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On Behalf of the Federal Public and Community Defenders

Before the United States Sentencing Commission
Public Hearing on Proposed Amendments to the Guidelines for Drug Offenses

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My name is Lex Coleman and I am an Assistant Federal Public Defender for the Southern District of West Virginia. I thank the Commission for inviting me to testify on behalf of the Federal Public and Community Defenders regarding the proposed amendment to the drug equivalency table for hydrocodone.

While we adhere to our position that the drug guidelines place too much emphasis on quantity rather than functional role in the offense, Defenders are encouraged by the Commission's focus on equianalgesic doses because it relies on an empirically based assessment of a particular drug in comparison to other drugs. But we do not think equianalgesic dosing should be the only consideration and we do not support either equivalency proposed – 1 gram of hydrocodone (actual) to 4467/6700 grams of marihuana.

Both of the Commission's proposals are premised on the false assumption that a change in scheduling warrants an increase in penalties and link the hydrocodone equivalency to an arbitrary oxycodone equivalency that was not based on the potency of oxycodone as compared to other opioids,¹ but was established to accomplish a specific sentencing outcome. Rather than respond to the “drug du jour” by arbitrarily increasing penalties and exacerbating existing disparities among various opioids, the better course is for the Commission to reassess its treatment of oxycodone and other opioids and arrive at a standardized methodology in determining drug equivalencies that focuses on specific factors such as potency, purity, toxicity, and abuse liability.

If the Commission nonetheless declines to set a rational penalty structure among the various opiates, the available evidence shows that oxycodone penalties should be reduced and hydrocodone penalties should be set below those for oxycodone. It is noteworthy that the Department of Justice in 2009 also believed that hydrocodone penalties should be lower than those for oxycodone when it advocated for a ratio of one gram of hydrocodone (actual) to 1675 grams of marihuana. The Commission should also be mindful of the long history of opioid abuse in the United States and how persons involved in unlawful opioid distribution are not always “pill mill” profiteers, but individuals who themselves suffer from pain and opioid addiction.

I. The Rescheduling of a Controlled Substance Should Not By Itself Warrant an Increase in Sentence Length.

After years of controversy surrounding the appropriate scheduling of hydrocodone, the Food and Drug Administration recommended that hydrocodone combination products (HCPs) be moved from schedule III to schedule II. HHS concluded that the frequency of use, the diversion of HCPs, and the use of HCPs by individuals without advice from a medical practitioner

¹ The term “opioids” refers to substances that relieve pain and are derived from opium.

warranted rescheduling of the drug. The rescheduling raised the statutory maximum penalty – absent aggravating factors such as bodily injury or death – from ten years to twenty years. 21 U.S.C. § 841(b).

This increase in the statutory maximum penalty does not warrant an increase in the sentencing guidelines for hydrocodone products. First, the Commission should not increase guideline ranges merely because the statutory maximum of a particular offense has been increased. Instead, the Commission should be guided by the purposes of sentencing and the need to avoid unwarranted disparities and unwarranted similarities.

Second, in assessing how a particular guideline amendment comports with the purposes of sentencing and avoids unwarranted disparities and similarities, the Commission should be mindful of “the cumulative effect of all the little decisions that the Commission makes.”² In the context of oxycodone and hydrocodone, those cumulative effects are sizable. In 2003, the Commission increased penalties for many formulations of single-entity oxycodone (OxyContin) by establishing a marijuana equivalency ratio of 1 gram oxycodone (actual) to 6700 grams of marijuana. Before the 2003 amendment, oxycodone had a ratio of 1 gram oxycodone to 500 grams of marijuana – the same as morphine, hydrocodone (schedule II), and methadone. Just six years ago in response to the Ryan Haight On-Line Pharmacy Act, the Commission substantially increased penalties for hydrocodone (schedule III) by raising the offense level cap from 20 to 30. Now, the Commission is contemplating a sizable increase in penalties for hydrocodone by raising the marijuana equivalency and eliminating the offense level cap.

Third, it makes no sense for the Commission to consider increasing penalties for a category of drug offenses given the longstanding criticism of the drug guideline and its emphasis on the quantity of drugs distributed rather than the functional role of the defendant. As the Commission learned with crack cocaine, a piecemeal reaction to the currently trendy drug is not a sound empirical approach to formulating drug policy. This is particularly true in light of the history of incarcerating persons convicted of non-violent drug offenses for long periods of time, even though the evidence shows that harsher punishment has, at best, marginal deterrent effects on crime rates.³ Indeed, the most recent research concludes that “the current exorbitant level of incarceration has reached a point where diminishing returns have rendered the crime reduction effect of incarceration so small, it has become nil.”⁴ Moreover, the Commission need only look

² USSC, *Minutes of the March 19, 2004 Public Meeting*, at 5 (Judge Sessions)

³ See Andrew von Hirsch et al., *Criminal Deterrence and Sentence Severity: An Analysis of Recent Research* (1999); Michael Tonry, *Purposes and Functions of Sentencing*, 34 *Crime & Justice: A Review of Research* 28-29 (Michael Tonry, ed., 2006). Daniel S. Nagin, *Deterrence in the Twenty-First Century*, 42 *Crime & Just.* 199, 201 (2013).

⁴ Oliver Roeder, et.al., Brennan Center for Justice, *What Caused the Crime Decline* 7 (2015), http://www.brennancenter.org/sites/default/files/analysis/Crime_rate_report_web.pdf. See also Ilyana

to how the increased penalties for OxyContin in 2003 and the increased penalties for hydrocodone in 2009 did nothing to deter the abuse or trafficking of prescription opioids. Given the long history of opium abuse in the United States, and the problem of chronic pain and addiction risk, increased criminal penalties are a foolish approach to a public health problem largely created by the aggressive marketing campaigns of pharmaceutical companies.⁵

II. The Drug Equivalency Table Should Be Amended so that the Same Methodology Is Used to Calculate the Equivalency for All Prescription Opioids.

The Commission has proposed using the actual weight of hydrocodone rather than the number of pills or the entire weight of the mixture or substance, particularly since hydrocodone products come in different pill sizes, formulations, and dosages. Defenders agree that using the entire weight of a mixture or substance to determine penalties is an unsound approach.⁶ We also believe that simply counting pills without any consideration for the nature of the dosage or abuse deterrent⁷ properties of certain drugs does not adequately capture the relative seriousness of the offense. Because the current drug equivalency table for opioids sometimes counts pills (hydrocodone when it was a Schedule III), sometimes counts actual weight (oxycodone), and sometimes counts the entire weight of the mixture or substance (e.g., oxymorphone, hydromorphone, morphine), we encourage the Commission to adopt the same methodology to calculate the marijuana equivalency for all prescription opioids. The methodology should at

Kuziemko & Steven D. Levitt, *An Empirical Analysis of Imprisoning Drug Offenders*, 88 J. Public Economics, 2043 (2004) (concluding imprisonment of persons convicted of drug offenses has not been cost effective).

⁵ See Laura Unger, *Lawsuit Seeks to Make Drug Maker Pay for OxyContin Abuse*, USA Today (Dec. 29, 2014) (discussing Kentucky lawsuit against Purdue Pharma for aggressive and deceptive marketing). The rescheduling of hydrocodone from Schedule III to Schedule II may have a greater effect on rates of abuse than increased punishment because it will be more difficult to obtain the drug. Prescriptions can no longer be refilled and the protocols for dispensing the drugs are stricter.

⁶ Last year, our testimony discussed how Congress's decision to base quantity on the "entire weight of any mixture of substance containing a detectable amount of the controlled substance" rather than the purity of the substance inexplicably departed from existing practice and created considerable confusion and disparity. The Commission has generally followed "entire weight" approach, but has periodically departed from it, e.g., when it amended the guideline for LSD and oxycodone. Statement of Molly Roth Before the U.S. Sent'g Comm'n, Washington, D.C., March 13, 2014 (Addendum).

⁷ See Food and Drug Administration, *Guidance for Industry: Abuse-Deterrent Opioids – Evaluation and Labeling* (2013) (identifying six categories of abuse-deterrent formulations, including physical and chemical barriers to prevent crushing; inclusion of an opioid antagonist, which interferes with the euphoria from abuse; and a prodrug, which "lacks opioid activity until transformed in the gastrointestinal track), <http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm334743.pdf>.

least consider the actual weight of the controlled substance, as well as the abuse deterrent properties of certain formulations.

To avoid unwarranted disparity, the Commission should not calculate guideline ranges in hydrocodone cases – or many other controlled substances – using the entire weight of the mixture or substance containing hydrocodone. Hydrocodone comes in many different forms – combination products, single entity products, capsules, tablets, and liquid. Trade names for combination products include Vicodin, Lortab, Lorcet-HD, Hycodan, and Vicorpopfen. Two single-entity products have also been approved – Hysingla ER and Zohydro ER. The same amount of the active ingredient can be found in a pill and liquid, but the combination products weigh more because they contain acetaminophen. For example, Vicodin contains 5 mg of hydrocodone and 300 mg acetaminophen; Vicodin ES contains 7.5 mg of hydrocodone and 300 mg acetaminophen; Vicodin HP contains 10 mg of hydrocodone and 300 mg acetaminophen.⁸ Lortab Elixir—an oral solution – contains 7.5 mg of hydrocodone and 500 mg acetaminophen per 15 mL.⁹ In contrast, Zohydro ER – a single entity formulation of hydrocodone contains more hydrocodone, but, as Table 1 shows, the entire weight of the capsule is considerably less than a combination product with the same or a lesser amount of hydrocodone¹⁰:

Table 1

Dosage strength of hydrocodone in Zohydro ER	Weight of the entire Zohydro ER capsule
10mg	104 mg
15mg	132 mg
20 mg	158 mg
30 mg	214 mg
40 mg	279 mg
50 mg	340 mg

⁸ *About Vicodin*, www.vicodin.com.

⁹ RxList, *Lortab Elixir*, <http://www.rxlist.com/lortab-elixir-drug.htm>.

¹⁰ This information was obtained directly from the manufacturer of Zohydro.

The difference is sizable. For example, a Vicodin HP with 10 mg of hydrocodone weighs at least 310 mg per tablet whereas a Zohydro ER with 10 mg hydrocodone weighs 104 mg per capsule. Given these vastly different formulations, counting the entire weight of the mixture or substance leads to unwarranted disparity, especially since Vicodin HP is less likely to be abused than Zohydro ER because it contains acetaminophen.¹¹

This holds true for many other opioids, which come in multiple formulations and contain different quantities of the controlled substances. Table 2 shows some of the other opioid products along with the quantity of controlled substance contained in each. While the table does not reflect the total weight of each mixture and substance, it is obvious that the total weight of certain formulations will vary even though they contain the same amount of an actual substance.¹²

Table 2

Morphine	Avinza 30 mg, 45 mg, 60 mg, 75 mg, 90 mg, 120 mg capsules Kadian 10mg, 20 mg, 40 mg, 50 mg, 60 mg, 70 mg, 80 mg, 100 mg, 130 mg, 150 mg, 200 mg capsules MS Contin 15 mg, 30 mg, 60 mg, 100 mg, 200 mg, tablets
Morphine/naltrexone	Embeda ¹³ 20 mg/08 mg, 30 mg/1.2 mg, 50 mg/2 mg, 60 mg/2.4 mg, 80 mg/3.2 mg, 100 mg/4 mg capsules

¹¹ TJ Cicero, et.al., *Factors Influencing the Selection of Hydrocodone and Oxycodone as Primary Opioids in Substance Abusers Seeking Treatment in the United States*, 154 Pain 2639 (2013).

¹² For example, the capsule shell of an Avina 30 mg (morphine) contains “black ink, gelatin, titanium dioxide, D&C yellow No. 10 (30 mg), FD&C blue No. 2 (45 mg), FD&C green No. 3 (60 mg), FDA iron oxide and FDA yellow iron oxide (75 mg), FD&C red No. 40 (90 mg), FD&C red No. 3 (120 mg), and FD&C blue No. 1 (120 mg).” In contrast, MS Contin 30 mg “contains the following inactive ingredients common to all strengths: cetostearyl alcohol, hydroxyethyl cellulose, hypromellose, magnesium stearate, polyethylene glycol, talc and titanium dioxide.” See generally [www. rx.list.com](http://www.rx.list.com) for a list of ingredients in various drug formulations.

¹³ This product has been voluntarily recalled, but is still approved by the FDA. See FDA, *List of Extended-Release and Long-Acting Opioid Products Required to Have an Opioid REMS*, <http://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm251735.htm>.

Oxymorphone	Opana 5 mg, 10 mg tablets Opana ER 5 mg, 7.5 mg, 10 mg, 15 mg, 20 mg, 30 mg, and 40 mg tablets Opana Injection 1mg/mL
Methadone	Methadose Oral Concentrate 10 mg per ml liquid – single dose vial Methadose 5 mg, 10 mg tablets Dolophine 5 mg, 10 mg tablets
Hydromorphone	Dilaudid Injection 1 mg, 2 mg, 4 mg per ml – single dose vial Dilaudid-HP Injection 250 mg – single dose vial Exalgo 8 mg, 12, mg, 16 mg, 23 mg tablets Palladone 12 mg, 16 mg, 24 mg, 32 mg capsules
Codeine	Codeine 15 mg, 30 mg, 60 mg tablets
Codeine/acetaminophen	Tylenol-Codeine 300 mg/30 mg, 300 mg/60 mg tablets

Because these products either come in different sizes and formulations or come in the same size and formulation but contain different amounts of a scheduled opioid, counting the entire weight of the mixture or substance produces unwarranted disparity.¹⁴

The Commission should fix the inconsistent treatment of opioids and the unwarranted disparity it creates, but simply counting the actual weight of the controlled substance does not accomplish that goal. The actual weight of a controlled substance in a product is a poor measure of its analgesic effect, toxicity, or its potential for abuse or misuse. Combination drugs with the same amount of controlled substance do not produce the same effects as a single-entity substance

¹⁴ We also strongly encourage the Commission to restructure the drug quantity and equivalency tables so that quantity is no longer determined based upon the entire weight of the mixture or substance. Advances in science have made it quite feasible to determine the specific quantity and purity of a substance. Forensic labs typically conduct quantitative analysis to “determine the amount, or purity, of the illegal substance,” particularly in federal cases. National Forensic Science Technology Center, *A Simplified Guide to Forensic Drug Chemistry*, at 14, <http://www.crime-scene-investigator.net/SimplifiedGuideDrugChemistry.pdf>. Because the amount, or purity, of the illegal substance, is contained within forensic reports there is no reason, even of administrative convenience, to allow arbitrary differences in formulations to create unwarranted disparity.

because of the synergistic effect of other drugs such as acetaminophen, aspirin, or ibuprofen.¹⁵ Nor do drugs with abuse-deterrent properties have the same abuse potential as those that do not. For example, Zohydro ER is a single-entity hydrocodone product with no features to deter its abuse. In contrast, Hysingla ER – a single-entity hydrocodone product – has abuse deterrent characteristics that make it difficult to crush, break or dissolve. Those properties caused the FDA to approve its labeling as an abuse-deterrent opioid.¹⁶

To account for the abuse potential of various formulations, the Commission has several options: (1) establish a drug equivalency based on actual weight for formulations without abuse deterrent properties and a lesser drug equivalency for products, like Hysingla ER, with abuse deterrent properties; (2) establish a drug equivalency based on actual weight, but then provide for an offense level reduction if the offense involved a drug with abuse deterrent properties or a lesser potential for abuse.

III. The Marihuana Equivalency for Oxycodone Is Not Based on Any Pharmacological Equivalency or Abuse Liability Comparison and Must Be Revised Before the Commission Uses It to Compare Other Opioids.

The Commission's 2003 amendment to the drug equivalency table for oxycodone was not based on an analysis of oxycodone potency or abuse liability as compared to other opiates. Instead, the one gram of oxycodone (actual) to 6700 grams of marihuana ratio was designed to set a specific penalty for OxyContin 10 mg. A brief review of the history of the drug equivalency table for opioids shows how the 2003 amendment strayed off course and was not based upon any consistent methodology for setting drug equivalencies.

When the guidelines were first promulgated, the drug equivalency table listed Schedule I and II substances with "Heroin Like Effects." The original equivalencies treated heroin as two times more potent than morphine, hydrocodone, and oxycodone. Those equivalencies were

¹⁵ See Arnold R. Gammaitoni, et al., *Randomized, Double-Blind, Placebo Controlled 19 Comparison of the Analgesic Efficacy of Oxycodone 10 mg/Acetaminophen 325 mg versus Controlled-Release Oxycodone 20 mg in Postsurgical Pain*, 43 J. of Clinical Pharmacology 296 (2003). In a similar study, a combination of oxycodone 5 mg/ibuprofen 400 mg "provided significantly greater analgesia compared with oxycodone 5 mg/acetaminophen 325 mg, hydrocodone 7.5 mg/acetaminophen 500 mg, and placebo." L.J. Litkowski, et al., *Analgesic Efficacy and Tolerability of Oxycodone 5 mg/ibuprofen 400 mg Compared With those of Oxycodone 5 mg/acetaminophen 325 mg and Hydrocodone 7.5 mg/acetaminophen 500 mg in Patients with Moderate to Severe Postoperative Pain: A Randomized, Double-blind, Placebo-controlled, Single-dose, Parallel-group Study in a Dental Pain Model*, 27 Clin. Ther. 418 (2005).

¹⁶ FDA News Release, *FDA Approves Extended-Release, Single-Entity Hydrocodone Product with Abuse-Deterrent Properties* (Nov. 1, 2014), <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm423977.htm>.

generally supported by research literature on the potency of those opioids.¹⁷ Some of the equivalencies were:

- 1 gram morphine .5 gram heroin
- 1 gram methadone .5 gram heroin
- 1 gram hydrocodone .5 gram heroin
- 1 gram oxycodone .5 gram heroin
- 1 gram hydromorphone 2.5 grams heroin
- 1 gram oxymorphone 5 grams heroin
- 1 gram fentanyl 31.25 grams heroin¹⁸

In 1989, the Commission changed the equivalency for fentanyl to 2.5 grams of heroin so that the equivalency for fentanyl conformed to the Drug Quantity Table and statute.¹⁹

In 1991, the Commission sought to simplify application of the drug equivalency table by referencing all the conversions to marijuana rather than heroin.²⁰ Use of the marijuana equivalency made no substantive change to the relationship among the various Schedule I and II Opiates:

- 1 gram morphine 500 grams marijuana
- 1 gram methadone 500 grams marijuana
- 1 gram hydrocodone 500 grams marijuana
- 1 gram oxycodone 500 grams marijuana
- 1 gram heroin 1 kg marijuana

¹⁷ See Claus Reichle, et al., *Comparative Analgesic Potency of Heroin and Morphine in Postoperative Patients*, 136 J. of Pharmacology 43 (1962) (finding that “heroin was approximately two to four times as potent as morphine”). See generally Goodman & Gilman, *Manual of Pharmacology and Therapeutics* (12th ed. 2014).

¹⁸ USSG § 2D1.1 (1987).

¹⁹ USSG, App. C, Amend. 126 (Nov. 1, 1989).

²⁰ USSG App. C, Amend. 396 (Nov. 1, 1991).

- 1 gram hydromorphone 2.5 kg marihuana
- 1 gram oxymorphone 5 kg marihuana
- 1 gram fentanyl 2.5 kg marihuana

The relationship among the various opiates eventually changed when the Commission responded to the growing use of OxyContin – a single entity formulation of oxycodone. After the FDA approved OxyContin, its manufacturer, Purdue Pharmaceuticals, launched an aggressive marketing campaign that resulted in more and more doctors prescribing the drug for musculoskeletal and post-operative pain.²¹ By 2000, reports of abuse and diversion of OxyContin escalated. In 2003, the Commission amended the guidelines for oxycodone as part of an effort to ensure “proportionality” among products that contained only oxycodone and those that contained oxycodone and acetaminophen. But by focusing solely on proportionality among various oxycodone formulations, it ignored the broader question of ensuring “proportionality” between oxycodone and other opiates. Rather than revisit the appropriate equivalency for oxycodone (actual) by comparing its potency or even its relative abuse potential to any other natural, synthetic, or semi-synthetic opiate (e.g. morphine, methadone, heroin, hydromorphone, hydrocodone, oxymorphone), the Commission decided that no penalties for offenses involving OxyContin should be reduced.²² It therefore used the guideline range for the pre-amendment equivalency of the lowest-dose, 10 mg, OxyContin pills to set the new guideline range for oxycodone (actual). That methodology resulted in one gram of oxycodone (actual) being equivalent to 6700 grams of marihuana. In doing so, the Commission substantially raised penalties for all other OxyContin formulations and created unwarranted disparity in sentencing between oxycodone and other opiates by ensuring that oxycodone is sentenced more severely than other opiates with similar or higher potency. It also made it more difficult to fairly compare the various opiates because it based the marihuana equivalency for oxycodone on the amount of the actual substance but used gross weight to compare other opiates – whether prescription opioids or heroin.

Under current marihuana equivalencies, 1 gram of oxycodone (actual) is given an equivalency 13.4 times greater than a mixture or substance containing morphine, methadone, or hydrocodone; 6.7 times greater than a mixture or substance containing heroin; 2.65 times greater

²¹ General Accounting Office, *Prescription Drugs: OxyContin Abuse and Diversion and Efforts to Address the Problem* 4 (2003), <http://www.gao.gov/new.items/d04110.pdf>.

²² USSC, *Notice of Proposed Amendments, Oxycodone* (2003), <http://www.ussc.gov/amendment-process/federal-register-notices/notice-proposed-amendments-sentencing-guidelines-policy-statements-and-commentary-request-public>.

than a mixture or substance containing hydromorphone; and 1.34 times greater than a mixture or substance containing oxycodone – no matter the weight or purity of the controlled substance contained within the carrier medium.²³

The proportionality problems created by these different methodologies of determining the appropriate marijuana equivalency become apparent with comparisons to other opiates. Here, we use heroin and hydromorphone to demonstrate the point. Heroin is more potent than oxycodone,²⁴ but it is punished less severely. Data from the Heroin Domestic Monitor Program shows that the average purity of South American heroin was 31.1 % in 2011.²⁵ Because the amount of *actual* heroin subject to the 1 gram of heroin (total weight of mixture or substance) to 1 kg marijuana equivalency is only about one-third of a gram, one gram of *actual* heroin has a marijuana equivalency of 3000 grams – less than half the 6700 gram equivalency assigned to actual oxycodone.²⁶

The different ways the guidelines treat hydromorphone and oxycodone also demonstrate the proportionality problems with the drug equivalencies for opioids. Even though hydromorphone is 2.6 times more potent than oxycodone, the guidelines treat it as 1.3 times more potent.²⁷

²³ These marijuana equivalency comparisons do not, however, take into account differences in the size of effective or typical dosages, or the amount of dilution typically found in street drugs or in non-oxycodone commercial products.

²⁴ See, e.g., Patient.Co.Uk, *Opioid Analgesics* (5 mg subcutaneous diamorphine (heroin) equivalent to 20 - 30 mg oral oxycodone), <http://www.patient.co.uk/doctor/opioid-analgesics>; The Shrewsbury and Telford Hospital, *Equivalent Dose Ratios for Strong Opioids* (recommending 1.33:1 ratio) <http://www.sath.nhs.uk/>; Health in Wales, *Opiate Conversion Doses* (diamorphine 1/3 more potent), <http://www.wales.nhs.uk/sites3/Documents/814/OpiateConversionDoses%5BFinal%5DNov2010.pdf>.

²⁵ Drug Enforcement Administration, *2011 Heroin Domestic Monitor Program, Drug Intelligence Report* (2013). This means that the amount of *actual* heroin subject to the 1 gram of heroin to 1 kg marijuana equivalency is about one-third of a gram.

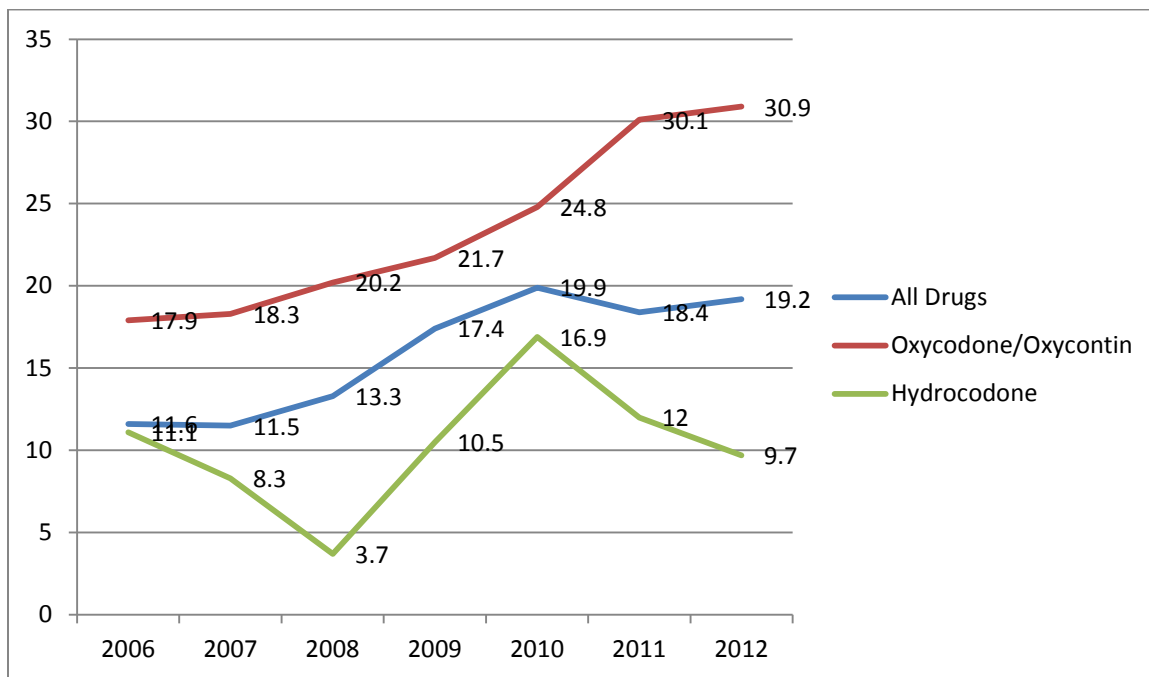
²⁶ Mexican Heroin had an average purity of 16.8%, meaning the amount of actual heroin subject to 1kg of marijuana is about one-sixth of a gram. *Id.* A gram of actual heroin would have a marijuana equivalency of 6000 grams – still less than the equivalency for oxycodone actual.

²⁷ A 4 mg hydromorphone tablet has a gross weight of about 90 mg. See *United States v. Lacour*, 32 F.3d 1157, 1157 (7th Cir. 1994). Using gross weight, ten thousand 4 mg hydromorphone tablets have a marijuana equivalency of 2,250 kg. Hydromorphone 4 mg and oxycodone 10 mg are about equianalgesic, which means that about 10,000 tablets of hydromorphone 4 mg would have the same effect as 26,000 tablets of oxycodone 10mg. The marijuana equivalency for 26,000 10 mg oxycodone tablets is 1,742 kg.

These irrational differences in drug equivalencies among opiates provide powerful evidence that the Commission should not arbitrarily link hydrocodone to the oxycodone equivalency without first undertaking an empirical assessment of the potency, purity, toxicity, pharmacological properties, and abuse liability of the various opiates and arriving at a rational and consistent approach to establishing the appropriate equivalency.

The below guideline sentencing rates for oxycodone also show that the Commission should revisit the oxycodone equivalency because many judges believe that the 1:6700 ratio is too high. In FY 2012, 30.9% of oxycodone/OxyContin cases received a non-government sponsored below range sentence. That is a 13% increase in the rate of below range sentences for oxycodone from FY 2006 to FY 2012 and is significantly above the overall rate of 19.2 % for all non-government sponsored below range sentences. See Table 3.²⁸

Table 3



Setting aside the proportionality issues and the importance of establishing a standard methodology for determining drug equivalencies, the Commission should revisit the 2003 oxycodone guideline because in 2010 OxyContin was reformulated to “be more difficult to manipulate for purposes of misuse or abuse.”²⁹ The tablets are now “difficult to crush, break, or

²⁸ USSC, *FY2006-FY2012 Monitoring Dataset*.

²⁹ FDA News Release, *FDA Approves Abuse-Deterrent Labeling for Reformulated Oxycontin* (April 16, 2013) (discussing FDA approval of the reformulation in 2010 and 2013 updated labeling).

dissolve,” and “forms a viscous hydrogel and cannot be easily prepared for injection.”³⁰ One research study shows that the percentage of individuals using OxyContin as “a primary drug of abuse decreased from 35.6% of respondents before the release of the abuse-deterrent formulation to just 12.8% 21 months later.”³¹ The FDA also recently approved an abuse-deterrent formulation of oxycodone and naloxone (Targiniq ER), which is designed to block the euphoric effects of oxycodone when it is snorted or injected.³²

IV. Hydrocodone Does Not Have the Same Abuse Potential and Trafficking Patterns as Oxycodone.

We believe that the drug equivalency tables should be revised and based more on scientific evidence about factors such as potency, purity, toxicity, and abuse liability, rather than prevalence of use, trafficking patterns, and other factors that can change over time. If, however, the Commission adheres to its past methodology of considering a multitude of factors in constructing the drug equivalency table, then the balance of evidence does not support treating hydrocodone like oxycodone.

To be sure, hydrocodone and oxycodone are both semi-synthetic opioids similar to morphine in producing opiate like effects.³³ But medical professionals do not agree on whether they have the same equianalgesic effects. Two equianalgesic dosing tables show that hydrocodone and morphine are 2/3 less potent than oxycodone;³⁴ and yet another shows that oxycodone is twice as potent.³⁵ We are aware of only one table that treats them the same.³⁶ But even if the equianalgesic doses are the same, other evidence shows that oxycodone is different than hydrocodone and should be treated so under the guidelines.

³⁰ *Id.*

³¹ Sjik Westra, et.al., *Effect of Abuse-Deterrent Formulation of OxyContin*, 367 *New. Eng. J. Med.* 187,188-89 (2012).

³² Susan Jeffrey, *FDA Approves Abuse-Deterrent Oxycodone/Naloxone Combo* (2014), <http://www.medscape.com/viewarticle/828812>.

³³ Drug Enforcement Administration, Office of Diversion Control, *Hydrocodone (Trade Names: Vicodin®, Lortab®, Lorcet-HD®, Hycodan®, and Vicoprofen®)*.

³⁴ Therapeutic Research Center, *Equianalgesic Dosing of Opioids for Pain Management* (2012), <http://stevespharm.com/Therapeutics/Opioid-equiv-chart-PL.pdf>Pharmacisti’s Letter; Globalrph, *Opioid Analgesic Converter*, <http://www.globalrph.com/narcoticonv.htm>.

³⁵ Veterans Affairs/Department of Defense, *Clinical Practice Guideline: Management of Opioid Therapy for Chronic Pain* 132, tbl. E6 (Equianalgesic and conversion doses for patients previously receiving other opioids), http://www.healthquality.va.gov/guidelines/Pain/cot/COT_312_Full-er.pdf.

³⁶ Goodman & Gilman, *Manual of Pharmacology and Therapeutics* (12th ed. 2014).

First, hydrocodone has a lesser abuse liability than oxycodone. An examination of nine studies that compared the likeability and abuse potential of hydrocodone, oxycodone, and morphine found that “[o]ral oxycodone has an elevated abuse liability profile compared to oral morphine and hydrocodone, which have no “clinically significant difference” between them.³⁷ Research also shows that fewer opioid dependent individuals preferred hydrocodone (29.4%) than oxycodone (44.7%) “because the quality of the high was viewed to be much better by 54% of the sample, compared to just 20% in hydrocodone users, who cited acetaminophen as a deterrent to dose escalation to get high and hence, its low euphoric rating.”³⁸ One explanation for the different abuse patterns is that hydrocodone is considered a “prodrug” – an abuse deterrent formulation – that must be “metabolized to an active form after ingestion to procure a pharmacological effect.”³⁹ Oxycodone, in contrast, “is a potent analgesic in its own right and not a prodrug.”⁴⁰ The difference in the way the two drugs are metabolized makes a difference for the potential of abuse because “[d]rug abusers prefer those drugs that give them a large brain concentration in the shortest time.”⁴¹ Of the different formulations of either oxycodone or hydrocodone, extended release and long-acting forms have greater abuse potential than shorter acting forms.⁴² That greater abuse potential led the FDA to subject extended release and long-

³⁷ Rachel Wightman, *Likeability and Abuse Liability of Commonly Prescribed Opioids*, 8 J. Med. Toxicol. 335 (2012). “The abuse liability of a drug characterizes its net positive and negative subjective effects and thus the likelihood of being used for recreational purposes.” *Id.*

³⁸ Theodore Cicero, et al., *Factors Influencing the Selection of Hydrocodone and Oxycodone as Primary Opioids in Substance Abusers Seeking Treatment in the United States*, 154 Pain 2639 (2013). See also Theodore Cicero, et al., *Multiple Determinants of Specific Modes of Prescription Opioid Diversion*, 41 J. Drug Issues 283, 293 (2011) (immediate release oxycodone was the primary opioid of abuse for 58.1% of opioid abusers; extended release oxycodone was the choice for 18.2%; hydrocodone was the primary opioid for only 15.5%).

³⁹ Prescription Painkillers: *History, Pharmacology, and Treatment*. See also E.J. Cone, *The New Science of Abuse-Deterrence Assessment of Pharmaceutical Products: FDA Proposed Guidance and Category I Laboratory Studies* (2014) (noting that FDA considers combination products and prodrugs as an abuse-deterrent formulation), <http://omicsonline.org/open-access/the-new-science-of-abusedeterrence-assessment-of-pharmaceutical-products-fda-proposed-guidance-and-category-laboratory-studies-2153-2435.1000317.pdf>.

⁴⁰ *Id.*

⁴¹ Tammi Schaeffer, *Abuse-Deterrent Formulations, an Evolving Technology Against the Abuse and Misuse of Opioid Analgesics*, 8 J. Med. Toxicol. 400, 400 (2012).

⁴² FDA, *FDA Introduces New Safety Measures for Extended-Release and Long-acting Opioid Medications* (2012), <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm310870.htm>

acting opioid analgesics (e.g., Hysingla ER, Zohydro ER, and OxyContin) to a Risk Evaluation and Mitigation Strategy (REMS).⁴³

Second, the risks associated with the two drugs differ. While not controlled for the rate of use, data from the Drug-related Emergency Department Visits for Misuse or Abuse of Drugs shows the number of visits in 2011 for oxycodone (175,229) was nearly double (1.8) the number for hydrocodone (97,183).⁴⁴ The number of visits for oxycodone increased by 220 percent from 2004 to 2011 whereas the number for hydrocodone increased by 96 percent.⁴⁵

Third, oxycodone and hydrocodone have different diversion patterns. Individuals who abuse oxycodone obtain their drugs from different sources than those who abuse hydrocodone. Two studies – one involving users in South Florida and another involving users in treatment centers across the country – showed that hydrocodone users were less likely to obtain their drugs from dealers than those who used oxycodone and more likely to obtain the drugs from legitimate medical sources (as opposed to illegitimate medical sources such as pharmacies and script doctors).⁴⁶ One explanation for this difference is that hydrocodone users are more risk-adverse.⁴⁷

No matter the source of diverted drugs, evidence from forensic drug laboratories shows fewer reports of testing for hydrocodone than oxycodone, while also showing a decreasing number of reports for oxycodone since 2010 and for hydrocodone since 2011.⁴⁸ Table 4.⁴⁹

⁴³ ER/LA Opioid Analgesics REMS Program, *Product's Covered Under the ER/LA Opioid Analgesics REMS Program*, <http://www.er-la-opioidrems.com/IwgUI/rems/products.action>. A REMS is meant to manage the risks associated with certain opioid products.

⁴⁴ SAMHSA, *The Dawn Report: Highlights of the 2011 Drug Abuse Warning Network (DAWN) Findings on Drug-Related Emergency Department Visits*, Table 2 (2013) <http://www.samhsa.gov/data/sites/default/files/DAWN127/DAWN127/sr127-DAWN-highlights.pdf>.

⁴⁵ *Id.* It should be noted that the total number of visits for either oxycodone or hydrocodone were significantly less than visits for cocaine, marijuana, heroin, and other illicit substances. *Id.*

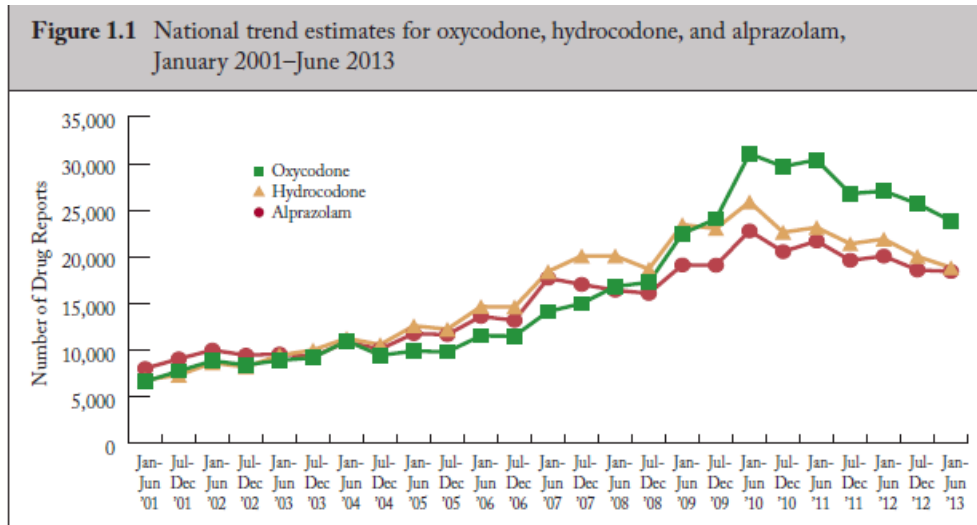
⁴⁶ Cicero, *supra* note 35, at tbl. 4, 291, tbl. 2, 295.

⁴⁷ *Id.*

⁴⁸ DEA, Office of Diversion Control, National Forensic Laboratory Information System, *2013 Midyear Report 6* (2013), <http://www.deadiversion.usdoj.gov/nflis/2013midyear.pdf>.

⁴⁹ *Id.*

Table 4



The Commission’s data also shows fewer offenses involving hydrocodone than oxycodone. Between FY 2006 and 2012, 3660 cases involved either hydrocodone or oxycodone. Only 11% of those involved hydrocodone.⁵⁰

Additional data on those convicted of federal hydrocodone and oxycodone offenses is also instructive. Among all drug types prosecuted in federal court, more women are convicted of offenses involving hydrocodone and oxycodone than any other drug. In FY 2006-2012, nearly a quarter of the individuals prosecuted for either oxycodone or hydrocodone were women (24%). More women were among those convicted of hydrocodone offenses (32.7%) than oxycodone (22.5%). By comparison, women comprised only 12.5% of those convicted of a powder cocaine offense and only 9% of those convicted of heroin. And like many individuals convicted of a drug offense, those convicted of oxycodone and hydrocodone offenses have minimal criminal history (51.4% of those convicted of oxycodone were in CH I and 67% of those convicted of hydrocodone were in CH I). Weapon involvement in these offenses was also small – 12.8% for oxycodone; 9.5% for hydrocodone.⁵¹

Almost half (47%) of the convictions for either drug were in the Fourth and Sixth circuits. More than half (53%) of the hydrocodone cases were concentrated in either the Fourth, Fifth, or Sixth circuits, particularly the Eastern and Western Districts of Texas, Eastern and Western Districts of Kentucky, and Western District of Tennessee – strikingly rural areas.⁵² The

⁵⁰ USSC, *FY2006-FY2012 Monitoring Dataset*.

⁵¹ *Id.*

⁵² *Id.*

prevalence of opioid abuse and diversion in Appalachia and other rural areas has been attributed to a variety of factors: the number of retirees and mine workers with health insurance that invited exploitation; economic depression that made it “tempting for people with legitimate prescriptions to sell them for profit”; and a history of self-medication in areas like Eastern Kentucky, which has high rates of cancer and of residents with chronic pain from mining and timber injuries.⁵³

Our review of cases involving individuals prosecuted for both oxycodone and hydrocodone offenses shows that federal law enforcement efforts are not always targeted toward high-level traffickers, pill mills, or doctors and pharmacists, but sweep in lower level individuals that may share legitimately prescribed drugs with friends and family or engage in small-time dealing to make some money and feed their own addiction.⁵⁴ The case of *United States v. Bell*, 667 F.3d 431 (4th Cir. 2011), provides an example of the government’s overzealous prosecution of a small time dealer. Nancy Bell was a 63-year-old woman, with no prior criminal history, who was convicted of conspiracy to distribute oxycodone that she obtained with a valid prescription over a five year period. She suffered from severe back ailments and occasional breakouts of shingles. Out of the 90 pills she was prescribed each month, she sold a portion to others, including relatives. At her original sentencing, the government claimed that she should be held responsible for every pill that she was prescribed even though some were put to legitimate use for her own pain management. It also sought a sentence at the high end of the guideline range and pressed for an aggravating role adjustment because she directed others, including her daughter, in the sales. The court initially sentenced Ms. Bell to 120 months imprisonment. After the appellate court vacated the sentence because of the manner in which the court used the total amount of oxycodone prescribed to Ms. Bell, she was sentenced to 97 months imprisonment. The court recently reduced her sentence to 63 months pursuant to amendment 782.

In a more recent case, a young man, in criminal history category I, was prosecuted in the Southern District of West Virginia for selling a small quantity of hydrocodone to a confidential informant. The quantity was small enough to yield an offense level of 2. Fortunately, the government eventually agreed to pretrial diversion, but the case is an example of how the lowest level dealers are targets of federal law enforcement officials.⁵⁵ Other low level defendants have

⁵³ Marvin Seppala & Mark Rose, *Prescription Painkillers: History, Pharmacology, and Treatment* (2010).

⁵⁴ Law enforcement authorities and public health officials have acknowledged the “culture of prescription drug sharing” in places like West Virginia. *A West Virginia Summit on Prescription Drug Abuse: Report and Recommendations* (2011), http://www.justice.gov/sites/default/files/usao-sdvw/legacy/2011/08/11/Summit_Report.pdf.

⁵⁵ If penalties for hydrocodone are increased, we fear that there will be even more prosecutions of street level distributors. Law enforcement officers often go after street level distributors in an effort to obtain cooperation about those higher up in the distribution chain. Higher penalties will permit them to leverage

not been so lucky. In the Southern District of West Virginia, prosecutors focus on small cases that may only involve two to eight pills. The volume of small pill cases has produced felony convictions that disqualify poor Appalachian citizens from receiving medical benefits, voting, and possessing firearms. And unlike urban areas, firearm possession in rural areas, where hunting is permitted, helps people feed their families. The benefit to society from these prosecutions is not worth the costs of prosecution or the devastating effect on defendants and their families. For each low level drug distributor that is removed from the street, another steps in to take his or her place.⁵⁶

V. The Commission’s Proposed Amendment and The Minimum Offense Level of 12 That Now Exists for Hydrocodone Will Dramatically Increase Sentences and Likely Lead to Judges Imposing More Below Guideline Sentences.

The Commission’s proposed amendments will cause sentences for hydrocodone to skyrocket. A case in the Western District of Kentucky demonstrates the point. Three individuals were convicted of conspiracy to distribute hydrocodone pills. One defendant worked in a local pharmacy. Over a six month period, she stole between 10,000 to 20,000 hydrocodone pills and sold them to another co-defendant who then sold the pills to a third defendant for eventual sale. For the first two defendants, the offense level was set at 13 (base offense level 16 for 10,000 to 20,000 hydrocodone units with minus 3 for acceptance of responsibility) – a guideline range of 12-18 months. Both received a sentence of two years’ probation. The third defendant received a sentence of 27 months imprisonment.

The guideline ranges would be dramatically higher under either of the Commission’s proposals. For example, if we assume the case involved 10,000 10 mg hydrocodone tablets, the new offense level at a ratio of 1:4467 would equal 446.7 kilograms of marijuana for a base offense level of 26. With 3 points for acceptance of responsibility and a criminal history category I, the guideline range would be 46-57 months imprisonment. If the case involved the lowest dose of hydrocodone – 5 mg – the base offense level would be 24 – 37-46 months imprisonment.

those defendants who can cooperate. Those who have no information to offer will face draconian sanctions. Higher penalties for certain substances also encourage law enforcement authorities to use controlled buys to steer sellers to those drugs in an effort to manipulate the sentence. E. P. Berlin, *Federal Sentencing Guidelines’ Failure to Eliminate Sentencing Disparity: Governmental Manipulations Before Arrest*, 1993 Wis. L. Rev. 187, 187 (1993) (“the Guidelines enable prosecutors and law enforcement officials to increase defendants’ prison terms by manipulating investigations and sting operations”).

⁵⁶ Jeremy Travis, et al., National Research Council, *The Growth of Incarceration in the United States: Exploring Causes and Consequences* 146 (2014), <http://www.nap.edu/catalog/18613/the-growth-of-incarceration-in-the-united-states-exploring-causes>.

Even in cases involving extremely small quantities of hydrocodone, like the one discussed above where the offense level was 2, the guideline recommended sentencing range already has increased significantly. The guidelines now call for a minimum offense level of 12 for Schedule II opiates. USSG §2D1.1, comment. (n.8(D)). The lowest level defendants with just a few pills who plead guilty and receive acceptance of responsibility can no longer receive a guideline recommended sentence of probation unless it also includes a condition of confinement or home detention. USSG §5C1.1(c). Such a result is not only unjust, but unnecessarily costly and a waste of limited resources. Instead of going to prison or spending time in community confinement, these individuals typically need proper medical treatment for their addictions and other health-related problems. We do not understand the rationale for setting a floor that does not fully consider the purposes of sentencing and none is provided in the commentary to §2D1.1 or Appendix C of the Guidelines Manual. In the absence of any justifiable reason for the floor, it should be deleted.

If the Commission were to keep the floor of 12 and raise the marijuana equivalency ratio for hydrocodone as set forth in the proposed amendment, it should expect to see the rate of below guideline sentences increase. Just as judges have declined to impose guideline recommended sentences in many oxycodone cases, see discussion *supra*, they are likely to do so with hydrocodone.

VI. Conclusion

We remain hopeful that the Commission agrees with us that the drug equivalency table for opioids needs to be revisited and that due consideration should be given to potency, purity, toxicity, and abuse liability. The suggestions we make here for revising the drug equivalency table require more study. In the meantime, the Commission needs to temporarily fix the drug equivalency table for hydrocodone because all Schedule III hydrocodone is now Schedule II. The easiest and fairest solution is to delete the reference to hydrocodone under the “Schedule I or II Opiates” and change the “Schedule III Hydrocodone” reference to “Schedule II Hydrocodone.” Such an amendment will maintain the status quo until the Commission can more thoroughly explore needed changes to the drug equivalency table.

Should the Commission, however, choose to ignore the fatal flaws in those drug equivalencies and limit itself to an amendment that bases the marijuana equivalency on the actual amount of hydrocodone, it should not adopt either a 1:4467 or 1:6700 hydrocodone to marijuana ratio. First, the difference between the two ratios would be meaningless in some cases. For example, the offense level for distribution of 10,000 10 mg pills would be 26 under both ratios. Second, the proposed ratios are significantly higher than the gram of hydrocodone (actual) to 1675 grams of marijuana the Commission considered in 2009. The Department of Justice expressly recommended the 1:1675 ratio in 2009, claiming that it would provide “a

minimally acceptable deterrent effect.”⁵⁷ The Department considered recommending a higher ratio of 3350 grams of marihuana for every gram of hydrocodone – still less than the 1:4467 or 1:6700 ratios proposed by the Commission – but rejected it as unnecessary.⁵⁸

For the Commission to adopt a significantly higher ratio than even the Department proposed in 2009 is not justified by the increase in the statutory maximum. For reasons stated above, the statutory maximums should not be a factor in the analysis. If the Commission nonetheless believes that the guideline range should reach the statutory maximum in some cases, it would be easily reached with a ratio lower than 1:4467. For example, a person convicted of trafficking 15,000 Hysingla ER 120 mg tablets would have a base offense level of 32 if the ratio were 1:1675. Aggravating role adjustments and criminal history increases could easily reach the statutory maximum penalty.

⁵⁷ Dep’t of Justice, Letter to the Honorable Ricardo Hinojosa, Acting Chair (March 27, 2009), at 39.

⁵⁸ *Id.*