

# PUTTING THE FOX IN CHARGE OF THE CHICKEN COOP: AN EXAMINATION OF THE CONTROLLED SUBSTANCES ACT AND THE RECLASSIFICATION OF HYDROCODONE

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## I. INTRODUCTION

The following story is true. The names have been changed to provide anonymity and preserve confidentiality. This is a story of an aging practitioner whose ability to treat his patients is being restricted by a regulatory system that too often disregards the real needs of law-abiding people. Dr. Jonathan Doe (often referred to as “Doc”) is a doctor in a small midwestern town and he maintains an extremely high active patient roster.<sup>1</sup> Doc has over 40,000 active patient files, sees an average of 1,600 to 1,800 patients per month, and has a 7–8% new patient ratio per month.<sup>2</sup> He maintains a medicine dispensary in his office for two main reasons: (1) so he can afford to pay for his entire staff’s medical insurance, which costs him over \$100,000 annually, and (2) to save his patients’ money on the cost of prescriptions at retail pharmacies.<sup>3</sup> Doc fills prescriptions at approximately 20–30% of the cost of a retail pharmacy.<sup>4</sup> For example, Doc charges \$30 for thirty Singulair 10 tablets, an asthma and allergy medication.<sup>5</sup> The retail pharmacy charges approximately \$200 for the same thirty tablets.<sup>6</sup> These are the cash prices, not insurance co-pays.<sup>7</sup> His patients appreciate the price and the convenience of his dispensary combined with his skill as a physician, as evidenced by the high active patient files and new patient percentage. Doc is loud, jovial, and often jokes with the patients and nurses. He’s genuine, hardworking (putting in five days a week when most doctors only work four<sup>8</sup>), accessible, and cares about his patients.

A good portion of Doc’s patient base is elderly and requires pain management.<sup>9</sup> He also treats a lot of blue-collar patients suffering from acute or chronic pain resulting from working conditions.<sup>10</sup> One hundred million Americans suffer from chronic pain.<sup>11</sup> Doc only prescribes two pain medications in the scope of his practice, hydrocodone combination products (“HCPs”) or Ultram, to effectively combat pain.<sup>12</sup> Doc is a large prescriber of all drugs, including pain medications, simply based on his volume of patients.<sup>13</sup> One day, Doc was “raided” by the Drug Enforcement Administration (“DEA”), which is authorized to evaluate him as a dispensing

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<sup>1</sup> Telephone Interview with Dr. Jonathan Doe, DO (Oct. 24, 2014) [hereinafter Interview].

<sup>2</sup> *Id.*

<sup>3</sup> *Id.*

<sup>4</sup> *Id.*

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

<sup>6</sup> *Singulair Prices, Coupons and Patient Assistance Programs*, DRUGS.COM, <http://www.drugs.com/p-ricerice-guide/singulair> (last visited Sept. 1, 2016).

<sup>7</sup> Interview, *supra* note 1.

<sup>8</sup> *Id.*

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

<sup>10</sup> *Id.*

<sup>11</sup> *AAPM Facts and Figures on Pain*, AM. ACAD. PAIN MED., [http://www.painmed.org/patientcenter/facts\\_on\\_pain.aspx#refer](http://www.painmed.org/patientcenter/facts_on_pain.aspx#refer) (last visited Sept. 1, 2016).

<sup>12</sup> See Interview, *supra* note 1; see also *Ultram*, DRUGS.COM, <http://www.drugs.com/ultram.html> (last visited Sept. 1, 2016).

<sup>13</sup> Interview, *supra* note 1.

physician and as a prescribing physician.<sup>14</sup> The DEA performed a purchasing audit and took inventory of Doc's controlled substances in order to determine whether his practice was a "pill mill."<sup>15</sup>

The DEA believes that over-prescribing is one of the main factors for HCPs' potential for abuse.<sup>16</sup> The DEA became convinced that regulating HCPs as Schedule II drugs would limit the amount of HCPs flowing into non-patient hands, which leads to abuse.<sup>17</sup> Changing a drug from Schedule III to Schedule II carries more strict prescribing, handling, and storage requirements.<sup>18</sup> The DEA successfully changed HCPs to Schedule II, and the final rule went into effect on October 6, 2014.<sup>19</sup>

Doc does not carry Schedule II drugs in his dispensary because of the scope of his practice, stigma, increased costs, and DEA visits that accompany those drugs.<sup>20</sup> As of October 23, 2014, less than three weeks after the final rule went into effect, all of the retail pharmacies in this small midwestern town were out of HCPs and unable to fill legitimate prescriptions.<sup>21</sup> Patients were told to drive to another town twenty miles away to attempt to get their prescriptions filled.<sup>22</sup> And, there is no guarantee the HCPs will be in stock in the other town when a patient needs it because a doctor cannot call-in a Schedule II prescription, it has to be handwritten and presented in person to the pharmacist.<sup>23</sup> What is grandma going to do about her back pain? What about Johnny Athlete with a torn ligament, or Susie Broken-Leg? In this small midwestern town, the DEA is likely proving successful in keeping HCPs out of the hands of abusers, but it is also successful in keeping HCPs out of the hands of patients that need it most.

What is Doc supposed to do? What can he do? He is still a physician

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<sup>14</sup> See *id.*; see also 21 U.S.C. §§ 802(21), 822(f), 880(b)(2) (2012).

<sup>15</sup> See 21 C.F.R. § 1316.03 (2015); see also Pia Malbran, *What's a Pill Mill*, CBS NEWS (May 31, 2007, 6:01 PM), <http://www.cbsnews.com/news/whats-a-pill-mill/> ("Pill mill" is a term used primarily by local and state investigators to describe a doctor, clinic or pharmacy that is prescribing or dispensing powerful narcotics inappropriately or for non-medical reasons.").

<sup>16</sup> Schedules of Controlled Substances: Rescheduling of Hydrocodone Combination Products From Schedule III to Schedule II, 79 Fed. Reg. 11,037, 11,040 (proposed Feb. 27, 2014) (to be codified at 21 C.F.R. pt. 1308) [hereinafter Proposed Rule].

<sup>17</sup> *Id.* at 11,042–43.

<sup>18</sup> Compare 21 U.S.C. § 829(b), and 21 C.F.R. § 1301.72(b), with 21 U.S.C. § 829(a), and 21 C.F.R. § 1301.72(a).

<sup>19</sup> Schedules of Controlled Substances: Rescheduling of Hydrocodone Combination Products From Schedule III to Schedule II, 79 Fed. Reg. 49,661, 49,661 (Aug. 22, 2014) (to be codified at 21 C.F.R. pt. 1308) [hereinafter Final Rule].

<sup>20</sup> Interview, *supra* note 1.

<sup>21</sup> *Id.*; Steven Moore, *Southern Nevada Doctors Change Prescriptions After Painkiller Reclassification*, LAS VEGAS REVIEW-JOURNAL, <http://www.reviewjournal.com/life/health/southern-nevada-doctors-change-prescriptions-after-painkiller-reclassification> (last updated Oct. 20, 2014, 9:36 PM) ("The unintended consequences of these laws is to make it more difficult for my patients in chronic pain to receive their medications . . .").

<sup>22</sup> Interview, *supra* note 1.

<sup>23</sup> 21 U.S.C. § 829(a).

with a calling to alleviate people's pain and suffering.<sup>24</sup> Doc knows that the possible side effects of other pain management drugs, such as Tylenol and NSAIDs, are liver damage, gastrointestinal bleeding, and kidney failure.<sup>25</sup> Therefore, he prescribes HCPs because he feels it provides the best option for his patients' pain-management needs with the least amount of side effects.<sup>26</sup> Sadly, there is now one unavoidable side effect of HCPs—patients will likely have difficulty getting what Doc believes is the right medication.

President Richard Nixon signed the Controlled Substances Act (“CSA”)<sup>27</sup> into law on October 27, 1970.<sup>28</sup> The CSA is a statute designed to regulate the manufacture, distribution, and sale of drugs, and the process of controlling drugs by means of a complicated scheme involving ten administrative agencies (four lead agencies, and six adjunct agencies), eight different criteria,<sup>29</sup> and four “indicators,” all of which result in a Schedule I to V classification system for hundreds of drugs based on potential for abuse.<sup>30</sup> Subsequently, President Nixon created the DEA<sup>31</sup> in July 1973 to “establish a single unified command” for drug enforcement.<sup>32</sup> These two enactments result in a byzantine process of drug regulation, which begins with an enforcement agency instead of a health-based agency and emphasizes politics over science, yielding a significant risk to public health. This flawed system is predisposed to primarily focus on the negatives of drugs. This Comment considers the current rescheduling of HCPs and its focus upon the potential for abuse as opposed to its ability to effectively manage pain, as an example for this analysis.

Five of the eight factors used by the DEA to schedule a drug address the concept of “abuse,” yet the CSA and DEA regulations fail to define that essential term.<sup>33</sup> This failure results in a system that regulates drugs that are formulated to accomplish certain medical goals in a way that is prone to misuse and politics. Scheduling decisions are driven by political concerns rather than public health values.

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<sup>24</sup> Interview, *supra* note 1.

<sup>25</sup> *Id.*; R. Morgan Griffin, *Pain Relief: How NSAIDs Work*, WEBMD, <http://www.webmd.com/arthritis/features/pain-relief-how-nsaids-work> (last visited Sept. 1, 2016).

<sup>26</sup> Interview, *supra* note 1.

<sup>27</sup> *See generally* 21 U.S.C. §§ 801–89.

<sup>28</sup> *See* Richard Nixon, *Remarks on Signing the Comprehensive Drug Abuse Prevention and Control Act of 1970*, AM. PRESIDENCY PROJECT, <http://www.presidency.ucsb.edu/ws/?pid=2767> (last visited Sept. 1, 2016); *see also* Comprehensive Drug Abuse Prevention and Control Act of 1970, Pub. L. No. 91-513, § 100, 84 Stat. 1236, 1242 (stating the CSA is Title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970).

<sup>29</sup> *See* Comprehensive Drug Abuse Prevention and Control Act of 1970 § 201; *see also* 21 U.S.C. § 811(c) (2012).

<sup>30</sup> Comprehensive Drug Abuse Prevention and Control Act of 1970 § 202.

<sup>31</sup> 21 C.F.R. §§ 1300–21 (2015).

<sup>32</sup> *DEA History*, U.S. DRUG ENFORCEMENT ADMIN., <https://www.dea.gov/about/history.shtml> (last visited Sept. 1, 2016).

<sup>33</sup> *See* 21 U.S.C. § 802; *see also* 21 C.F.R. § 1308.02 (stating the CSA and DEA regulations fail to define “abuse” or “potential for abuse”).

This Comment argues that creating and implementing a medically-based evaluation system, instead of relying upon the current “abuse”-based evaluation system, will streamline the scheduling process and result in scheduling decisions based upon scientific evidence as opposed to political motivations. Moreover, this Comment will make the case that when pain management is appropriately taken into account instead of regulation necessities in the process of scheduling of drugs, rule-makers will conclude that HCPs should remain a Schedule III drug.

Part II investigates the background of the drug scheduling process as well as the federal agencies involved and reviews their interactions. It examines the eight factors and the four indicators used by the DEA to schedule drugs. Part II also provides a detailed example of the rescheduling process used for HCPs. Part III takes the HCP example and demonstrates the inherent problem of drug enforcement politics coupled with the risk of abuse trumping the logic of science and the health benefits of effective pain management. Part IV proposes recommendations for improving the imbalanced rescheduling process by changing the agency in charge of rulemaking procedures and focusing on science and health benefits instead of politics and bias. These recommendations create accurate and efficient drug regulations through amendments to the CSA that adjust scheduling factors and transfer the scheduling process to a health or science-based agency.

## II. BACKGROUND

Drugs are scheduled based on criteria of eight factors.<sup>34</sup> The first and most controlling factor—potential for abuse—has four “indicators” that guide its determination.<sup>35</sup> This byzantine process of factor determination is composed of at least ten administrative agencies with each contributing a different piece to the puzzle.<sup>36</sup> This process is examined through the illustration of the recent HCP rescheduling to demonstrate these factors in action.

### A. *The Eight Factors and Four “Indicators” for Scheduling a Drug*

The eight factors guiding the entire process of scheduling drugs are

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<sup>34</sup> 21 U.S.C. § 811(c). The eight factors are:

(1) [i]ts actual or relative potential for abuse[;] (2) [s]cientific evidence of its pharmacological effect, if known[;] (3) [t]he state of current scientific knowledge regarding the drug or other substance[;] (4) [i]ts history and current pattern of abuse[;] (5) [t]he scope, duration, and significance of abuse[;] (6) [w]hat, if any, risk there is to the public health[;] (7) [i]ts psychic or physiological dependence liability[;] and] (8) [w]hether the substance is an immediate precursor of a substance already controlled under this subchapter.

*Id.*

<sup>35</sup> See *infra* text accompanying note 46.

<sup>36</sup> See *supra* text accompanying notes 29–30.

outlined in the CSA.<sup>37</sup> The first factor—the drug’s actual or potential for abuse—overwhelmingly controls much of the scheduling process.<sup>38</sup> This factor is “[a] key criterion for controlling a substance, and the one which will be used most often, is the substance’s potential for abuse.”<sup>39</sup> Furthermore, the scientific and medical data provided by the FDA applies to factors (2), (3), (6), (7), and (8).<sup>40</sup> The Secretary of the Department of Health and Human Services (“HHS”) must consider, along with those five factors, any medical and scientific data that applies to factors (1), (4), and (5).<sup>41</sup> Under 21 U.S.C. § 811(c) of the CSA, the Attorney General (now the DEA Administrator via delegation<sup>42</sup>) must consider the same eight factors when adding, removing, or transferring a drug’s schedule.<sup>43</sup>

### 1. The Drug’s Actual or Relative Potential for Abuse

The first factor aims to examine a drug’s “actual or relative potential for abuse.”<sup>44</sup> However, the CSA purposely does not define the term “abuse” to create a malleable standard by which it can schedule drugs.<sup>45</sup> A review of the CSA’s legislative history does, nevertheless, provide four indicators that are used to determine a drug’s potential for abuse:

- (a) Individuals are taking the drug or other substance in amounts sufficient to create a hazard to their health or to the safety of other individuals or to the community; or
- (b) There is a significant diversion of the drug or other substance from legitimate drug channels; or
- (c) Individuals are taking the drug or other substance on their own initiative rather than on the basis of medical advice from a practitioner licensed by law to administer such drugs; or
- (d) The drug is so related in its action to a drug or other substance already listed as having a potential for abuse to make it likely that it will have the same potential for abuse as such substance, thus making it reasonable to assume that there may be significant diversions from legitimate channels, significant use contrary to or without medical advice, or that it has a substantial capability of creating hazards to the health

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<sup>37</sup> See *supra* note 34.

<sup>38</sup> H.R. Rep. No. 91-1444 (1970), as reprinted in 1970 U.S.C.C.A.N. 4566, 4601 [hereinafter House Report].

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

<sup>40</sup> 21 U.S.C. § 811(b) (2012).

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

<sup>42</sup> See *id.* § 871(a); see also 28 C.F.R. 0.10(b) (2015).

<sup>43</sup> 21 U.S.C. § 811(c).

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

<sup>45</sup> See *id.* § 802 (lacking a definition for the term abuse); see also Proposed Rule, *supra* note 16, at 11,040.

of the user or to the safety of the community.<sup>46</sup>

These four indicators are disjunctive, which means the satisfaction of one qualifies a drug as having the potential to be abused.<sup>47</sup> Since they appear in the legislative history, these indicators are only persuasive legal authority.<sup>48</sup>

## 2. Scientific Evidence of the Drug's Pharmacological Effect, if Known

The second factor, the pharmacology of a drug or substance, is fundamental for scheduling.<sup>49</sup> Pharmacology is “the properties and reactions of drugs especially with relation to their therapeutic value.”<sup>50</sup> Moreover, “[t]he best available knowledge of the pharmacological properties of a drug should be considered.”<sup>51</sup> Such pharmacological properties contain data such as “chemical synthesis and solubility” as well as “absorption and metabolism.”<sup>52</sup>

## 3. The State of Current Scientific Knowledge Regarding the Drug

Factors two and three are closely related because both deal with the science of drugs.<sup>53</sup> While the second factor deals with the pharmacological effects of a drug, the third factor encompasses “all scientific knowledge with respect to the substance.”<sup>54</sup> The science and medical data will include “information gathered from studies designed to investigate whether animals develop physical dependence and will work to self-administer the drug . . . .”<sup>55</sup> Additionally, “[h]uman adverse events (relating to the drug's ability to cause physical dependence, alter moods, cause hallucinations, etc.) are collected and reviewed from clinical trial reports . . . .”<sup>56</sup>

## 4. The Drug's History and Current Pattern of Abuse

The fourth factor surveys the drug's history and current pattern of abuse, which is pertinent in determining exactly how a drug should be controlled.<sup>57</sup> History and pattern of abuse include when the drug was

<sup>46</sup> Proposed Rule, *supra* note 16, at 11,040.

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

<sup>48</sup> *Id.*; House Report, *supra* note 38, at 4601; *Federal Legislative History*, DUKE U. SCH. L. 1, 1, <https://law.duke.edu/sites/default/files/lib/fedleghist.pdf> (last updated May 2016).

<sup>49</sup> U.S. DEP'T OF JUSTICE DRUG ENFORCEMENT ADMIN., DRUGS OF ABUSE: A DEA RESOURCE GUIDE 9 (2011), [http://www.justice.gov/dea/docs/drugs\\_of\\_abuse\\_2011.pdf](http://www.justice.gov/dea/docs/drugs_of_abuse_2011.pdf) [hereinafter DRUGS OF ABUSE].

<sup>50</sup> *Pharmacology*, MERRIAM-WEBSTER.COM, <http://www.merriam-webster.com/dictionary/pharmacology> (last visited Sept. 1, 2016).

<sup>51</sup> DRUGS OF ABUSE, *supra* note 49, at 9.

<sup>52</sup> *Scheduling of Drugs Under the Controlled Substances Act*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/newsevents/testimony/ucm115087.htm> (last updated Aug. 6, 2009) [hereinafter *Scheduling of Drugs*].

<sup>53</sup> DRUGS OF ABUSE, *supra* note 49, at 9.

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

<sup>55</sup> *Scheduling of Drugs*, *supra* note 52.

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

<sup>57</sup> DRUGS OF ABUSE, *supra* note 49, at 9.

introduced for clinical use, reports of abuse or addiction popularity, similarities to other abused drugs, as well as national and regional drug abuse data.<sup>58</sup>

#### 5. The Scope, Duration, and Significance of Abuse

Similarly, the fifth factor examines abuse, except here, it looks at how widespread is the abuse.<sup>59</sup> This factor assesses drug risks, illicit use, and whether the amounts taken are “sufficient to create a hazard to [an individual’s] health and to the safety of other individuals and the community.”<sup>60</sup> When looking at drugs that have a potential for abuse, this factor scrutinizes “increasing trends in serious adverse side effects,” in addition to methods of diversion.<sup>61</sup>

#### 6. What, if any, Risk There is to Public Health

The DEA Administrator uses the sixth factor to consider “if a drug creates dangers to the public health, in addition to or because of its abuse potential . . . .”<sup>62</sup> Risks to public health can include: “developing tolerance, dependence and addiction, and the attendant problems associated with these risks including death.”<sup>63</sup>

#### 7. The Drug’s Psychic or Physiological Dependence Liability

The seventh factor analyzes animal and human studies, which can be used to determine dependence potential.<sup>64</sup> The crux of this factor is to determine “the extent to which a drug is physically addictive or psychologically habit forming.”<sup>65</sup>

#### 8. Whether the Substance is an Immediate Precursor of a Substance Already Controlled under the CSA

The final factor examines whether the drug or substance is a precursor<sup>66</sup> for another drug or substance that is currently scheduled under the CSA. “The Attorney General may, without regard to the findings required by [§ 811](a) . . . place an immediate precursor in the same schedule in which the controlled substance of which it is an immediate precursor is placed or in

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<sup>58</sup> See generally Proposed Rule, *supra* note 16, at 11,042.

<sup>59</sup> DRUGS OF ABUSE, *supra* note 49, at 9.

<sup>60</sup> Proposed Rule, *supra* note 16, at 11,042.

<sup>61</sup> *Id.*

<sup>62</sup> DRUGS OF ABUSE, *supra* note 49, at 9.

<sup>63</sup> Proposed Rule, *supra* note 16, at 11,043.

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

<sup>65</sup> DRUGS OF ABUSE, *supra* note 49, at 9.

<sup>66</sup> Precursor, DRUGS.COM, <http://www.drugs.com/dict/precursor.html> (last visited Sept. 1, 2016) (“That which precedes another or from which another is derived, applied especially to a physiologically inactive substance that is converted to an active enzyme, vitamin, hormone, etc., or to a chemical substance that is built into a larger structure in the course of synthesizing the latter.”).

any other schedule with a higher numerical designation.”<sup>67</sup>

*B. The Mechanics of Scheduling a Drug and the Agencies Involved*

The DEA can begin a scheduling or rescheduling investigation of a drug in several ways.<sup>68</sup> Interested parties, such as a manufacturer of a drug, a pharmacy association, a state or local government agency, or even an individual citizen can file a petition to begin the scheduling process.<sup>69</sup> “The DEA also may begin an investigation of a drug at any time based upon information received from law enforcement laboratories, state and local law enforcement and regulatory agencies, or other sources of information.”<sup>70</sup> The Attorney General is, by statute, the officer in charge of receiving petitions for the scheduling and rescheduling of drugs.<sup>71</sup> However, this power can be delegated to “any officer or employee of the Department of Justice,” and is currently delegated to the DEA Administrator.<sup>72</sup> The DEA Administrator uses this delegated power to request HHS to create a recommendation, comprised of a scientific and medical evaluation, “as to whether the drug or other substance should be controlled or removed from control,” and within what schedule the drug should be placed.<sup>73</sup>

After HHS receives the request from the DEA for the scientific and medical analysis, HHS uses the Food and Drug Administration (“FDA”) in a consultant-type role to conduct this analysis.<sup>74</sup> The FDA, in turn, uses several smaller agencies to assist with the scientific and medical data gathering. Initially, the FDA’s Center for Drug Evaluation and Research (“CDER”) “conducts a review of the drug,” which includes “chemical properties, pharmacology studies and clinical studies and reports related to the drug.”<sup>75</sup> This consultation, review, and recommendation also includes input from the National Institute on Drug Abuse (“NIDA”), the Interagency Drug Scheduling Working Group (“IDSWG”), and the Substance Abuse and Mental Health Services Administration (“SAMHSA”) under a Memorandum of Understanding allowing for the sharing of information among the agencies.<sup>76</sup> The FDA’s Office of Health Affairs coordinates all of the activities for HHS and is responsible for assembling the report and scheduling recommendation.<sup>77</sup> Several other agencies are often involved in this process: Controlled Substance Staff; Division of Anesthesia, Analgesia and Addiction

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<sup>67</sup> 21 U.S.C. § 811(e) (2012).

<sup>68</sup> DRUGS OF ABUSE, *supra* note 49, at 8.

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

<sup>70</sup> *Id.*

<sup>71</sup> 21 U.S.C. § 811(a).

<sup>72</sup> *See id.* § 871(a); *see also* 28 C.F.R. 0.100(b) (2015).

<sup>73</sup> DRUGS OF ABUSE, *supra* note 49, at 8; 21 U.S.C. § 811(a).

<sup>74</sup> *Scheduling of Drugs, supra* note 52.

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

<sup>76</sup> *Id.*

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

Products; Office of New Drugs; and the Office of Chief Counsel.<sup>78</sup>

After all of these agencies perform their appropriate tasks, add their respective input, and compile the reports and recommendations, the FDA sends the report, based on the eight factors, to the Assistant Secretary of Health (“ASH”).<sup>79</sup> The ASH then “makes the final determination on behalf of the Secretary [of HHS].”<sup>80</sup> Once the ASH’s decision is made, a schedule classification is recommended and all of this information is sent back to the DEA.<sup>81</sup> While the medical and scientific data from HHS are binding on the DEA, the schedule recommendation is not.<sup>82</sup> Therefore, when the DEA receives the report and recommendation from HHS, and the DEA chooses to proceed with the scheduling or rescheduling, the DEA must use Notice and Comment Rulemaking powers.<sup>83</sup>

### C. *Rescheduling Hydrocodone Combination Products*

A German pharmaceutical company named Knoll first created Hydrocodone in the 1920s.<sup>84</sup> The process of attaching a hydrogen atom with codeine molecules was thought to be easier on the user’s stomach than codeine alone.<sup>85</sup> In March 1943, the FDA approved hydrocodone for sale under the name of hycodan.<sup>86</sup> When the CSA was enacted in 1971, pure hydrocodone was placed directly into Schedule II.<sup>87</sup> However in 1971, HCPs, which are no more than fifteen milligrams of hydrocodone combined with other nonnarcotic drugs, were placed in Schedule III.<sup>88</sup> HCPs are effective in treating mild to moderate pain and as a cough suppressive because they act as a depressant on the central nervous system by slowing down how the brain reacts to pain.<sup>89</sup>

In 1999, a physician specializing in addiction medications submitted a petition to the DEA requesting that HCPs be rescheduled because he

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<sup>78</sup> *Drug Safety and Risk Management Advisory Committee (DSaRM)*, U.S. FOOD & DRUG ADMIN. 1, 28 (Jan. 24–25, 2013), <http://www.fda.gov/downloads/advisorycommittees/committeesmeetingmaterials/drugs/drugsafetyandriskmanagementadvisorycommittee/ucm337148.pdf> [hereinafter DSaRM].

<sup>79</sup> *Scheduling of Drugs*, *supra* note 52.

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

<sup>81</sup> *Id.*

<sup>82</sup> DRUGS OF ABUSE, *supra* note 49, at 8.

<sup>83</sup> 21 C.F.R. § 1308.43 (2013); 5 U.S.C. § 553 (2000); *Notice-and-Comment Rulemaking*, CTR. FOR EFFECTIVE GOV’T, <http://www.foreffectivegov.org/node/2578> (last visited Sept. 1, 2016) (“Notice-and-comment rulemaking is a common rulemaking procedure under which a proposed rule is published in the Federal Register and is open to comment by the general public.”).

<sup>84</sup> *History of Hydrocodone*, HYDROCODONE HELP, <http://www.hydrocodonehelp.com/history-of-hydrocodone> (last visited Sept. 1, 2016).

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

<sup>86</sup> *Drugs @ FDA*, U.S. FOOD & DRUG ADMIN., <http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.DrugDetails> (last visited Sept. 1, 2016) (search “hycodan”).

<sup>87</sup> Proposed Rule, *supra* note 16, at 11,039.

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

<sup>89</sup> *How Does Hydrocodone Work?*, ADDICTION BLOG (June 14, 2012), <http://prescription-drug.addictioblog.org/how-does-hydrocodone-work/>.

believed there was evidence HCPs had a potential for abuse.<sup>90</sup> The DEA first submitted the request for the scientific and medical evaluation and scheduling recommendation of HCPs to HHS in 2004.<sup>91</sup> In 2008, HHS responded to the DEA's request by not recommending a change of schedule for HCPs.<sup>92</sup> The DEA was unsatisfied with this recommendation to not reschedule.<sup>93</sup> This is evidenced by the DEA's speedy 2009 request that HHS "re-evaluate their data and provide another scientific and medical evaluation and scheduling recommendation based on additional data and analysis."<sup>94</sup>

The Food and Drug Administration Safety and Innovation Act ("FDASIA") was signed on July 9, 2012, during the second evaluation of HCPs.<sup>95</sup> This significant piece of legislation required the FDA "to hold a public meeting to 'solicit advice and recommendations' pertaining to the scientific and medical evaluation in connection with its scheduling recommendation to the DEA regarding drug products containing hydrocodone . . . ."<sup>96</sup> The FDA subsequently held a public "Advisory Committee" meeting on January 24–25, 2013 and "the Secretary was required to solicit stakeholder input 'regarding the health benefits and risks, including the potential for abuse' of hydrocodone combination products and the impact of up-scheduling of these products."<sup>97</sup> The DEA made a presentation to the Advisory Committee, which consisted of twenty-nine members, including "scientific and medical expert[s]" and one "patient representative."<sup>98</sup> The Committee voted 19–10 in favor of rescheduling HCPs.<sup>99</sup> HHS came to three conclusions prior to making its recommendation:

[1] that individuals are taking HCPs in amounts sufficient to create a hazard to their health or to the safety of other individuals or to the community; [2] that there is significant diversion of HCPs; and [3] that individuals are taking HCPs on their own initiative rather than on the basis of medical advice from a practitioner licensed by law to administer such drugs.<sup>100</sup>

The Secretary of HHS considered the Advisory Committee recommendation, public comments, health benefits and risks, and the impact of rescheduling on

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<sup>90</sup> U.S. DEP'T OF JUSTICE DRUG ENFORCEMENT ADMIN., SCHEDULES OF CONTROLLED SUBSTANCES: PLACEMENT OF HYDROCODONE COMBINATION PRODUCTS INTO SCHEDULE II, at 2 (2014), <http://ws.westernu.edu/WesternU-News/docs/DEAs-Eight-Factor-Analysis-HCP.pdf>.

<sup>91</sup> Proposed Rule, *supra* note 16, at 11,039.

<sup>92</sup> *Id.*

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

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

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

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

<sup>97</sup> *Id.*

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

<sup>99</sup> *Id.*

<sup>100</sup> *Id.* at 11,040.

the medical community using the required eight-factor analysis.<sup>101</sup> The Secretary then decided to recommend that the DEA reschedule HCPs as a Schedule II drug.<sup>102</sup>

The HHS recommendation was submitted to the DEA on December 16, 2013.<sup>103</sup> The DEA published a notice of proposed rulemaking<sup>104</sup> in the Federal Register on February 27, 2014 to change HCPs from Schedule III to Schedule II.<sup>105</sup> A written comment period of sixty days was made available to the public, and any interested person could request a hearing with the DEA by March 31, 2014.<sup>106</sup> No hearing was requested.<sup>107</sup> The comment period ended on April 28, 2014, and the DEA received 573 comments on the proposed rule, 52% in favor of rescheduling, 41% not in favor, and 7% did not have a preference.<sup>108</sup> The DEA's final rule rescheduling HCPs to Schedule II was published in the Federal Register on August 22, 2014.<sup>109</sup> The final rule only allowed for a forty-five day implementation period and established the rule's effective date as October 6, 2014.<sup>110</sup>

### III. ARGUMENT

The DEA cannot regulate a drug or substance until it has been placed in a schedule.<sup>111</sup> The CSA predisposes the increased regulation of substances from a political/policing point of view instead of scheduling substances based on medical or scientific needs and uses. This predisposition is established when the CSA vests the scheduling power to the Attorney General, who, by statute, appointed the DEA Administrator to regulate substances.<sup>112</sup> The DEA primarily consists of drug police, not scientists or doctors.<sup>113</sup> This predisposal to regulation may hinder accessibility to useful substances, like HCPs, for suffering patients.<sup>114</sup> The DEA's likely counterargument is that the CSA and the U.S. Supreme Court gave it the authority to do just that.<sup>115</sup>

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<sup>101</sup> See 21 U.S.C. § 811(b) (2012).

<sup>102</sup> Proposed Rule, *supra* note 16, at 11,040.

<sup>103</sup> Final Rule, *supra* note 19, at 49,663.

<sup>104</sup> 5 U.S.C. § 553 (2000) (explaining the Administrative Procedure Act's notice and comment rulemaking requires an agency to follow three steps: notice, an opportunity for comment, and a final rule).

<sup>105</sup> See Proposed Rule, *supra* note 16, at 11,037.

<sup>106</sup> Final Rule, *supra* note 19, at 49,663.

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

<sup>108</sup> *Id.*

<sup>109</sup> *Id.* at 49,661.

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

<sup>111</sup> See 21 U.S.C. §§ 811–12 (2012).

<sup>112</sup> See *supra* text accompanying notes 42, 71–72.

<sup>113</sup> DRUG ENF'T ADMIN., DEA FACT SHEET (2012), <http://www.justice.gov/dea/docs/1207fact-sheet.pdf> (stating in 2012, the "DEA employ[ed] more than 10,000 men and women, including nearly 5,000 Special Agents, 500 Diversion Investigators, 800 Intelligence Research Specialists, and 300 Chemists").

<sup>114</sup> See *infra* text accompanying note 150.

<sup>115</sup> See *infra* note 128.

*A. The CSA is Predisposed Towards Increased Regulation*

The CSA was signed into law in October 1970 as a precursor to President Nixon's June 1971 War on Drugs.<sup>116</sup> The War on Drugs led to the establishment of the DEA, an agency whose sole purpose is to crack down on drug abuse.<sup>117</sup> While the CSA and some of its eight factors require the DEA to consider medical and scientific analysis,<sup>118</sup> "the DEA has consistently demonstrated that it is incapable of accurately assessing the state of medical and scientific knowledge about . . . drugs and scheduling them appropriately."<sup>119</sup> Additionally, after the DEA considers the eight factors required by the CSA in scheduling a substance, it "may consider 'all other relevant data' in making its decisions."<sup>120</sup> This statutory "catch-all" gives the DEA the potential for free reign to find other relevant data to provide reasons to regulate drugs as it sees fit.

Two of the eight factors specifically relate to the medical and scientific properties of a drug.<sup>121</sup> HHS, FDA, and other adjunct agencies perform the analysis of those factors, which ultimately is not the DEA's focal point.<sup>122</sup> The presentation by the DEA at the FDASIA Advisory Committee meeting on January 24, 2013 regarding the rescheduling of HCPs focused on diversion and abuse, and allowed for a question and answer session.<sup>123</sup> The presenter, DEA Deputy Assistant Administrator for the Office of Diversion Control, Joseph T. Rannazzisi, stated, "I'm not going to talk about denominators. I'm not a statistician. I'm not a PhD. I'm just a cop. That's all I am, but I'm a cop with a lot of practical knowledge because I don't care what the denominators say, every day I deal in reality."<sup>124</sup> This "cop," who also has a J.D. and a pharmacy degree, does not want to talk about statistics or science and medicine in a room full of doctors and medical professionals.<sup>125</sup> He only wants to discuss, from his regulation-based point of view, why HCPs need to be rescheduled and why the DEA needs tighter control.

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<sup>116</sup> See *supra* note 28; see also *Thirty Years of America's Drug War: A Chronology*, PBS, <http://www.pbs.org/wgbh/pages/frontline/shows/drugs/cron/> (last visited Sept. 1, 2016).

<sup>117</sup> See *supra* text accompanying notes 31–32.

<sup>118</sup> See *supra* text accompanying Sections II.A.2, II.A.3.

<sup>119</sup> *The DEA: Four Decades of Impeding and Rejecting Science*, DRUG POL'Y ALLIANCE 1, 5 (June 9, 2014) <http://www.drugpolicy.org/resource/dea-four-decades-impeding-and-rejecting-science> (addressing marijuana as a Schedule I substance; the argument is the same for all drugs).

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

<sup>121</sup> See discussion *supra* Sections II.A.2, II.A.3.

<sup>122</sup> DSaRM, *supra* note 78, at 200. This meeting was required by FDASIA legislation and facilitated a presentation by DEA Deputy Assistant Administrator for the Office of Diversion Control Joseph T. Rannazzisi, and in reference to rescheduling drugs he stated, "my determination is based on abuse and *then* the scientific factors that HHS and FDA look at regarding the pharmacology, public health risks, and things like that." *Id.* (emphasis added).

<sup>123</sup> *Id.* at 155–213.

<sup>124</sup> *Id.* at 162.

<sup>125</sup> See discussion *supra* Sections II.A.2, II.A.3; see also Joseph T. Rannazzisi, NAT'L RX DRUG ABUSE & HEROIN SUMMIT, <http://nationalrxdrugabusesummit.org/biographies/joseph-t-rannazzisi/> (last visited Sept. 1, 2016).

The language of the CSA is predisposed to increase regulation of drugs or other substances by scheduling and permits DEA discretion in regards to decreasing regulation of drugs or other substances.<sup>126</sup> How likely is a person whose job is directly dependent on regulation to decrease that regulation? As discussed previously, a majority of the eight factors are based on the undefined concept of abuse, a malleable term into which the DEA can manipulate almost any drug or substance.<sup>127</sup> This undefined principle of abuse, combined with the “catch-all” of “other relevant data,” works to override scientific data and provides the DEA with ample opportunity to schedule drugs as it pleases.

While the Administrative Procedure Act (“APA”) provides checks and balances to agency rulemaking through a judicial challenge, courts give a high amount of deference to agency decisions.<sup>128</sup> Thus, as long as the DEA can show that a drug fits into one of the four “indicators” that show potential for abuse under the first factor,<sup>129</sup> or locate “other relevant data” that shows a drug is abused, a court will likely give deference to the DEA’s decision to schedule or reschedule that drug.<sup>130</sup> This predisposition for regulation coupled with a high amount of deference by the court can lead to the overscheduling of useful drugs or substances.<sup>131</sup>

### *B. HCPs, the Fox, and the Chicken Coop*

HCPs are effective opioid pain management medications used by approximately fifty million Americans that can be abused when taken in excess or without a prescription.<sup>132</sup> Nevertheless, HCPs should remain a Schedule III drug. Logically, any drug can be abused by not following the proper instructions. The goal of scheduling drugs is to balance the positives (drug usefulness or effectiveness) with the negatives (potential for abuse) to

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<sup>126</sup> 21 U.S.C. § 811(a) (2012) (“[T]he [DEA Administrator] may by rule—(1) add to such a schedule or transfer between such schedules any drug or other substance . . . ; or (2) remove any drug or other substance from the schedules if he finds that the drug or other substance does not meet the requirements for inclusion in any schedule.” (emphasis added)).

<sup>127</sup> See *supra* text accompanying notes 33, 46–48.

<sup>128</sup> See *Chevron, U.S.A., Inc. v. NRDC, Inc.*, 467 U.S. 837, 844 (1984) (“[The Court] ha[s] long recognized that considerable weight should be accorded to an executive department’s construction of a statutory scheme it is entrusted to administer, and the principle of deference to administrative interpretations ‘has been consistently followed by this Court whenever decision as to the meaning or reach of a statute has involved reconciling conflicting policies, and a full understanding of the force of the statutory policy in the given situation has depended upon more than ordinary knowledge respecting the matters subjected to agency regulations.’”).

<sup>129</sup> See *supra* text accompanying notes 47–48.

<sup>130</sup> See *Chevron*, 467 U.S. at 844.

<sup>131</sup> See Lars Noah, *Challenges in the Federal Regulation of Pain Management Technologies*, 31 J.L. MED. & ETHICS 1, 2 (2003) (“For the DEA, most of the important restrictions on access to controlled substances represent an outgrowth of initial decisions about appropriate scheduling, which may cause the agency to over-schedule substances in order to serve law enforcement purposes.”).

<sup>132</sup> See *Pharmacy Associations Oppose Rescheduling of Hydrocodone Combination Product*, PHARMACY TIMES (June 16, 2014), <http://www.pharmacytimes.com/publications/issue/2014/June/2014/Pharmacy-Associations-Oppose-Rescheduling-of-Hydrocodone-Combination-Products>; *Hydrocodone*, DRUGS.COM, <http://www.drugs.com/hydrocodone.html> (last visited Sept. 1, 2016).

provide doctors and patients with viable medical solutions to ailments.<sup>133</sup>

The DEA initially attempted to reschedule HCPs in 2004, but the 2008 HHS recommendation in response to this request was to leave HCPs as a Schedule III narcotic.<sup>134</sup> The DEA resubmitted its request to HHS to reschedule HCPs in 2009 with additional information regarding abuse, and HHS came back in 2012 with a recommendation to reschedule HCPs to Schedule II.<sup>135</sup> The DEA's final rule to reschedule took effect October 6, 2014.<sup>136</sup>

The second request by the DEA contained updated abuse statistics on opioids, which examined HCPs and oxycodone (a Schedule II drug) products when looking at the first of the eight factors, which contains the four potential for abuse "indicators."<sup>137</sup> Specifically in the proposed rulemaking, the Drug Abuse Warning Network ("DAWN") reported statistics to the DEA from 2011 stating, "the total number of [emergency department] visits related to nonmedical use of HCPs and oxycodone products were 82,479 and 151,218, respectively."<sup>138</sup> The National Poison Data System reported that for the years 2011 and 2012, HCPs were present in 30,792 and 29,391 toxic exposures, respectively, while oxycodone products were present in 19,423 and 18,495 for those same years.<sup>139</sup> Additionally, DAWN reported data for five states from 2004 to 2010 showing an increase in deaths related to HCPs of 63%, while deaths related to oxycodone increased 133%.<sup>140</sup> The DEA goes on to state that in 2012 HCPs and oxycodone were diverted from legitimate drug channels in 34,832 and 41,915 cases respectively.<sup>141</sup>

The DEA's proposed rule cited the National Survey on Drug Use and Health ("NSDUH") for users that have "ever used" HCPs and oxycodone products for nonmedical purposes in 2012 as "over 25.6 million and 16 million, respectively."<sup>142</sup> To conclude its analysis of the first factor and the four "indicators," the DEA states, "[c]ollectively these data demonstrate that HCPs have a high potential for abuse similar to other schedule II opioid analgesic drugs such as morphine and oxycodone products."<sup>143</sup>

HCPs are abused, and the above statistics present societal problems that are difficult to accept. Nevertheless, the statistics are worth deeper examination. The DEA's use of statistics comparing HCPs with oxycodone,

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<sup>133</sup> See *supra* text accompanying note 35.

<sup>134</sup> See *supra* text accompanying notes 92, 93.

<sup>135</sup> See *supra* text accompanying notes 94–109.

<sup>136</sup> Final Rule, *supra* note 19, at 49,661.

<sup>137</sup> See Proposed Rule, *supra* note 16, at 11,040–41.

<sup>138</sup> *Id.* at 11,040.

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

<sup>140</sup> *Id.*

<sup>141</sup> *Id.* at 11,041.

<sup>142</sup> *Id.*

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

a Schedule II substance, is an attempt to equate the two drugs, but they are not abused the same. One of the main reasons to move HCPs to Schedule II is an attempt to limit or reduce its availability to nonmedical users. Based on emergency department visits, percentage increase in deaths, and diversion from legitimate drug channels, the above statistics demonstrate that even as a Schedule II drug, oxycodone is abused more than HCPs.<sup>144</sup> It is common knowledge that statistics can be manipulated, but the question becomes, if HCPs are moved to Schedule II, how can the DEA expect these statistics to decrease if another “similar” drug is already a Schedule II substance and its statistics are worse? The answer is the DEA does not know how, or if, the statistics will change.<sup>145</sup> During the DEA’s presentation at the DSaRM Committee meeting on January 24, 2013, Deputy Rannazzisi’s answer to a question is telling:

Dr. Morrato: But we saw evidence earlier this morning that the median duration of use [of HCPs] is more like, I believe, 14 days. So I’m not arguing that there aren’t extremes and there is definite abuse and that, but I’m trying to kind of wrap my mind around what is the norm and what is the extremes, and should the extremes be targeted in a different manner. Because we have to weigh the burden on to the system, on to patients. And I think having clear evidence that justifies the benefit of what [the DEA is] doing helps people understand why they’re taking on more burden.

Mr. Rannazzisi: I’m not going to be able to provide you clear evidence because there is no clear evidence until the drug actually gets to that schedule and we see what it’s like in practice. We’re dealing with hypotheticals here.<sup>146</sup>

The DEA is attempting to solve a problem through increased regulation without knowing the downstream effects of its actions. This solution is an apt example of the DEA’s predisposition for more regulation.

Later in the meeting, Deputy Rannazzisi was asked about what the DEA has “done to systematically find out what’s happening to the patients” after HCPs are rescheduled.<sup>147</sup> His response was, “[w]e haven’t [done anything] because the fact is we don’t *believe* that there’s going to be an issue with patients getting those drugs.”<sup>148</sup> This is unacceptable. This is the fox in charge of the chicken coop. An agency that initiates a Notice and Comment rulemaking procedure because statistics show a drug is abused, before

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<sup>144</sup> See *supra* text accompanying notes 138–41.

<sup>145</sup> See *infra* text accompanying note 148.

<sup>146</sup> DSaRM, *supra* note 78, at 199–200.

<sup>147</sup> *Id.* at 201.

<sup>148</sup> *Id.* (emphasis added).

determining what the downstream effects of rescheduling this drug might be, is engaging in a failed attempt at “fixing” public health problems. The DEA may create other problems that could outweigh the abuse issue on a national scale. This is a prime example of the DEA’s predisposition towards regulation, and its disregard for medical ramifications.

While the DEA did not “believe” research was necessary to determine potential effects of rescheduling prior to initiating the rulemaking, other organizations have had the time and were willing to ascertain those effects.<sup>149</sup> An article from two attorneys at Dinsmore & Shohl, LLP, found that the DEA’s seemingly “small change” of rescheduling HCPs will have “considerable effects for health care providers and their patients” in six significant ways:

1. Schedule III substances can be written for a thirty day period with up to five refills while Schedule II drugs are not eligible for refills;
2. Patients will be forced to see a doctor at least every ninety days for a new prescription, which likely means more appointments, more time, and more costs for patients;
3. HCPs, as a Schedule II drug, cannot be “called in” to a pharmacist;
4. Heightened security and increased recordation is required in the supply chain for all Schedule II drugs;
5. The DEA will likely greater scrutinize providers prescribing HCPs as Schedule II drugs; and
6. Facilities that dispense HCPs must also comply with specific state regulations that complement this new federal law.<sup>150</sup>

These six chilling effects on the future of patients and providers dealing with HCPs are certainly not exhaustive and, as the DEA stated, “we [will] see what

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<sup>149</sup> See *supra* text accompanying note 148.

<sup>150</sup> Eric Plinke and Daniel Zinsmaster, *DEA Strengthens Restrictions on Hydrocodone Combination Medications*, DINSMORE (Sept. 8, 2014), [http://www.dinsmore.com/dea\\_strengthensrestrictionsonhydrocodone/](http://www.dinsmore.com/dea_strengthensrestrictionsonhydrocodone/); see also Elizabeth Leis Newman, *Pharmacists Object to Further Restrictions for Hydrocodone Combination Products*, MCKNIGHT’S (Aug. 25, 2014), <http://www.mcknights.com/pharmacists-object-to-further-restrictions-for-hydrocodone-combination-products/article/367636/> (“It’s a bad idea . . . [rescheduling HCPs] creates [a] huge access issue for patients with pain, and will be most acutely felt in long-term care.”); see also Ken Baumgartner, *Moving Hydrocodone Combination Drugs to Schedule II Burdens Patients, Practitioners*, 43 CONTROLLED SUBSTANCES HANDBOOK NEWSL. 3 (2014) (“The recent transfer to Schedule II of hydrocodone combination drugs (HCPs) places burdens on both patients and their doctors.”).

it's like in practice.”<sup>151</sup>

In the HCP Final Rule, published in the Federal Register, the DEA responded to numerous submissions posed during the Notice and Comment period of the proposed rule. Several commenters were concerned with the economic costs to patients, and the DEA responded, “[t]he DEA may not reschedule, or refuse to reschedule, a drug or other substance based on the population it is intended or approved to treat, or potential impacts thereon.”<sup>152</sup> The DEA goes on to say that “the DEA does not *believe* that there will be significant impacts, *if any*, on ultimate users associated with this rulemaking.”<sup>153</sup> In response to comments about prescribers using stronger narcotics or, alternatively, less effective over-the-counter medicines to treat pain, the DEA stated that it “does not regulate the general practice of medicine and the agency lacks authority to issue guidelines (or make policy statements) that constitute advice on the general practice of medicine.”<sup>154</sup>

An alternative to providing the DEA with the authority to schedule drugs is to allow an agency that *does* have the authority to make policy decisions or issue guidelines to head the scheduling process, such as HHS. The CDER, which falls under the FDA and ultimately HHS, has an Office of Medical Policy Initiatives.<sup>155</sup> Moreover, the DEA’s focus is clearly on regulation alone and not the effects on the end users.<sup>156</sup> According to the Statute, the DEA is required to consider the medical and scientific reports in its analysis, but Deputy Rannazzisi is just a “cop” that is not concerned with what the statistics say.<sup>157</sup> In the end, the question becomes, was the DEA’s conclusion to reschedule HCPs unbiased? Arguably, it was not. “Federal officials must resist the temptation to place law enforcement imperatives ahead of genuine medical need.”<sup>158</sup>

#### IV. RECOMMENDATIONS

Congress should amend the CSA language to remove the provision that allows the Attorney General the ability to delegate which agency has the

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<sup>151</sup> See *supra* text accompanying note 146.

<sup>152</sup> See Final Rule, *supra* note 19, at 49,677; see also 21 U.S.C. § 812(b) (2012) (outlining the DEA’s required findings when selecting a drug’s schedule, and population impact is not a requirement for any of the five schedules).

<sup>153</sup> Final Rule, *supra* note 19, at 49,678 (emphasis added).

<sup>154</sup> *Id.* at 49,669.

<sup>155</sup> See *CDER Office of Medical Policy Organizational Chart*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/AboutFDA/CentersOffices/OrganizationCharts/ucm350906.htm> (last updated June 8, 2016).

<sup>156</sup> See *supra* text accompanying notes 146–48.

<sup>157</sup> See 21 U.S.C. § 811(c); see also *supra* text accompanying note 124.

<sup>158</sup> Noah, *supra* note 131, at 28 (“If an analgesic drug or medical device offers a relatively safe and effective option for the treatment of pain in some group of patients, then any concerns about misuse and diversion need to balance the therapeutic benefit for legitimate users against the risk that individuals who act unlawfully may injure themselves and others. It would be unfortunate if an inability to deal with the latter problem by other means (including educational efforts as well as state and local policing) led to regulatory decisions that denied effective relief to those in pain.”).

authority to schedule drugs. Moreover, Congress should restructure the eight factors to focus less on abuse and more on legitimate patient consequences. During the hearings over control determinations for the CSA, “[c]onsiderable controversy arose . . . with respect to the proper role of the Attorney General and the Secretary of [HHS] in making determinations concerning which drugs should be controlled.”<sup>159</sup> Thus, this argument is not new, radical, or impossible. Congress should further amend the CSA to state that HHS and its subsidiary agencies, organizations such as the Institute of Medicine (“IOM”), or the adjunct agency Centers for Disease Control and Prevention (“CDC”), is responsible for overseeing the scheduling and rescheduling of all drugs and substances.

Alternatively, Congress could remove the scheduling requirements from the CSA, promulgate a new statute, and assign that function to an agency or organization. The DEA has a place in the new scheduling process. It is, after all, a regulatory agency charged with enforcing drug crimes based on schedules.<sup>160</sup> Thus, the DEA should become one of the consulting agencies in the drug scheduling process.

Finally, Congress should require the agency or organization in charge to perform an examination of all drugs and substances currently scheduled to determine if any drug or substance has been erroneously scheduled by the DEA, and then correct that error.<sup>161</sup> An alternative argument exists from the Cato Institute calling for a complete repeal of the CSA, disbandment of the DEA, and individual state determination of drug policy.

#### A. Congress Should Amend the CSA to Delegate Scheduling Power to HHS

The CSA’s section 871(a) is a main component of the predisposition towards regulation of drugs and substances. Section 871(a) is what allows the Attorney General to “delegate any of his functions under this subchapter to any officer or employee of the *Department of Justice*.”<sup>162</sup> The Department of Justice (“DOJ”) has a mission to prevent and control crime while punishing the guilty and administering justice.<sup>163</sup> All of which are necessary to ensure

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<sup>159</sup> House Report, *supra* note 38, at 4589.

<sup>160</sup> See *supra* text accompanying notes 30–32.

<sup>161</sup> See generally Matt Ferner, *New Report Blasts DEA for Spending 4 Decades Obstructing Marijuana Science*, HUFFINGTON POST (June 13, 2014, 6:53 PM), [http://www.huffingtonpost.com/2014/06/11/dea-blocks-marijuana-science\\_n\\_5482367.html](http://www.huffingtonpost.com/2014/06/11/dea-blocks-marijuana-science_n_5482367.html) (“The DEA is a police and propaganda agency . . . [i]t makes no sense for it to be in charge of federal decisions involving scientific research and medical practice.”). The DEA has repeatedly stalled rescheduling requests for marijuana, a Schedule I drug that shows signs of medical viability. *Id.*

<sup>162</sup> 21 U.S.C. § 871(a) (emphasis added).

<sup>163</sup> U.S. DEP’T OF JUSTICE, ABOUT DOJ, <https://www.justice.gov/about> (last visited Sept. 1, 2016). The DOJ Mission Statement is

[t]o enforce the law and defend the interests of the United States according to the law; to ensure public safety against threats foreign and domestic; to provide federal leadership in preventing and controlling crime; to seek just punishment for those

the system of justice works efficiently in the United States. However, these objectives for justice do not lend themselves to administering scientific and medical assessments when it comes to modern health care. On the other hand, HHS “is the U.S. government’s principal agency for protecting the health of all Americans and providing essential human services, especially for those who are least able to help themselves.”<sup>164</sup> The differences between HHS and the DOJ are deafening. However, according to statute, any officer or employee of the DOJ can be delegated any function of the CSA.<sup>165</sup> This is unrealistic when modern medicine is at risk.

Congress should amend the CSA to give HHS and its subsidiary agencies the authority to schedule and reschedule all drugs and substances. In the alternative, Congress could repeal the parts of the CSA that addresses scheduling, and promulgate new law giving that authority to HHS. The recommendation of partial repeal and new promulgation is likely clearer than trying to wordsmith certain sections of the CSA into different agencies’ responsibility. The DEA, and potentially others, will likely argue that giving HHS the scientific and medical research aspects in conjunction with the scheduling authority is simply a fox of a different color. While that could potentially occur, Congress should tailor the new statute to avoid a predisposition towards stricter regulation and instead focus on the medical and scientific facts to schedule drugs and substances. This tailoring will require Congress to fine-tune this new language to create a more neutral framework, which must include a factor that examines the potential impact on patients nationwide. Furthermore, the suggested language for Congress should encompass the following factors, weights, standards, and definitions:

1. What are the known effects of scheduling or rescheduling on the end users?
2. What are the potential benefits and detriments of scheduling or rescheduling?
3. Actually define abuse instead of using a malleable four-indicator test stemming from forty-year-old legislative history.
4. If the drug or substance is abused (using the new definition), do the effects of the abuse at large outweigh the usefulness of the drug or substance to legitimate patients nationwide?

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guilty of unlawful behavior; and to ensure fair and impartial administration of justice for all Americans.

*Id.*

<sup>164</sup> *About HHS*, U.S. DEP’T HEALTH & HUMAN SERV., <http://www.hhs.gov/about/> (last visited Sept. 1, 2016).

<sup>165</sup> *See* 21 U.S.C. § 871(a).

5. Is the drug or substance a precursor to another drug or substance already in a more restricted schedule? If yes, are there enough distinctions based on these factors to justify placing the drugs or substances in different schedules?
6. The weight of the scientific, medical, and pharmacological information on the drug or substance balanced with the symptoms, diseases, viruses, bacteria, etc. the drug or substance is used to treat.
7. There is a rebuttable presumption that a medicine is more valuable in practice (Schedule II through V) than in prohibition (Schedule I).
8. Weigh the totality of the benefits against the detriments to determine, by a preponderance of the evidence, how a drug or substance should be scheduled, in the established I to V schedules. It requires a demonstration by a preponderance of the evidence to increase a drug or substance from its current schedule. It requires a demonstration by a preponderance of the evidence to decrease or remove a drug or substance from its current schedule.

The goal of this new language is clear: remove the antiquated War on Drugs mentality of regulation from the CSA and allow for science, medicine, and patient care to lead the charge of modern medicine in the United States.

This new procedure for scheduling, either through an amendment to the CSA or partial repeal and promulgation of new law, will still require DEA input as part of the process. Abuse and diversion statistics are still relevant when scheduling a drug, but these statistics should not be the primary focus for HHS. Rather, HHS should focus on the benefits of the drug or substance, as proven in clinical trials and studies. Primarily focusing on how drugs and substances can benefit patients of modern medicine (the positives) instead of abuse and diversion (the negatives) will likely yield better medical solutions for patients and practitioners. At the very least, the process should not be predisposed towards stricter regulation.

This new scheduling process is incomplete without an examination of all drugs and substances currently scheduled. This means a daunting review of all drugs and substances to determine if they are correctly scheduled. This recommendation suggests drastic steps. Yet, HHS could begin this process slowly with the drugs or substances that were requested or

petitioned for rescheduling in the last ten years.<sup>166</sup> Marijuana is the obvious frontrunner when it comes to rescheduling.<sup>167</sup> The controversial drug, methamphetamine, which has a trade name Desoxyn, is a highly addictive stimulant and considered a major drug of abuse by the DEA, yet it has been a Schedule II drug since 1971.<sup>168</sup> Methamphetamine destroys people's lives, families, and futures, and the fact that methamphetamine has never been rescheduled is laughable.<sup>169</sup> Arguably, after HHS corrects scheduling errors, patients will have access to effective drugs and substances that provide proper treatment and relief of modern medical issues.

### *B. The Institute of Medicine Option*

The IOM is an independent, non-profit organization under the National Academy of Sciences “that works outside of government to provide unbiased and authoritative advice to decision makers and the public.”<sup>170</sup> The IOM membership consists of experts and professionals from the health care, legal, administration, engineering, and humanities fields, as well as natural, social, and behavioral sciences.<sup>171</sup> While there is an argument that the IOM lacks accountability because it is not a government agency, an alternative argument is that an unbiased, independent body may be the best option to a purely objective approach towards scheduling.

In 2011, the IOM published a report titled *Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education, and Research*.<sup>172</sup> This report focuses on transforming how people perceive pain by “gaining a better understanding of pain . . . and improving efforts to prevent, assess, and treat pain.”<sup>173</sup> The report makes several conclusions, including “significant barriers to pain care and management exist in the primary care setting,” and “[r]egulatory, legal, educational, and cultural barriers inhibit the medically appropriate use of opioid analgesics.”<sup>174</sup> Expanding on the idea of education

<sup>166</sup> See *supra* note 161.

<sup>167</sup> *25 Legal Medical Marijuana States and DC*, PROCON.ORG, [http://medicalmarijuana.procon.org/view\\_resource.php?resourceID=000881](http://medicalmarijuana.procon.org/view_resource.php?resourceID=000881) (last updated June 28, 2016, 10:44 AM) (stating twenty-five states and the District of Columbia have legalized medical marijuana); see also Mollie Reilly, *18 Members of Congress Call on Obama to Drop Marijuana from 'Most Dangerous' Category*, HUFFINGTON POST (Feb. 12, 2014, 12:23 PM), <http://www.huffingtonpost.com/2014/02/12/obama-reschedule-marijuanan4774715.html>.

<sup>168</sup> See DRUG ENF'T ADMIN., METHAMPHETAMINE (2013), [http://www.deadiversion.usdoj.gov/drug\\_c\\_hem\\_info/meth.pdf](http://www.deadiversion.usdoj.gov/drug_c_hem_info/meth.pdf); see also *The Truth about Crystal Meth*, FOUND. FOR DRUG-FREE WORLD, <http://www.drugfreeworld.org/drugfacts/crystalmeth.html> (last visited Sept. 1, 2016) (Methamphetamine is “[h]ighly addictive, [it] burns up the body's resources, creating a devastating dependence that can only be relieved by taking more of the drug.”).

<sup>169</sup> See generally *The Deadly Effects of Meth*, FOUND. FOR DRUG-FREE WORLD, <http://www.drugfreeworld.org/drugfacts/crystalmeth/the-deadly-effects-of-meth.html> (last visited Sept. 1, 2016).

<sup>170</sup> INST. OF MED. OF THE NAT'L ACADS., *ADVISING THE NATION / IMPROVING HEALTH* 20 (2009).

<sup>171</sup> *Id.*

<sup>172</sup> See generally INST. OF MED. OF THE NAT'L ACADS., *RELIEVING PAIN IN AMERICA: A BLUEPRINT FOR TRANSFORMING PREVENTION, CARE, EDUC., AND RESEARCH* (2011).

<sup>173</sup> *Id.* at 48.

<sup>174</sup> *Id.* at 162–63.

and appropriate opioid (HCPs) use, the IOM recommends that primary care practitioners and providers increase their knowledge regarding the assessment and treatment of pain, which involves “safe and effective opioid prescribing.”<sup>175</sup> In short, the IOM feels that increased education, not regulation, is the answer to this prescription drug epidemic.

The IOM is well versed in the fields of health, medicine, and other sciences, making it a viable candidate for delegation of the new scheduling process. It understands the issues barring the effective practice of modern medicine, especially pain management. The IOM needs increased staff and funding to perform the new scheduling function, but it certainly possesses the appropriate medical and scientific objectivity desired when dealing with health care issues in America. The IOM, like HHS, needs to examine the current schedule of drugs and substances, perform an analysis based on Congress’ revamped eight factors, and reschedule those drugs or substances accordingly.

### C. *The Centers for Disease Control and Prevention Option*

The CDC is a subsidiary agency of HHS<sup>176</sup> and is included by association in the HHS recommendation above, yet CDC’s mission, role, and pledge aptly lend themselves to overseeing the scheduling duties of all drugs and substances.<sup>177</sup> The CDC’s mission “[a]s the nation’s health protection agency,” is to increase our nation’s health security through saving lives and protecting people from health threats.<sup>178</sup> The CDC’s role in the United States includes the following:

1. Detecting and responding to new and emerging health threats[;]
2. Tackling the biggest health problems causing death and disability for Americans[;]
3. Putting science and advanced technology into action to prevent disease[;]
4. Promoting healthy and safe behaviors, communities and environment[;]
5. Developing leaders and training the public health workforce, including disease detectives[; and]

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<sup>175</sup> *Id.* at 163.

<sup>176</sup> *HHS Organizational Chart*, U.S. DEP’T HEALTH & HUMAN SERV., <http://www.hhs.gov/about/orgchart/> (last visited Sept. 1, 2016).

<sup>177</sup> *See generally Mission, Role and Pledge*, CTR. FOR DISEASE CONTROL & PREVENTION, <http://www.cdc.gov/about/organization/mission.htm> (last updated Apr. 14, 2014).

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

## 6. Taking the health pulse of our nation.<sup>179</sup>

These all-encompassing roles for the CDC could certainly include the scheduling of drugs and substances, as drug abuse is arguably related to every item in the list. The CDC pledges, among other things, to “[b]ase all public health decisions on the highest quality scientific data that is derived openly and objectively.”<sup>180</sup> The CDC’s logical approach is directly opposite of the DEA’s wait-and-see attitude.<sup>181</sup>

The CDC, like the DEA, also has knowledge and experience with prescription drug abuse and even labeled prescription opioid drug overdoses an epidemic in the United States in a 2012 report.<sup>182</sup> This same report outlines three prevention strategies for addressing two high-risk groups of opioid users.<sup>183</sup> The first strategy is to reduce doctor shopping through the combined use of insurance restrictions and prescription data.<sup>184</sup> The second prevention strategy includes the enforcement of already existing laws in a few states regarding pill mills, and improving legislation in states lacking such laws.<sup>185</sup> A third strategy suggested by the CDC aims to “improve medical practice in prescribing opioids” through increased prescriber education.<sup>186</sup> The CDC never advocates for the rescheduling of opioids as a strategy in this report.<sup>187</sup>

Overall, the CDC is recommending “[a] public health approach to the problem of prescription drug overdose[s]” through the greater availability of opioid antidotes as well as a shift from substance abuse programs to less stigmatizing office-based care.<sup>188</sup> The CDC, much like the DEA, is well acquainted with drug abuse and its effects in the United States. The CDC’s “public health approach” combined with its pledge of the “highest quality scientific data,” perfectly positions this adjunct agency to take on the duty of scheduling drugs and substances. Like the IOM, the CDC will need increased staff and funding to efficiently perform these duties. As is the case with the HHS and IOM recommendations, a thorough CDC examination of the current drug schedule is required to determine any erroneous scheduling by the DEA.

### *D. The Cato Institute Option: Repeal the CSA & Allow States to Determine Drug Policy*

In 2008, the Cato Institute (“Cato”), “a public policy research

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<sup>179</sup> *Id.*

<sup>180</sup> *Id.*

<sup>181</sup> See *supra* text accompanying note 146.

<sup>182</sup> *CDC Grand Rounds: Prescription Drug Overdoses — a U.S. Epidemic*, MMRW, Jan. 13, 2012, at 10, <http://www.cdc.gov/mmwr/pdf/wk/mm6101.pdf>.

<sup>183</sup> *Id.* at 10–11.

<sup>184</sup> *Id.* at 10.

<sup>185</sup> *Id.* at 10–11.

<sup>186</sup> *Id.* at 11.

<sup>187</sup> See generally *id.* at 10–13.

<sup>188</sup> *Id.* at 11.

organization,<sup>189</sup> created a report for the 111th Congress addressing policy recommendations, including the War on Drugs.<sup>190</sup> Marijuana and other illegal drugs are the emphasis of Cato's War on Drugs policy argument.<sup>191</sup> Cato argues that drug prohibition through the CSA should be repealed, much like alcohol prohibition in 1933, and that states should be allowed to set their own policies on illegal drugs.<sup>192</sup> After the repeal of the CSA, Cato next calls for the disbandment of the DEA, and a reallocation of the 10,000 federal agents to areas such as counterterrorism.<sup>193</sup> Through these efforts, Cato hopes to recapture the \$19 billion spent annually on federal drug enforcement, and hopes to eliminate \$40 billion in profit for criminals.<sup>194</sup>

While this recommendation from Cato focuses on illegal drugs, a similar argument could be made for prescription drugs. Yet Cato neglects to address the side effect on prescription drugs caused by eliminating the CSA. Prescription drugs still require scheduling because it provides a foundation in practitioner training and education, which helps treat patients safely and effectively. The problem is individual states do not have the infrastructure to accomplish this task, and state-specific drug schedules will likely create a new problem of prescription drug trafficking between states.

Cato's arguments, while extreme for prescription drugs, still have merit and deserve recognition, especially for marijuana. However, that is not to suggest that a large deviation from the scheduling system currently in place is the answer for prescription drugs. Rather, a national drug scheduling system based on science and medical data is still required for prescription drugs.

## V. CONCLUSION

The DEA abuses the power given to it by Attorney General through the antiquated CSA to consistently increase regulation on drugs and substances without regard to the effects on modern medicine and society at large. In the case of HCPs, this blind ambition for regulation is already showing the negative effects on downstream users because the DEA is not required to appropriately consider scientific and medical data when scheduling drugs. In an era of modern medicine, almost fifty years after the promulgation of the CSA, this predisposition towards increased regulation is unacceptable. Doc and his patients are not the only ones experiencing the downstream effects of the DEA's biased rescheduling. The solution is achieved through amendments to the CSA that reallocate scheduling duties to

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<sup>189</sup> *About Cato*, CATO INST., <http://www.cato.org/about> (last visited Sept. 1, 2016).

<sup>190</sup> *See* CATO INST., CATO HANDBOOK FOR POLICYMAKERS 337–44 (7th ed. 2009).

<sup>191</sup> *See id.* at 343.

<sup>192</sup> *Id.* at 338–39, 343.

<sup>193</sup> *Id.* at 339–40.

<sup>194</sup> *Id.* at 340.

both HHS and CDC, combined with an updated factor test, and an examination of all currently scheduled drugs to correct the imbalance of DEA authority over modern medicine.