>130</sup> *Id.*

<sup>131</sup> *Id.*

<sup>132</sup> *Id.*

<sup>133</sup> See Spillane, *supra* note 127.

<sup>134</sup> See Robert L. Balster & George E. Bigelow, *Guidelines and Methodological Reviews Concerning Drug Abuse Liability Assessment*, 70 *DRUG AND ALCOHOL DEPENDENCE* S13 (2003).

<sup>135</sup> *Id.*



regulatory system when it passed the Drug Abuse Control Amendments (“DACA”).<sup>136</sup> Similar to the Durham-Humphrey Amendment, DACA amended the Food, Drug, and Cosmetic Act. DACA created four new classes of drugs (beyond those regulated by the Harrison Narcotic Act) to be regulated: barbiturates, amphetamines, CNS stimulants, and any other drug with a potential for abuse based upon a depressant, stimulant, or hallucinatory effect.<sup>137</sup> As Joseph Spillane asserted, the four categories were intended to regulate the most problematic drugs at that time (barbiturates and amphetamines), and the fourth category was meant to be a broad catch-all category within which any new drug that had any abuse liability might be classified.<sup>138</sup> Although originally pharmaceutical companies routinely fought all regulatory oversight of their products, at this point in time, they realized that more comprehensive regulations were inevitable.<sup>139</sup> Yet, drug regulators and pharmaceutical companies viewed DACA as a step in the right direction, but ultimately the legislation was unsatisfactory.<sup>140</sup> While the enacted regulatory scheme offered some criteria to help determine these substances’ classification, the regulations were organized around only pharmaceutical properties and failed to consider different drugs’ abuse liability.<sup>141</sup>

After failing for about one hundred years to enact a comprehensive regulatory system for new and existing drugs within the United States, Congress finally adopted the Comprehensive Drug Abuse Prevention and Control Act of 1970, an all-encompassing regulatory system which covered a variety of issues, including the Controlled Substances Act (“CSA”).<sup>142</sup> Through a variety of legislative mechanisms, the CSA created a regulatory framework in which the DEA, FDA, Secretary of Health and Human Services (“HHS”), and the United States Attorney General could collectively decide the regulatory status of all new and existing drugs without continual intervention by Congress every time a new drug came along.<sup>143</sup> Obviously, Congress retained the power to pass legislation on specific drugs if it chose to; however, the intention was to create a regulatory framework in which Congress would not have to constantly

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<sup>136</sup> Spillane, *supra* note 127.

<sup>137</sup> *Id.*

<sup>138</sup> *Id.*

<sup>139</sup> *Id.*

<sup>140</sup> *Id.* at 20-21.

<sup>141</sup> *Id.*

<sup>142</sup> Spillane, *supra* note 127.

<sup>143</sup> *Id.*

intervene. Furthermore, the new framework was also intended to be a progressive framework through which new drugs would be evaluated on scientific criteria rather than negative reputation and hyperbole that often surrounded drugs.<sup>144</sup>

Rather than the simple determination of the Humphrey-Durham Amendment's prescription of over-the-counter classifications or DACA's four drug-class dependent categories, the CSA established five categories of drugs, which the legislation refers to as *schedules*.<sup>145</sup> Whenever an investigation is begun of a new substance, an eight-factor analysis is conducted of the substance, primarily by the FDA.<sup>146</sup> The FDA will provide the results of their analysis.<sup>147</sup> Ultimately, a decision is made regarding the substance by the Attorney General, HHS, and the DEA.<sup>148</sup> However, within the actual decision-making process, it seems that the DEA has the final say on scheduling decisions. While an eight-factor analysis is conducted of drugs, three criteria seem to be the most important: the medical utility of a substance, potential for abuse, and the safety of use while a patient is under medical supervision.<sup>149</sup> Drugs are classified into Schedules I through V, with Schedule I being the most restrictive and Schedule V being the least restrictive.<sup>150</sup> The implications of placing a substance into Schedule I are somewhat drastic; physicians are unable to prescribe any Schedule I substance to patients and severe restrictions are placed on any person who wants to conduct research on a Schedule I substance.<sup>151</sup>

One of the most controversial aspects of the CSA is the scheduling process.<sup>152</sup> In particular, a problem exists when formulating the ultimate schedule placement of drugs after a review of the eight criteria. Furthermore, one of the criteria to place a substance into Schedule I is that

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<sup>144</sup> *Id.* at 21-23.

<sup>145</sup> GAHLINGER, *supra* note 40.

<sup>146</sup> See Douglas C. Throckmorton, *FDA Regulation of Marijuana: Past Actions, Future Plans*, FOOD AND DRUG ADMINISTRATION (April 12, 2016).

<sup>147</sup> *Id.*

<sup>148</sup> GAHLINGER, *supra* note 40.

<sup>149</sup> *Id.*

<sup>150</sup> *Id.* at 72-74.

<sup>151</sup> See Jerome H. Jaffe, *Impact of Scheduling on the Practice of Medicine and Biomedical Research*, 14 DRUG AND ALCOHOL DEPENDENCE 403 (1985).

<sup>152</sup> See Carolyn Coulson & Jonathan P. Caulkins, *Scheduling of Newly Emerging Drugs: A Critical Review of Decisions Over 40 Years*, 107 ADDICTION 766 (2012); Jonathan P. Caulkins et al., *Basing Drug Scheduling Decisions on Scientific Ranking of Harmfulness: False Promise From False Premises*, 106 ADDICTION 1886 (2011).

a drug has no medical utility.<sup>153</sup> This has created a quandary for many and a question that still seemingly lacks an answer: “if a drug has no ‘recognized’ medical utility, should the drug automatically be placed into Schedule I, or should the lack of medical utility only be considered within the context of the decision along with the other seven factors?” Another problem is determining who ultimately decides the question of medical utility: is it really a decision made collectively by the four decision-makers or is it, ultimately, at least within the United States, the decision of the DEA? For instance, Coulson and Caulkins stated that the concerns of law enforcement regarding a drug have frequently trumped the opinions of medical professionals.<sup>154</sup> If that is the case, such a process would seemingly go against the basic rationale for the passage of the CSA. While a clear need exists for some administrative decision-making in such a process, the very nature of the regulatory scheme established by the CSA, at least in application, constitutes a democratic deficit. Ultimate authority seems limited to one bureaucratic agency, which is not necessarily the agency that should be empowered with making a deliberate scientific decision.

## VII. EVALUATING SCHEDULING DECISIONS

One of the reasons that scheduling decisions can be so controversial is due to the varying definitions of harm. As Caulkins, Reuter, and Coulson have noted, harm can happen at two different levels: individual and societal.<sup>155</sup> Some drugs may pose a greater danger to an individual rather than society, and vice versa. This is problematic because it leaves regulators with a problem of considering both individual harm in some combination with societal harm. Along the same lines, such a utilitarian decision must also consider what benefit a drug has to individuals or society. Inevitably, these considerations are often imprecise and can be hotly contested.<sup>156</sup> Furthermore Coulson and Caulkins argued that two types of errors can occur within the scheduling process.<sup>157</sup> Type I errors occur when a government authority “overschedules” a drug and allows fears of potential harm to overshadow the potential benefits of a drug.<sup>158</sup> Type II

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<sup>153</sup> GAHLINGER, *supra* note 40, at 73.

<sup>154</sup> Coulson & Caulkins, *supra* note 152, at 767.

<sup>155</sup> *Id.*

<sup>156</sup> See Caulkins et al., *supra* note 152 at 1886-87 (2011).

<sup>157</sup> *Id.*

<sup>158</sup> Coulson & Caulkins, *supra* note 152, at 766-67.

errors occur when a government authority either fails to schedule a substance or fails to do so in a timely manner.<sup>159</sup>

Perhaps one of the reasons that Type I errors might happen, and also a source of a democratic deficit, is the Comprehensive Crime Control Act of 1984.<sup>160</sup> The legislation was an omnibus bill and contained an amendment to the CSA.<sup>161</sup> This amendment granted the United States Attorney General emergency scheduling powers.<sup>162</sup> If the Attorney General deemed that a drug posed a substantial danger to the American public and determined that Congress, the DEA, or the FDA would not have time to properly conduct a scheduling analysis for that drug, the Attorney General could automatically place that drug into Schedule I for one year, with the possibility of a six-month extension.<sup>163</sup> If no one challenged the emergency scheduling, the drug would permanently remain in Schedule I.<sup>164</sup> In 1990, Attorney General Richard Thornburgh delegated this substantial power, through a Department of Justice rule, to the DEA Administrator.<sup>165</sup> Thus, the DEA, an executive agency, not only has the power to enforce laws regarding drugs, but also essentially has the power to make laws. Such an occurrence does not fit the spirit of checks and balances or separation of powers upon which the United States was founded.

The constitutionality of the Attorney General, and then later the DEA, having emergency scheduling powers was addressed in 1991 when the United States Supreme Court heard *Touby v. United States*.<sup>166</sup> In that case, the appellants were charged with the manufacture of the drug Euphoria, which had been classified as Schedule I by emergency scheduling powers.<sup>167</sup> Among several claims, the appellants argued that the grant of power by Congress to the Attorney General was unconstitutional because these administrative rules went beyond typical administrative law in which a government agency could only impose fines upon people who violated these rules.<sup>168</sup> Instead, any person who possessed, manufactured, or distributed a Schedule I substance could not only be found guilty of a crime,

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<sup>159</sup> *Id.*

<sup>160</sup> Comprehensive Crime Control Act of 1984, Public Law 98-472, 98 Stat. 1976 (1984).

<sup>161</sup> *Id.*

<sup>162</sup> *Id.*

<sup>163</sup> Griffin, *supra* note 49, at 672-73.

<sup>164</sup> *Id.*

<sup>165</sup> *Id.*

<sup>166</sup> *Touby v. United States*, 500 U.S. 160 (1991).

<sup>167</sup> *Id.*

<sup>168</sup> *Id.*

but potentially serve time in prison.<sup>169</sup> Appellants argued that this grant of power went beyond the authority that an executive agency should have.<sup>170</sup> The Supreme Court ultimately disagreed, ruling that the grant of legislative powers was constitutional, because a notification of an emergency scheduling must be given thirty days before an emergency scheduling could take place and emergency scheduling decisions could be challenged.<sup>171</sup>

While the rationale of the Supreme Court in *Touby* is technically correct in that emergency scheduling powers can be challenged, the practicality of actually challenging an emergency scheduling order successfully is entirely different. As Coulson and Caulkins noted, one of the most controversial scheduling decisions was of 3-4 methylene-dioxy-methamphetamine ("MDMA") or as many people know it—*ecstasy*.<sup>172</sup> MDMA was originally synthesized in 1912 by the German pharmaceutical company Merck.<sup>173</sup> Experiments were conducted on MDMA for the purposes of appetite suppression, and the drug was even investigated by the United States government for the purposes of conducting interrogations.<sup>174</sup> Neither proposed utility for MDMA seemed promising, and the drug was forgotten.<sup>175</sup> In 1965, Dr. Alexander Shulgin essentially rediscovered MDMA and synthesized the drug while under the employment of Dow Chemical.<sup>176</sup> Shulgin found that the drug worked as an "empathogen" and was capable of making timid or shy people more gregarious.<sup>177</sup> He speculated that MDMA might be useful in psychotherapy for patients who were hesitant to disclose difficult details to their therapists.<sup>178</sup> Shulgin also believed that MDMA might be useful in marriage counseling so that spouses would have less difficulty opening up to one another.<sup>179</sup> Additional researchers have suggested that MDMA could be useful to treat

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<sup>169</sup> *Id.*

<sup>170</sup> *Id.*

<sup>171</sup> *Id.* See also Griffin, *supra* note 49, at 673.

<sup>172</sup> Coulson & Caulkins, *supra* note 152, at 770.

<sup>173</sup> BRUCE EISNER, *ECSTASY: THE MDMA STORY* 1 (2d ed. 1994).

<sup>174</sup> *Id.*

<sup>175</sup> GAHLINGER, *supra* note 40, at 339.

<sup>176</sup> See Jose Carlos Bouso, *Using MDMA in the Treatment of Post-Traumatic Stress Disorder*, in *ECSTASY: THE COMPLETE GUIDE* 248-60 (Julie Holland ed. 2001).

<sup>177</sup> *Id.*

<sup>178</sup> *Id.*

<sup>179</sup> GAHLINGER, *supra* note 40, at 339-40.

posttraumatic stress,<sup>180</sup> depression,<sup>181</sup> and schizophrenia.<sup>182</sup>

While MDMA did not necessarily seem like a “miracle drug,” there was certainly evidence that the drug had medical utility.<sup>183</sup> However, as the medical utility of MDMA began to become apparent, so did its use for recreational purposes, and that began to overshadow the medical utility.<sup>184</sup> In particular, MDMA began to be associated with all-night dance parties known as raves.<sup>185</sup> Tales of the alleged harm involving MDMA, particularly that the drug caused brain damage, began to spread.<sup>186</sup> Additionally, some of the secondary effects of taking MDMA at raves, such as extreme dehydration among users that in some cases could lead to heat stroke, seizures, and even death were publicized as well.<sup>187</sup> Less publicized was the fact that the science behind the brain damage studies was flawed, or that dehydration among users could easily be combated by a user simply consuming more fluids while dancing for extended periods of time at raves.<sup>188</sup> Perhaps the final straw was that certain unscrupulous manufacturers of MDMA heard rumors that the DEA was investigating the scheduling of MDMA.<sup>189</sup> As a result, those manufacturers rapidly increased production so that they could make as much money as possible before MDMA regulation took effect.<sup>190</sup> Those manufacturers forced the DEA to emergency schedule MDMA, which the agency did in 1984.<sup>191</sup> This action was quickly challenged and hearings took place in Washington, D.C., Kansas City, and Los Angeles to determine whether the emergency scheduling was appropriate.<sup>192</sup>

While several researchers at the hearings demonstrated the potential

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<sup>180</sup> See Bouso, *supra* note 176.

<sup>181</sup> See June Riedlinger & Michael Montagne, *Using MDMA in the Treatment of Depression*, in ECSTASY: THE COMPLETE GUIDE 261-72 (Julie Holland ed., 2001).

<sup>182</sup> See Julie Holland, *Using MDMA in the Treatment of Schizophrenia*, in ECSTASY: THE COMPLETE GUIDE 273-85 (Julie Holland ed., 2001).

<sup>183</sup> EISNER, *supra* note 173.

<sup>184</sup> *Id.*

<sup>185</sup> *Id.*

<sup>186</sup> *Id.*

<sup>187</sup> *Id.*

<sup>188</sup> O Hayden Griffin, III., *Is the Government Keeping the Peace or Acting like our Parents? Rationales for the Legal Prohibitions of GHB and MDMA*, 42 J. DRUG ISSUES 247, 252 (2012).

<sup>189</sup> *Id.*

<sup>190</sup> JEROME BECK & MARSHA ROSENBAUM, PURSUIT OF ECSTASY: THE MDMA EXPERIENCE 17-19 (1994).

<sup>191</sup> *Id.*

<sup>192</sup> EISNER, *supra* note 173, at 7-27.

medical utility of MDMA, the DEA primarily relied on arguments that since MDMA was primarily trafficked by people who sold other drugs, this demonstrated that MDMA was probably a dangerous drug.<sup>193</sup> Furthermore, the agency presented some preliminary animal testing that did not show a great potential of harm for humans.<sup>194</sup> After the hearings concluded in 1986, an administrative judge recommended that MDMA be placed into Schedule III.<sup>195</sup> In September of 1987, the First District Court of Appeals ruled that the DEA had not properly considered the testimony which indicated the potential medical use of MDMA and vacated the decision by the DEA to classify MDMA as a Schedule I substance.<sup>196</sup> However, these court decisions were not binding on the DEA. In 1988, the DEA once again classified MDMA as a Schedule I substance.<sup>197</sup> MDMA has remained a Schedule I substance since.<sup>198</sup>

While the Supreme Court stated in *Touby* that the emergency scheduling powers of the Attorney General and DEA Administrator were permissible since any action could be challenged, doing so was practically impossible. Two courts recommended that MDMA be rescheduled and, yet, the DEA still placed MDMA into Schedule I.<sup>199</sup> Therefore, not only can the DEA effectively make the law it is tasked with enforcing, it is clear that it can also disregard the role of the judicial branch of government in overseeing the constitutionality of this power. Such a situation is an inherent democracy deficit. Nevertheless, such a situation is not likely to cause much public outrage. According to Rosenbaum, the public reaction to MDMA during the mid-1980s was akin to the “reefer madness” panic of the 1930s.<sup>200</sup> Yet, speaking of marijuana, one could potentially argue that a democracy deficit exists regarding the regulation of this substance as well. Considering that marijuana use is far more common than MDMA use, this issue may appear more relevant to the American public.

When the CSA was enacted, many drugs were immediately scheduled and not evaluated by the FDA and the DEA in a similar manner

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<sup>193</sup> Griffin, *supra* note 188, at 259.

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

<sup>195</sup> *Id.*

<sup>196</sup> *Id.*

<sup>197</sup> EISNER, *supra* note 173, at 27-31.

<sup>198</sup> *Id.*

<sup>199</sup> Griffin, *supra* note 188, at 252-53.

<sup>200</sup> See Marsha Rosenbaum, *Ecstasy: America's New "Reefer Madness,"* 34 J. PSYCHOACTIVE DRUGS 137 (2002).

to newly discovered drugs.<sup>201</sup> Among the drugs immediately scheduled was marijuana, which was placed into Schedule I.<sup>202</sup> This classification has caused considerable controversy considering marijuana is not a toxic substance and it is not as habit-forming as other drugs, such as cocaine, prescription opioids, and others that are in Schedule II.<sup>203</sup> In 1972, not long after the decision was made to place marijuana in Schedule I, the National Organization for the Reform of Marijuana Laws (NORML) challenged the scheduling of marijuana and requested that marijuana be placed into either Schedule V or be unscheduled.<sup>204</sup> The United States Court of Appeals for the District of Columbia Circuit rejected that marijuana should be unscheduled, citing international treaties that the United States had signed and ratified to regulate marijuana and many other drugs.<sup>205</sup> However, the court recommended the DEA reconsider the Schedule I designation for marijuana.<sup>206</sup> After reconsideration, the DEA left marijuana in Schedule I.<sup>207</sup> Eventually, the case was remanded and an administrative law judge held that marijuana and resin from the marijuana plant should be placed in Schedule II, marijuana leaves should be placed in Schedule V, and both marijuana seeds and synthetic THC should not be scheduled.<sup>208</sup> Similar to the case with MDMA, the DEA disregarded the ruling of the court and stated that marijuana had no recognized medical utility and should remain in Schedule I.<sup>209</sup> In the 1980s, a similar process occurred, and another administrative law judge ruled that marijuana should be placed into a lower schedule.<sup>210</sup> Much like before, the DEA disregarded the decision.<sup>211</sup> In 2001 and 2006, after receiving petitions to reevaluate the legal status of marijuana, the DEA requested the FDA to conduct an eight-factor scheduling analysis.<sup>212</sup> Both times the FDA stated that there

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<sup>201</sup> Annaliese Smith, *Marijuana as a Schedule I Substance: Political Ploy or Accepted Science*, 40 SANTA CLARA L. REV. 1137, 1137-38, 1148 (1999).

<sup>202</sup> *Id.*

<sup>203</sup> *Id.*

<sup>204</sup> *Id.* at 1138.

<sup>205</sup> *Id.* at 1151-52.

<sup>206</sup> *Id.*

<sup>207</sup> *Id.*

<sup>208</sup> *Id.*

<sup>209</sup> *Id.*

<sup>210</sup> *Id.* at 1154-55.

<sup>211</sup> *Id.*

<sup>212</sup> Matt Ferner, *FDA to Evaluate Marijuana for Potential Reclassification as Less Dangerous Drug*, HUFFINGTON POST (June 24, 2014). See Throckmorton, *supra* note 146.



was not enough evidence that marijuana had medical utility.<sup>213</sup> Currently, the FDA is conducting another analysis after the result of another rescheduling petition, the results of which are pending.<sup>214</sup>

There are many reasons that the decisions of the FDA and DEA are disingenuous. The first is that the FDA has approved several versions of synthetic cannabinoids. One example of these THC-based medications is Marinol, which is available by prescription and is a Schedule III substance.<sup>215</sup> Furthermore, at present time, twenty-seven states and the District of Columbia allow medical marijuana and fifteen states allow cannabidiol (CBD), the second leading active chemical in marijuana.<sup>216</sup> Thus, nearly forty-six percent of the states allow medical marijuana and eighty-four percent of states allow some form of a chemical from the marijuana plant.<sup>217</sup> Additionally, eight states (Alaska, Colorado, California Maine, Massachusetts, Nevada, Oregon, and Washington) have taken the extraordinary action in legalizing the recreational use of marijuana.<sup>218</sup> Washington, D.C. has also legalized the recreational sale and possession of marijuana, but the federal government is currently blocking implementation of that legal change.<sup>219</sup> Thus, there does not necessarily seem to be an issue of if marijuana actually has medical utility. Instead, the issue is if the FDA and DEA recognize that marijuana has medical utility.

## VIII. DISCUSSION

Writing in 1893, Emile Durkheim predicted that as societies modernized, an increase in functional legislation would be needed to regulate the growing complexities that inevitably occurred.<sup>220</sup> This has certainly been the case in the United States, as a seemingly endless amount of administrative law has been spawned to regulate the ongoing complexities of American society. Drug policy in the United States has certainly undergone a similar transition, as the rapidly increasing

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<sup>213</sup> *Id.*

<sup>214</sup> *Id.*

<sup>215</sup> GAHLINGER, *supra* note 40, at 327.

<sup>216</sup> NORML, *State Info on Marijuana Laws*, NORML, <http://norml.org/states> (last visited, March 29, 2017).

<sup>217</sup> *Id.*

<sup>218</sup> Robinson, *supra* note 14.

<sup>219</sup> *Id.*

<sup>220</sup> See EMILE DURKHEIM, *THE DIVISION OF LABOR IN SOCIETY* (2014).

pharmacopeia of new drugs has required repeated and significant changes in legislation in an attempt to protect the American public. Protecting the American public from dangerous substances is certainly a laudable goal, but who gets to determine these decisions and what the broader consequences of these decisions are requires more scrutiny and, perhaps, illustrates a need for shared governance.

Partly as a reaction to poisonings and other harmful side effects from dangerous medications, the FDA was formed to act as a clearinghouse to determine if medications were both safe and effective, and if they should be available for sale on the American pharmaceutical market. The formation of such a federal agency seems valid, as it would be impractical and costly to have each state establish state-run agencies for a similar purpose. Furthermore, creating the FDA might even seem to be what the Founding Fathers envisioned when they delegated to the federal government the ability to regulate interstate commerce. As much as some people would like the market to decide whether to have dangerous or ineffective medications on the pharmaceutical market, having a group of experts make such decisions seems like a reasonable use of administrative law. Lastly, it seems that most would argue that these decisions are based on science. Thus, much like the EPA, a federal agency full of technocrats would be needed to make these decisions that many lay people would have a difficult time understanding.

Where the process gets murky, is deciding other issues, such as whether a prescription should be necessary before a person can obtain a medication, or within what schedule a drug should be classified. On its face, it appears that these are again, scientific and technical questions that could easily be reserved for an administrative agency, such as the FDA. However, in practicality, many scheduling decisions have ultimately been made by the DEA—a law enforcement agency. Thus, instead of being based on science, scheduling decisions are more often based upon risk management. Questions of whether recreational users will abuse a medication will often trump the concerns of patients who need medications. Furthermore, when determining medical utility, which is likely the most scientific aspect of the scheduling process, often the pleas of medical experts, who have challenged decisions that have placed drugs in Schedule I, are ignored. In the case of marijuana, the fact that more than half of the states allow some part or chemical within the marijuana plant for medicinal purposes is ignored. Therefore, it does not seem that the question is whether a substance actually has medical utility; rather, the question is whether the FDA or the DEA believes a drug has medical utility. This is a policy decision that may be informed by science, but not merely a

technical question that considers only science.

To some, the decision of how certain drugs end up in one schedule or another may seem trivial. Indeed, with the vast pharmacopeia available in the United States, if a patient cannot have one drug, they may be able to easily find another that will provide similar treatment ability. However, that is not the end of the problem. The CSA is not just an administrative statute, it includes criminal penalties as well. As mentioned previously, standards of due process and the principles of legality have generally required that any statute that can criminally punish must be enacted in the traditional legislative process. Thus, via the Supremacy Clause found in the United States Constitution, the FDA and DEA are essentially able to enact federal crimes entirely on their own. This certainly seems like a democracy deficit. Criminal statutes are being enacted that can include criminal penalties of incarceration without the consent of any legislative body. While the federal government does provide grants to the states to aid in endeavors with the war on drugs, it is entirely doubtful that these legislative grants truly cover the cost of states maintaining and enforcing drug laws.

While the democracy deficit of federal drug policy not only includes an unfunded mandate, this policy also effectively blocks states from considering policy changes. Although many states have enacted laws that allow medical marijuana, many of these clinics and marijuana growers who supply the marijuana have suffered raids from the DEA. Many of these people are operating within the provisions of state law, yet are still violating federal law, since under the CSA marijuana is a Schedule I drug with no recognized medical utility. These raids began under the administration of President George W. Bush and continued during the presidency of President Barack Obama. However, after President Obama's reelection in 2012, DEA raids of state medical marijuana clinics began to taper off and in 2013, what many believed was unthinkable happened—two states (Colorado and Washington) legalized the recreational sale of marijuana. In August of 2013, former United States Attorney General Eric Holder announced that the federal government would not intervene with states that legalized marijuana, so long as the states did not sell marijuana to minors, diversion did not occur from legal state marijuana enterprises to illegal drug traffickers, and marijuana did not spread to states that still prohibited marijuana. This last point may be the biggest stumbling block as states bordering Colorado, such as Oklahoma and Nebraska, have already complained about legal marijuana bought in Colorado ending up in their states. Both states have threatened legal action and have argued that the federal courts should overturn the validly passed Colorado law. What the

courts will ultimately do with these complaints during Donald Trump's presidency is anyone's guess. While this might contradict the concept of a democracy deficit, the states that have allowed medical marijuana or the states that have legalized the recreational sale of marijuana are still very much operating in a legal grey area. Despite the passage of state legislation, the states are still acting in conflict with federal legislation.

## IX. CONCLUSION

Different researchers have used the term democracy deficit to describe situations where citizens are essentially disenfranchised and excluded from important decisions regarding the implementation of government policies. While the United States has often had a problematic relationship regarding the supremacy of the federal government over the states, and the growth of federal administrative law is often seen as a valid exercise, federal drug policy has grown beyond the federal government trying to just implement administrative safety standards to dictating criminal justice policy to the states with little or no input from the states. Furthermore, the passage of the CSA and the Comprehensive Crime Control Act has allowed the DEA to not only enforce law, but it has also granted the agency the ability to create law and block any judicial oversight of this new legislation. While federal drug policy was meant to bring efficiency to the process of regulation, this policy has also brought a resulting deficiency in how law is created. To some, this may seem as a natural growth of administrative law, but it also seems like a violation of due process and the principles of legality.