

2015

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### Recommended Citation

Christopher J. Frisina *Let FDA Regulate Its Own Drugs!: An Argument for Narcotic Control and Enforcement Under the Risk Evaluation and Mitigation Strategies (REMS)*, 27 Loy. Consumer L. Rev. 238 (2015).

Available at: <http://lawcommons.luc.edu/lclr/vol27/iss2/3>

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# LET FDA REGULATE ITS OWN DRUGS!: AN ARGUMENT FOR NARCOTIC CONTROL AND ENFORCEMENT UNDER THE RISK EVALUATION AND MITIGATION STRATEGIES (REMS)

Christopher J. Frisina\*

## I. INTRODUCTION

America has a problem with prescription drugs. In 2012, nearly 500,000 Americans over the age of twelve used a prescription painkiller for a non-medical purpose for the first time.<sup>1</sup> Deaths resulting from the overdose of prescription painkillers have reached a staggering 17,000 per year in the United States.<sup>2</sup> While few people doubt the extent of the prescription drug problem in the United States, few people see the actual impact outside of incomprehensible statistics and nightly news graphics. These large numbers do not demonstrate the full extent of the problem. The opioid abuse problem has become so prevalent and pervasive that an alarming number of newborns enter this world addicted to narcotics, a syndrome known as

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<sup>1</sup> See *Prescription Drug Abuse Statistics*, CENTER FOR LAWFUL ACCESS (2014), <http://CLAAD.org/rx-drug-abuse-stats> [hereinafter *Prescription Drug Abuse Statistics*].

<sup>2</sup> See *id.*

neonatal abstinence syndrome (“NAS”).<sup>3</sup> East Tennessee Children’s Hospital in Knoxville, TN diagnoses two-dozen newborns with NAS daily.<sup>4</sup> In 2009, over 13,500 newborns were diagnosed with NAS – about one newborn every hour.<sup>5</sup> Despite strong evidence of widespread abuse, doctors prescribe prescription painkillers to one out of every three Tennesseans each year.<sup>6</sup> Tennessee represents just one example of the nationwide prescription drug abuse epidemic.<sup>7</sup>

Despite having reached epic proportions, the abuse of prescription drugs is not a new phenomenon. For the last century, the U.S. Government has attempted to curtail the abuse of prescription drugs through several laws and regulations.<sup>8</sup> Despite the Government’s efforts, the abuse of prescription drugs has tripled in the last two decades.<sup>9</sup> At present rates, fatal overdoses from prescription drug abuse have surpassed those of cocaine and heroin, combined,<sup>10</sup> constituting three-quarters of U.S. drug overdose deaths.<sup>11</sup> In 2010, approximately one hundred Americans died from prescription drug overdose every day.<sup>12</sup> Worldwide, more than half of

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<sup>3</sup> See JoNel Aleccia, *‘Just Flooding Us’: Tenn. Spike in Drug-Dependent Newborns is Warning to Nation*, NBC NEWS (October 11, 2013, 7:15 PM), <http://www.nbcnews.com/health/just-flooding-us-tenn-spike-drug-dependent-newborns-warning-nation-8C11375654>.

<sup>4</sup> See *id.* (noting that at times the number reaches three to four dozen daily).

<sup>5</sup> See *id.* (citing Stephen W. Patrick, et al., *Neonatal Abstinence Syndrome and Associated Health Care Expenditures: United States, 2000-2009*, 18 JAMA 1934 (2012)).

<sup>6</sup> See Dennis Thompson, *Study Finds 1 in 3 Tennesseans Uses Narcotic Painkillers Each Year*, HEALTH.COM (March 3, 2014), <http://news.health.com/2014/03/03/study-finds-1-in-3-tennesseans-uses-narcotic-painkillers-each-year/>.

<sup>7</sup> See *Prescription Drug Abuse Statistics*, *supra* note 1 (noting that the Centers for Disease Control declared prescription drug abuse an epidemic).

<sup>8</sup> See Amel Ahmed, *Painkiller Addiction Worst Drug Epidemic in US History*, AL JAZEERA, August 30, 2013, <http://america.aljazeera.com/articles/2013/8/29/painkiller-kill-morepeoplethanmarijuanause.html>.

<sup>9</sup> See *id.*

<sup>10</sup> See *id.*

<sup>11</sup> See Barry Meier, *F.D.A. Urges Tighter Rein on Painkillers*, N.Y. TIMES, October 24, 2013, available at <http://www.nytimes.com/2013/10/25/business/fda-seeks-tighter-control-on-prescriptions-for-class-of-painkillers.html?r=0>.

<sup>12</sup> See *Fact Sheet: Opioid Abuse in the United States*, OFF. NAT’L DRUG CONTROL POL’Y,

the 78,000 drug-use deaths resulted from prescription painkiller abuse in that same year.<sup>13</sup> Notably, the “United States consumes 80% of the world’s painkiller supply.”<sup>14</sup> The Food and Drug Administration (“FDA”) has acknowledged it is “failing miserably” to solve this growing problem.<sup>15</sup>

The prescription drug problem has also affected the pharmaceutical industry, an undoubtedly less sympathetic victim than the Tennessee infants, with its \$180 billion U.S. market.<sup>16</sup> Under current FDA regulations, a manufacturer may not market its potentially addictive New Chemical Entity (“NCE”) until the Drug Enforcement Administration (“DEA”) has “scheduled” the drug, listing it in one of five legal categories by which the DEA may exercise its enforcement powers.<sup>17</sup> However, the current black market for “designer drugs,” chemical entities comparable to already regulated drugs, has backlogged the DEA so much that it is unable to schedule legitimate drugs in a timely fashion.<sup>18</sup> As of September 9, 2013, FDA-approved products constituted only four out of the thirty chemical entities docketed for scheduling.<sup>19</sup> The average time between FDA approval of an NCE and DEA’s completion of scheduling is now 237.6 days.<sup>20</sup>

The prescription drug abuse problem has not gone unnoticed by the FDA. For example, in October 2013 the FDA recommended that the DEA reschedule the narcotic hydrocodone (Lortab) as a Schedule II drug, placing it under greater supply and prescription restrictions.<sup>21</sup> If the DEA follows the recommendation, which it tends

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[http://www.whitehouse.gov/sites/default/files/ondcp/Fact\\_Sheets/opioids\\_fact\\_sheet.pdf](http://www.whitehouse.gov/sites/default/files/ondcp/Fact_Sheets/opioids_fact_sheet.pdf).

<sup>13</sup> Ahmed, *supra* note 8.

<sup>14</sup> *Id.*

<sup>15</sup> *See id.*

<sup>16</sup> *See* CARL L. HART, DRUGS, SOCIETY, & HUMAN BEHAVIOR 55 (15th ed. 2013).

<sup>17</sup> *See In re: Eisai Inc.*, Petition for a Writ of Mandamus, No. 13-1243, at 5 (D.C. Cir. Aug. 19, 2013) [hereafter Petition for Mandamus].

<sup>18</sup> *See In re: Eisai Inc.*, Response in Opposition to Petition for Writ of Mandamus, No. 13-1243 (D.C. Cir. Aug. 19, 2013) (Declaration of Joseph Rannazzisi appended to the Response ¶22) [hereinafter DEA Response].

<sup>19</sup> *See id.* (Declaration of Joseph Rannazzisi appended to the Response ¶23).

<sup>20</sup> *See* Petition for Mandamus, at 17.

<sup>21</sup> *See generally* Meier, *supra* note 11.

to do,<sup>22</sup> prescriptions of hydrocodone will be limited to ninety-day supplies per doctor's visit, requiring chronic pain patients to see their doctors more frequently. This potential regulation will have wide-reaching effects, as doctors prescribe approximately five billion pills of hydrocodone each year for pain.<sup>23</sup>

In light of the 2007 Food and Drug Administration Amendments Act ("FDAAA"), the FDA's reliance on the DEA seems unreasonable and unnecessary. The FDAAA gave the Agency the power to regulate potentially harmful pharmaceuticals through Risk Evaluation and Management Strategies ("REMS").<sup>24</sup> These REMS allow the FDA to restrict distribution and prescription methods under its own power rather than relying on the DEA. While the DEA may be required to reschedule drugs like hydrocodone to increase its own enforcement power over the drug, the FDA can move quickly in the interim to begin to stem the tide of this growing epidemic.

This article recommends that the U.S. Congress rework existing legislation to allow the FDA to run scheduling procedures for itself rather than relying on the DEA to work through its back log of knockoff prescription drugs. This recommendation arises from a careful analysis of the FDA's approach to pharmaceuticals, including opium and heroin, since the enactment of the Pure Food and Drugs Act of 1906 until the creation of the DEA under the Controlled Substances Act of 1970 in Section II. Section II also details the FDA's new power under its REMS Regime. Section III details the breadth and scope of the pharmaceutical abuse and designer drug problems, demonstrating how this problem affects the DEA's resources by analyzing scheduling delays for Eisai Inc.'s Fycompa. Section IV then analyzes the different options before the FDA, recognizing the need to move life-saving drugs onto the market cautiously to prevent further abuse. Ultimately, this article

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<sup>22</sup> Petition for Mandamus, *supra* note 17, at 11 (noting that the DEA has followed every HHS scheduling recommendation since 1997).

<sup>23</sup> See Meier, *supra* note 11 (noting that the rescheduling has been opposed by lobbying groups such as the American Cancer Society and National Community Pharmacist Association due to the burden placed on patients).

<sup>24</sup> See 21 U.S.C. § 355-1; see also Approved Risk Evaluation and Mitigation Strategies, FOOD & DRUG ADMINISTRATION (January 28, 2015), <http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientandProviders/ucm111350.htm>.

recommends that the FDA schedule drugs on its own behalf. Alternatively, this article suggests that the FDA and DEA could enter into joint rulemaking to pool their resources for more efficient scheduling of potentially abusive drugs.

### A. Definitions

The DEA's scheduling delays result not only from FDA-approved drugs, but also from designer drugs, which are chemical knockoffs of FDA approved drugs. This brief section will define each drug category to clarify the following discussion.

*Prescription Drugs.* Generally, prescription drugs subject to abuse come in three broad categories: opioid painkillers, anti-anxiety medication and sedatives, and stimulants.<sup>25</sup> Analgesic opioid painkillers, more commonly called narcotics, are derived from the opium poppy. Common narcotics prescriptions include morphine, OxyCotin, Vicodin, and Demorol.<sup>26</sup> Notably, this category also includes "illicit drugs" like heroin. Legally, "narcotic" does not denote a chemical definition but a statutory one. For instance, while cocaine is not chemically a narcotic, the U.S. government classifies it as one for enforcement and punishment purposes.<sup>27</sup> Anti-anxiety medications and sedatives include Xanax, Valium, and Ambien. These types of drugs are used to treat both anxiety and sleep disorders.<sup>28</sup> Stimulants, which treat ADHD and certain sleep disorders, include Ritalin and Adderall.<sup>29</sup>

*Designer Drugs.* Designer drugs are chemical knockoffs that resemble legally scheduled drugs. Designer drugs are referred to by many names, including research chemicals, bath salts, plant foods,

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<sup>25</sup> See *Prescription Drugs & Cold Medicine*, NAT'L INST. ON DRUG ABUSE (March 2014), <http://www.drugabuse.gov/drugs-abuse/prescription-drugs>.

<sup>26</sup> See *id.*

<sup>27</sup> See C.B. Schultz, *Statutory Classification of Cocaine as a Narcotic: An Illogical Anachronism*, 9 AM. J.L. & MED. 225 (1983) (noting that statutory definition allows law enforcement to impose greater penalties on cocaine than other non-narcotic drugs).

<sup>28</sup> See *Prescription Drug Abuse*, THE MAYO CLINIC (Oct. 11, 2012), <http://www.mayoclinic.org/diseases-conditions/prescription-drug-abuse/basics/definition/CON-20032471?p=1>.

<sup>29</sup> See *Prescription Drugs & Cold Medicine*, *supra* note 25.

incense, and plants.<sup>30</sup> These unscheduled chemical entities elude DEA enforcement as they are outside of the agency's jurisdiction until it completes its final rule after the notice and comment period.<sup>31</sup> These substances include synthetic marijuana and chemicals that "mimic cocaine, LSD, and other drugs."<sup>32</sup> These designer drugs are extremely pervasive and, at times, subject to much hysteria. For example, at least 124 variations of cannabinoid products, known as K2 or "spice," were in circulation in 2012.<sup>33</sup> In late 2013, the rumored "flesh-eating zombie drug" krokodil made its way from Russia to the United States. The drug itself is a combination of codeine, gasoline, red phosphorus, and hydrochloric acid. Ultimately, the rumors about its potential effects appear to be unfounded.<sup>34</sup>

## II. FDA'S ENFORCEMENT HISTORY AND THE GROWING DRUG PROBLEM

This section addresses the historical underpinnings to the present problem of drug enforcement in the United States. When Congress created the Food and Drug Administration in 1906, the Agency took direct control over narcotic enforcement in the United States.<sup>35</sup> Until the passage of the Controlled Substances Act, the FDA, through its many statutes, regulated how drugs, both prescription and over the counter, made their way into the U.S. market. This section details the United States Government's

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<sup>30</sup> See Bertha K. Madras, *Designer Drugs: An Escalating Public Health Challenge*, 6 J. GLOBAL HEALTH POL'Y & PRAC. 1 (Sept. 10, 2012), available at <http://www.globaldrugpolicy.org/Issues/Vol%206%20Issue%203/Designer%20Drugs%20FINAL%20V6%20formatted.pdf>.

<sup>31</sup> See *id.*

<sup>32</sup> *D.E.A. Cracks Down on Designer Drug Operations*, N.Y. TIMES (June 26, 2013), available at <http://www.nytimes.com/2013/06/27/us/dea-cracks-down-on-designer-drug-operations.html?r=0>.

<sup>33</sup> Madras, *supra* note 22, at 5.

<sup>34</sup> Jacob Sullum, *Krokodil Crock: How Rumors Of A 'Flesh-Eating Zombie Drug' Swept The Nation*, FORBES (Jan. 10, 2014, 7:00 AM), <http://www.forbes.com/sites/jacobsullum/2014/01/10/krokodil-crock-how-rumors-of-a-flesh-eating-zombie-drug-swept-the-nation/>.

<sup>35</sup> *Centennial of FDA*, FOOD & DRUG ADMIN., <http://www.fda.gov/AboutFDA/WhatWeDo/History/CentennialofFDA/default.htm> (last updated May 13, 2009).

enforcement power over narcotics and associated entities from the creation of the Pure Food and Drugs Act of 1906 to the passage of the Controlled Substances Act. This section concludes by addressing the Food and Drug Administration Amendments Act and the power given to the FDA to curtail the distribution of prescription drugs.

*A. A History of Drug Enforcement Through the Twentieth Century*

1. The Pure Food and Drugs Act of 1906

The Pure Food and Drugs Act of 1906<sup>36</sup> (“1906 Act”) marks one of the first attempts by the United States Government to curtail the use of narcotics domestically.<sup>37</sup> At the beginning of the twentieth century, many ailments, including headaches and alcoholism, were treated with many different types of remedies that were often laced with addictive substance like cocaine, morphine, and heroin.<sup>38</sup> Despite the Government’s influence on the market, the 1906 Act did not outright criminalize the possession or use of narcotics. The 1906 Act allowed the federal government to exercise jurisdiction over chemicals that were “misbranded or adulterated.”<sup>39</sup> Congress defined *drug* as “any substance or mixture of substance intended to be used for the cure, mitigation, or prevention of disease.”<sup>40</sup>

Congress did not intend to prevent the admittance of these drugs onto the market, but wanted to ensure that the consumers were able to “determine the identity of the article, possibly, including its

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<sup>36</sup> Pure Food and Drugs Act of 1906, Pub. L. No. 59-384, 34 Stat. 768 (1906).

<sup>37</sup> Notably this is the first example of legislation concerning the sale of narcotics, but not the first attempt to regulate narcotics in the domestic market. The Tariff Act of 1832 mentions opium, the first mention of a narcotic. The Tariff Act prevented duties on the import trade of opium. However, ten years later opium was added to the import list at seventy-five cents per pound. Morphine was added to the list in 1862 at two dollars per pound. See Thomas M. Quinn & Gerald T. McLaughlin, *The Evolution of Federal Drug Control Legislation*, 22 CATH. U. L. REV. 586, 589-90 (1973).

<sup>38</sup> See *id.* at 591.

<sup>39</sup> See HART, *supra* note 16, at 53-54 (noting that the Pure Food and Drug Act was administered and enforced by the U.S. Department of Agriculture).

<sup>40</sup> Compare Pub. L. No. 59-384, 34 Stat. 768, with The Federal Food Drug and Cosmetic Act § 201(g)(1)(B), 21 U.S.C. § 321(g)(1)(b) (1938) (“articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or animals”).

strength, quality, and purity.”<sup>41</sup> Ultimately, the 1906 Act intended to protect consumers from “unscrupulous merchants” rather than to protect the consumers from themselves.<sup>42</sup> The Act required producers of remedies containing alcohol, morphine, cocaine, heroin, or any derivatives of these drugs to clearly indicate their presence in the labeling or be deemed misbranded.<sup>43</sup> Although the sale of remedies containing these narcotics dropped thirty-three percent after the Act’s passage, the 1906 Act did not outlaw the possession, sale, or use of any of the above-mentioned narcotics.<sup>44</sup> In fact, following the 1906 Act, pharmacies continued to sell heroin by its common name as well as morphine, opium, and cocaine over the counter.<sup>45</sup> While the act created public awareness of the potential dangers associated with these drugs, “a 1910 pharmaceutical journal reported that one drug store earned a profit of \$60 a day from sales of cocaine alone.”<sup>46</sup>

## 2. The Harrison Narcotics Tax Act of 1914

The Government expanded its regulation of the sale and distribution of narcotic drugs through the Harrison Narcotics Tax Act

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<sup>41</sup> *United States v. Johnson*, 221 U.S. 488, 497 (1911); *see also* PETER B. HUTT, RICHARD A. MERRILL, & LEWIS A. GROSSMAN, *FOOD AND DRUG LAW: CASES AND MATERIALS* 641-42, 644 (4th ed. 2014).

<sup>42</sup> HART, *supra* note 12, at 53; *See also* PETER B. HUTT, RICHARD A. MERRILL, & LEWIS A. GROSSMAN, *FOOD AND DRUG LAW: CASES AND MATERIALS* 468 (3d ed. 2007) (quoting PETER B. HUTT, *The Regulation of Drug Products by the United States Food and Drug Administration*, in *THE TEXTBOOK OF PHARMACEUTICAL MEDICINE* (John P. Griffen & John O’Grady, eds., 5th ed. 2006) (“Although it was quite short, and very broad and general in nature, it was extremely progressive for its time and included sufficient authority to permit FDA to take strong enforcement action against the unsafe, ineffective, and mislabeled products that flooded the United States market in the late 1800s.”).

<sup>43</sup> *See* Quinn & McLaughlin, *supra* note 28, at 591 (noting that any confectionary containing a narcotic substance was also considered adulterated under the 1906 Act); *see also* Hart, *supra* note 12, at 55 (noting that when brought to litigation, the Government had the burden of showing that the labeling claim was not only false but known to be false by the manufacturer).

<sup>44</sup> *See* DAVID F. MUSTO, *THE AMERICAN DISEASE: ORIGINS OF NARCOTIC CONTROL* 22 (3d ed. 1999).

<sup>45</sup> *See* Quinn & McLaughlin, *supra* note 37, at 591 (noting that the “sale of these drugs continued to flourish”).

<sup>46</sup> *Id.*

of 1914 (“Harrison Act”).<sup>47</sup> Initially, in a coordinated effort with the Chinese, the Harrison Act intended to curtail the import of opium.<sup>48</sup> At the time, the British had a very large, controlling share of the opium market. In a 1912 meeting of the world’s biggest economies at the Hague International Opium Convention, the British government agreed to restrict imports of opium so long as morphine, heroin, and cocaine were added to the restricted list— an effort to limit the German hold on those markets. The nations agreed.<sup>49</sup> Prior to the meeting, the Secretary of the Treasury already had authorization to limit the importation of opium, usually only for medical use. Congress eventually outlawed the import and export of all “smoking opium” while “heavily taxing its domestic manufacture”<sup>50</sup> through the Narcotic Drug Export Act.<sup>51</sup>

With the Harrison Act, Congress moved to drastically regulate narcotics in the domestic market. The Act itself allowed the Treasury Department to oversee opioids<sup>52</sup> and cocaine from the time of their importation or manufacture until the products were ultimately used.<sup>53</sup> Through the Act, Congress and the Treasury Department required dispensaries of opioids to “register annually, pay a small fee, and use special order forms provided by the Bureau of Internal Revenue.”<sup>54</sup> Furthermore, the Harrison Act limited prescriptions of opioids to patients who had undergone an examination and received a diagnosis by a physician.<sup>55</sup> Congress feared that pharmacists would create

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<sup>47</sup> Harrison Narcotics Act of 1914, Pub. L. No. 63-223, 38 Stat. 785 (1914).

<sup>48</sup> See HART, *supra* note 16, at 54; Quinn & McLaughlin, *supra* note 28, at 592.

<sup>49</sup> See *id.*

<sup>50</sup> See Quinn & McLaughlin, *supra* note 37, at 592.

<sup>51</sup> 38 Stat. 275 (1914).

<sup>52</sup> Opioids are used primarily for pain relief. “They reduce the intensity of pain signals reaching the brain and affect those brain areas controlling emotion, which diminishes the effects of a painful stimulus.” *What are Opioids?*, NAT’L INST. ON DRUG ABUSE (October 2011), <http://www.drugabuse.gov/publications/research-reports/prescription-drugs/opioids/what-are-opioids>.

<sup>53</sup> See Quinn & McLaughlin, *supra* note 37, at 593.

<sup>54</sup> HART, *supra* note 16, at 54; Quinn & McLaughlin, *supra* note 37, at 593 (noting that Congress choose to assert its power through its revenue powers rather than through the Commerce Power).

<sup>55</sup> See *Webb v. United States*, 249 U.S. 96 (1919); *Jin Fuey Moy v. United States*, 254 U.S. 189 (1920).

dispensaries to continue to distribute drugs to anyone and everyone.<sup>56</sup> The Act allowed doctors to prescribe the narcotics, but only to their patients.<sup>57</sup>

Later amendments to the Harrison Act in 1914 criminalized the sale, purchase, or distribution of opioids, cocaine, or their compounds not sold in the original stamped packages. The lack of adequate packaging was *prima facie* illegal. The annual tax was also increased.<sup>58</sup> Notably, the notion of a blanket prohibition and criminalized possession would have been considered anathema to the general public and would not have likely withstood Supreme Court scrutiny.<sup>59</sup>

Congress continued to limit the importation and distribution of narcotic products through the Narcotic Drug Import and Export Act of 1922 (“Import-Export Act”). The Import-Export Act continued the import ban on opium from the Narcotic Drug Export Act, but also added cocaine to the banned list. As with Schedule I drugs today, the Government did allow small quantities to enter the country for medical uses and other “legitimate” needs.<sup>60</sup> The Act was later amended to ban the import of opium used in the manufacture of heroin domestically.<sup>61</sup> Despite these efforts, drug abuse and addiction continued to rise throughout the 1920s. By the end of the 1920s, the Government even noted a pronounced rise in inmate addictions.<sup>62</sup>

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<sup>56</sup> See also HUTT, MERRILL, & GROSSMAN, *supra* note 41, at 808 (“in the course of professional practice only”).

<sup>57</sup> See MUSTO, *supra* note 44, at 58; see also *Webb v. United States*, 249 U.S. 96 (1919) (holding that narcotics may only be distributed via prescription for a legitimate medical purpose arising out of a consultation with a doctor but not for a drug addiction).

<sup>58</sup> See Quinn & McLaughlin, *supra* note 37, at 594.

<sup>59</sup> See HART, *supra* note 16, at 54; but see Musto, *supra* note 35, at 68 (noting that the passage of the Constitutional amendment on prohibition also allowed narcotic regulation under the Harrison Act to a “more prohibition style,” citing its moral effect).

<sup>60</sup> See Quinn & McLaughlin, *supra* note 37, at 597.

<sup>61</sup> See *id.* at 597-98.

<sup>62</sup> See *id.* at 599 (noting that the prison system created two “United States Narcotic Farms” to treat patient inmates for their addictions).

### 3. The Federal Food, Drug, and Cosmetic Act of 1938

The largest and most enduring drug legislation is undoubtedly the Federal Food, Drug, and Cosmetic Act of 1938 (“FDCA”).<sup>63</sup> The Act allowed the FDA to regulate drugs for safety prior to their emergence on the market. The final impetus for the FDCA’s enactment involved a toxic drug named “Elixir Sulfanilamide.” The drug was an effective antibiotic with one harmful and deadly side effect—kidney poisoning. Ultimately, the “Elixir” led to 107 deaths, the largest fine ever to arise from the 1906 Act, and the creator’s suicide. The resulting public crisis demonstrated the need for safety controls.<sup>64</sup>

Before 1938, the FDA had no premarket approval power over drugs. The Agency could only take post-market enforcement action against drugs that were considered adulterated or misbranded. Notably, the premarket notification created by the FDCA still required a New Drug Application (“NDA”) but was not an approval process. The application simply allowed the NDA to say “yes” or “no” to the new drug. The NDA required the producer to prove that its drug was not toxic by including “full reports of investigations which have been made to show whether or not such a drug is safe for use.”<sup>65</sup>

The FDCA had profound effects on the drug market in the United States. First, the Act placed the FDA in a key position to guard the market from potentially dangerous drugs. While the Act only allowed the FDA to approve or deny the drug based on the limited safety materials presented, the FDCA greatly expanded the FDA’s power to enforce its new mandates. Undoubtedly the safety requirement kept many drugs off the market that would have normally been available for public use.<sup>66</sup>

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<sup>63</sup> 21 U.S.C. §§ 301 *et seq.*

<sup>64</sup> See HART, *supra* note 16, at 56 (“There was no legal requirement that medicine be safe.”); see also Rakhi B. Shah & Mansoor A. Khan, *The Evolution of FDA’s Role in Ensuring Product Quality*, 31.7 PHARMACEUTICAL TECHNOLOGY 52 (2007) (noting that the FDCA arose from problems arising from pharmaceutical quality).

<sup>65</sup> See HART, *supra* note 16, at 56.

<sup>66</sup> See *id.* at 56. (suggesting that the FDCA’s safety requirement likely would have prevented smaller companies run by less-trained researchers from having a competitive position in the market if able to have a position at all).

Between 1938 and 1962, the effectiveness of the drug was not an explicit factor in NDA approval decisions. A company had to only show that its drug was safe.<sup>67</sup> Although not a requirement, effectiveness snuck into the approval process before 1962, though not as a formal matter.<sup>68</sup> The FDCA required approved drugs to be accompanied by labeling that “contain[ed] adequate information for safe and effective use of the drug.”<sup>69</sup> The FDA exercised its power to enforce the effectiveness of drugs through its misbranding provision, FDCA § 502(a).<sup>70</sup>

Second, the FDCA required that labeling contain either instructions (“adequate directions”) for use or to specify if the drug should be used only after receiving a prescription from a doctor. Notably, the FDA read its new powers to indicate that drugs did not require labels if they were meant for prescription since there was no risk to public health.<sup>71</sup> The problem, however, was that the FDCA did not indicate which drugs should only be prescription, and which should be over-the-counter! Ultimately, the drug companies decided for themselves whether their drugs were prescription or not, under the threat of the now robust FDA’s power to label a drug misbranded if the Agency happened to disagree with the company’s decision.<sup>72</sup> By 1941 FDA selected twenty drugs or drug groups that could only be sold with a written prescription from a doctor or a dentist, including barbiturates and amphetamines.<sup>73</sup>

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<sup>67</sup> See *Weinberger v. Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609, 615 (1973) (“the 1938 Act permitted evaluation of a new drug solely on the grounds of its safety”).

<sup>68</sup> See *United States v. 62 Packages, More or Less, of Marmola Prescription Tablets*, 48 F.Supp. 878, 887 (W.D. Wis. 1943) (noting that the FDCA “was enacted to make self-medication safer and *more effective*”) (emphasis added).

<sup>69</sup> Legal Status of Approved Labeling for Prescription Drugs; Prescribing for Uses Unapproved by the Food and Drug Administration: Notice of Proposed Rule Making, 37 Fed. Reg. 16503 (August 15, 1972).

<sup>70</sup> See e.g., *United States v. 10 Cartons, Labeled in Part “Hoxsey”*, 152 F.Supp. 360 (W.D. Pa. 1957); *United States v. 47 Bottles, More or Less, Jenasol RJ Formula 60*, 200 F.Supp. 1 (D. N.J. 1961).

<sup>71</sup> See HUTT, MERRILL, & GROSSMAN, *supra* note 41, at 803 (quoting Peter Temin, *The Origins of Compulsory Drug Prescriptions*, 21 J.L. & ECON. 91 (1973)).

<sup>72</sup> See *id.* (quoting Peter Temin, *The Origins of Compulsory Drug Prescriptions*, 21 J.L. & ECON. 91 (1973)).

<sup>73</sup> See *Brochure: The History of Drug Regulation in the United States*, FOOD & DRUG ADMIN.,

The FDCA marks a large step in the FDA's control over pharmaceuticals. Congress did not give the FDA explicit control, acting more as a gatekeeper with limited exclusionary discretion. As noted, the FDA did use its misbranding provisions to ensure that the new safe drugs entering the market were also effective. While the FDCA did not give the FDA explicit control over narcotics and habit-forming drugs, the FDA certainly used the Act's provisions to extend its control over the market.

#### 4. Durham-Humphrey Amendments of 1951

Thirteen years passed before Congress felt moved to revise regulations concerning prescription drugs once again. The FDCA left much to be desired by way of deciding what drugs should be considered prescription versus over-the-counter, leading to many conflicts between the FDA and the industry. Between 1940 and 1962, pharmacies were undoubtedly the largest distributors of illegal drugs, including both illicit over-the-counter sales and unauthorized refills.<sup>74</sup> The 1951 Durham-Humphrey Amendments<sup>75</sup> ("1951 Amendments") amended FDCA § 503(b) and clearly divided pharmaceuticals into two strict categories: legend (prescription) and over-the-counter ("OTC"). The 1951 Amendments made the act of dispensing prescription drugs without a physician prescription a statutory violation.<sup>76</sup> The distinction between the categories hinges on whether the drug may be used safely without the supervision of a doctor.<sup>77</sup> The relevant section reads<sup>78</sup>:

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<http://www.fda.gov/aboutfda/whatwedo/history/forgshistory/cder/centerfordruevaluationandresearchbrochureandchronology/ucm114470.htm> (last updated June 23, 2013) (hereafter *FDA Brochure*).

<sup>74</sup> *FDA Brochure*, *supra* note 73; *see also* MUSTO, *supra* note 44, at 231 (noting that during the McCarthy-era of American politics, drug use was associated with a Communist conspiracy to destroy Western society, even going to far as to connect "Red China" with the influx of drugs in the domestic market).

<sup>75</sup> Act of Oct. 26, 1951, Pub. L. No. 82-214, 65 Stat. 648.

<sup>76</sup> *See* HUTT, MERRILL, & GROSSMAN, *supra* note 41, at 807-08.

<sup>77</sup> *See* M.L. Yakowitz, *The Evolution of Drug Laws in the United States, 1906-1964*, 19 FOOD DRUG COSM. L.J. 296, 299 (1964) (detailing the history of drug enforcement from the Pure Food and Drug Act of 1906 until the Kefauver-Harris Amendments of 1962).

<sup>78</sup> *See* HUTT, MERRILL, & GROSSMAN, *supra* note 41, at 805.

- (1) A drug intended for use by man which—
- (A) is a habit-forming drug to which section 502(d) applies; or
  - (B) because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, is not safe for use except under the supervision of a practitioner licensed by law to administer such drug; or
  - (C) is limited by an approved application under section 505 to use under the professional supervision of a practitioner licensed by law to administer such drug;

shall be dispensed only [upon prescription] . . . The act of dispensing a drug contrary to the provisions of this paragraph shall be deemed to be an act which results in the drug being misbranded while held for sale.

Under the 1951 Amendments, any legend (i.e., prescription) pharmaceutical sold without a prescription became subject to the FDCA's misbranding provisions in violation of 503(b)(1).<sup>79</sup> Congress intended the law to ensure that a drug was not sold both as a prescription and OTC.<sup>80</sup> Further, the Amendments required any prescription drug to be labeled, "Caution: Federal law prohibits dispensing without a prescription."<sup>81</sup> Congress changed the labeling to "Rx Only" in 1997.<sup>82</sup>

The Durham-Humphrey Amendments marked the first time that the Congress gave the FDA explicit power to regulate how addictive drugs entered the market. Originally, a key factor the FDA used to determine whether a drug was considered prescription or OTC was whether the drug was habit-forming subject to § 502(d). Section 502(d) detailed substances known to be habit-forming, such as cannabis, cocaine, codeine, heroin, marijuana, amongst several others. The section also required that labeling bear the statement "Warning --

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<sup>79</sup> Shah & Khan, *supra* note 64, at 54.

<sup>80</sup> HUTT, MERRILL, & GROSSMAN, *supra* note 41, at 805.

<sup>81</sup> Act of Oct. 26, 1951, *supra* note 77, at 649.

<sup>82</sup> Food and Drug Administration Modernization Act of 1997, Pub. L. No. 105-115, § 126(b), 111 Stat. 2296, 2327; *see also* HUTT, MERRILL, & GROSSMAN, *supra* note 41, at 807.

May be habit forming.”<sup>83</sup> Section 503(a)(1)(A) required a physician prescription for any drug containing any amount of those substances.<sup>84</sup> Congress repealed §§ 502(d) and 503(a)(1)(A) when it passed the Food and Drug Administration Modernization Act of 1997.<sup>85</sup>

### 5. Narcotic Control Act of 1956

In an effort to deter the illegal importation and distribution of narcotics, Congress passed the Narcotic Control Act of 1956 (“1956 Act”) in response to the growing international drug trade resulting from safer travel after World War II.<sup>86</sup> Through the 1956 Act, Congress created mandatory penalties for offenders, believing the stronger penalties would deter potential offenders from participating in the illegal market.<sup>87</sup> Under the 1956 Act, judges could only sentence an offender to parole for first offenses. Second offenses, however, required mandatory minimums for prison sentences. Strikingly, anyone caught selling to a minor was eligible for the death penalty.<sup>88</sup>

By the 1970s, Congress realized the absolute failure of the minimum sentences. Then-Congressman George Bush argued that the “minimums were ineffective and unjust.”<sup>89</sup> Despite the calls for repeal, Congress enacted stiffer penalties and minimums in 1984, adding five years to any drug sentence wherein the offender carried a

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<sup>83</sup> See 21 U.S.C. §352(d) (1993).

<sup>84</sup> See *De Freese v. United States*, 270 F.2d 730, 736 n.11 (5th Cir. 1959).

<sup>85</sup> See HUTT, MERRILL, & GROSSMAN, *supra* note 41, at 805; see also § 126(b), 111 Stat. *supra* note 71, at 2327.

<sup>86</sup> See HART, *supra* note 16, at 62.

<sup>87</sup> See Stephen J. Schulhofer, *Rethinking Mandatory Minimums*, 28 WAKE FOREST L. REV. 199, 200-01 (1993) (noting that mandatory minimums were rare in the federal system before the Narcotic Control Act, but were stiffened every few years after the 1970s despite calls that the minimums did not deter violations whatsoever).

<sup>88</sup> See JOHN C. MCWILLIAMS, *THE PROTECTORS: HARRY J. ANSLINGER AND THE FEDERAL BUREAU OF NARCOTICS, 1930-1962* 116 (1990); see also Musto, *supra* note 35, at 242 (suggesting that the Narcotic Control Act marked the end of an era of ever increasing punishment severity for drug violations beginning with the passage of the Harrison Act).

<sup>89</sup> Schulhofer, *supra* note 87, at 201.

firearm. Congress continued to strengthen these minimums every two years between 1986 and 1990.<sup>90</sup>

#### 6. Drug Abuse Control Amendments of 1965

The 1956 Narcotic Control Act had little to no effect in deterring the growing illegal drug trade. Not only did the drug trade continue to grow, but the emphasis changed from opioids and cocaine to depressants, stimulants, and hallucinogens such as LSD.<sup>91</sup> In 1965, Congress responded with the Drug Abuse Control Amendments to the Food Drug and Cosmetic Act (“1965 Amendments”).<sup>92</sup> The 1965 Amendments allowed the FDA to prevent the illicit use of barbiturates and amphetamines.<sup>93</sup> While many drugs regulated under the 1965 Amendments had a legitimate medical use, the abuse of those drugs led to a public health crisis.<sup>94</sup> The abuse of these drugs became so prevalent in the early 1960s that large city hospitals reported fifteen percent of emergency room visits concerned adverse reactions to these drugs.<sup>95</sup>

Congress wrote the 1965 Amendments with some flexibility. While the stimulants, depressants, and hallucinogens mentioned were explicitly controlled, the Amendments allowed the Commissioner of the FDA to add any drug which the Commissioner deemed to be habit-forming or had the potential for abuse due to its stimulant, depressant, or hallucinogenic nature. The bill also allowed exceptions to the Act for drugs that can be legally distributed without a prescription, combinations with other drugs “where the Secretary finds that the combination does not have the effect at which the bill is aimed,” or those “whose regulation the Secretary finds not necessary

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<sup>90</sup> See *id.* at 201.

<sup>91</sup> See HART, *supra* note 16, at 63; see also *Significant Dates in U.S. Food and Drug Law History*, FOOD & DRUG ADMIN., <http://www.fda.gov/aboutfda/whatwedo/history/milestones/ucm128305.htm> (last updated Dec. 19, 2014).

<sup>92</sup> Pub. L. No. 89-74, 79 Stat. 226 (1965); see also Harold F. O’Keefe, *Compliance with the Drug Abuse Control Amendments of 1965*, 21 FOOD DRUG & COSM. L.J. 360 (1966) (noting that the 1965 Amendments were widely popular with the pharmaceutical industry and Congress, passing with an almost unanimous vote).

<sup>93</sup> HUTT, MERRILL, & GROSSMAN, *supra* note 41, at 808.

<sup>94</sup> See O’Keefe, *supra* note 92, at 361.

<sup>95</sup> See HART, *supra* note 16, at 64.

for protection of the public health.”<sup>96</sup> Furthermore, the 1965 Amendments prohibited anyone outside of his or her normal practice to transport, sell, or distribute any stimulant or depressant. Finally, any producer or distributor of the regulated drugs was required to register with the FDA to comply with the Amendments.

Penalties under the 1965 Amendments were not as stringent as the 1956 Narcotic Control Act. FDCA § 303 (a) provided that an individual convicted of possession could not receive more than a \$1,000 fine or one-year imprisonment.<sup>97</sup> The Amendments included a provision stating that any person eighteen years of age who sells or dispenses any hallucinogen, stimulant, or depressant to another under the age of twenty-one will be fined no more than \$5,000, sentenced to two years in prison, or both. A second violation of the 1965 Amendments resulted in an increased fine of no more than \$15,000, or a sentence of no more than six years in prison, or both.<sup>98</sup> Notably, the 1965 Amendments also allowed the Secretary to designate employees for enforcement, creating FDCA §702(e). These new enforcement employees may carry a gun, execute and serve search and arrest warrants, execute seizures, and make warrantless arrest when a drug offense occurs in front them.<sup>99</sup> The segments of § 303(a) that were amended in 1965 are no longer law. Congress folded penalties for possession of prescription and illegal drugs into the Comprehensive Drug Abuse Prevention and Control Act in 1970.<sup>100</sup>

The 1965 Amendments also included provisions to prohibit the manufacture of counterfeit drugs.<sup>101</sup> In enacting these amendments, Congress noted that these drugs posed a serious threat to public health, as they were not manufactured under the same conditions as FDA-approved drugs. The Amendments placed the counterfeit drugs under the misbranding provisions of the FDCA.<sup>102</sup> The “counterfeit drug” definition remains in the current version of FDCA § 201(g)(2). For the purposes of this discussion, the manufacture of designer drugs, would likely fall under this provision

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<sup>96</sup> O’Keefe, *supra* note 92, at 361.

<sup>97</sup> See 21 U.S.C.A. § 333(a)(1) (2012).

<sup>98</sup> See Pub. L. No. 89-74 § 7, 79 Stat. 227, 233 (1965).

<sup>99</sup> See *id.* at 234.

<sup>100</sup> See 21 U.S.C.A. §§ 841-865.

<sup>101</sup> See Pub. L. No. 89-74 § 9, 79 Stat. 227, 234-35 (1965).

<sup>102</sup> See *id.* at 234.

as a drug that “falsely purports or is represented to be the product of . . . such other drug manufacturer, processor, packer, or distributor.”

#### 7. The Drug Price Competition and Patent Term Restoration Act – The Hatch-Waxman Act

The Drug Price Competition and Patent Term Restoration Act (“Hatch-Waxman”) has nothing to do with the regulation of prescription drugs or narcotic enforcement.<sup>103</sup> However, patent restoration and market exclusivity are fundamental to understanding the policy options that I will present later in this paper. As such, we will take a few moments to discuss them here.

The Hatch-Waxman Act allows “generic drugs” to forgo the clinical trials required by pioneer manufacturer’s brand-name drug. The Act allows generic companies to develop a cheaper version of a brand-name drug inexpensively by submitting an Abbreviated New Drug Application (ANDA). The ANDA uses the pioneer drug’s clinical trials to prove safety and effectiveness. The generic company then only has to show that its drug is bioequivalent to the pioneer.<sup>104</sup> In return, the pioneer drug company receives five years of market exclusivity. After the FDA approves the pioneer New Chemical Entity (“NCE”), the FDA cannot approve a generic of the pioneer drug for a period of five years. Companies that undertake an Investigational New Drug Application (“INDA”) may also apply for patent term extension equivalent to half of the investigational period. The extension cannot exceed five years. The total market exclusivity period may not exceed fourteen years.<sup>105</sup>

#### B. Comprehensive Drug Abuse Prevention and Control Act – Direct Enforcement and Scheduling

Despite recent changes in federal drug law, “the patch-work of laws and amendments that built up over the years since the 1914 Harrison Act [needed] major reform.”<sup>106</sup> Congress started anew when

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<sup>103</sup> Pub. L. No. 98-417, 98 Stat. 1585 (1984).

<sup>104</sup> See HUTT, MERRILL, & GROSSMAN, *supra* note 41, at 1002.

<sup>105</sup> Gerald J. Mossinghoff, *Overview of the Hatch-Waxman Act and Its Impact on the Drug Development Process*, 54 Food & Drug L.J. 187, 189-90 (1999).

<sup>106</sup> HART, *supra* note 16, at 63.

it enacted the Comprehensive Drug Abuse Prevention Act in 1970.<sup>107</sup> First, the Act provided additional funding for the Department of Health and Human Services (“HHS”). HHS would use this funding for research, treatment, and prevention of narcotic drug abuse. Second, direct drug enforcement would fall under the new Drug Enforcement Administration (“DEA”) under the Department of Justice. The Act removed mandatory minimums and laws that could result in capital punishment for pure drug crimes.<sup>108</sup> Furthermore, the DEA now controlled how specific drugs would fall under the provisions of the Act, removing enforcement from the political arena.<sup>109</sup>

The best-known section of the 1970 Act is the Controlled Substances Act<sup>110</sup> (CSA). The CSA created a “uniform structure for classifying drugs of abuse and regulating their manufacture, distribution, and use in medical studies,” which is enforced primarily through the DEA.<sup>111</sup> Section 812(b) created the classifications, called “Schedules,” to reflect a drug’s potential for abuse, presence of a legitimate medical use, and addictiveness. Scheduling brings the drugs under the jurisdiction of the DEA so that it may “prohibit[] the manufacture, sale, or possession for recreational use of any substance it controls.”<sup>112</sup>

#### Classification under the Controlled Substances Act<sup>113</sup>

	<b>Abuse Potential</b>	<b>Medical Use</b>	<b>Safety and Dependence</b>	<b>Examples<sup>114</sup></b>
<b>Schedule I</b>	High potential	<u>No</u> currently	Lack of accepted	Heroin Marijuana

<sup>107</sup> 21 U.S.C. § 801 (2014).

<sup>108</sup> *Contra* Narcotic Control Act of 1956, Pub. L. No. 84-278, 70 Stat. 567 (1956) (allowing distribution to a minor to be treated as a capital crime).

<sup>109</sup> See HART, *supra* note 16, at 63 (noting that this is arguably a more liberal approach to drug enforcement).

<sup>110</sup> 21 U.S.C. § 811 (2014).

<sup>111</sup> ALEX KREIT, CONTROLLED SUBSTANCES: CRIME, REGULATION, AND POLICY 627 (2013) [hereinafter KREIT (book)].

<sup>112</sup> Alex Kreit, *Controlled Substances; Uncontrolled Law*, 6 ALB. GOV’T L. REV. 332, 336 (2013) [hereinafter Kreit (article)].

<sup>113</sup> See KREIT (book), *supra* note 111, at 627.

<sup>114</sup> See HART, *supra* note 16, at 64.

	for abuse	accepted medical use	safety for use under medical supervision	MDMA
<b>Schedule II</b>	High potential for abuse	Has a currently accepted medical use	Abuse may lead to severe dependence	Morphine Cocaine Methamphetamine
<b>Schedule III</b>	Potential for abuse less than Schedules I and II	Has a currently accepted medical use	Abuse may lead to moderate or low physical dependence or high psychological dependence	Anabolic steroids Most Barbiturates THC
<b>Schedule IV</b>	Low potential for abuse relative to Schedule III	Has a currently accepted medical use	Abuse may lead to limited dependence relative to Schedule III	Xanax Ambien
<b>Schedule V</b>	Low potential for abuse relative to Schedule IV	Has a currently accepted medical use	Abuse may lead to limited dependence relative to Schedule IV	Mixtures having small amounts of cocaine or opium

Implicit to this system is the recognition that many addictive drugs have legitimate medical uses.<sup>115</sup> Note that the primary difference between Schedule I and II is a “legitimate medical use.” When the DEA enters rulemaking to schedule a drug, it will consider whether the substance in question is used “by a substantial segment of medical

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<sup>115</sup> See Lars Noah, *Challenges in the Federal Regulation of Pain Management Technologies*, 31 J.L. MED. & ETHICS 55 (2003).

practitioners in the United States” for such a use.<sup>116</sup> Notably, the CSA does not require the DEA to perform any research to evaluate potential medical use when rulemaking.<sup>117</sup> Consequently, if the DEA classifies a drug as Schedule I, it becomes extraordinarily difficult for medical professionals to attain quantities of the drug for testing and research.<sup>118</sup> The CSA provides for eight considerations the DEA must examine when scheduling during its rulemaking procedures. All three classifications—potential for abuse, legitimate medical purpose, and addictiveness—are determined by these eight factors:

“(1) Its actual or relative potential for abuse. (2) Scientific evidence of its pharmacological effect, if known. (3) The state of current scientific knowledge regarding the drug or other substance. (4) Its history and current pattern of abuse. (5) The scope, duration, and significance of abuse. (6) What, if any, risk there is to the public health. (7) Its psychic or physiological dependence liability. (8) Whether the substance is an immediate precursor of a substance already controlled under this subchapter.”<sup>119</sup>

Notably, these factors are only considerations. The CSA does not require any written record of the considerations when the DEA performs its rulemaking procedures, though the DEA maintains the practice of a “written discussion of the eight factors.”<sup>120</sup>

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<sup>116</sup> *Schedules of Controlled Substances; Scheduling of 3,4-Methylenedioxymethamphetamine (MDMA) Into Schedule I of the Controlled Substances Act; Remand*, 53 Fed. Reg. 5156-01, 5157-58 (1998) (detailing the rationale behind scheduling for medical use) (codified in 21 C.F.R. 1308).

<sup>117</sup> See KREIT (book), *supra* note 111, at 683.

<sup>118</sup> See *id.* (detailing the extreme difficulty facing researchers who petition the DEA for drug rescheduling); see also Kreit (article), *supra* note 112, at

356 (noting that the rationale behind restricting research access to Schedule I drugs appear to be a fear that abusers will break in laboratories to access the drugs—a fear that seems ridiculous in light of the prevalence of other Schedule I drugs on the black market).

<sup>119</sup> Kreit (article), *supra* note 112, at 345 (quoting *United States v. Pastor*, 419 F. Supp. 1318, 1339 n.6 (S.D.N.Y. 1975)); 21 U.S.C. § 811(c).

<sup>120</sup> Kreit (article), *supra* note 112, at 347 (noting that *United States v. Pastor* held that the DEA did not have to make a written record of its consideration of these factors).

The CSA puts a number of restrictions on the manufacture and distribution of scheduled substances beyond those mandated by the FDCA. First, any manufacturer or distributor of a scheduled drug must register with the Attorney General.<sup>121</sup> Subsection (a) requires a separate registration for the manufacture and distribution of Schedule I drugs.<sup>122</sup> The Attorney General's primary consideration in determining whether to register a manufacturer or distributor is the establishment and maintenance of effective controls against illegal distribution.<sup>123</sup>

The CSA also limits prescriptions based on scheduling. Schedules II-IV may only be dispensed for a legitimate medical purpose through an oral or written prescription by a practitioner, except in emergency situations.<sup>124</sup> The CSA allows Schedule III and IV drugs to be refilled up to five times in a six-month period.<sup>125</sup> Schedule II drugs, however, may not be refilled.<sup>126</sup> The DEA recently promulgated a rule allowing doctors to write three prescriptions for Schedule II substances per patient visit to bypass the no-refill rule.<sup>127</sup> Schedule V is restricted only to legitimate medical purposes.<sup>128</sup>

The CSA provides for specific penalties for possession of specific drugs. Penalties also vary by the amount in possession. For example, possession of one kilogram of heroin, five kilograms of coca leaves, cocaine, ecgonine, or any combination thereof, 100 grams of PCP, ten grams of LSD, 1000 kilograms of marijuana, or fifty grams of methamphetamine carries a sentence of no less than ten years imprisonment and not more than life imprisonment.<sup>129</sup> If serious bodily injury or death results from a violator's distribution or use, the penalty jumps to no less than twenty years but not more than life.<sup>130</sup> While possession or use of 100 grams of heroin, 500 grams of coca

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<sup>121</sup> See 21 U.S.C. § 822(a)-(b).

<sup>122</sup> See 21 U.S.C. § 822(a).

<sup>123</sup> See 21 U.S.C. § 823.

<sup>124</sup> 21 U.S.C. § 829(a)-(b).

<sup>125</sup> 21 U.S.C. § 829(b).

<sup>126</sup> 21 U.S.C. § 829(a) ("No prescription for a controlled substance in schedule II may be refilled.").

<sup>127</sup> See Issuance Of Multiple Prescriptions For Schedule II Controlled Substances, 72 Fed. Reg. 64,921 (Nov. 19, 2007) (to be codified at 21 C.F.R. 1306).

<sup>128</sup> See 21 U.S.C. § 829(c).

<sup>129</sup> 21 U.S.C. § 841(b)(1).

<sup>130</sup> See § 841(b)(1)(A).

leaves, cocaine, ecgonine, or any combination thereof, twenty-eight grams of PCP, one gram of LSD, 100 kilograms of marijuana, or five grams of methamphetamine mandates only a sentence of no less than five years but not more than forty years.<sup>131</sup> As with the larger quantities, any distribution or use that results in serious bodily harm or death is subject to larger penalties—no less than twenty years but not more than life.<sup>132</sup>

The CSA also imposes penalties based on the possession, use, or distribution of scheduled drugs not specifically listed. The chart below details the CSA breakdown:

**CSA Criminal Penalties<sup>133</sup>**

Schedule (and additional drugs)	Penalty <sup>134</sup>	Penalty with death or serious bodily injury
Schedule I and II, as well as flunitrazepam (Rohypnol, or “roofies”) and gamma hydroxybutyric acid (GHB)	No more than 20 years	No less than 20 years, but not more than life
Schedule III	No more than 10 years	No more than 15 years
Schedule IV	No more than 5 years	N/A
Schedule IV	No more than 1 year	N/A
< 50 grams of marijuana	No more than 5 years	N/A

As with the Acts that preceded the CSA, distribution to another under the age of twenty-one subjects the violator to greater penalties. The Act allows the courts to double a violator’s sentence for a first offense if he or she distributes to another under the age of twenty-one.<sup>135</sup> A second conviction of distribution to another under

<sup>131</sup> See § 841(b)(1)(B).

<sup>132</sup> See *id.*

<sup>133</sup> See § 841(b)(1)(B)-(E).

<sup>134</sup> This penalty only concerns for first offenses.

<sup>135</sup> See § 859.

the age of twenty-one allows the court to impose a penalty not exceeding three times the maximum amount allowed by § 841.<sup>136</sup>

The DEA has an obligation to consult with the FDA before scheduling FDA-approved drugs.<sup>137</sup> For scientific and medical matters, the DEA is bound by the FDA's recommendation. 21 U.S.C. § 811(b) prevents the DEA from scheduling a drug if the FDA recommends against the procedure.<sup>138</sup> However, if the FDA recommends the placement of a drug into a specific section, the DEA is not bound by this recommendation but must make its own determination.<sup>139</sup> Notably, the DEA has not disagreed with the FDA's recommended schedule since 1997.<sup>140</sup> If the FDA recommends scheduling, the Agency prohibits the manufacturer from marking its new drug upon FDA approval if the DEA has not completed its rulemaking.<sup>141</sup> If the FDA finds in its initial review of the NDA that the drug has the potential for addiction or abuse, the Agency will make a scheduling recommendation to the DEA based on the same criteria that the DEA will use in its rulemaking. Although, the DEA and FDA must work together in determining scheduling,<sup>142</sup> the agencies have very different goals concerning narcotics.<sup>143</sup>

### C. Risk Evaluation and Management Strategies ("REMS")

In the same way that Congress recognized that many potentially addictive drugs have very beneficial effects on the body in 1971, Congress again realized that many very beneficial drugs also have enormous risks associated with them in 2007. The 2007 Food

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<sup>136</sup> See § 859(b).

<sup>137</sup> See § 811(b).

<sup>138</sup> HUTT, MERRILL, & GROSSMAN, *supra* note 41, at 810.

<sup>139</sup> Cf. § 811(b) (noting that if the Secretary of Health and Human Services recommends a specific classification or the declassification of a substance, the Attorney General shall initial rulemaking in consideration of the Secretary's recommendation).

<sup>140</sup> See Petition for Mandamus, *supra* note 17, at 11, 30.

<sup>141</sup> See Form FDA 356h, at 3 (Apr. 2013), available at <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/ucm082348.pdf> ("If this application applies to a drug product that FDA has proposed for scheduling under the [CSA], I agree not to market the product until the [DEA] makes a final scheduling decision.").

<sup>142</sup> See 70 Fed. Reg. 73775 (Dec. 13, 2005).

<sup>143</sup> See KREIT (Book), *supra* note 111, at 687.

and Drug Administration Amendments Act (“FDAAA”) authorizes the FDA to require NDA applicants to submit a Risk Evaluation and Mitigations Strategies (“REMS”) report with their NDAs to ensure that the benefits of any potentially risky drug actually outweigh its risks.<sup>144</sup> At a minimum, the REMS regime requires the company to submit safety assessment at eighteen months, three years, and seven years.<sup>145</sup> The FDAAA also authorizes the FDA to require that the NDA applicant include the REMS report in its labeling.<sup>146</sup> Ultimately, the FDAAA allows the FDA, under certain safety conditions, to approve risky drugs that would have otherwise been forbidden to enter into or would have otherwise been removed from the market.<sup>147</sup>

Before the 2007 enactment of the REMS regime, the FDA had little power to impose distribution controls over approved pharmaceuticals. In *American Pharmaceutical Association v. Weinberger*,<sup>148</sup> the district court struck down an FDA regulation restricting methadone distribution to hospital pharmacies,<sup>149</sup> stating that the FDA “could not restrict distribution as a condition of approving an NDA.”<sup>150</sup> The FDA found a mechanism to restrict distribution as a condition of its accelerated approval process. If the manufacturer refused to comply with the restricted distribution, the FDA would simply deny the accelerated approval application.<sup>151</sup> Manufacturers could also impose limitations on themselves. In the case of Acutane®, the manufacturer required pharmacist education programs and registration with the company.<sup>152</sup> The limitations also required females to sign an informed consent form and agree to use two forms of birth control before, during, and after using the drug.<sup>153</sup>

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<sup>144</sup> 21 U.S.C. § 355-1.

<sup>145</sup> *Id.* at § 355-1(d).

<sup>146</sup> See HUTT, MERRILL, & GROSSMAN, *supra* note 41, at 829.

<sup>147</sup> See Andrew Wilson & Christopher-Paul Milne, *FDA’s Risk Evaluation and Mitigation Strategies (REMS): Effective and Safety Tools or Process Poltergeist?*, 66 FOOD & DRUG L.J. 569, 571 (2011).

<sup>148</sup> 377 F. Supp. 824 (D.D.C. 1974).

<sup>149</sup> See Approved New Drugs Requiring Continuation of Long-Term Studies, 37 Fed. Reg. 26790 (Dec. 15, 1972) (to be codified at 21 C.F.R. pt. 130)

<sup>150</sup> See HUTT, MERRILL, & GROSSMAN, *supra* note 41, at 828.

<sup>151</sup> *See id.*

<sup>152</sup> *See id.*

<sup>153</sup> See HUTT, MERRILL, & GROSSMAN, *supra* note 41, at 828.

The REMS provisions can require specific types of communications to inform both practitioners and patients of potential risks as an additional step.<sup>154</sup> The REMS can require Medication Guides (“Med Guides”), patient-labeling inserts, and communication plans for providers.<sup>155</sup> The Med Guides instruct patients on how to use the potentially risky substance effectively to avoid adverse events.<sup>156</sup> The communication plans may involve either direct mail or conference presentations, amongst other avenues, to communicate risks to practitioners.<sup>157</sup>

Beyond active communication, the FDA may restrict distribution to ensure safe use of the drug.<sup>158</sup> The FDA must address any specific side effect listed in the labeling.<sup>159</sup> Section (f)(3) details the requirements that the FDA may place on REMS-covered drugs<sup>160</sup>: 1) Health care providers must have particular training or experience; 2) Pharmacies or other dispensaries must be specially certified; 3) Dispensed only in certain healthcare conditions; 4) Dispensed only with evidence of safe-use conditions (e.g., pregnancy testing before administration); 5) Subjecting the patient to certain monitoring; and 6) Enrolling each patient in a registry for the drug.<sup>161</sup>

#### Components of REMS Outlined in FDA Guidance<sup>162</sup>

A. “Minimal Strategy”	C. Elements to Assure Safe Use
All REMS must include a timetable for assessment at defined intervals: * 18 months * 3 years * 7 years	May include one or more of the following: *Special training and/or certification requirements for prescribers or dispensers of the drug;

<sup>154</sup> 21 U.S.C. § 355-1(e).

<sup>155</sup> See HUTT, MERRILL, & GROSSMAN, *supra* note 41, at 829 (arguing that this is less burdensome than having to proceed through a risk-benefit analysis, citing 21 U.S.C. § 355-1(e)).

<sup>156</sup> See Wilson & Milne, *supra* note 147, at 570-71.

<sup>157</sup> See *id.* at 571.

<sup>158</sup> See 21 U.S.C. §355-1(f).

<sup>159</sup> See § 355-1(f)(3).

<sup>160</sup> See *id.*

<sup>161</sup> See HUTT, MERRILL, & GROSSMAN, *supra* note 41, at 829.

<sup>162</sup> See Wilson & Milne, *supra* note 147, at 571.

<b>B. “Additional Potential Elements”</b>	<ul style="list-style-type: none"> <li>*Restricting distribution of the drug to particular care settings;</li> <li>* Dispensing a drug based on evidence or documentation of safe use conditions (e.g., patient counseling and acknowledgement of risks and benefits, informed consent);</li> <li>* Patient monitoring and follow-up (e.g., periodic lab testing);</li> <li>* Use of patient registries.</li> </ul> <p>Sponsors may also develop implementation systems with which to monitor, evaluate, and improve implementation of “elements to assure safe use.”</p>
<p>REMS may include:</p> <ul style="list-style-type: none"> <li>* Medication guides and/or patient package inserts</li> <li>* Communication plans</li> </ul>	

The FDA has used its REMS power to require specific communications from producers of opioids. In 2012, FDA’s opioid REMS required specific physician education and patient labeling instructing on safe use of the product.<sup>163</sup> In September 2013, the FDA released new requirements on extended release and long-acting opioids, requiring labeling changes for physicians to combat drug abuse and post-market studies to ensure safe use.<sup>164</sup> The labeling changes indicate that opioids should be limited to chronic, round-the-clock pain that cannot be reasonably treated by an alternative means.<sup>165</sup> The indications note that if alternatives to opioids are available for treatment, the physician should turn to those in an effort to prevent abuse.<sup>166</sup> Notably, the REMS also included a boxed

<sup>163</sup> See HUTT, MERRILL, & GROSSMAN, *supra* note 41, at 813.

<sup>164</sup> *See id.*

<sup>165</sup> *See FDA announces safety labeling changes and postmarket study requirements for extended-release and long-acting opioid analgesics*, FOOD & DRUG ADMIN. (Sept. 10, 2013), <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm367726.htm>.

<sup>166</sup> *See id.*

warning indicating that opioid abuse by pregnant women may lead to neonatal opioid withdrawal syndrome in newborns.<sup>167</sup>

Regarding distribution control, the FDA's REMS power is extremely specific. Under the CSA, the distributor must only be registered with the Attorney General to be allowed to distribute Schedule II-IV drugs.<sup>168</sup> The FDA can require that a pharmacy wanting to distribute a particular drug obtain certification from the drug's company for the specific drug. With Revlimid, a drug structurally similar to thalidomide, the REMS requires that the pharmacist be certified for the drug before dispensing it, or in the alternative the pharmacist may contact a Revlimid REMS-certified pharmacy to fill the prescription to ensure compliance.<sup>169</sup> Furthermore, the FDA can also require prescribers to register with the FDA, duplicating the registration system in place with the DEA.<sup>170</sup>

The control of opioid abuse in the United States has evolved over the last century, beginning with simply making consumers aware of their presence to restricting supply through REMS restrictions. Ultimately, the DEA has primary jurisdiction over abuse and misuse of prescription drugs. However, as noted, the FDA now has power similar to DEA's scheduling procedures to limit the production and distribution of potentially harmful and addictive pharmaceuticals. Notably, the FDA's history demonstrates an emphasis on protecting public health from the misuse of narcotic drugs. The FDA's new REMS regime allows the FDA to move decisively to prevent abuse of its approved drugs. The next section details why these controls are necessary by demonstrating how the drug abuse problem has continued to grow despite more extensive restriction.

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<sup>167</sup> Cf. Aleccia, *supra* note 3 (detailing the growing number of newborns born with opioid addictions in Tennessee).

<sup>168</sup> See 21 U.S.C. § 823(b), (d).

<sup>169</sup> *Risk Evaluation and Mitigation Strategies – Revlimid*, FOOD & DRUG ADMIN., at 1-2, available at <http://www.fda.gov/downloads/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/UCM222644.pdf> (last modified Sept. 2014) [hereinafter *Revlimid*].

<sup>170</sup> *Questions and Answers: FDA Requires a Risk Evaluation and Mitigation Strategy (REMS) for Long-Acting and Extended-Release Opioids*, FOOD & DRUG ADMIN., <http://www.fda.gov/drugs/drugsafety/informationbydrugclass/ucm251752.htm> (last updated April 19, 2011).

### III. THE PROBLEM: NARCOTIC ABUSE, DESIGNER DRUGS, AND THE STATUS QUO

#### A. *Narcotic Abuse in the United States*

Narcotic abuse is not a new phenomenon. As early as the 1920's, Government regulators noted the problem with drug abuse in federal prisons. In response, the Government created two special prisons ("Narcotic Farms") to treat convicted felons addicted to opioids and cocaine.<sup>171</sup> Despite several acts, amendments, and regulations, the U.S. Government has not been able to slow the tide of drug abuse. The abuse of prescription drugs in particular has become the "fastest growing drug problem in the United States."<sup>172</sup>

Traditional drugs of abuse, such as heroin and cocaine, are losing prevalence in the United States. Prescription narcotics are quickly filling this void.<sup>173</sup> Hydrocodone prescriptions in the United States alone constitute almost ninety-percent of the world's narcotic prescriptions.<sup>174</sup> The rise of narcotic prescriptions began in the 1980s when the academic journal *Pain* recommended that narcotic pain medication could be distributed for non-cancer pain without risk of classic opioid abuse. Following this recommendation, pharmaceutical companies, like Johnson & Johnson, began aggressively marketing their narcotic products for general pain.<sup>175</sup>

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<sup>171</sup> See Quinn & McLaughlin, *supra* note 37, at 599; MUSTO, *supra* note 35, at 239 (noting that the 1965 Amendment shifted the FDA's power away from the taxing power to the interstate and commerce powers per the recommendation of the 1963 Advisory Committee).

<sup>172</sup> The White House, *National Drug Control Strategy*, 30 (2010), <http://www.whitehouse.gov/sites/default/files/ondcp/policy-and-research/ndcs2010.pdf>.

<sup>173</sup> Michelle Castillo, *UN: Designer Drug Abuse a Growing Problem*, CBS NEWS (June 26, 2013), [http://www.cbsnews.com/8301-204\\_162-57591114/](http://www.cbsnews.com/8301-204_162-57591114/).

<sup>174</sup> Celine Grounder, *Who is Responsible for the Pain-Pill Epidemic?*, THE NEW YORKER (November 12, 2013), <http://www.newyorker.com/online/blogs/currency/2013/11/who-is-responsible-for-the-pain-pill-epidemic.html> (suggesting that doctors are very responsible for the current pain-med epidemic).

<sup>175</sup> *Id.* (noting that the aggressive marketing of fast-acting narcotics has led to criminal convictions for misleading the public and practitioners concerning the safety of these products of slow-acting narcotics).

Al-Jazeera did not exaggerate by calling the prescription drug problem an “epidemic” in the United States.<sup>176</sup> The number of deaths resulting from narcotic abuse in the United States has quadrupled since 1999.<sup>177</sup> Notably, no hard evidence appears to support the use of narcotics for long-term pain, as studies have shown that most narcotics only remain effective for twelve to sixteen weeks.<sup>178</sup> Despite nearly five billion pills prescribed annually, federal reports note that the average patient only takes narcotics for about fourteen days, creating ample opportunity for illegal distribution.<sup>179</sup> As noted above, the extent of the problem has reached such epidemic proportions that the FDA must now consider potential side-effects (i.e., addictiveness and abuse-potential) before approving NDAs to assess whether the new drug “pose[s] too great a hazard to justify granting approval.”<sup>180</sup>

Beyond the abuse of pharmaceuticals, the DEA must also deal with the influx of designer drugs. Designer drugs are “chemically altered compounds derived from federally controlled substances.”<sup>181</sup> The United Nations Office on Drugs and Crime notes that there are almost a limitless number of possible alterations that can be made to a drug’s chemical structure to alter the drug enough from its scheduled counterpart, removing it from DEA control.<sup>182</sup> Approved drugs have a level of stability that makes them safer for human consumption. However, the lack of control over the manufacturing process and the tweaks necessary to create designer chemicals make the effects of these drugs unpredictable. At times, these drugs produce violent behavior when their scheduled counterparts do not.<sup>183</sup> Because these substances are chemically different than the scheduled product, the DEA lacks jurisdiction and now must race to catch up. As of

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<sup>176</sup> See Ahmed, *supra* note 8.

<sup>177</sup> Meier, *supra* note 11.

<sup>178</sup> Grounder, *supra* note 174.

<sup>179</sup> Meier, *supra* note 11.

<sup>180</sup> Noah, *supra* note 115, at 56.

<sup>181</sup> D.K. Beebe & E. Walley, *Substance Abuse: The Designer Drugs*, 43.5 AM. FAM. PHYSICIAN 1689 (1991).

<sup>182</sup> See Castillo, *supra* note 173 (focusing on the problem internationally).

<sup>183</sup> See *Designer Drugs on the Rise as Demand for Traditional Drugs Levels Off*, UN Reports on World Drug Day, UN NEWS CENTRE (June 26, 2013), <http://www.un.org/apps/news/story.asp?NewsID=45272&Cr=unodc&Cr1=#.UoP6UJTWLVs>.

September 9, 2013, only four of the thirty products awaiting DEA scheduling procedures were FDA-approved products.<sup>184</sup>

The market failure model associated with the abuse of prescription drugs includes preference related problem, illegitimate preferences, and irrational groups. With legal sales of narcotics topping \$8.5 billion dollars a year, the illegal use of prescriptions and designer drugs is undoubtedly a very lucrative albeit illegal market.<sup>185</sup> Furthermore, the number of prescriptions written for narcotic drugs has “nearly tripled in the last two decades,” glutting the market (i.e., illegitimate preferences).<sup>186</sup> In 2010, the number of prescriptions written for narcotic painkillers in the United States could medicate every American citizen for one month. Not surprisingly, the rise in prescriptions written directly correlates with the increased addiction rates (i.e., irrational groups).<sup>187</sup>

This market failure is directly connected to a government failure. The FDA, when approving prescription drugs, has little control over the practice of medicine, allowing doctors to prescribe FDA-approved drugs for unapproved uses.<sup>188</sup> As of the passage of the FDAAA in 2007, the FDA has gained some regulatory power over the distribution of drugs through the Risk Evaluation and Mitigations Strategies (“REMS”) system.<sup>189</sup> The FDA can impose a REMS paradigm on a New Chemical Entity (“NCE”) at the time of approval or anytime thereafter.<sup>190</sup> The REMS system allows the FDA to limit distribution to health care providers with particular training or experience, specially certified pharmacies or dispensers, distribution in special settings, distribution only with evidence of safe-use conditions (e.g., making a woman verify that she is not pregnant before administering a drug), subjection to patient monitoring

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<sup>184</sup> See DEA Response, *supra* note 18 (statistics comes from the Declaration of Joseph Rannazzisi appended to the Response).

<sup>185</sup> See Barry Meier, *A New Painkiller Crackdown Targets Drug Distributors*, N.Y. TIMES (October 17, 2012), available at [http://www.nytimes.com/2012/10/18/business/to-fight-prescription-painkiller-abuse-dea-targets-distributors.html?pagewanted=all&\\_r=0](http://www.nytimes.com/2012/10/18/business/to-fight-prescription-painkiller-abuse-dea-targets-distributors.html?pagewanted=all&_r=0).

<sup>186</sup> Ahmed, *supra* note 8.

<sup>187</sup> See *id.*

<sup>188</sup> See 21 U.S.C. § 301 *et seq.*

<sup>189</sup> See 21 U.S.C. § 355-1.

<sup>190</sup> See 21 U.S.C. § 355-1(a)(1)-(2).

services, or patient enrollment in a drug registry, amongst other precautions.<sup>191</sup> Ultimately, these are very limited distribution controls.<sup>192</sup> Note, however, that none of these restrictions allow the FDA to regulate the specific uses or types of pain that these REMS-regime drugs may be prescribed to treat. Currently, narcotic prescriptions are limited to Schedule II drugs, restraining prescriptions to three thirty-day supplies per doctor's visit.<sup>193</sup>

*B. The Status Quo: The Case of Eisai Inc.*

On August 19, 2013 Eisai Inc. ("Eisai") filed for a Writ of Mandamus in the United States Court of Appeals for the District of Columbia to force the DEA to schedule its NCE, Fycompa (generically paempanel). Without DEA scheduling, Eisai is unable to market its new drug.<sup>194</sup> The FDA approved Fycompa on October 22, 2012 "as adjunctive therapy for treatment of partial-onset seizures with or without secondarily generalized seizures in patients with epilepsy aged 12 years and older."<sup>195</sup> Eisai asked for the Court's assistance because the DEA had delayed on scheduling Fycompa for nearly ten months since FDA-approval.<sup>196</sup> For Eisai, ten months is an unreasonable amount of time because the delay prevents patients from accessing a much-needed drug, and scheduling does not require significant resources from the DEA.<sup>197</sup> Ultimately, the court did not

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<sup>191</sup> See § 355-1(f)(3)(D).

<sup>192</sup> See *Food and Drug Administration Amendments Act of 2007*, COVINGTON & BURLING LLP (October 9, 2007), <http://www.cov.com/files/Publication/2d3ce0d0-ec9e-4d8b-a376-3d79293d830f/Presentation/PublicationAttachment/a514e76e-029b-4f0e-b9e1-06e3ef3dc7ef/Food%20and%20Drug%20Administration%20Amendments%20Act%20of%202007.pdf> [hereinafter Covington Memo].

<sup>193</sup> See 21 C.F.R. § 1306.12(b).

<sup>194</sup> See Petition for Mandamus, *supra* note 17.

<sup>195</sup> Letter from Robert Temple, Deputy Director, Center for Drug Evaluation and Research, to Heather Bradley, Eisai Inc., (Oct. 22, 2012), *available at* [http://www.accessdata.fda.gov/drugsatfda\\_docs/nda/2012/202834Orig1s000Approv.pdf](http://www.accessdata.fda.gov/drugsatfda_docs/nda/2012/202834Orig1s000Approv.pdf) (approved labeling also available at site).

<sup>196</sup> See Petition for Mandamus, *supra* note 17, at 13.

<sup>197</sup> See *id.*

agree that the DEA's delay "warrant[ed] the extraordinary remedy of mandamus."<sup>198</sup>

The delay of Fycompa is simply one delay in a growing number of DEA scheduling delays over the last fifteen years. The average time between FDA approval of an NCE and DEA's completion of scheduling is now 237.6 days, an almost 200-day increase from 49.3 days in 1997-1999.<sup>199</sup> In the case of Fycompa, Eisai contends that the budget and sequester are no excuse for DEA's delays because the number of staff compared to the total budget are still higher than 1997 levels, when the delays first began. It explicitly states that the delays began long before Congress enacted the sequestration. Eisai also notes that the 21 U.S.C. § 821 allows the DEA to impose user-fees on manufacturers and distributors to expedite the scheduling process.<sup>200</sup> However, Eisai's understanding of the DEA's budget fails to account for its increased spending in educational efforts to contend with the designer drug problem. These educational efforts include twenty-eight presentations in the last three years. Increased trial preparation also strains the DEA's budget.<sup>201</sup> Ultimately, the DEA appears to be ill-equipped to deal with FDA-approved scheduling on top of the rest of its responsibilities.

For Eisai, the delay in DEA scheduling has two immediate consequences: 1) The DEA's delay prevents a much-needed product from reaching patients suffering from epilepsy, and 2) The DEA's delay costs Eisai capital that it will not be able to recoup due to loss of market exclusivity. In its Petition for a Writ of Mandamus, Eisai first details how complex epilepsy is, focusing on the numerous versions of the disease and how no one drug has shown the ability to prevent all types of seizures, even with the best available treatment. Thus, having variety in available treatments is extremely important when considering epilepsy. Eisai designed Fycompa to treat partial-onset (focal) seizures, which "occur in about 60 percent of people with epilepsy."<sup>202</sup> Notably, patients are suffering an actual harm,

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<sup>198</sup> See *In re: Eisai Inc.*, Order, No. 13-1243, at 1 (D.C. Cir. Oct. 22, 2013) (dismissing the issue as moot in response to DEA's notice of proposed rulemaking announcement).

<sup>199</sup> See Petition for Mandamus, *supra* note 17, at 10.

<sup>200</sup> See *id.* at 11-12.

<sup>201</sup> See DEA Response, *supra* note 18, at 13-14.

<sup>202</sup> See Petition for Mandamus, *supra* note 17, at 16.

exemplified by the 102 healthcare providers who have inquired with the company about the drug's availability for their patients.<sup>203</sup>

Second, Eisai's financial forecast for 2013 anticipated Fycompa's approval and admittance onto the market. Considering Fycompa's potential market, the company estimated that during fiscal year 2013, the drug would bring in \$21.5 million in net sales. According to Eisai, if the company is unable to count on Fycompa's income, it will have to revise reinvestment and innovation plans for the following year. Furthermore, the company believes that because of this delay, it will not be able to recover for the research, development, and NDA user-fees needed to develop the product. Recovering the costs used to develop a drug usually requires several years of exclusive marketability. Eisai notes that Fycompa is the only drug that targets "glutamate activity at postsynaptic AMPA receptors."<sup>204</sup> Because of the delay, Eisai fears that competitors will find another means to affect the AMPA receptors, limiting Fycompa's marketability further.<sup>205</sup> Notably, the reinvestment of capital is a major component of Congress's intent with the Hatch-Waxman Amendments to the FDCA.

Interestingly, Eisai's Citizen's Petition to the FDA requests restoration of Fycompa's data exclusivity when the DEA reaches its final scheduling decision.<sup>206</sup> Since the FDA approved Fycompa on Oct. 22, 2012, its exclusivity period would terminate on Oct. 22, 2017. However, based on Fycompa's patent data, Eisai could still have exclusivity for its product until June 8, 2021, barring a suit to challenge the patent.<sup>207</sup> So long as the patent is valid, patent exclusivity lasts even when market exclusivity has expired. While patent exclusivity may be challenged and lost, market exclusivity is

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<sup>203</sup> See *id.* at 17.

<sup>204</sup> See *id.* at 6-7.

<sup>205</sup> See *id.* at 7.

<sup>206</sup> Letter from Allen Waxman, Senior Vice President & General Counsel, Eisai Inc., to Food & Drug Administration, at 2 (July 25, 2013), [http://www.hpm.com/pdf/blog/Eisai\\_Inc\\_Citizen\\_Petition.pdf](http://www.hpm.com/pdf/blog/Eisai_Inc_Citizen_Petition.pdf) [hereinafter Citizen's Petition].

<sup>207</sup> *Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations*, U.S. FOOD & DRUG ADMIN., (March 21, 2014), [http://www.accessdata.fda.gov/scripts/cder/ob/docs/patexclnew.cfm?Appl\\_No=202834&Product\\_No=006&table1=OB\\_Rx](http://www.accessdata.fda.gov/scripts/cder/ob/docs/patexclnew.cfm?Appl_No=202834&Product_No=006&table1=OB_Rx) [hereinafter *Orange Book*].

guaranteed when receiving FDA approval.<sup>208</sup> As noted, Eisai's primary concern with Fycompa is that a competitor will create another means to affect the AMPA receptors and it will not have recouped its expenditures beforehand.

The DEA's delays result from inefficient inter-agency cooperation and coordination, primarily the DEA's and FDA's differing policy goals. The DEA concerns itself with scheduling for abuse enforcement. In contrast, the FDA's primary goal is to get drugs that are safe and effective onto the market quickly. While some cooperation does exist between the agencies, their rulemaking procedures are largely independent of each other due to the agencies' different goals. When a company submits an NDA, the FDA will evaluate the drug briefly for potential abuse risks. Health and Human Services will then perform an analysis and make a recommendation to the DEA concerning the NCE's scheduling.<sup>209</sup> After receiving the recommendation, the DEA begins its own analysis, using the same standards as HHS, before making its final rule.<sup>210</sup>

The DEA justifies the distinction between the rulemaking procedures by focusing on the different goals of the two agencies. If there is an administrative hearing or challenge to the rulemaking, the DEA will have to defend its rulemaking but the FDA will not be held accountable for its recommendation.<sup>211</sup> The DEA reinforces the contention that their goals are separate by showing that the DEA and FDA have different resources available to their analysis of the NCE. Because the DEA is primarily concerned with abuse enforcement, it supplements its research with data from the National Forensic Laboratory Information System and the System to Retrieve Information from Drug Evidence. The DEA further notes that even with equal access to information, the analysis and conclusions "may

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<sup>208</sup> See Charles Clift, *Data Protection and Data Exclusivity in Pharmaceuticals and Agrochemicals*, in *The IP Handbook of Best Practices* 431, 433 (Anatole Krattiger, ed., 2012), available at <http://www.iphandbook.org/handbook/chPDFs/ch04/ipHandbook-Ch%2004%2009%20Clift%20Data%20Protection%20and%20Exclusivity.pdf>.

<sup>209</sup> See 21 U.S.C. § 811(b) (2012).

<sup>210</sup> See § 811(c); DEA Response, *supra* note 18, at 4-8.

<sup>211</sup> See DEA Response, *supra* note 18, at 6-7; see also Placement of Carisoprodol into Schedule IV, 76 Fed. Reg. 77,330, 77,335 (Dec. 12, 2011) (to be codified at 21 C.F.R. pt. 1308).

differ” due to the agencies’ intentions and experience.<sup>212</sup> Notably, if the FDA does not recommend scheduling, the DEA will not consider the NCE at all.<sup>213</sup> Due to the growing drug problem, however, FDA may be overly cautious when making recommendations.

#### IV. FDA’S POWER: SUBSTITUTING THE STATUS QUO WITH RISK EVALUATION AND MANAGEMENT STRATEGIES

For the first sixty-four years of its existence, the FDA controlled almost all regulation regarding narcotics in the U.S. market, black or otherwise. Congress took a new approach with the creation of the DEA and the Controlled Substances regime. However, the narcotic abuse and designer drug problem has taxed the limitations of this regime. It seems that no matter how much funding pours into the DEA, the problem is unstoppable. The problem has sapped the DEA’s resources so badly that the FDA has felt the direct effects of the growing problem for the last fifteen years. Now, under the REMS regime, it is time for the FDA to take full responsibility for the chemicals passing through its system, acting not only to move pharmaceuticals onto the market faster but also ensure their safe distribution.

This section recommends the different steps that the FDA could take to remedy the present problem. First, this paper briefly describes why simply renewing the five-year exclusivity period upon receiving DEA approval is insufficient to meet the needs of this problem. Second, it strongly recommends that the FDA simply take over the scheduling procedure for its own products, to which the DEA would then adhere for enforcement. Finally, as an alternative, this paper recommends that the DEA and FDA enter into joint rulemaking to schedule FDA-approved (or soon-to-be approved) pharmaceuticals.

##### *A. Delaying Approval*

Eisai’s primary injury from the delay of Fycompa is the loss of market exclusivity guaranteed to the company under the Hatch-Waxman Amendments to the FDCA. As noted above, because of the

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<sup>212</sup> See DEA Response, *supra* note 18, at 7.

<sup>213</sup> See *id.* at 5.

delay, Fycompa has lost over a year of its market exclusivity, as the FDA started the “clock” when it approved the drug in October 2012. Along with its Petition for Writ of Mandamus with the D.C. Circuit, Eisai also filed a Citizens Petition with the FDA in an effort to restore its full market exclusivity for Fycompa and another drug Belviq.<sup>214</sup>

When considering Eisai’s Citizen’s Petition, the obvious question becomes, is it not the easiest solution to simply delay the FDA’s approval of an NDA subject to DEA scheduling until the DEA finishes its rulemaking? This is undoubtedly the easiest solution, second only to continuing on with the status quo. However, there are important public policy points to consider that make this an undesirable solution.

### 1. Loss of Capital

One of Eisai’s major complaints was the loss of income associated with marketing Fycompa. The company noted it had made its fiscal year 2013 projections based upon receiving approval to market its drug. Eisai noted that because it had not received approval, it would now not be able to meet projections that would have allowed it to reinvest its capital into further development or pay for the research, development, and implementation of Fycompa.<sup>215</sup>

Restoring the five-year exclusivity would solve this problem, in part. It would grant the company a full term to restore its losses. In its Petition for Mandamus, the corporation noted that it often takes many years of marketing for a company to recoup the losses associated with the development of the product.<sup>216</sup> Simply delaying approval until the DEA completes its scheduling fails to account for predictability. Eisai was unable to account for the DEA’s delay when creating its fiscal plan for 2013. Furthermore, Eisai notes that the delays between the FDA’s recommendation to the DEA and the DEA’s final rulemaking have grown substantially in the last fifteen years without pause.<sup>217</sup> With the current backlog at the DEA and the ever-growing designer drug problem, waiting for DEA approval before commencing market exclusivity does not allow corporations to

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<sup>214</sup> See Citizen’s Petition, *supra* note 206.

<sup>215</sup> See Petition for Mandamus, *supra* note 17, at 6-7.

<sup>216</sup> See *id.*

<sup>217</sup> See Petition for Mandamus, *supra* note 17, at 11-12.

have any more predictability in their financial planning, despite giving them their full term to recoup losses.

## 2. Potential Competition

Eisai also feared that the delay would allow its competitors to mimic its product. In the Petition for Mandamus, Eisai noted that Fycompa was the only anti-seizure drug whose active ingredient focuses on the AMPA receptors to prevent symptoms. The company suggested that the delay may allow time for competitors find another way to target the AMPA receptors in a way that would not violate Fycompa's exclusivity.<sup>218</sup> Waiting for FDA approval would protect any company from competition as the contents of the NDA would remain private until approval and the patent would not be listed in the Orange Book until NDA approval. For Eisai, not only is Fycompa's patent public in the Orange Book,<sup>219</sup> but the company is also losing the exclusivity period that would keep generics out of the market. Notably, the FDA has just approved a new drug for focal seizures, like Fycompa, under a REMS regime requiring the inclusion of Med Guides.<sup>220</sup>

## 3. In the case of Life Saving Drugs

Finally, Eisai noted there was no drug like Fycompa on the market. Epilepsy comes in many forms without a single best treatment. As such, having more products on the market provides more options for physicians and patients. Fycompa is the only drug that currently focuses on the AMPA receptors. With NDA approval, the FDA has certified that the drug is safe and effective for use for a legitimate medical purpose. Waiting on DEA scheduling does nothing to hasten this process. As discussed in the section on capital loss, the time between FDA-approval and DEA scheduling is ever increasing. At this point, relying on DEA approval shows no signs of

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<sup>218</sup> See *id.* at 7.

<sup>219</sup> See *Orange Book*, *supra* note 207.

<sup>220</sup> See *FDA approves Aptiom to treat seizures in adults*, FOOD & DRUG ADMIN., (Nov. 8, 2013), available at <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm374358.htm>.

ensuring that potentially life-saving drugs reach the market any faster.<sup>221</sup>

### B. The FDA's Power Under a REMS Regime

Prior to the FDAAA, having the FDA regulate potentially addictive drugs would have been wildly inefficient. The FDA would have lacked the statutory authority to limit distribution for potentially hazardous drugs or to ensure that the dispensers of the drug were adequately trained for potential adverse events.<sup>222</sup> While the FDA has had limited controls over the practice of medicine, the REMS regime allows the FDA to have some control over the distribution of potentially harmful drugs.

There are several similarities between the REMS regime and the CSA provisions. Unlike the CSA, the REMS regime does not give the FDA statutory power to require registration with the Attorney General before producing potentially addictive drugs that would have been highly scheduled under the CSA.<sup>223</sup> However, like the CSA, REMS allow the FDA to specify the type of pharmacy or healthcare setting where the drug can be dispensed.<sup>224</sup> With this in mind, it seems obvious that the FDA has significant power under the REMS regime to limit the distribution of potentially harmful drugs, including narcotics that may be approved under a non-DEA approval regime. This FDA power is further bolstered by the fact that the REMS allow the FDA to limit distribution to a "certain healthcare setting, such as [a] hospital."<sup>225</sup> The FDA can also require prescribers of REMS-restricted drugs to register with the agency as a prerequisite to prescribing the drug.<sup>226</sup>

The REMS regime permits the FDA powers beyond that of the CSA in restricting use. For instance, when approving Revlimid, the

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<sup>221</sup> See Petition for Mandamus, *supra* note 17, at 7.

<sup>222</sup> See *Am. Pharm. Ass'n v. Weinberger*, 377 F. Supp. 824 (D.D.C. 1974).

<sup>223</sup> *But see* 21 U.S.C. § 822(a)-(b).

<sup>224</sup> Compare § 823(b) (requiring registration with the Attorney General before distribution of Schedule II drugs based on five criteria) with FDCA § 505-1(f)(3)(B) (requiring that pharmacies who which to dispense drugs under certain REMS paradigms attain special certification before being able to lawfully dispense them).

<sup>225</sup> FDCA § 505-1(f)(3)(C).

<sup>226</sup> See *supra* text accompanying notes 145-46.

FDA instituted a REMS regime to prevent fetal exposure to the drug.<sup>227</sup> As part of the REMS, the consumer had to enroll in a patient registry in accordance with § 505-1(f)(3)(E).<sup>228</sup> More to the point, the REMS requires that before receiving the drug initially, the patient must submit to a pregnancy test. The patient then must submit to another pregnancy test each time a doctor prescribes the drug from that point forward.<sup>229</sup> FDA-mandated drug screening is common in opioid REMS. The screens check not only the presence of opioids but also the presence of any other illicit product. If the prescribed opioid is not present in the user's system, the REMS prevents a doctor from continuing to prescribe the narcotics to the patient.<sup>230</sup> The REMS for Nucynta, an extended release opioid for pain control, requires "regular evaluation and documentation" of urine drug screening, but leaves to the discretion of the physician what qualifies as "regular."<sup>231</sup>

The FDA also has the power under REMS to limit prescriptions. Under the CSA, Schedule II drugs are limited to 90 days supplies, passed out through three separate, non-refillable prescriptions.<sup>232</sup> In the case of Revlimid, the FDA has severely limited how the drug may be prescribed, a prescription regime much more severe than those pushed by Schedule II under the CSA. The REMS mandates that the drug not be prescribed for more than a 28-day supply. The prescription cannot be subject to refill or prescriptions by phone—a physician must sign them. Finally, a pharmacy can only fill a prescription within seven days of the completion of the existing prescription.<sup>233</sup> Notably, when considering

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<sup>227</sup> See *Revlimid*, *supra* note 169, at 1.

<sup>228</sup> See *id.*

<sup>229</sup> See *id.* at 2.

<sup>230</sup> See Ted Jones et al, *Urine Drug Testing as an Evaluation of Risk*, PRACTICAL PAIN MGMT. (June 1, 2010), <http://www.practicalpainmanagement.com/treatments/pharmacological/opioids/urine-drug-testing-evaluation-risk> (noting that urine tests, frequent visits, and pill counts should be mandatory for all patients receiving opioid).

<sup>231</sup> See *Risk Evaluation and Mitigation Strategies – Nucynta*, FOOD & DRUG ADMIN., 36 (August 25, 2011), available at <http://www.fda.gov/downloads/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/UCM270224.pdf>.

<sup>232</sup> See 21 C.F.R. § 1306.12(b); 70 Fed. Reg. 50408 (Aug. 25, 2005); 71 Fed. Reg. 52724 (Sept. 6, 2009).

<sup>233</sup> See *Revlimid*, *supra* note 169, at 77-78.

the REMS and prescriptions, the FDA considers the duration of drug treatment when creating the REMS,<sup>234</sup> allowing for specific controls on each drug under the regime.

Finally, the FDA is not unfamiliar with the standards by which the DEA performs its schedule rulemaking. As noted above, when the FDA makes its recommendation to the DEA concerning an NDA, the FDA uses the same criteria to make its recommendation.<sup>235</sup> In the last fifteen years, the same time that the DEA's scheduling delays began, the FDA's recommendations and the DEA's scheduling decisions have not differed.<sup>236</sup> Furthermore, the FDA is required to enter into notice and comment rulemaking before scheduling drugs, as is the DEA.<sup>237</sup> Though the FDA's REMS considerations do not have the exact language of the CSA, it is important to note that occurrences of overdose, abuse, or withdrawal qualify as an "adverse drug experience" for consideration in the REMS' creation.<sup>238</sup>

The largest problem with this recommendation is that FDA lacks sufficient enforcement power. The FDA can bring civil actions against companies violating the REMS, but not in excess of "\$10 million for all violations in a single proceeding."<sup>239</sup> These suits would fall under the misbranding provisions of the FDCA.<sup>240</sup> While there are criminal penalties for violations of the FDCA,<sup>241</sup> the FDA's Office of Criminal Investigations focuses primarily on protecting its regulatory process. For the FDA, criminal investigations are a

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<sup>234</sup> See 21 U.S.C. § 355-1(a)(1)(D).

<sup>235</sup> See *supra* text accompanying notes 119-20.

<sup>236</sup> See Petition for Mandamus, *supra* note 17, at 11.

<sup>237</sup> HUTT, MERRILL, & GROSSMAN, *supra* note 41, at 810; see e.g., Int'l Drug Scheduling; Convention on Psychotropic Substances; Single Convention on Narcotics, 70 Fed. Reg. 73,779 (Dec. 13, 2005).

<sup>238</sup> See 21 U.S.C. § 355-1(b)(1)(B)-(D).

<sup>239</sup> *Questions and Answers on the Federal Register Notice on Drugs and Biological Products Deemed to Have Risk Evaluation and Mitigation Strategies*, FOOD & DRUG ADMIN., <http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticAct/FDCA/SignificantAmendmentstotheFDCA/FoodandDrugAdministrationAmendmentsActof2007/ucm095439.htm> (last updated June 18, 2009).

<sup>240</sup> But see Kathleen Struck, *OIG: Drug REMS Falling Short*, MEDPAGE TODAY (Feb. 14, 2013), <http://www.medpagetoday.com/Washington-Watch/FDAGeneral/37369> (suggesting that these penalties are actually quite lax, especially considering that the FDA can only request information but not require it).

<sup>241</sup> See 21 U.S.C. § 333.

response to an inability to remedy a situation in its regulatory scheme.<sup>242</sup> Where penalties arguably exist, the criminal penalty cannot exceed one year.<sup>243</sup> Furthermore, if a drug under a REMS regime faces abuse like that of hydrocodone, but was not scheduled by the DEA, the agency will have no power to bring charges against individual abusers.

This regime would still require the DEA to schedule its own drugs, but would not require the NDA applicant to wait for that scheduling before entering the market.<sup>244</sup> Arguably, this would allow the DEA discretion over whether to schedule an FDA-approved drug at all. For example, if Fycompa has potential for abuse but abuse does not appear to be an issue, the DEA would not need to waste resources scheduling the drug. An FDA REMS over Fycompa could limit distribution beyond that of DEA scheduling and ensure that physicians act with proper care. While a pure FDA REMS regime is not without its risks, the solution would allow both the FDA and the DEA to better assess their use of resources.

### *C. Alternatives to Outright Action: Joint Rulemaking*

With the ever-growing narcotic abuse epidemic resulting in thousands of deaths a year, undoubtedly concerns would arise if DEA was left out of the approval process for new drugs showing the potential for abuse. As an alternative to FDA's complete control, the FDA and DEA could enter into joint rulemaking procedures to schedule drugs. In this regard, the NCE would fall under the FDA's REMS regime for distribution and under the CSA's scheduling for

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<sup>242</sup> See *Inspections, Compliance, Enforcement, and Criminal Investigations*, FOOD & DRUG ADMIN., <http://www.fda.gov/ICECI/CriminalInvestigations/ucm123027.htm> (last updated Jan. 28, 2015).

<sup>243</sup> See FDCA § 301(c) ("The receipt . . . of any food, drug . . . that is adulterated or misbranded, and the delivery of proffered delivery therefore for pay or otherwise."); FDCA § 301(a)(1) ("Any person who violates a provision of section 301 shall be imprisoned for not more than one year.").

<sup>244</sup> *But see Improving Coordination of Related Agency Responsibilities*, at 7-8, ADMIN. CONFERENCE OF THE UNITED STATES (June 15, 2012), available at <http://www.acus.gov/sites/default/files/Final-Recommendation-2012-5-Improving-Agency-Coordination.pdf> (recommending better coordination between agencies for improving joint rulemaking and interagency agreements).

any potential abuse enforcement. This process would be particularly efficient as the FDA and DEA have the same considerations when assessing potentially abusive drugs.<sup>245</sup>

Agencies have entered into joint rulemaking where their responsibilities have overlapped. A major recent example is the joint rulemaking between the Environmental Protection Agency (“EPA”) and the Department of Transportation (“DOT”) to regulate greenhouse gas emission from automobiles.<sup>246</sup> The factors involved in this rulemaking made it particularly complex. The two agencies, along with the automobile industry, had to consider “complex differences in the statutes involved, the substantial costs and benefits, environmental effects, and international implications.”<sup>247</sup> The FDA and DEA would have similar challenges, particularly concerning the complexity of their statutes, their different agendas, and public health concerns. While joint rulemaking is not unfeasible, the process may not prevent the delays currently faced by the DEA-only system.

#### D. Evaluating Outcome Criteria

Criteria for evaluating solutions for this problem appear to be antithetical to each other in many regards. On one hand, the solution to this problem should create a quicker, more efficient process for pharmaceutical companies to place potentially addictive drugs on the open market. On the other hand, the solution should neither undercut the DEA’s enforcement ability nor remove the DEA’s ability to regulate the sale, distribution, and use of legitimate pharmaceuticals on the market. The best solution to this problem would allow both agencies to increase their individual effectiveness while reducing their individual monetary and personnel costs.

The primary solution criterion would be the quickened admittance of FDA-approved NCE onto the market, while maintaining the strict safety standards in the present system.

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<sup>245</sup> See *id.*

<sup>246</sup> See *President Obama Announces National Fuel Efficiency Policy*, WHITE HOUSE (May 19, 2009), available at <http://www.whitehouse.gov/the-press-office/president-obama-announces-national-fuel-efficiency-policy>.

<sup>247</sup> Neil Eisner, *DOT-EPA: Serving as a Model for Joint Rulemaking*, ADMIN. CONFERENCE OF THE UNITED STATES, available at <http://www.acus.gov/best-practices/success-story/dot-epa-serving-as-a-model-for-joint-rulemaking/>.

Undoubtedly, the primary concern for pharmaceutical companies is profits. Recognizing the manufacturers' concerns, the Hatch-Waxman Act automatically grants every NCE approved by the FDA an automatic five-year exclusivity period wherein no generic can enter the market, allowing the parent company to recoup its capital to reinvest in further research and development. In the case of Eisai, the company's primary concern with the DEA's "unreasonable delay" is that it has now lost ten months of this exclusivity without actually marketing Fycompa in the United States.<sup>248</sup> Assuming pharmaceutical companies do reinvest their capital into further research and development, the FDA REMS regime is multiplicative, as each new drug developed by the manufacturers will benefit from the streamlined process.

Notably, the Hatch-Waxman Act does provide for patent-term restoration when an administrative agency has delayed.<sup>249</sup> However, this offers little help to companies under a split FDA-DEA regime. Under the law, a company must apply for patent term extension within sixty days of agency approval.<sup>250</sup> For the FDA, the sixty-day period begins when the NDA is approved, regardless of subsequent DEA action. Eisai indicated in its Citizen's Petition that it intends to argue that the period should not begin until the company can market Fycompa.<sup>251</sup> However, the company's primary concern is ensuring that the five-year exclusivity period begins upon DEA approval. Additionally, simply extending the patent term or exclusivity period does not address the issue of quickly admitting a potentially life-saving drug onto the market.

Second, but of equal importance, any solution **must not** limit the DEA's enforcement power in any regard due to the grave nature of the designer drug problem in the United States. As stated above, the DEA only has jurisdiction over drugs upon which it has performed rulemaking procedures. In its Petition for Writ of Mandamus, Eisai

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<sup>248</sup> See Petition for Mandamus, *supra* note 17, at 10.

<sup>249</sup> Hatch- Waxman Act of 1984, Pub. L. No. 98-417 § 203, 98 Stat. 1585, 1603 (1984) (to be codified at 35 U.S.C §282).

<sup>250</sup> See *Small Business Assistance: Frequently Asked Questions on the Patent Term Restoration Program*, FOOD & DRUG ADMIN., <http://www.fda.gov/drugs/developmentapprovalprocess/smallbusinessassistance/ucm069959.htm> (last updated March 31, 2009).

<sup>251</sup> See Citizen's Petition, *supra* note 206, at 11 n. 16.

argues that the DEA's delay is further unreasonable because each drug that has needed scheduling since 1997 has followed the recommendation of HHS, often without public hearings before rulemaking completion.<sup>252</sup> However, simply codifying HHS's recommendation without DEA rulemaking would not grant DEA enforcement power as the law stands now. In this regard, the EPA and DOT's combined rulemaking regarding the regulation of greenhouse gas emissions demonstrates that joint rulemaking is not out of the question.<sup>253</sup> As of now, the FDA's REMS regime is ill-equipped to combat the growing designer drug problem, but could more effectively control its own approved drugs.<sup>254</sup> A strong solution would not only maximize efficiency in rulemaking procedure, accounting for the time spent by the agencies in their rule making and the efficient use of agency resources (i.e., tax payer money), but would also bolster the efficacy of both agencies to actually "have teeth" in enforcement.

## V. CONCLUSION

The United States Government's attempts to control and regulate the import, manufacture, distribution, and consumption of narcotic drugs has varied as Congress's powers have changed over the last century and as the public health crisis associated with narcotic abuse has become more prevalent and fatal. As the designer drug problem has worsened, the approval of new beneficial drugs has become more cumbersome and time consuming.

Recognizing that many beneficial drugs are also very dangerous, Congress, through the FDAAA, gave more power to the FDA to limit the supply of drugs with potential for abuse in the market. With these regulations alone, the FDA has the power to quickly and effectively allow life-saving drugs to enter the market quickly while still addressing policy concerns and without further contributing to the designer drug epidemic. In this light, Congress

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<sup>252</sup> See *id.* at 11.

<sup>253</sup> See *President Obama Announces National Fuel Efficiency Policy*, *supra* note 245 (allowing the EPA and FTC to focus on the common problem of regulating green house gas emissions in a way that maximized their resources).

<sup>254</sup> See Covington Memo, *supra* note 192.

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should give the FDA more power to regulate its own drugs with the potential for abuse through its REMS regime, allowing the DEA to perform its own rulemaking if the need arises.