

**Written Statement of Jon Sands  
Chair, Federal Defender Sentencing Guidelines Committee**

**Before the United States Sentencing Commission  
Public Hearing on Proposed Amendments for 2009**

**March 17-18, 2009**

**Re: Ryan Haight Online Pharmacy Consumer Protection Act of 2008**

We offer this written testimony regarding proposed amendments to “address changes made by the Ryan Haight Online Pharmacy Consumer Protection Act of 2008, Public Law 110-465 (the “Act.”).” These written comments supplement our earlier concerns, and respond to the Department of Justice’s (“DOJ”) January 5, 2009 letter (“DOJ Letter”) regarding possible amendments to the guidelines in light of the Act. Our December 5, 2008 letter is included as Appendix A.

Here, we reiterate our firm belief that the new offense of Dispensing of Controlled Substances by Means of the Internet should be referred to USSG § 2D1.1 and that the guidelines provide ample flexibility for a court to impose a “sufficient, but not greater than necessary” sentence, *see* 28 U.S.C. § 991(a)(b) (directing Commission to establish sentencing policy that meets the purposes of sentencing set forth in 18 U.S.C. § 3553(a)(2)), for offenses involving Schedule III, IV, and V drugs, including hydrocodone combination products and for Schedule III offenses where “death or serious bodily injury results from the use of such substance.”

As to the issues for comment, we do not believe that the current “empirical data and national experience,” *Kimbrough v. United States*, 128 S.Ct. 558, 574 (2007), provides a basis to otherwise “amend, or establish a new, guideline or policy statement.” Judicial feedback regarding online pharmacy cases and cases involving Schedule III-V substances does not show that the guidelines for those offenses are too low or in need of any increase. In the absence of widespread judicial dissatisfaction with the current guidelines, any amendments that would further complicate the sentencing process or increase sentences may very well invite judges to conclude that the guidelines are unsound, *Rita v. United States*, 127 S.Ct. 2456, 2465 (2007), particularly if the amendments are not firmly supported by “empirical data and national experience.” *See Spears v. United States*, 129 S.Ct. 840 (2009).

**I. When It Passed the Act, Congress Sent a Message that It Wants the Commission to Proceed Cautiously Before Tinkering with the Guidelines.**

The Act creates two new offenses involving controlled substances,<sup>1</sup> increases the statutory maximum terms of imprisonment for Schedule III-V offenses,<sup>2</sup> and adds a new statutory maximum for a Schedule III offense where “death or serious bodily injury results from the use of such substance.” 21 U.S.C § 841(b)(1)(E).

Notwithstanding these statutory changes, Congress did not envision that its actions would serve as the reason for the Commission to raise the guidelines for online pharmacy offenses involving larger volumes of drugs or for offenses involving Schedule III-V substances. Instead, signaling a desire that the Commission exercise its “characteristic institutional role,” 128 S.Ct at 575, and amend the guidelines only after careful study of “empirical data and national experience,” *id.* at 574, Congress expressly stated that the Commission “should not construe any change in the maximum penalty for a violation involving a controlled substance in a particular schedule as being the sole reason to amend, or establish a new, guideline, or policy statement.”

Giving lip-service to this congressional directive, which plainly instructs the Commission to proceed cautiously and amend the guidelines only with good reasons unrelated to congressional action, DOJ nonetheless claims that because Congress “chose to address” the “problem” of online pharmacies and Schedule III substances especially, the Commission should do so as well. *See* DOJ Letter at 3. That DOJ invites the Commission to rely on congressional action as even one reason to amend the guidelines suggests the relative weakness of the other “reasons” it posits for increasing sentences yet again. *Id.* at 3-4.

**II. Existing Guidelines are Adequate to Provide for “Proportionality,” and “Sufficient, But Not Greater than Necessary” Sentences.**

**A. *At least four provisions in the existing guidelines account for offense severity in cases involving high volume distribution of Schedule III-V drugs.***

The guidelines currently cap the base offense level for Schedule III, IV, and V drugs at 40,000 units. DOJ has expressed the view that the operation of online pharmacies, which are

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<sup>1</sup> The two new offenses are: (1) 21 U.S.C. § 841(h) (Offenses Involving Dispensing of Controlled Substances by Means of the Internet); and (2) 21 U.S.C. § 843(c)(2)(A) (Prohibiting the Use of the Internet to Advertise for Sale a Controlled Substance).

<sup>2</sup> The Act increased the penalties as follows: (1) Schedule III increased from 5 years to 10 years; (2) Schedule IV increased from 3 years to 5 years; and (3) Schedule V increased from 2 years to 5 years if the offense is committed after a prior drug conviction. It also added a sentencing enhancement – a maximum of 15 years imprisonment -- for Schedule III substances where death or serious bodily injury results. 21 U.S.C. § 841(b) (1)(E).

capable of distributing amounts of scheduled substances greater than the current cap of 40,000 units, provides reason to remove the caps. At least four provisions in the guidelines, however, already give courts the tools to account for offense severity and the additional harm caused by offenses involving distribution of large quantities through the internet compared to more traditional methods of distribution.

First, in November 2004, the Commission amended USSG § 2D1.1(b)(6) to account for the distribution of controlled substances over the internet, USSG App. C, amend. 667 (Nov. 1, 2004), acknowledging that the internet provided a tool to reach a large number of purchasers of controlled dangerous substances (“CDS”). If the caps were removed now, then the guidelines would have two provisions (drug quantity and use of the internet) that reach the same harm – distribution of large quantities of CDS. Such multiplying effects are more likely to result in disproportionality, not proportionality.

Second, application note 16 in § 2D1.1 calls for an upward departure in cases where the “drug quantity substantially exceeds the quantity for the highest offense level established for that particular controlled substance.” Courts have relied on this provision when they considered it appropriate to account for offense severity or otherwise satisfy the purposes of 18 U.S.C. § 3553(a). *See, e.g., United States v. Mancini*, 279 Fed. Appx. 95 (2d Cir. 2008) (upwardly departing to 72 months under application note 16 for pharmacist involved in distributing 5.4 million hydrocodone pills). The rate of departure under this guideline has not signaled a widespread dissatisfaction with sentences for offenses involving distribution of large quantities of Schedule III-V substances.<sup>3</sup>

In the past, the Commission has relied on upward departure rates as a reason to increase sentencing ranges. For example, when the Commission in 2004 increased the guidelines for homicide and manslaughter, it did so after noting the rates of upward departures for voluntary manslaughter and second degree murder. USSG App. C, amend. 663 (Nov. 1, 2004) (noting 28.6% upward departure rate for voluntary manslaughter and 34.3% upward departure rate for second degree murder). Here, neither the Commission nor DOJ has disclosed any similar data to support the conclusion that judges view the current penalties as inadequate for internet pharmacy operations and/or those otherwise dealing in large quantities of Schedule III-V substances.

Indeed, line prosecutors did not even press for upward departures in the cases DOJ complains about, *see* discussion *infra* – powerful evidence that the sentences available under the current guidelines are more than adequate to capture the severity of the conduct involved in the

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<sup>3</sup> DOJ complains in its January 2009 letter that under the current guideline a defendant has to distribute more than ten times the capped amount to get an upward departure. According to its earlier claims, however, it would not take many months of operation for a rogue pharmacy to meet that amount. *See* DOJ Letter at 3 (claiming rogue pharmacy “routinely dispenses more than” 1.76 million dosage units.).

large scale distribution of Schedule III, IV, and V substances, through the internet or otherwise. As to DOJ's speculative complaint that application note 16 "might produce inconsistent and unpredictable results," DOJ Letter at 8, it offers no data whatsoever to support that assertion. Ratcheting up sentences based on speculation does not make for sound sentencing policy. Without feedback from the courts showing dissatisfaction with the current sentences available under the guidelines for the large scale distribution of Schedule III-V substances, it would be far more prudent for the Commission to collect additional data on sentencing practices under the new statute before increasing sentences yet again in the name of "proportionality."

Third, several other guidelines, which uniquely apply to online pharmacies responsible for distributing large quantities of CDS, provide appropriately different punishment to account for offense severity, and thus satisfy concerns about "proportionality." Pharmacists, doctors, and others responsible for distributing large quantities, unlike street level dealers who traffic in smaller quantities, will inevitably be subject to an increased adjustment under §§ 3B1.3 (Abuse of Position of Trust or Use of Special Skill) or 3B1.1 (aggravating role).

Fourth, for defendants involved in the large scale distribution of CDS, forfeiture is a readily available and significant penalty, which may not be a viable sanction in cases involving a lesser amount of drugs. Unlike smaller distributors or street level organizations, where the distribution is not as lucrative or it might be more difficult to track income and proceeds, online pharmacies leave more "paper trails" that permit law enforcement to readily identify the income derived from the sale of illicit substances and then trace the proceeds. Just recently in the District of Maryland, two pharmacy owners were convicted of selling 10 million hydrocodone pills over the internet, laundering \$20 million in proceeds, and failing to pay taxes. In addition to being sentenced to five years in prison, they were ordered to pay \$11 million, forfeiting "their homes, seven cars, monies held in 33 bank accounts and a business property" to do so. *See* Press Release from Office of United States Attorney for the District of Maryland, *Internet Pharmacy Owners Sentenced to Five Years in Prison*, available at [www.usdoj.gov.usao/md/Public-Affairs/press\\_releases/press08](http://www.usdoj.gov.usao/md/Public-Affairs/press_releases/press08). In the Northern District of Iowa case involving "Pharmacom International" that the government complains of in its letter, DOJ Letter at 7-8, the two lead defendants were ordered to forfeit \$7.54 million in proceeds from the pharmacy operation. All of the other cases have likewise resulted in forfeitures.<sup>4</sup> These kinds of "alternatives to incarceration," which are significant punishments, cannot be ignored in assessing whether a punishment is "proportionate" to the severity of the offense.<sup>5</sup>

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<sup>4</sup> *See* DOJ Letter at 7 (forfeitures ordered in all eight cases DOJ claims are "representative" of those receiving "inadequate" sentences; median forfeiture amount was \$66,199); Appendix A (chart).

<sup>5</sup> *See* Teresa Carns: *Alternative Punishments: a Judicial Council Seminar*, 4 Alaska Justice Forum 10 (1994), available at <http://justice.uaa.alaska.edu> (reporting on Alaska Sentencing Commission's recommendation to use asset forfeiture as alternative to incarceration); Todd L. Cherry, *Financial Penalties as an Alternative Criminal Sanction: Evidence from Panel*

To summarize, the multiple effects of existing guidelines would permit a court to raise offense levels above the current caps by anywhere from 2 to 6 levels and result in a substantial financial penalty. Take, for instance, a pharmacist who distributes 41,000 units of hydrocodone after setting up a web distribution site that enlists a web-operator, three doctors, and a technician. The pharmacist could easily receive a 2 level increase for mass-marketing, a 4 level increase for aggravating role, and a 2 level increase for abuse of position of trust, placing him at an offense level of 28 or 78-97 months – not far shy from the statutory maximum of 120 months. If the offense level involved additional quantities, the court could easily use application note 16 of § 2D1.1 to depart 2 or 4 levels to reach a range that encompasses the statutory maximum. Criminal forfeiture would then serve as an additional punitive sanction. For these reasons, the existing guidelines provide for “appropriately different sentences for criminal conduct of differing severity,” *i.e.*, proportionality. USSG § Ch. 1, Pt. A, intro.comment.<sup>6</sup>

***B. No empirical evidence shows that the current guidelines are incapable of capturing the severity of the offense conduct in online pharmacy cases.***

DOJ has not produced any evidence from actual practice in the field showing that current sentences are disproportionately low compared to the severity of the offense or that high quantity is a reliable measure of offense severity. DOJ identifies eight of twenty-nine defendants prosecuted in the N.D. Iowa, who it claims “received sentences that do not reflect their level of culpability in the distribution of schedules III and IV controlled substances.” DOJ Letter at 7. DOJ offers no explanation for why it believe these penalties were inadequate – a most curious omission given that prosecutors in those cases did not use all of the tools currently available under the guidelines to seek higher sentences. A closer look at those cases shows that the government agreed to the sentence in each case, and in many cases, moved to reduce the sentence

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*Data*, 29 Atlanta Ec. Jrnl. 450 (2006) (exploring how financial penalties may serve deterrent effect similar to other sanctions and help reduce criminal justice expenditures for nonviolent offenders who might otherwise be incarcerated).

<sup>6</sup> While Chapter One of the guidelines manual refers to "proportionality," the principle is not explicit in any provision of the Sentencing Reform Act or 18 U.S.C. § 3553(a) and should not frame the Commission's decision-making. Instead, the Commission must ensure that the guidelines meet the purposes of sentencing set forth in section 3553(a)(2), avoid both unwarranted disparities and unwarranted similarities, reflect advancement in knowledge of human behavior, and measure the effectiveness of the guidelines in meeting those goals. 28 U.S.C. § 991(b). The Commission is also to minimize prison overcrowding. 28 U.S.C. § 994(g). To accomplish these goals, the Commission is to continually review and revise the guidelines in light of sentencing decisions, sentencing data, and comments from experts and practitioners, *see* 28 U.S.C. §§ 994(o), and conduct empirical research of sentences imposed, the relationship of such sentences to the purposes of sentencing, and their effectiveness in meeting those purposes. *See* 28 U.S.C. § 995(a)(12)-(16).

to better reflect the defendant's culpability.

- Apryl McNeil and Abyslom Nyamkeye – Two married physicians involved in an internet distribution of Schedule III and IV CDS for approximately four months received 20 month terms of imprisonment only after they received 35% reductions in their sentences upon government motions. The government did not seek an upward departure under application note 16 of § 2D1.1. *United States v. Apryl McNeil*, No. CR-05-1023 (N.D. Iowa 2005); *United States v. Abyslom Nyamkeye*, No. CR-05-1022 (N.D. Iowa 2005).
- Edward Schwab – A 72 year old osteopath received a 22 month sentence for participating in the distribution of large quantities of Schedule III and IV drugs over the course of ten months. The government did not contest findings in the presentence report, which calculated his adjusted offense level at 17, Criminal History I. *United States v. Edward Schwab*, No. CR-06-1011-LRR (N.D. Iowa. 2006) (Docket Entry 30; minute entry for proceedings of 9/21/2006). Nor did it move for upward departure under application note 16 to § 2D1.1. It moved for a 2-level downward departure under § 5K1.1, which was granted. See Appendix A (chart).
- Thomas Hanny – A 66 year old physician wrote prescriptions over a four month period. Although the offense involved at least 130,320 dosage units of Schedule III substances, the government did not seek an upward departure based on drug quantities under application note 16 to § 2D1.1. The court, sua sponte, raised the upward departure question, but ultimately rejected it. The government moved for a sentence reduction, not once, but twice. *United States v. Thomas Hanny*, No. CR-06-1032-LRR (N.D. Iowa 2006) and No. 07-1010 (9th Cir. Dec. 12, 2007).
- Roselyn Rice – The offense involved the dispensing of over 1 million dosage units of Schedule III drugs over a six month period. The government did not seek an upward departure under USSG § 2D1.1, n. 16. The court clearly recognized its authority to depart upwardly, but declined to do so. *United States v. Rice*, No. CR-07-1018-LRR (N.D. Iowa. 2008) (Docket Entries 36 and 43).
- Peter Lopez – Another uncontested sentencing involving over 2 million units of Schedule III drugs. The government did not seek an upward departure under USSG § 2D1.1, n. 16. *United States v. Peter Lopez*, No. CR-07-1023 (N.D. Iowa 2007).
- Jose Crespin – Another uncontested sentencing case where the government moved for a downward departure under USSG § 5K1.1. The drug quantities involved in this case (38,760 Schedule III dosage units and 105,980 Schedule IV units) were such that removing the caps would have no impact on the sentence. Even with an extended table for Schedule IV drugs, the BOL for the 38,760 Schedule III

substance would control the guideline calculation. *United States v. Jose Crespin*, No. CR-06-1038 (N.D. Iowa 2006) and No. 06-20656 (S.D. Fla. 2007).

- Renee Guerra – A co-defendant of Jose Crespin, who was charged by information with unlawfully dispensing Schedule III and IV controlled substances for just one month. Dr. Guerra was held responsible for distributing the same amounts as Dr. Crespin, who was involved in the alleged conspiracy for four months. *United States v. Guerra*, No. CR-06-1036 (N.D. Iowa).

***C. Ratcheting up sentences for online pharmacy participants and those who otherwise distribute hydrocodone would punish those offenders more severely than other offenders who have committed more serious offenses. Eventual discontent with such disproportionate results may, if history repeats itself, lead to further upward ratcheting***

Throughout the history of the guidelines, the principle of “proportionality,” which is not explicit in any provision of the Sentencing Reform Act, as a directive to the Commission or as a purpose of sentencing, has driven sentences upward. A seeming modest adjustment in one guideline eventually leads to adjustments in other guidelines in an effort to achieve the elusive goal of proportionality.<sup>7</sup>

Here, even if one were to accept the dubious proposition that the current guidelines do not provide “appropriately different punishment for criminal conduct of different severity,” *i.e.*,

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<sup>7</sup> See, e.g., USSG App. C, amend. 663 (Nov. 1, 2004) (“[T]he Commission increased the base offense levels of many of the homicide guidelines to punish them more appropriately and with an eye toward restoring the proportionality found in the original guidelines.”); *Id.* (“To maintain proportionality, reflect increased statutory penalties, and comply with the directive, the two non-aggravated assault guidelines also were amended.”); *Id.*, amend. 664 (Nov. 1, 2004) (“The Commission increased the base offense level for possession offenses from level 15 to level 18 because of the increase in the statutory maximum term of imprisonment from 5 to 10 years, and to maintain proportionality with receipt and trafficking offenses.”); *Id.* (“[T]he amendment increases the base offense level at § 2A3.1 (Criminal Sexual Abuse; Attempt to Commit Criminal Sexual Abuse) from level 27 to level 30 to maintain proportionality between this guideline and §2 G2.1, the production of child pornography guideline, the base offense level of which was raised to level 32 by this amendment.”); *Id.*, amend. 678 (Nov. 1, 2005) (“Raising the base offense level of § 2R1.1 helps restore the historic proportionality in the treatment of antitrust offenses and sophisticated frauds.”); *Id.*, amend. 692 (Nov. 1, 2006) (“The addition of this specific offense characteristic [4 level enhancement for fraudulent use of passport] to § 2L2.1 promotes proportionality between the document fraud guidelines, §§ 2L2.1 and 2L2.2.”); *Id.* (“The addition of this specific offense characteristic to § 2L2.1 promotes proportionality between the document fraud guidelines, §§ 2L2.1 and 2L2.2.”).

proportionality, for offenses involving greater than 40,000 units of Schedule III, IV, or V substances generally or for offenses involving hydrocodone in particular, increasing sentences for these offenses would create disproportionality elsewhere.

If the Commission were to raise the cap for Schedule III substances (including hydrocodone combination products) from 20 to 26 or even higher, sentences could quickly approach those handed out to offenders who would generally be considered more culpable and dangerous. As an example:

Dr. A is recruited by an on-line pharmacy operator to write prescriptions for four months. He reviews 12 on-line questionnaires a day, writing 60 prescriptions a week. Over the course of four months, he writes 960 prescriptions for 180 Lortab® 7.5 mg (a one month supply for a recommended dosage of 1 every 4 to 6 hours). He is responsible for distributing 172,800 units. His offense level would be 26.

Dr. A's base offense level of 26 would be the same as a defendant

- who steals anywhere from \$1-2 million dollars, § 2B1.1(b)(1)(N)
- who commits aggravated assault with a firearm that results in permanent or life-threatening bodily injury, in violation of a protective order, § 2A2.2 (BOL 14 + 10 level adjustment for discharge and injury + 2 for violation of court order)
- who provides material support to terrorist organizations, § 2M5.3
- who exports arms to the Middle East without a license, § 2M5.2.

If specific-offense characteristics are piled on for mass-marketing under § 2D1.1(b)(6), and use of a special skill under § 3B1.3, the total adjusted level reaches 30 – higher than the guidelines for voluntary manslaughter under § 2A1.1 (BOL 29); attempted murder under § 2A2.1 (BOL 27); abusive sexual conduct with a minor under § 2A3.2(B)(2) (BOL 22); and bank robbery where a firearm was discharged under § 2B3.1. (BOL 29).

One need not be much of a student of the historical genesis of the guidelines to realize that if the Commission increases the sentencing ranges for Schedule III-V cases involving quantities great than 40,000 units because of the perception that the current ranges are not “proportional,” DOJ, or Congress, will soon complain that the sentencing guidelines for certain violent crimes and sex offenses do not provide for “appropriately different punishment for criminal conduct of differing severity.” USSG Ch. 1, Pt. A, intro. comment. And with that, the inevitable ratcheting up of the guidelines will continue evermore.

With a congressional directive that cautions the Commission not to reflexively raise sentences in response to congressional action, the Commission has a unique opportunity to stop



the cycle of ever-increasing sentences and to act only if the empirical data clearly show that increasing the term of imprisonment for a particular offense is necessary to meet the purposes of sentencing set forth in 18 U.S.C. § 3553(a). See *Plenary Speech by Mr. Robert C. “Bobby” Scott* at 11, Sentencing Advocacy, Practice and Reform Institute, American Bar Association Criminal Justice Section, October 24, 2008 (noting that current “congress . . . is inclined to trust the Commission and not so inclined to tamper with the guidelines”). Here, because the empirical data and sentencing practice does not support increased sentences, the Commission should do nothing in response to the Act other than referring the new offenses and sentencing enhancement to § 2D1.1.

### **III. Drug Quantity is an Especially Complicated and Poor Measure of Offense Severity in Online Pharmacy Cases.**

Calculating drug quantities in large-scale conspiracies has never been an easy task. Forcing judges to perform more precise quantity calculations may very well lead to even more judicial resistance of the guidelines. At a minimum, it would unduly complicate sentencing by requiring judges, probation officers, and the parties to delve more deeply into thorny issues of relevant conduct as they debate the proper quantity for which the defendant should be held accountable. Quantity calculations are confusing and difficult enough for judges, who often must rely on questionable informants and other inherently unreliable sources in making such calculations. Rogue internet pharmacies, which operate in cyber-space with the participants often spread out and only loosely connected, compound those difficulties.

An example demonstrates the point.

Pharmacist A may establish a business relationship with web Operator B who advertises the sale of on-line pharmaceuticals. As the business grows, Operator B recruits Doctors C and D – practice partners – to write prescriptions after viewing on-line medical questionnaires. Doctors C and D then enlist Doctors E and F. Although each doctor has his own caseload of questionnaires to review, they may occasionally fill-in for each other during vacations or other absences.

Whether these doctors may be held accountable for the prescriptions written by each other is a complex question of fact and law – one that may not be worth pursuing simply to arrive at a base offense level driven by quantity. The case may become even more complicated – for example, when questions arise as to whether a particular defendant doctor actually authorized the prescription or if the pharmacy used a doctor’s electronic signature without permission.<sup>8</sup>

Even without the additional complications of calculating drug quantity, online cases

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<sup>8</sup> *Apryl McNeil*, No. CR-05-1023.

present other factual nuances that may be much more relevant than quantity in measuring the severity of the offense. For example, for a doctor or pharmacist involved in distributing CDS over the internet, a judge could find that many other factors are more reliable indicators of overall offense severity:<sup>9</sup>

- (1) how long did the defendant participate in the offense;<sup>10</sup>
- (2) how addictive was the particular drug involved;
- (3) were the prescriptions written in accordance with standard dosing amounts or involve greater amounts, thereby increasing the risk of abuse/overdose/toxicity;
- (4) did the physician actually review the on-line questionnaire, follow-up with patients, or merely rely on others to do so;<sup>11</sup>
- (5) did the physician review medical records from examining physicians;<sup>12</sup>
- (6) did the physician attempt to act responsibly by rejecting prescriptions from people who appeared at high risk for abuse, known addicts, or for whom the drugs were otherwise contraindicated because they posed risks to the ingestor or secondary health consequences - *e.g.*, to pregnant women and developing fetuses;<sup>13</sup>
- (7) did the pharmacy dispense FDA approved drugs or were they counterfeit, out-of-date, or imported from other countries;
- (8) was the same drug prescribed to the same person at the same time;
- (9) were dosages increased without a reason; and
- (10) were refills authorized before they were due?<sup>14</sup>

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<sup>9</sup> See generally *DEA Diversion, Cases Against Doctors: Fred Williams*, available at [http://www.deadiversion.usdoj.gov/crim\\_admin\\_actions](http://www.deadiversion.usdoj.gov/crim_admin_actions) (listing various factors in describing seriousness of offense).

<sup>10</sup> A defendant need not participate in the offense for very long before the number of units exceeds 40,000. See, *e.g. Nyamekye and McNeil*, No. CR-05-1022-23 (information alleged dispensing of at least 357,330 dosage units of Schedule III over four months).

<sup>11</sup> Dr. Nyamkey, for example, actually called over 580 patients who he believed had become his patients over the internet. *Nyamekye*, No. CR-05-1002 (Defendant's Exhibit A from 4/21/06 sentencing hearing); see also *Hanny*, No. CR-06-1022 and 1032 (Defendant's Exhibit Q from sentencing).

<sup>12</sup> See, *e.g. McNeil*, No. CR-05-1002 (Defendant's Exhibit H (patient medical records reviewed by Dr. McNeil)).

<sup>13</sup> Dr. Hanny – another defendant who DOJ claims received a sentence that did not reflect his culpability – rejected 20-25% of the prescriptions presented to him.

<sup>14</sup> Also relevant is the lower risk of violence typically associated with online pharmacy distribution. Unlike street level drug distribution, which may erupt in violence as traffickers seek to protect their drugs or their turf, online pharmacies operate in cyberspace. Because they are

All of these factors are significantly better indicators of offense severity than quantity. Judges should be permitted to do that which they are uniquely suited to do – assess these factors under the totality of the circumstances and arrive at an appropriate sentence. Instead of trying to substitute quantity as a measure of offense severity, or micro-manage the guideline calculation with specific-offense characteristics, the Commission should consider providing a list of the kinds of mitigating and aggravating factors that may be relevant, without attaching any particular number of offense levels to each one, and then let judges judge.

#### **IV. Changing the Drug Equivalency Tables for Hydrocodone or Treating It Differently than Other Schedule III Substances Would Have a Disproportionate Impact on Lower Level Offenders.**

Apparently prompted by DOJ's assertion that the "guidelines no longer make sense" "for defendants who use the internet to distribute massive quantities of [hydrocodone]," DOJ Letter at 4, the Commission has sought comment on whether it should review the guidelines as they relate to hydrocodone. For reasons stated earlier in this submission and our December 2008 letter, we believe that the guidelines adequately address issues arising from the use of the internet to distribute hydrocodone or any other Scheduled III -V substance. We also are gravely concerned about DOJ's proposals to change the current drug equivalency for hydrocodone from its current conversion ratio of 1 capsule = 1g of marijuana or that would treat hydrocodone like oxycodone – *i.e.*, by weight of actual substance rather than unit dose.

DOJ admits that "for many defendants with modest or low level involvement in the distribution of schedule III controlled substances, the 1995 guidelines may well remain adequate." DOJ Letter at 4. It also claims that it "is not and has not proposed that § 2D1.1 be changed for low level distributors of controlled substances." DOJ Letter at 11. How increasing either the conversion ratio in the drug equivalency table (DET) or calculating guidelines by weight of hydrocodone rather than unit dose will not impact these lower level defendants remains a mystery.

A close review of how DOJ's proposal would dramatically alter the sentence of a low level offender shows how any change in the guideline in the name of "proportionality" for internet distributors, will result in disproportionately high sentences for other offenders. Take the case of Jean Panak – a 76 year old dental receptionist prosecuted for conspiracy to distribute 31,000 units of Vicodin ES® 7.5/750 mg (or a net of 232.5 grams of hydrocodone). *United States v. Panak*, 552 F.3d 462 (6<sup>th</sup> Cir. 2009). Under existing guidelines, her BOL is 18. With a 2 point reduction for acceptance of responsibility and a criminal history category of I, her guideline range would be 21 to 27 months - a Zone D sentence.

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relatively anonymous, they cannot compete with each other in violent ways. Nor do they need to resort to violence to protect their supplies from theft or robbery. On balance, internet pharmacies, which distribute large quantities, are a less dangerous enterprise than street traffickers who may distribute smaller quantities.

If the Commission were to adopt DOJ's proposal of using the actual weight of active ingredient at a conversion ratio of 1 gm of hydrocodone (actual) to 1675 gram of marijuana (with no cap), her offense level would jump to 26.<sup>15</sup> With 2 points for acceptance of responsibility, Ms. Panak's guideline range would be 51 to 63 months under the government's proposal – a 143% increase from the current guidelines.<sup>16</sup> Doctors prosecuted for unlawfully dispensing hydrocodone would face similarly stiff sentences, even though they were low level distributors who the government claims are not within its sights.<sup>17</sup>

In addition to doctors engaged in small scale distribution, other persons engaged in low level distribution would face harsh penalties if the Commission were to revise the guidelines for hydrocodone. Defender offices in the Northeast report federal prosecutions of female defendants with addiction and pain management problems who get involved in street sales of multiple-prescription medications in order to feed their own habit. *See also* Mike McKinney, *Providence Woman Admits Forging Prescriptions*, available at <http://newsblog.projo.com> (describing federal prosecution of woman who forged prescriptions for oxycodone and hydrocodone, sold the pills, or exchanged them for crack). A recent study on the street level diversion of prescription pain killers confirms that such “dealers” often use pain killers themselves for legitimate medical reasons or to ease the symptoms of withdrawal from more powerful narcotics, like heroin. *See* W. Rees Davis and Bruce Johnson, *Prescription Opioid Use, Misuse, and Diversion among Street Drug Users in New York City*, 92 *Drug and Alcohol Dependency* 267-76 (2008). These are not people who need to spend more time in prison, but individuals in desperate need of proper medical treatment for their addictions and other health-related problems. *Id.*

Our fears of stiffer penalties for those involved in modest or low level distribution of hydrocodone are not alleviated by DOJ's representation that “street level distributors are seldom prosecuted in federal court, unless they are part of a larger prosecution focused on more culpable defendants.” DOJ Letter at 11. Law enforcement officers often go after street level distributors

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<sup>15</sup>  $31,000 \times 7.5 \text{ mg} = 232,500 \text{ mgs}$  (232.5 grams);  $232.5 \text{ grams hydrocodone} \times 1675 \text{ grams of marijuana} = 389437.5 \text{ grams of marijuana}$  (389.5375 kg);  $389 \text{ kg of marijuana} = \text{OL } 26$

<sup>16</sup> The dentist, who pled guilty to conspiracy to distribute 2690 tablets of Vicodin ES® 7.5/750mg and received two years probation with 6 months home detention, would be subject to a Zone D sentence of 21 to 27 months – a 110% increase in sentence. *See United States v. Donald Chionchio*, No. 4:06CR-425 (N.D. Ohio 2007).

<sup>17</sup> *See, e.g., United States v. Peter Ahles*, No. SACR 05-00168-JVS (C.D. Cal. 2006) (67 year old doctor charged with dispensing 1500 units of hydrocodone to confidential informants; sentenced to six months home detention and \$250,000 fine); *United States v. Steven Ringel*, No. 2:04-cr-20106-CM-1 (D. Kan. 2005) (doctor prosecuted for distributing more than 30,000 units of Lortab®; sentenced to 30 months imprisonment); *United States v. In Whan Yun*, No. CR 107-99 (S.D. Ga. 2007) (doctor prosecuted for unlawfully dispensing hydrocodone; sentenced to five years probation; ordered to forfeit \$200,000).

in an effort to obtain cooperation about those higher up in the distribution chain. Higher penalties will permit them to leverage those defendants who can cooperate. Those who have no information to offer will face draconian sanctions. In any event, DOJ has no consistent national policy against prosecuting street level dealers.

Moreover, if the Commission were to raise penalties across-the-board for the distribution of hydrocodone combination products, higher penalties would inevitably provide law enforcement with greater incentives to investigate, prosecute, and convict street sellers of hydrocodone. The Commission long ago recognized that it should design sentencing policy to avoid the potential of “prosecutorial and investigative sentencing manipulation.” USSC, *Special Report to the Congress: Cocaine and Sentencing Policy*, at 8 (April 1997). Just like law enforcement officers wait for, or encourage, powder cocaine to be converted into crack because of the “dramatic impact on a defendant’s final sentence,” a real danger exists that they will steer sellers of other Schedule III-V drugs toward hydrocodone combination products 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”).

**V. The Guidelines Should Continue to Use the Unit Dose of Hydrocodone Combination Products Rather than Weight to Calculate Drug Quantity. Weight Is an Exceedingly Poor Measure of the Harm of These Substances.**

DOJs proposal to increase the marijuana equivalency for hydrocodone and to measure the quantity by actual weight rather than unit dose is unsound. As discussed in our December 2008 letter, we believe the guidelines should continue to calculate hydrocodone combination products (and every other Schedule III-V substance) based on unit dose rather than weight. We are gravely troubled by any proposal to quantify the “harm” of hydrocodone combination products (or any other controlled substance) by analyzing their analgesic potency or their pharmacological properties and then comparing one to the other. The vast number of Schedule III-V drugs available, the myriad – and sometimes conflicting studies – on the overall effects of certain drugs, and their wide range of dosing, makes it exceedingly difficult to judge the relative harm of these drugs. It would be much simpler, and would produce more consistent results, if the Commission deferred to the expert decisions of other agencies tasked with the responsibility of assessing the abuse potential of these drugs.

**A. The Commission should defer to DEA’s and FDA’s assessments of the abuse potential and dangerousness of scheduled substances.**

Hydrocodone combination products, such as Vicodin® and Lortab®, are Schedule III drugs, which the Commission should not single out for exceptional treatment under the

guidelines or treat as if they were Schedule II drugs. Schedule II drugs, like oxycodone (Oxycontin®) “have a high potential for abuse with severe psychological or physical dependence.” DEA, *Practitioner’s Manual: An Informational Outline of the Controlled Substance Act* (2006). Schedule III drugs, like hydrocodone combination products containing less than 15 mg of hydrocodone (Vicodin®) “have a potential for abuse less than substances in Schedules I or II.” *Id.* Hydrocodone combination products were placed in Schedule III, not II, only after careful study.

Not one, but at least two government agencies – DEA and the Center for Drug Evaluation and Research, U.S. Food and Drug Administration (FDA) – were responsible for assessing the abuse potential of hydrocodone combination products and other prescription drugs. “FDA performs a medical and scientific assessment as required by the Controlled Substances Act, and recommends to DEA an initial schedule level to be assigned to a new controlled substance.” U.S. General Accounting Office, *Prescription Drugs: OxyContin® Abuse and Diversion and Efforts to Address the Problem*, GAO-04-110, 12-13 (Dec. 2003). Its analysis is based on “the drug’s chemistry, pharmacology, clinical manifestations, similarity to other drugs in a class, and the potential for public health risks.” See Statement of Robert J. Meyer, Director Office of Drug Evaluation, *FDA’s Role in Preventing Prescription Drug Abuse* (2005), available at [www.hhh.gov/asl/testify/t050913.html](http://www.hhh.gov/asl/testify/t050913.html). In fulfilling its statutory responsibility of evaluating drugs and making recommendations to the Attorney General about the classification of such drugs, FDA does not assess a drug’s potential for abuse by looking at a single factor – such as its analgesic effects compared to other drugs. See 21 U.S.C. § 811(b) and (c). Notwithstanding the fact that its own agency – continues to classify hydrocodone combination products as Schedule III, DOJ wants the Commission to ignore that decision and punish hydrocodone more harshly than other Schedule III substances, and in some respects more severely, than Schedule II drugs, including Schedule II hydrocodone (a non-combination product).<sup>18</sup>

***B. No new empirical evidence supports a complicated change in the guidelines for hydrocodone combination products.***

The current drug equivalency for 1 unit of a Schedule III hydrocodone combination product is 1 gram of marijuana. The Commission established this, and other, single conversion ratios for all Schedule III-V substances in 1991 because it wanted to “*simplify application of the guidelines.*” It found a “generic listing” of Schedule III[-V] substances “appropriate” because “*the equivalencies for Schedule III substances are not statutorily based, nor are the pharmacological*

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<sup>18</sup> DOJ’s assertion that the Commission can simply ignore how DEA and FDA treat hydrocodone combination products is stunning. See DOJ Letter at 7. Congress and the Supreme Court expect the Commission to act as policy makers who collect data, consult experts, and act on empirical evidence. In performing that role, the Commission cannot disregard medical evidence and the expert views of others charged with assessing the harm of prescription drugs.

*equivalencies as clear as with Schedule I or II Substances.*” USSG App. C., amend. 396 (Nov. 1, 1991). Four years later, the Commission once again sought to simplify the guidelines “and more fairly assess the scale and seriousness of the offense” by switching from a weight- based equivalency to a unit- based one, recognizing that there may be “little or no relationship between the gross weight and the potency of the pill.” *Id.*, amend 517 (Nov. 1, 1995).

Now, without a scientific consensus about the abuse potential or health risks of the various formulations of hydrocodone combination products as compared to other prescription opioids, DOJ wants the Commission to change the equivalency from unit to actual weight and increase penalties by making the equivalency 1 gram of hydrocodone (actual) = 1675 grams of marijuana. DOJ seeks to justify this change on its perceived differences in the “potency” of a 5mg hydrocodone combination product with a 10mg hydrocodone combination product.

From a scientific perspective, at least two major problems exist with DOJ’s reasoning. First, the amount of hydrocodone in a single pill is a very poor measure of its harm because of the toxic effects of acetaminophen. While DOJ expresses its concerns with the public health ramifications of the use of hydrocodone combination products, it ignores the toxic effects associated with too much acetaminophen. According to the FDA, acetaminophen is toxic to adults at the 10g level. *See FDA, Label for Lortab®*, available at <http://dailymed.nlm.nih.gov/dailymed/drugInfo>. Under DOJ’s proposal, the distribution of 20 Lortab® 2.5./500 (2.5mg hydrocodone/500mg acetaminophen) would be treated the same as the distribution of just 4 Lortab® 10/500. Yet, if a drug user were to take the 20 Lortab® 2.5/500, she would reach a toxic level of acetaminophen (potentially suffering circulatory failure), whereas the user who ingested 2 Lortab® 10/500 would not reach a toxic level of acetaminophen and may very well not overdose on hydrocodone. *Id.* In this context, the defendant who distributes larger quantities of a lower dose hydrocodone combination product arguably places more people at risk than the defendant who distributes smaller quantities of a higher dose hydrocodone combination product. For this reason, the weight of the hydrocodone, rather than unit dose, is a poor measure of harm.

The second problem with DOJ’s reasoning is that it uses “potency” as a rough measure of harm. “Potency,” as measured by simple milligrams of a combination product is a poor measure of its analgesic effect or its potential for abuse or misuse. Studies show that comparisons of one drug to another must be made with great care. Combination drugs with even the same amount of the exact same substance may not produce the same effects. With combination products, the synergistic effect of the controlled substance with its combination product – be it acetaminophen, ibuprofen, or aspirin – is critically important when assessing its pharmacological, psychopharmacological properties, and its pain-relieving effects.

For example, in one study of dental patients, researchers compared the analgesic efficacy of a combination product – oxycodone 10 mg /acetaminophen 325 mg with controlled-release

(CR) oxycodone 20 mg. The authors concluded that the “[combination agent was statistically superior to CR oxycodone in four of five outcome measures of pain intensity and pain relief.”<sup>19</sup> Hence, on a simple comparison of analgesic efficacy, *the combination product with less oxycodone was more effective than twice the amount of plain oxycodone*. Hence, for those who misuse or abuse prescription pain killers for their pain-relieving properties, and assuming they have a “choice” in which drug to take, the combination drug with the lesser amount of controlled substance might be the preferred choice. The guidelines for Oxycontin® assume the opposite – precisely because they were not based on empirical evidence, but on a general view that the amount of oxycodone in the substance was the best measure of its “harm.” USSG App. C, amend. 657 (Nov. 1, 2003).

**C. The Commission Should Not Amend the Guidelines for Hydrocodone Combination Drugs or Any Other Schedule III-V Drug.**

The preceding discussion highlights just two of the reasons why it makes no sense to treat hydrocodone combination products like oxycodone by tying the base offense levels to weight rather than unit dose. Superficial conclusions that the weight of the active ingredient bears upon its harm in a meaningful way do not make for sound sentencing policy.<sup>20</sup>

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<sup>19</sup> Arnold R. Gammaitoni, *et.al*, *Randomized, Double-Blind, Placebo Controlled Comparison of the Analgesic Efficacy of Oxycodone 10mg/Acetaminophen 325 mg versus Controlled-Release Oxycodone 20 mg in Postsurgical Pain*, 43 *Jrnl. of Clinical Pharmacology* 296 (2003). In a similar study, a combination of oxycodone 5mg/ibuprofen 400 mg "provided significantly greater analgesia compared with oxycodone 5mg/acetaminophen 325 mg, hydrocodone 7.5mg/acetaminophen 500mg, and placebo." LJ 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).

<sup>20</sup> Another mistake would be to assume that simply because Schedule II oxycodone and Schedule II hydrocodone may have the same abuse potential among ex-opiate abusers, S.L. Walsh, *et.al.*, *The Relative Abuse Liability of Oral Oxycodone, Hydrocodone and Hydromorphone Assessed in Prescription Opioid Abusers*, 98 *Drug Alcohol Depend.* 191(2008), means that they do so when combined with other drugs or when used in a healthy population.

At least one study proves that assumption false. See James Zany, *Subjective, Psychomotor, and Physiological Effects Profile of Hydrocodone/Acetaminophen and Oxycodone/Acetaminophen Combination Products*, 9 *Pain Medicine* 433-43 (2007) (10mg oxycodone /650 mg acetaminophen combination produced a wider spectrum of subjective effects



Buying into DOJ's argument that the strength of hydrocodone in a product justifies punishing defendants based on weight rather than dosage unit will create a "slippery slope" for the future. If the Commission switches back to a methodology it already rejected – calculating the weight of hydrocodone rather than unit doses – DOJ will inevitably return in future amendment cycles with proposals to increase sentences by using the actual amount of controlled substance ingredient in other Schedule III-V products as well. Many of those products come in different potencies, for example: alprazolam (Xanax®) – .25mg, .5 mg, 1mg, and 2mg; zolpidem (Ambien®) – 5mg, 10mg; zolpidem (Ambien CR®) – 6.25mg, 12.5mg; diazepam (Valium®) 2mg, 5mg, 10mg; clonazepam (Klonopin® and Klonopin Rapidly Disintegrating®) – .125mg, .25mg, .5mg, 1mg, 2mg. The guidelines for unlawful distribution of these products is now based upon unit dose.

In short, it makes far more sense to stick to the original reason why the Commission switched from a weight-based approach to units in the first instance: to simplify the guidelines, especially given the difficulty in assessing the equivalencies of various forms of similar drugs. *See also* USSG App. C, amend. 369 (Nov. 1, 1991) (in adding offenses involving anabolic steroids, Commission reasoned: “[b]ecause of the variety of substances involved, the Commission has determined that a measure based on quantity unit, rather than weight, provides the most appropriate measure of the scale of the offense.”).

## **VI. The Need to Deter the Operation of Rogue Internet Pharmacies Does Not Provide A Sufficient Policy Reason to Increase the Penalty Structure for Schedule III -V Offenses.**

DOJ's push for higher penalties for Schedule III (as well as IV and V) substances is premised on its view that increased prison terms are the way to deter rogue pharmacy operations, and the brazen claim that “the Commission is not free . . . to question the fundamental utility of making incremental changes to the sentence to be applied to specific crimes.” DOJ Letter at 10.

### ***A. The Commission's mission is to determine whether, and to what extent, general deterrence is a relevant sentencing factor.***

Contrary to DOJ's view, assessing the need to make any changes to the guidelines for specific crimes is the Commission's *core* mission. Questioning whether higher terms of

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in healthy participants that were statistically significant than did the 10mg hydrocodone/650mg acetaminophen combination). Only one study suggests that oral oxycodone and hydrocodone – non-combination products exhibit a similar potential for abuse. S.L. Walsh, et.al., *The Relative Abuse Liability of Oral Oxycodone, Hydrocodone and Hydromorphone Assessed in Prescription Opioid Abusers*, 98 Drug Alcohol Dependence 191 (2008).

imprisonment are necessary to deter crime is a fundamental part of that mission. The Sentencing Reform Act (“SRA”) expressly directs the Commission to consider “the deterrent effect a particular *sentence* may have on the commission of the offense by others” to the extent it has relevance. 28 U.S.C. § 994(c)(6). Nothing in the SRA requires the Commission to conclude that *higher terms of imprisonment* are necessary to have a deterrent effect. Section 991(B)(1)(A) of title 28 specifies that the “purposes . . . of the Commission are to . . . establish sentencing policies and practices . . . that assure the meeting of the purposes of sentencing as set forth in section 3553(a)(2) of title 18, United States Code.” Section § 3553(a)(2)(B), in turn, requires courts to consider the need to “afford adequate deterrence to criminal conduct.” Nowhere does it say that a term of imprisonment is the way, the best way, or the only way to deter conduct or that a lengthy sentence is required to accomplish that purpose. DOJ’s argument that “harsher sentences are a more effective deterrent than lenient sentences,” DOJ Letter at 10, is a limitless rationale for increased sentences for all crimes.

We remain hopeful that the Commission will see the wisdom of basing sentencing policy on empirical data regarding deterrence and not on DOJ’s drive to incarcerate more offenders for longer periods of time. As discussed in our December submission, research shows that especially for nonviolent offenders likely to be involved in rogue internet pharmacies, it is the *certainty of punishment (i.e., the risk of getting caught and prosecuted) rather than the severity of punishment, which deters*. Whether doctors and pharmacists involved in this activity before the Act “knew” their conduct was unlawful or not, they no longer have a legal gray area in which to operate.<sup>21</sup> Thus, it is likely that fewer doctors and pharmacists will be willing to run the risk of breaking the law, getting caught, being prosecuted, losing their licenses, serving any kind of sentence (imprisonment or probation)<sup>22</sup> and facing hefty forfeiture and other financial penalties.

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<sup>21</sup> See generally Congressional Research Service, *Legal Issues Related to Prescription Drug Sales on the Internet* 1-2 (2005) (describing online pharmacy sites as acting in “legal grey area”; practice of on-line prescribing “not necessarily illegal”; “some state laws specify whether or not prescriptions based on online questionnaires are valid, other state laws fail to address the issue”); see also *Drugstores on the Net: Hearing Before the Subcomm. on Oversight and Investigations of the H. Comm. on Commerce*, 106<sup>th</sup> Cong. (1999) (DEA witness admitting that “online prescribing of approved drugs can present difficult legal issues” and “[w]hether a particular online pharmacy, such as one that provides an online questionnaire for the consumer to complete before the drug is dispensed, can satisfy [legal] standards will depend on the specific facts involved and evidence presented”).

<sup>22</sup> Here, it is worth noting the Supreme Court’s view that probation is a sentence, which “substantially restrict[s] [a defendant’s] liberty.” *United States v. Gall*, 128 S.Ct. 586, 595 (2007).

**B. *Other enforcement mechanisms are available to deter the operation of rogue pharmacies.***

The argument that DOJ needs stiffer terms of imprisonment to deter the operation of internet pharmacies rings hollow. DOJ admits that the number of pharmacies operating in the United States has decreased from 2007 (581) to 2008 (365) – a 37% decrease. DOJ Letter at 3, n.3. DEA offered its reasons for this reduction in its National Drug Threat Assessment:

the number of sites offering [primarily Schedule III and IV] drugs has decreased, most likely because of increased law enforcement pressure through improved cooperation among federal and state law enforcement agencies, Internet service providers (ISPs), package delivery services, and financial services companies typically used by rogue Internet pharmacy operators.

National Drug Intelligence Center, *National Drug Threat Assessment 2009* (2009), at 33. The Act – which now clearly outlaws rogue pharmacies – only increases the pressure for these sites to shut down.

Other agencies also are fighting to shut down illegitimate online pharmacies.

- Legit Script, in collaboration with a domain registrar, Directi, reported in November 2008 that it had successfully shut down some 500 internet sites that were either selling drugs without a valid prescription or selling non-FDA drugs. *Rogue Internet Pharmacies on the Run: LegitScript Shuts Down 500 No-Prescription Required Online Pharmacies*, available at [www.tmcnet.com](http://www.tmcnet.com).
- The National Association of Boards of Pharmacy lists internet pharmacies that appear out of compliance with state/local laws. Such listings discourage illicit online pharmacy operations by putting a spotlight on them. See <http://www.nabp.net>.
- State prescription monitoring programs, which are increasing in number, help law enforcement authorities more quickly identify and shut-down illegal operations, thereby reducing illegal drug diversion. See U.S. General Accounting Office, *State Monitoring Programs May Help to Reduce Illegal Diversion*, GAO-04-524T ( March 4, 2004).

Other civil and administrative enforcement mechanisms also provide deterrent effects.

- Doctors and pharmacists lose their licenses.
- The Federal Trade Commission may impose civil sanctions for deceptive trade practices.
- DEA issues suspension orders.
- The Act itself contains civil remedies, including injunctive relief, damages, restitution, compensation and civil penalties. *See* 21 U.S.C. § 882.

To summarize, passage of the Act – combined with public education and the extensive publicity surrounding the Act – is likely to deter, at a minimum, those physicians and pharmacists who were previously willing to operate in the gray area of online practice. Others will be deterred by the ever-widening group of agencies – public and private — joining forces to combat the problem. For those willing to take more risks, forfeiture and the threat of *any* loss of liberty will provide deterrent effects. The research shows that these actions to increase the certainty of detection and punishment will increase deterrence, while marginal increases in sentence length will not. The Commission should simply refer to USSG § 2D1.1 the new offense at 21 U.S.C. § 841(h), and do nothing more.

**VII. No Rise in the Availability of Prescription Drugs for “Nonmedical” Use Justifies Increased Terms of Imprisonment. Data, Released in February 2009, Show that the Problem of Prescription Pain Killer Misuse or Abuse is not as Widespread as DOJ Claims.**

***A. The rate of nonmedical prescription drug use has not increased significantly since 2002.***

The DOJ continues to distort the data on non-medical use of pain relievers to create the false impression of a growing epidemic. In its latest letter attempting to refute our December submission, DOJ reports increases in the rate of lifetime use of these substances. By definition, lifetime use increases as more people use the drug for the first time because those who *once used, but stopped*, continue to be counted as “lifetime users.” The more accurate data on trends is past month use, and here the authors of the National Survey on Drug Use and Health are quite clear.

The most recently available data show that in 2007 the rate of persons aged 12 or older who reported “using prescription pain relievers nonmedically in the past month . . . does not differ significantly from that in 2002.” Office of Applied Studies, SAMHSA, National Survey on Drug Use and Health, *Substance Trends in Nonmedical Use of Prescription Pain Relievers: 2002 to 2007* (Feb. 2009).

The data show a decline among youths aged 12 to 17 – from 3.2 % in 2002 to 2.7 % in 2007. While these data show an increase in use over time for adults aged 18 or older, they do not support DOJ’s claims that the availability of “hydrocodone and other schedule III controlled substances . . . has continued to be an epidemic of Controlled Prescription Drug (CPD) *abuse*.” DOJ Letter at 2. “The numbers of nonmedical users of pain relievers, tranquilizers, and sedatives in 2007 were similar to the corresponding numbers in 2006, and the percentage rates also remain stable.” Office of Applied Studies, SAMHSA, *Results from the 2007 National Survey on Drug Use and Health: National Findings* (2008).<sup>23</sup> “In both 2006 and 2007, an estimated 5.2 million persons aged 12 or older (2.1 percent in each year) were current nonmedical users of prescription pain relievers. This number was higher than the estimated 4.4 million in 2002, but the difference between the rates in 2002 and 2007 (1.9 and 2.1 percent, respectively) was not statistically significant.” *Id.*

**B. “Nonmedical use” should not be equated with “dependence” or “abuse.”**

The Department of Justice exaggerates the harm of hydrocodone combination products by equating all “non-medical” use with “abuse.” See, e.g., Slide 7 “Prescription Drug Abuse,” November 20, 2008 (claiming “5.2 million abuse pain relievers non-medically”); DOJ Letter at 5 and n. 7 (referring to lifetime abusers). The NSDUH, however, defines “nonmedical use” as the “use of prescription-type drugs not prescribed for the respondent by a physician or used only for the experience or feeling they caused.” Under that definition, a person who took a single hydrocodone combination pill prescribed to a family member or friend, even if they took it for legitimate pain relief, is a “non-medical user.”

Nor does “nonmedical” use of a prescription pain reliever necessarily lead to dependence or addiction. For example, in 2005, while “12.4 % of persons aged 18 to 25 used prescription pain relievers nonmedically in the past year, far fewer – 1.7 % – met the criteria for past year prescription pain reliever dependence or abuse.” Office of Applied Studies, SAMHSA, *The NSDUH Report: How Young Adults Obtain Prescription Pain Relievers for Nonmedical Use* (2006). Other studies show that a high rate of lifetime “nonmedical use” (non-medical use at

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<sup>23</sup> available at <http://www.oas.samhsa.gov/NSDUH/2k7NSDUH/2k7results.cfm#Ch2>

sometime, even once, during the respondent's life) of hydrocodone combination products does not correlate with serious risk of substance abuse. For example, an analysis of NSDUH data from 2003 shows that of the persons reporting lifetime nonmedical use of an opioid analgesia, 2.9 % reported lifetime nonmedical use of Dilaudid whereas 51.9 % reported lifetime nonmedical use of hydrocodone. Yet, the nonmedical users of Dilaudid were at "higher risk for engaging in more serious substance abuse-related behaviors than those who reported lifetime nonmedical use of hydrocodone combination products." Meredith Smith, et.al., *Correlates of Nonmedical Use of Hydromorphone and Hydrocodone: Results from a National Household Survey*, 21 J. Pain. Palliat Care. 5 (2007).

Similarly, substance abuse treatment episode data from 1992 to 2006, shows that admissions for "opiates and synthetics" rank significantly behind those for alcohol (47.6%), cocaine/crack (15.1%) marijuana/hashish (13.1%), heroin (14.2%), and methamphetamine (4.3%). Only 1.9 % of treatment episodes involved "other opiates and synthetics." The percent involving hydrocodone as opposed to other opiates, like oxycodone, is not available. See Office of Applied Studies, SAMHSA, Quick Table: Treatment Episode Data Set, 1992-2006 (Concatenated) (Results: Primary Substance of Abuse by Gender), *available at* <http://www.icpsr.umich.edu/quicktables/quidoptions.do>.

Nor can "nonmedical" use be equated with "addiction." "Studies indicate that most patients who receive opioids for pain, even those undergoing long-term therapy, do not become addicted to these drugs." Center for Substance Abuse Treatment, SAMHSA, *CSAT Advisory: Breaking News for the Treatment Field* (April 2001) (OxyContin® Prescription Drug Abuse). One study sponsored by the National Institute of Drug Abuse (NIDA) found that "only four out of more than 12,000 patients who were given opioids for acute pain actually became addicted to the drugs ... . In a study of 38 chronic pain patients, most of whom received opioids for 4 to 7 years, only 2 patients actually became addicted, and both had a history of drug abuse." *Id.*

**C. *DAWN data provides an incomplete picture of the problems associated with prescription drugs.***

DOJ continues to claim that the DAWN data support its position that the Commission must increase penalties for distribution offenses involving hydrocodone combination products. DOJ Letter, at n.8. DOJ characterizes our December 2008 discussion of the data as "inexplicable." *Id.* The DAWN report itself, however, notes that "for the period 2005 to 2006, *no change* was detected in the overall number of ED visits related to nonmedical use of pharmaceuticals nor were changes noted for the substances most frequently implicated in nonmedical-use visits." Office of Applied Studies, SAMHSA, *Drug Abuse Warning Network, 2006: National Estimates of Drug-Related Emergency Department Visits* (2008), at 45. In addition, the report indicates that the estimated 22% increase from 2005 to 2006 *was not statistically significant*. See *id.* Table 15, n. 4; see also *id.* at 16. ("Differences that are not

statistically significant indicate that there was *no real change* between the two years.”).

The DAWN report also notes inherent weaknesses in the data:

- “Regarding the significant increases detected, it is worthwhile to consider that the number of pharmaceuticals dispensed for legitimate therapeutic uses may be increasing over time, and DAWN estimates are not adjusted to take such increases into account. Nor do DAWN estimates take into account the increases in the population or in ED use between 2004 and 2006.” *Id.* at 10.
- “DAWN is not able to assess whether increases or decreases in ED visits associated with specific pharmaceuticals are related to changes in the quantity of these pharmaceuticals being prescribed for therapeutic uses.” *Id.* at 10.
- “The DAWN data does not distinguish visits among those who used the drugs with a legitimate prescription as opposed to other sources.” *Id.* at 9.

Our concern here is that the Commission base its decisions on *sound* empirical data and assess the relative strengths and weaknesses of data submitted for its consideration. When DAWN itself plainly acknowledges its inability to assess certain trends, the Commission should heed those warnings and not draw unsupported inferences from the available data.<sup>24</sup> Indeed, DEA itself has stated that the development of enhanced data collection systems is needed to provide “credible, legally defensible evidence concerning drug abuse trends in America.” U.S. Gen. Accounting Office, *Prescription Drugs: OxyContin® Abuse and Diversion and Efforts to Address the Problem* GAO-04-110, at 33 (2003).

***D. The Commission cannot assume that the Florida experience with “hydrocodone-related” deaths is representative of the entire country.***

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<sup>24</sup> DOJ’s use of statistics is misleading in other ways as well. Although it cites to statistics showing that the *use* of Schedule III-V drugs “ranks second to marijuana,” it fails to acknowledge its own drug threat assessment, which paints an entirely different picture. The National Drug Threat Assessment plainly states: “Cocaine is the leading drug threat to society. Methamphetamine is the second leading drug threat, followed by marijuana, heroin, pharmaceutical drugs, and MDMA (3,4-methylenedioxymethamphetamine, also known as ecstasy) respectively.” National Drug Intelligence Center, *National Drug Threat Assessment 2009* (2009), at vi.

DOJ points to the number of “hydrocodone related” deaths in Florida as proof that the abuse of hydrocodone combination products is a trend throughout the country. DOJ represents that it has “no reason to believe that Florida’s experience is unique.” DOJ Letter at 6.

DOJ’s use of the Florida data is another example of hyperbole. We suggest that Florida’s experience with illegal drug use is NOT representative of the experience nationwide. *First*, the Florida Medical Examiner reported 807 cases in 2007 where hydrocodone was found in the decedent’s body. Florida Dep’t of Law Enforcement, *Drugs Identified in Deceased Persons by Florida Medical Examiners* (2008), at 3. In 1/3 of those cases (264), it listed hydrocodone as the cause of death. *Id.* at 3-6. Of those, how many were attributable to suicide, accidental ingestion, accidental overdose by persons to whom the drug was legitimately prescribed,<sup>25</sup> illicit overdose, or homicide is unknown. *Second*, like the DAWN data, the Florida report does not adjust for population growth. Without such an adjustment, it is impossible to make meaningful extrapolations that the data show a rising problem. *Third*, the STRIDE data show that close to two-thirds of the hydrocodone products analyzed originated in the south. DEA, Office of Diversion Control, *National Forensic Laboratory Information System 2007 Annual Report* (“NFLIA”) (2008), at 7 (Table 1.1) (22,496 samples in the South compared to 3,936 in the West, 5,475 in the Midwest, and 4,897 in the Northeast). *Lastly*, in pointing to Florida, DOJ fails to acknowledge what DEA itself has found: “The Tampa area has become ‘ground zero’ for Internet diversion.” DEA Briefs and Background, *Drugs and Drug Abuse, State Factsheets, Florida* (2008).

We bring this data to the Commission so that it can get a fuller picture of the issues related to hydrocodone combination products. Because the data is incomplete, and the Online Pharmacy Act new, we strongly encourage the Commission to “wait and see” before ratcheting up drug sentences once again.

#### **VIII. The Commission Need Not Make Any Change in the Guidelines for Cases in Which Death Or Serious Bodily Injury Resulted from the Distribution of a Schedule III Substance.**

The Commission proposes three options for incorporating the sentencing enhancement for cases involving schedule III controlled substances where “death or serious bodily injury results from the use of such substances.” Congress has not directed the Commission to make these

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<sup>25</sup> Problems with the safe labeling of hydrocodone combination products led the FDA to warn prescribing physicians and patients about its potential dangers, particularly among children given the drug as a cough-suppressant. *See, e.g.* FDA, *Information on Long-Acting Hydrocodone-Containing Cough Product* (marketed as Tussionex Pennkinetic Extended-Release Suspension) (March 2008), available at <http://www.fda.gov/cder/drug/infopage/hydrocodone>.



changes. Nor has DOJ proposed any such change. DOJ letter at 7, n.12. Because existing guidelines provide ample authority for a court to increase a sentence where death or serious bodily injury occurs, we do not believe that any of the three options proposed are necessary. Should the Commission feel the need to make sure that judges understand their authority to upwardly depart in such cases, then option 3 – the upward departure provision – is preferable.

In the rare case<sup>26</sup> involving a Schedule III drug where death or serious bodily injury occurs, both USSG §§ 5K2.1 (death) and 5K2.2 (physical injury) invite upward departures to account for the conduct. These departure mechanisms are preferable to either a rigid base offense level or a specific offense characteristic because they permit the court to consider the myriad circumstances under which death or serious bodily injury may occur. For instance, neither Option 1 nor Option 2 take into account a defendant's relative culpability, including whether he acted negligently or knowingly risked death. Such culpability, however, should be relevant in determining the appropriate sentence.

## **IX. Conclusion**

Congress, in its directive to the Commission in the Online Pharmacy Act, quite plainly meant for the Commission to respond cautiously to the Act and to amend the guidelines only with good reasons based on reliable and accurate empirical evidence. Because such evidence has not emerged, we encourage the Commission to simply refer the two new offenses created by the Act to USSG § 2D1.1.

Thank you for considering our comments. As always, we look forward to working with the Commission on these and other issues.

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<sup>26</sup> According to the legislative history, “[a]s of July 2004, DEA investigations had discovered 14 deaths or overdoses and 15 persons who have entered rehabilitation or sustained injuries from drugs obtained over the Internet.” H.R. Rep. 110-937 (2009).

## Appendix A

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December 8, 2008

Honorable Ricardo H. Hinojosa  
Chair  
United States Sentencing Commission  
One Columbus Circle, N.E.  
Suite 2-500, South Lobby  
Washington, D.C. 20002-8002

Re: Public Comment Testimony Related to Briefing on Online Pharmacy Consumer Protection Act of 2008

Dear Judge Hinojosa:

Thank you for the opportunity to testify on behalf of the Federal Public and Community Defenders at the briefing on November 20 regarding the Online Pharmacy Consumer Protection Act of 2008 (the Act). This letter provides written testimony and responds to the testimony of the Drug Enforcement Administration's witness, Mr. Rannazzisi.

The Act creates a new offense prohibiting the delivery, distribution or dispensation of a controlled substance by means of the Internet "except as authorized by this title." 21 U.S.C. § 841(h). To be "authorized by this title," a prescription for a "controlled substance that is a prescription drug" requires that the issuing practitioner "has conducted at least 1 in-person medical evaluation of the patient," or is a "covering practitioner," *i.e.*, at the request of a practitioner who has conducted at least one in-person or telemedicine evaluation of the patient within the past 24 months and is temporarily unavailable. *See* 21 U.S.C. § 829(e). An online pharmacy must also be registered as such. *See* 21 U.S.C. § 823(f).

The Act also increases the statutory maximum for Schedule III substances from 5 to 10 years (and from 10 to 20 years with a prior felony drug offense), and for Schedule IV substances from 3 to 5 years (and from 6 to 10 years with a prior felony drug offense). It does not raise the

maximum for Schedule V substances unless there is a prior felony drug offense, from 2 to 4 years. 21 U.S.C. § 841(b)(1)(E), (b)(2), (b)(3). And it raises the statutory maximum by 10 years if death or serious bodily injury resulted from the use of a Schedule III substance. 21 U.S.C. § 841(b)(1)(E)(i), (ii).

The one and only directive to the Commission in the Act instructs it not to construe “any change in the maximum penalty for a violation involving a controlled substance in a particular schedule as being the sole reason” for any change in the guidelines. P.L. 110-425, Sec. 3(k)(2).

Congress recognized that the Internet has provided Americans with better access to convenient and more affordable medicine, but was also concerned that the Internet had made it easier to obtain prescription drugs which may be dangerous without adequate medical oversight, as in the highly publicized case of Ryan Haight. *See* Statement of Senator Leahy, 154 Cong. Rec. S10184-03, S10184 (Sept. 30, 2008). Previously, for a prescription to be valid under federal law, it had to be “issued for a legitimate medical purpose in the usual course of professional practice,” 21 C.F.R. § 1306.04(a), but no in-person examination was explicitly required. Further, while all of the states allowed the purchase of medications over the Internet, some did not require in-person examinations. *See House Rep. No. 110-869(I), Committee Oversight Findings* (Sept. 23, 2008). Congress intended to “fill [this] gap in existing law,” *see* Statement of Senator Leahy, 154 Cong. Rec. S10184-03, S10184 (Sept. 30, 2008), and to “clarif[y] that knowingly or intentionally delivering, distributing, or dispensing controlled substances over the Internet in violation of this Act can be prosecuted and penalized just like hand-to-hand distributions.” House Rep. No. 110-869(I), Section-by-Section Analysis, Sept. 23, 2008. Congress made no findings and expressed no concern regarding any particular schedule or type of prescription drug.

As set forth in more detail below, the Defenders recommend that the Commission handle the new offense at 21 U.S.C. § 841(h) by referring it to USSG § 2D1.1 and do nothing further. We also recommend that the Commission not increase guideline ranges for any Schedule or type of prescription drug, or for death or serious bodily injury resulting from the use of a Schedule III controlled substance. The guidelines and policy statements already account for use of the Internet, unusually high quantities, and death or serious bodily injury, and there is no credible reason grounded in the legitimate purposes of sentencing to raise penalties. The only reason for doing so would be the increased maximums, which would violate the directive.

#### **I. The Government and the Courts Have All the Tools that are Necessary to Punish the Blameworthy, and to Distinguish Defendants of Differing Culpability.**

Despite the gap in existing law, numerous participants in Internet pharmacies were prosecuted before the Act. We identified and reviewed many such cases by inquiring of Defenders, from a DEA website entitled “Cases Against Doctors,” [http://www.deadiversion.usdoj.gov/crim\\_admin\\_actions/index.html](http://www.deadiversion.usdoj.gov/crim_admin_actions/index.html), and other research. The cases, none of which involved Schedule I or II substances, are detailed in the attached chart.

The defendants in these cases break up generally into (1) owner/operators, (2) doctors (3) pharmacists, and (4) web designers, sales agents, and shipping clerks. The defendants, by category and individually, differed vastly in their level of culpability. In every case, the owner/operators and/or their lawyers told the other participants that the business was legal and/or that there was no law against it (which was literally true). The vast majority of the doctors believed this and pled guilty on what can best be described as a willful blindness theory. The pharmacists appear to have varied in their level of knowledge and involvement, though we obtained specific information in this regard for only one of them. For defendants without medical or pharmaceutical training, the representation that the business was legal was reinforced by seeing and/or being reminded that licensed doctors were authorizing the prescriptions and licensed pharmacists were filling them.

What is most striking about these cases, in the aggregate, is that prosecutors were able to obtain severe punishment for the most blameworthy, and also went out of their way to see that the less blameworthy – measured in personal culpability and not necessarily quantity of drugs -- received below-guideline sentences.

Owner/Operators. Of the eleven owner/operators in our sample, five were convicted by a jury and received lengthy sentences based on the charges of conviction as follows:

Puzstai -- convicted of conspiracy to distribute misbranded drugs, mail fraud, money laundering -- 188 months based on 2S1.1

Yates – convicted of conspiracy to distribute misbranded drugs, mail fraud, money laundering -- 78 months based on 2S1.1

Fuchs – convicted of CCE, 841, 846, money laundering – 20 years based on 2D1.5 (CCE)

Bansal – convicted of CCE, 846, 963, conspiracy to distribute misbranded drugs, money laundering – 30 years based on 2D1.5 (CCE), 2D1.1, and 2S1.1

Smith – convicted of CCE, 841, distribution of misbranded drugs, money laundering – 30 years, level 40 under 2D1.5 (CCE, 42 for misbranded drugs via 2B1.

Four other owner/operators received very favorable treatment from the government. Chhabra, who was charged with CCE, among other things, pled to one § 846 count and received a sentence of 33 months under an 11(c)(1)(C) plea. The co-owner, Faruqi, pled to one § 846 count and received a sentence of 12 months probation, also under an 11(c)(1)(C) plea. The reason for the 11(c)(1)(C) pleas is unknown. Bezonsky, who appears to have been the owner/operator of several online pharmacies, pled to RICO, one § 846 count and one money laundering count, and will be sentenced after the outcome of his cooperation against numerous underlings. Glass, who

was charged only by Information, pled to one 18 U.S.C. § 371 count and one money laundering conspiracy count, and is also cooperating against less culpable defendants.

Heredia, an administrator and manager, is awaiting trial on hundreds of charges including RICO, drug trafficking, wire fraud, mail fraud, money laundering, and conspiracy to distribute misbranded drugs. A rough estimate of his guideline range is 324-405 months. Bezonsky and Glass are cooperating against him.

One doctor, Daniel Thompson, whose role was somewhat like that of an owner/operator for part of the Chhabra scheme, was convicted of one § 846 count and two § 841 counts and was acquitted of other § 841 counts in a trial in which he represented himself. Dr. Thompson stopped participating when he learned of a new state law requiring an in-person examination and pled guilty in state court to violating it. The judge gave him an acceptance of responsibility adjustment and sentenced him to 37 months.

Doctors. Of twenty-two doctors, nineteen pled guilty, one was convicted by a jury, and two were acquitted by a jury. All of the doctors were told the business was legal, and their guilty pleas were based on a willful blindness theory.

The doctors were typically charged with drug trafficking and money laundering, though they would have received the same guideline range for drug trafficking alone. Many participated before the Internet SOC under USSG § 2D1.1(b)(6) was added; those whose participation ended after it was added received the enhancement. Under the current guidelines, their guideline ranges would be as follows.

<b>Statutes of Conviction</b>	<b>Trial</b>	<b>Plea</b>
Drug Trafficking and Money Laundering	<u>51-63 months</u> 20 + 2 for interactive computer service, § 2D1.1(b)(6) + 2 for conviction under § 1956, § 2S1.1(b)(2)(B) =24	<u>30-37 months</u> 20 + 2 for interactive computer service, § 2D1.1(b)(6) - 2 for safety valve + 2 for conviction under § 1956, § 2S1.1(b)(2)(B) - 3 for acceptance = 19
Drug Trafficking	20 + 2 for interactive computer service, § 2D1.1(b)(6) +2 for use of special skill, § 3B1.3	20 + 2 for interactive computer service, § 2D1.1(b)(6) - 2 for safety valve +2 for use of special skill, §

	=24	3B1.3 - 3 for acceptance = 19
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The government moved for upward departure in one case in which a doctor prescribed a number of units that “substantially exceed[ed]” 40,000 under USSG § 2D1.1 (comment. (n.16)). *See Chart of Online Pharmacy Prosecutions (Millette)*. The government did not move for upward departure in other cases involving a larger number of units, and it is apparent that such a departure would have been greater than necessary to satisfy the purposes of sentencing. The prosecutor joined the defense motion for downward departure for Doctor McNeil and Doctor Nyamekeye based on their extraordinary community service in treating police, firefighters, and other city workers after the World Trade Center bombings (which was denied) and moved for a cooperation departure (which was granted). Doctor Hanny, who operated an ambulance service for the injured in the 1956 Soviet invasion of Hungary and then escaped, and was totally wiped out financially by his conviction, received a sentence of 33 months, which was reduced to 23 months based on the government’s Rule 35 motion. Dr. Cockerille, who was 72 years old, also wiped out financially, and who appears to have had no idea that an online pharmacy was illegal, received downward departures under §§ 5K1.1, 5H1.4, 5H1.6 and 5K2.0. Dr. Schwab, a 72-year-old retired Air Force doctor, received a 2-month downward departure under § 5K1.1 and was sentenced to prison for 22 months.

Several of the doctors, far from being hardened criminals, had made heroic contributions to the community or devoted their careers to public service. *See Chart of Online Pharmacy Prosecutions (Nelson, McNeil, Nyamekeye, Dominique, Hanny, Baron)*. Five doctors received defense-initiated downward departures, at least two of which the government did not oppose, and one received acceptance after trial. Thirteen doctors received cooperation departures, and some of these appear to have been motivated more by the lack of need for a lengthy prison term or any prison term than by the level of assistance rendered. Only three received no downward departure or variance. All of the doctors lost their licenses, livelihoods and reputations, and were subject to forfeiture orders.

Pharmacists. Of six pharmacists, three pled guilty, one was convicted by a jury, and two are awaiting trial. Shokrallah pled guilty to drug trafficking and received three years probation pursuant to a cooperation departure. Coukos pled guilty to conspiracy to introduce misbranded drugs and received a 60-month sentence, which was later reduced to 8 months on the government’s motion. Lemons was found guilty by a jury of one § 846 count and received five years probation, including 6 months of home confinement and 200 hours of community service, which was terminated two years early, unopposed by the government. Lemons was involved for a very short time, made little money, and had little knowledge of what was going on. Varelli pled guilty to drug trafficking and received a guideline sentence of 30 months.

For a pharmacist convicted after trial of drug trafficking, the total offense level under the current guidelines would be 24 (20 + 2 for interactive computer service under § 2D1.1(b)(6) +2 for use of a special skill) with a range of 51-63 months. If the pharmacist pled guilty, the total offense level would be 19 (20 + 2 for interactive computer service under § 2D1.1(b)(6) – 2 for safety valve +2 for use of a special skill – 3 for acceptance) with a range of 30-37 months. Pharmacists also lose their licenses, livelihoods and reputations.

Web site designers, marketers, shipping clerks. There are 10 defendants in this category, eight of whom are charged in the Heredia case and have not yet been sentenced. Degomme pled to an information charging a misdemeanor and received one year probation. Darrell Griep, a good example of a person at this level, was charged with drug trafficking and conspiracy to distribute misbranded drugs. He had a high school education, was trained only in sales, and when he got wind that the DEA had issued a warning about online pharmacies, he repeatedly questioned the owner/operator (who received 30 years) and the company lawyer (who was acquitted), who assured him it was legal. Griep also relied on the fact that licensed doctors and pharmacists were involved. Believing he was not guilty, he went to trial. On the eve of closing arguments, the government offered him a deal in which he would plead to drug trafficking, which he did under a “head in the sand” theory, and was sentenced to three years probation. The eight marketers in the Heredia case likewise were told that the business was legal and were constantly reminded that doctors were issuing prescriptions which pharmacists were filling. They were charged with RICO, drug trafficking, mail fraud, wire fraud, misbranding and conspiracy to launder money. Two have accepted the government’s offer of a guideline calculation of 30-37 months, but have not yet been sentenced. The rest are set for trial.

In-Person “Pill Mills.” To the extent DEA or DOJ claims that penalties are insufficient for “pill mills” that dispense prescription drugs in person, the same charges and sentencing laws and guidelines that were used in the online pharmacy cases are available there, except the 2-level enhancement for use of the Internet. In one such case, *United States v. Herpin*, 4:2004cr00442 (S.D. Tex.), Callie Herpin, a doctor and owner/operator of a clinic in Houston, two of her employees, several pharmacists, and a few street dealers, were charged in a 169-count indictment with drug trafficking, money laundering, health care fraud, and conspiracy to defraud the United States. The drugs involved were Schedule III hydrocodone and Schedule V promethazine with codeine. Doctor Herpin pled guilty to conspiracy to defraud the United States and drug trafficking, and was sentenced to ten years in prison. She could have been charged with Continuing Criminal Enterprise, subject to a 20-year mandatory minimum. Her employees received sentences of 84 and 24 months. The pharmacists received sentences ranging from 24 months to 151 months. The three street dealers were sentenced to 41, 46 and 72 months.

Typical Defender Clients. Most Defender clients charged with trafficking in Schedule III or IV prescription drugs are addicts, usually women, selling pills to feed their habit. In considering whether to increase guideline ranges for prescription drugs, the Commission should keep in mind this least culpable group of defendants, whose number is likely to be much larger than that of defendants involved in large operations.



## II. Issues for the Commission to Consider

### A. New Offense, 21 U.S.C. § 841(h)

We recommend that the Commission refer 21 U.S.C. § 841(h) to USSG § 2D1.1 in Appendix A and take no further action.

The new subsection prohibits delivery, distribution or dispensation of a controlled substance by means of the Internet “except as authorized by this title,” or aiding or abetting such activity, to be sentenced in accordance with 21 U.S.C. § 841(b). *See* 21 U.S.C. § 841(h). Congress intended this conduct to be “prosecuted and penalized just like hand-to-hand distributions.” House Rep. No. 110-869(I), Section-by-Section Analysis, Sept. 23, 2008. “Rogue pharmacies that sell drugs over the Internet will face the same penalties as people who illegally sell the same drugs on the street.” 154 Cong. Rec. S10184-03, Statement of Senator Feinstein (Sept. 30, 2008).

In addition to being penalized the same as those who sell the same drugs on the street, these defendants will receive a two-level increase under USSG § 2D1.1(b)(6) because their conduct or relevant conduct of another consists of “distribut[ing] a controlled substance through mass-marketing by means of an interactive computer service.” An “interactive computer service” “includ[es] specifically a service or system that provides access to the Internet,” 47 U.S.C. § 230(f), and subsection (b)(6) applies to “a defendant who operated a website to promote the sale” of controlled substances. USSG § 2D1.1, comment. (n.23). The enhancement has been applied to defendants involved in online pharmacies whose conduct took place after the SOC was added,<sup>1</sup> *see* Chart of Online Pharmacy Prosecutions (*Bansal, Hanny, Smith*), and has been upheld. *See, e.g., United States v. Hanny*, 509 F.3d 916 (8th Cir. 2007).

### B. Increased Statutory Maximums

The only directive to the Commission in the Act instructs it not to increase guideline ranges for the “sole reason” of “any change in the maximum penalty for a violation involving a controlled substance in a particular schedule.” P.L. 110-425, Sec. 3(k)(2). Congress often raises maximum penalties based on newsworthy events and lobbying by law enforcement that is unrelated to empirical evidence or the purposes of sentencing, and the Act is no exception. While the Commission has often reacted in the past by increasing guideline ranges, this has long been a source of concern to both Commissioners and outside observers.<sup>2</sup> The directive reflects the fact

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<sup>1</sup> USSG, App. C, Amend. 667 (Nov. 1, 2004).

<sup>2</sup> Jeffery S. Parker & Michael K. Block, *The Sentencing Commission, P.M. (Post-Mistretta): Sunshine or Sunset?*, 27 Am. Crim. L. Rev. 289, 318-23 (1989) (discussing perceived problems of political expediency and disarray of research activities with respect to amendments); Aaron Rappaport, *Unprincipled Punishment: The*

that Congress intended the Act to have a very narrow impact, *see* Statement of Senator Leahy, 154 Cong. Rec. S10184-03, S10184-85 (Sept. 30, 2008), and may suggest a refreshing new awareness on the part of Congress. The directive must, of course, be honored.

The question for the Commission, then, is whether there is any credible and substantial reason which would further the legitimate purposes of sentencing to increase guideline ranges for prescription drugs. We will not address the increases based on prior felony drug offense because the guidelines do not base offense levels on prior convictions where there is no mandatory minimum. The DEA witness advanced certain reasons in support of his argument for increasing guideline ranges for Schedule III hydrocodone, which do not support higher sentences for the reasons detailed below. The DEA witness advanced no specific reasons for increasing guideline ranges for other Schedule III drugs, or for any Schedule IV or V drug, other than the general reason of use of the Internet, which also does not support any increase and is addressed below.

### **1. The Need for Deterrence Provides No Reason To Increase Guideline Ranges.**

The DEA representative argued that current penalties for the “lynchpins in these schemes, i.e., doctors, pharmacists and the web site operators, are not adequate to deter.” As two of the Commissioners indicated, an effective deterrent would be to notify doctors that this conduct is now a federal crime, rather than any change in the guidelines.

The conduct criminalized by the Act was not illegal prior to its passage, or at least was not clearly illegal or recognized as illegal by the targets of the legislation. An in-person evaluation was not specifically required, and there were no particular registration requirements for pharmacies dispensing by means of the Internet. As the DEA witness notes, doctors and pharmacists are “lynchpins” in online pharmacy schemes. They will no longer be able to accept representations that issuing and filling prescriptions over the Internet without an in-person examination is legal. No lawyer will be able to give such advice. A doctor or pharmacist who chooses to violate the new law would be convicted of a crime and lose his license and means to earn a living, a most unlikely scenario. With doctors and pharmacist removed from the picture, the inducement for lower level participants to believe that the business is legal will also disappear.

That there is no need for higher sentences grounded in a need for deterrence is supported by considerable empirical research. The general finding is that “deterrence works,” in the sense that there is less crime with a criminal justice system than there would be without one. But the question for the Commission is “marginal deterrence,” *i.e.*, whether an increase in punishment

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*U.S.Sentencing Commission’s Troubling Silence About the Purposes of Punishment*, 6 Buff. Crim. L. Rev. 1043 (2003) (powerful interest groups uniformly request increases in penalties for their own reasons without regard to whether the increase is in fact “*necessary*” to achieve the statutory purposes).

results in increased deterrence and thus decreased crime. Here the findings are uniformly negative: *there is no evidence that increases in sentence length reduce crime through deterrence*. Indeed, in one of the best studies of specific deterrence, which happened to involve federal white collar offenders in the pre-guideline era, no difference in deterrence was found even between probation and imprisonment. See David Weisburd et. al., *Specific Deterrence in a Sample of Offenders Convicted of White-Collar Crimes*, 33 *Criminology* 587 (1995).

The deterrence literature has been reviewed several times by groups of scientific experts at the request of sentencing policymakers, including the Commission. See Professor Gordon Waldo, *Strategies in Deterrence Research on the Federal Sentencing Guidelines*, United States Sentencing Commission Research Conference, Washington, D.C. (1993). Typical of the findings on marginal deterrence is that of the Institute of Criminology at Cambridge University. See Andrew von Hirsch, et al, *Criminal Deterrence and Sentence Severity: An Analysis of Recent Research* (1999). The report, commissioned by the British Home Office, examined penalties in the United States as well as several European countries. It examined the effects of changes to both the *certainty* and the *severity* of punishment. While significant correlations were found between the certainty of punishment and crime rates, the “correlations between sentence severity and crime rates . . . were not sufficient to achieve statistical significance.” *Id.* at 2. The report concludes that “the studies reviewed do not provide a basis for inferring that increasing the severity of sentences generally is capable of enhancing deterrent effects.” *Id.* at 1

The reason for this is that potential criminals are not generally aware of penalties for their prospective crimes, do not believe they will be apprehended and convicted, and simply do not consider sentence consequences in the manner one might expect of rational decision makers. A recent review of this issue concluded: “There is generally no significant association between perceptions of punishment levels and actual levels . . . implying that increases in punishment levels do not routinely reduce crime through general deterrence mechanisms.” Gary Kleck, et al, *The Missing Link in General Deterrence Theory*, 43 *Criminology* 623 (2005).

The DEA representative further implied that an increase in guideline ranges for Schedule III hydrocodone would deter these offenses because, he claimed, the guideline increases for Schedule II oxycodone promulgated in 2003 had “helped curtail” abuse of that drug. In fact, there is no data establishing that the Commission’s actions regarding oxycodone deterred these offenses. Nor is there research suggesting that an increase in penalties for hydrocodone would deter more effectively than current penalties, especially in light of the new legislation.

Of special concern to Congress in passing the Act was abuse of prescription drugs by young people such as Ryan Haight. See Statement of Senator Leahy, 154 Cong. Rec. S10184-03, S10184 (September 30, 2008). The best measure of trends in drug abuse among this population is the annual survey, *Monitoring the Future*, conducted by the Institute for Social Research at the University of Michigan under grants from the National Institutes of Health and Drug Abuse.

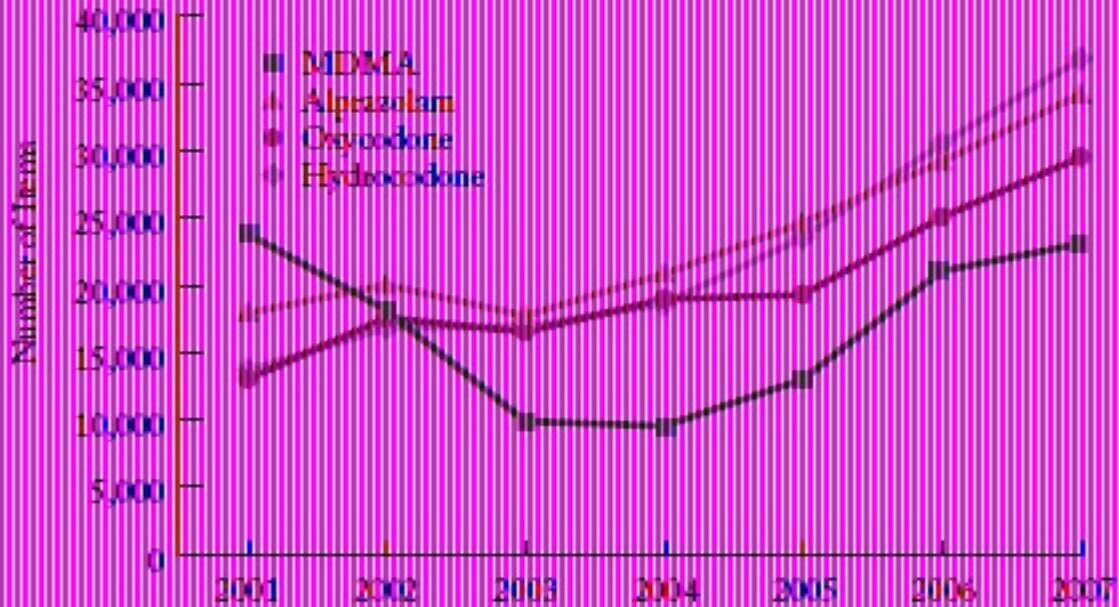
Below is an excerpt from the most recent report, showing trends in annual abuse rates of both OxyContin (oxycodone) and Vicodin (hydrocodone) among 8<sup>th</sup>, 10<sup>th</sup>, and 12<sup>th</sup> graders.

	<u>Annual</u>																2006- 2007	
	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000	2001	2002	2003	2004	2005	2006	2007	change
OxyContin**																		
8th Grade	—	—	—	—	—	—	—	—	—	—	—	1.3	1.7	1.7	1.8	2.6	1.8	-0.7
10th Grade	—	—	—	—	—	—	—	—	—	—	—	3.0	3.6	3.5	3.2	3.8	3.9	+0.1
12th Grade	—	—	—	—	—	—	—	—	—	—	—	4.0	4.5	5.0	5.5	4.3	5.2	+0.9
Vicodin**																		
8th Grade	—	—	—	—	—	—	—	—	—	—	—	2.5	2.8	2.5	2.6	3.0	2.7	-0.3
10th Grade	—	—	—	—	—	—	—	—	—	—	—	6.9	7.2	6.2	5.9	7.0	7.2	+0.2
12th Grade	—	—	—	—	—	—	—	—	—	—	—	9.6	10.5	9.3	9.5	9.7	9.6	-0.2

This data, collected beginning in 2002, does not show that the Commission’s action in late 2003 had the effect of reducing rates of OxyContin use. Nor does it reveal any difference in overall trends between OxyContin, the drug subject to the increased penalties, and Vicodin, the drug that was not. This data does not establish even that there are statistically significant trends. It certainly does not support the assertion that the 2003 guideline amendment had an effect in deterring oxycodone offenses.

Similar conclusions must be drawn from the DEA’s own National Forensic Laboratory Information System (NFLIS). While Mr. Rannazzisi presented data showing a growth in the number of hydrocodone items analyzed in recent years (which may show increased enforcement rather than an increase in the number of offenses or an increase in abuse), he did not present similar data for oxycodone. The Figure below is taken from the DEA’s Office of Diversion Control *2007 Annual Report* on the NFLIS.

**Figure 1.2 National trend estimates for other selected drugs, by year, 2001–2007.**



Far from showing that the Commission’s action in 2003 “helped curtail” oxycodone abuse, it shows a sharp increase in oxycodone items analyzed from 2005 to 2007.

Further, SAMHSA reports that the percentage of those aged 12 or older who reported nonmedical use of Oxycontin® more than doubled from 2002 to 2007. SAMHSA, *Results from the 2007 National Survey on Drug Use and Health: National Findings*, Table G.2. And emergency department visits for oxycodone increased by 56% from 2004 to 2006. SAMHSA, *Drug Abuse Warning Network, 2006: National Estimates of Drug-Related Emergency Department Visits* at 46.

In sum, there is simply no evidence that the Commission’s 2003 actions regarding oxycodone had a deterrent effect, and no reason to believe that a similar approach to hydrocodone would do so.

**2. None of the Claims Asserting That Prescription Drug Offenses Have Become More Serious Provide A Reason to Increase Guideline Ranges.**

**a. The Internet**

After hearings on the Act, Congress recognized that the Internet has provided Americans with better access to affordable medicine, but also accepted that “rogue online pharmacies” are “an increasing source for the sale of dangerous controlled substances” and “were making it increasingly easy for teens such as Ryan [Haight] to access deadly prescription drugs.” See Cong. Rec. S10184-03 (September 30, 2008). Similarly, Mr. Rannazzisi now argues that the Internet has “changed the method of diversion,” affording “anonymity” to “drug traffickers,” and allowing them to avoid making deals in “back alleyways.” Like previous legislation, *see USSC, Cocaine and Federal Sentencing Policy* (1995), the Online Pharmacy Act was primarily driven by popular alarm and misconceptions that are not supported by the empirical evidence. In fact, a miniscule percentage of prescription drug users obtain their drugs from the Internet, or from drug dealers for that matter; the most common sources by far are friends, relatives, and doctors. Further, while the Internet may provide anonymity and convenience to a small percentage of prescription drug abusers, the “drug traffickers” in these cases are the owner/operators, doctors, pharmacists, and web designers, whose activities the Internet exposes to the public and to law enforcement.

The Substance Abuse and Mental Health Services Administration (SAMHSA) reports that in 2007, among all nonmedical users of pain relievers aged 12 and older in the past 12 months:

56.5 percent reported that the source of the drug the most recent time they used was from a friend or relative for free. Another 18.1 percent reported they got the drug from just one doctor. Only 4.1 percent got the pain relievers from a drug dealer or other stranger, and **0.5 percent reported buying the drug on the Internet**. Among those who reported getting the pain reliever from a friend or relative for free, 81.0 percent reported in a follow-up question that the friend or relative had obtained the drugs from just one doctor.

SAMHSA, *Results from the 2007 National Survey on Drug Use and Health: National Findings, Highlights* (emphasis supplied), <http://www.oas.samhsa.gov/NSDUH/2k7NSDUH/2k7results.cfm>.

The National Survey on Drug Use and Health (NSDUH) reports that among young adults aged 18 to 25 who used prescription pain relievers nonmedically in the past year and met the criteria for dependence or abuse, only 1.3% obtained the drugs from the Internet; 12.5% bought them from a drug dealer or stranger, 63.7% got them from a relative or friend, and 16.4% got them from one or more doctors. *See NSDUH, How Young Adults Obtain Prescription Pain Relievers for Nonmedical Use*, Issue 39 (2006), <http://www.oas.samhsa.gov/2k6/getPain/getPain.htm>.

A recent research report in the scholarly journal *Pain Medication* identified the source of drugs for a population of over 1116 prescription opioid analgesic abusers of all ages admitted to treatment. Though the sample was biased to Internet users (white, well educated, affluent), only 6% reported the Internet as one source of their drugs. “The assertion that the Internet has become a dangerous new avenue for the diversion of scheduled prescription opioid analgesics appears to be based on no empirical evidence and is largely incorrect.” *See Theodore J. Cicero, et al. Source*

*of Drugs for Prescription Opioid Analgesic Abusers: A Role for the Internet?* 9 Pain Medicine 718 (2008).

In those rare cases where the Internet is used to sell controlled substances, the guidelines provide for a two-level increase. *See* USSG § 2D1.1(b)(6); *United States v. Hanny*, 509 F.3d 916 (8th Cir. 2007).

The government has also suggested that greater punishment is needed because use of the Internet makes law enforcement somehow more difficult. Even if this were true, the Commission is required to develop guidelines based on the purposes of sentencing set forth in § 3553(a)(2), not on the spurious notion that the government should be compensated for its trouble with higher sentences. In any event, the Internet makes these cases like shooting fish in a barrel. As with Internet sex crimes, the government uses undercover agents posing as customers to investigate and prove these cases. *See, e.g., United States v. Smith et al.*, No. 05-282 (D. Minn.), Third Superseding Indictment at 25, 27 (listing sales to undercover agents as overt acts), available on PACER; *United States v. Roberts*, No. 3:02-CR-115 (E.D. Tenn.), Plea Agreement (listing controlled substances dispensed to undercover officers and cooperating witnesses), available on request. Further, the government has no difficulty in inducing participants at any level to cooperate against others of greater or lesser culpability. *See* Chart of Online Pharmacy Prosecutions. Thus, complaints of law enforcement difficulties are both unrelated to the purposes of sentencing and inaccurate.

#### **b. Quantity**

The guidelines, in general, were based on empirical evidence of past practice as a proxy for the purposes of sentencing. *Rita v. United States*, 127 S. Ct. 2456, 2464 (2007), citing U.S. Sentencing Guidelines Ch. 1, Pt. A(3) (1988). As described in the Commission's own reports, *see* USSC, *Fifteen Years of Guidelines Sentencing at 47-52* (2004), and recently noted by the Supreme Court, the drug trafficking guideline was not based on past practice or on any specific theory of how the penalties the guideline recommends would advance the purposes of sentencing. *Gall v. United States*, 128 S. Ct. 586, 594 n.2 (2007); *Kimbrough v. United States*, 128 S. Ct. 558, 567 (2007). Rather, it was designed to track, and extrapolate from, the statutory mandatory minimums enacted by the Anti-Drug Abuse Act of 1986. The basis for these, in turn, was not clearly stated by Congress, but appeared designed to establish a two-tiered penalty structure differentiating serious traffickers from kingpins.<sup>3</sup> Thus, at best, it can be said that the drug trafficking guideline is based on the offender's level of culpability as reflected by drug type and quantity alone. Congress has not enacted mandatory minimums for Schedule III or IV controlled

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<sup>3</sup> U.S. Sentencing Commission, *Report to Congress – Cocaine and Federal Sentencing Policy* at 5-7 (May 2002); *Fifteen Years of Guidelines Sentencing: An Assessment of How Well the Federal Criminal Justice System is Achieving the Goals of Sentencing Reform* at 48-49 (2004); 132 Cong. Rec. 27,193-94 (daily ed. Sept. 30, 1996); 132 Cong. Rec. 22,993 (daily ed. Sept. 11, 1986); H.R. Rep. No. 99-845, 99th Cong., 2d Sess. 1986, 1986 WL 295596.

substances, apparently believing that distributors of those substances are not serious drug traffickers or kingpins, and it has now directed the Commission not to raise guideline ranges based solely on the increased statutory maxima contained in the Online Pharmacy Act.

The DEA's witness, however, argues that because Vicodin®, one of several brands of hydrocodone,<sup>4</sup> comes in 5 mg, 7.5 mg., and 10 mg. dosage units, guideline ranges for all Schedule III hydrocodone should be based on the number of milligrams (with 1 mg. equal to 1675 g. of marijuana) rather than the number of units, and that the 20-level cap should be removed.

This theory of punishment under the drug trafficking guideline is not only in conflict with the deterrence research, but there is no basis to believe that the strength of the tablets distributed by a particular defendant relates to the defendant's culpability. The tenuous relationship between drug quantity and culpability has been a long-standing and often-criticized problem with the drug guideline, let alone the more specific question of slightly varying dosages per unit of a particular prescription medication. If the amount of active ingredient involved in an offense is an important principle underlying the drug trafficking guideline, the Commission should be even more concerned with the general rule requiring inclusion of any "mixture or substance containing a detectable amount" of a controlled substance. If the much more serious problem of arbitrary sentencing based on inert substances mixed with drugs has not merited attention, then it is entirely unclear why slightly varying dosages per unit of a particular brand of a particular prescription medication merits attention now.

As the pre-Act cases demonstrate, the government has more than sufficient tools to ensure that the most culpable offenders, whether in online pharmacies or in-person "pill mills," are severely punished. As to less culpable offenders, the line prosecutors who knew the defendants' true and relative culpability seemed to believe that guideline penalties (even without the Internet SOC) were sufficient and in most cases too high. Moreover, the guidelines already cover the unusual case in which the amount of hydrocodone distributed by a particular defendant makes his or her offense more serious than average in two ways: the invited upward departure for a substance of "unusually high purity," USSG § 2D1.1, comment. (n.9), and the invited upward departure for a drug quantity that "substantially exceeds the quantity for the highest offense level established for that particular controlled substance." USSG § 2D1.1, comment. (n.16).

In addition, the DEA witness provided no reasoned explanation for the particular drug quantity levels, and resulting severe penalty levels, that he recommends. He requests that 1 gram of hydrocodone be equated with 1675 grams of marijuana. This would result in punishment more severe than that for heroin, morphine, codeine, opium, and thirteen other Schedule I or II opiates, including Schedule II hydrocodone. *See* USSG § 2D1.1, comment. (n.10(E)). It would result in

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<sup>4</sup> Hydrocodone is also sold as Symtan, Anexsia, Dicodid, Hycodan, Hydromet, Hycomine, Hycet, Lorcet, Lortab, Norco, Novahistex, Hydrovo, Duodin, Kolikodol, Orthoxycol, Mercodinone, Synkonin, Norgan, and Hydrokon.



punishment more severe than that for cocaine and most other Schedule I or II stimulants, nearly all Schedule I or II hallucinogens, and all Schedule I or II depressants. *Id.* Absent any enhancements, it would double the current guideline range for 40,000 units containing 5 or 7.5 mg. of hydrocodone for a defendant in Criminal History Category I (from 33-41 months to 63-78 months), and would nearly triple the current guideline range for 40,000 units containing 10 mg. of hydrocodone (from 33-41 months to 78-97 months). With the Internet enhancement and/or any role or special skill adjustment, this quickly meets or exceeds the statutory maximum.

Moreover, if Mr. Rannazzisi's point is that a 10 mg. pill is more subject to abuse and therefore more harmful than a 5 mg. pill, it is important to note that the composition of the various types of Vicodin® is designed to limit the potential for abuse. A tablet of Vicodin® contains 5 mg. of hydrocodone and 500 mg. of acetaminophen; a tablet of Vicodin ES® contains 7.5 mg. of hydrocodone and 750 mg. of acetaminophen; and a tablet of Vicodin HP® contains 10 mg. of hydrocodone and 660 mg. of acetaminophen. The acetaminophen is added to reduce abuse potential, as multiple doses cause nausea and stomach complications. This deters many drug users from taking excessive amounts and limits the potential for abuse.

### **c. Empirical, Scientific and Medical Evidence**

According to what is likely to be the best scientific and medical evidence, 15 mg. or less per dosage unit of hydrocodone has a lower potential for abuse than drugs in Schedule I or II, has a currently accepted medical use in treatment, and abuse may lead to moderate or low physical dependence or high psychological dependence.<sup>5</sup> *See* 21 U.S.C. § 812(b)(3). The DEA is asking the Commission to make different findings, *i.e.*, that dosages less than 15 mg. per unit have a high potential for abuse, lead to severe dependence, and are unsafe. If the detrimental consequences of Schedule III hydrocodone are so severe, the DEA should work with the Secretary of Health and Human Services and medical and industry experts to have it reclassified. The information offered by the DEA at the briefing appears to be insufficient to do so, much less to convince this Commission to raise guideline ranges.

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<sup>5</sup> Before promulgating a regulation classifying a drug in any schedule, the Attorney General is required to "gather[] the necessary data," and seek a "scientific and medical evaluation" and "recommendations" from the Secretary of Health and Human Services, which is binding on the Attorney General as to "scientific and medical matters." *See* 21 U.S.C. § 812(b). The Secretary, and the Attorney General, must consider (1) actual or relative potential for abuse, (2) scientific evidence of pharmacological effect, (3) current scientific knowledge of the drug, (4) history and current pattern of abuse, (5) scope, duration, and significance of abuse, (6) what if any risk there is to public health, and (7) psychic or physiological dependence liability. *See* 21 U.S.C. § 812(c). The regulations are subject to the Administrative Procedures Act, and medical and industry experts are actively involved in the process. *See* 21 U.S.C. § 812(a). According to this process, 15 mg. or less per dosage unit has been classified as a Schedule III controlled substance, *see* 21 C.F.R. § 1308.13(e)(iii) & (iv), *i.e.*, it has a lower potential for abuse than drugs in Schedule I or II, has a currently accepted medical use in treatment, and abuse may lead to moderate or low physical dependence or high psychological dependence. *See* 21 U.S.C. § 812(b)(3).

The DEA witness testified that the “lifetime” nonmedical use of hydrocodone (*i.e.*, the person used it once in her life) had increased 48.7% from 2002 to 2006, citing SAMHSA’s 2007 National Survey on Drug Use and Health. That report, however, contains no separate data for hydrocodone (or Vicodin®). It reports data for: (1) psychotherapeutics, which include any type of prescription-type pain relievers, tranquilizers, stimulants (including, oddly, methamphetamine), or sedatives; (2) prescription-type pain relievers of any type; and (3) Oxycontin®, one type of prescription-type pain reliever.

According to the survey, lifetime, past year and past month use of all psychotherapeutics showed no significant change from 2002 to 2007. SAMHSA, *Results from the 2007 National Survey on Drug Use and Health: National Findings*, Table B.8 (hereinafter “2007 National Survey”).<sup>6</sup> The percentage of those aged 12 or older who reported nonmedical use of any pain reliever in their lifetime increased by only 5% between 2002 and 2007, though the percentage for Oxycontin®, the misuse of which the DEA claims the guidelines curtailed, more than doubled in that period. *Id.*, Table G.2.

The number of persons aged 12 or older who used any pain reliever nonmedically in the past month in 2007 was the same as that in 2006, at 5.2 million, and did not change significantly from the number in 2002. *Id.*, Figure 2.3 and accompanying text. Of note, past month use of pain relievers declined significantly from 2002 to 2007 among youths aged 12 to 17. *Id.*, Figure 2.5 and accompanying text; Table G.7.

There were 2.1 million past year initiates in the nonmedical use of all pain relievers among persons age 12 or older in 2007, down from 2.5 million in 2003. *Id.*, Table G.26. But there were 554,000 new nonmedical users of Oxycontin® in 2007, up from 533,000 in 2006 and 526,000 in 2005. *Id.*

The rate of dependence or abuse for all pain relievers did not change significantly from 2002 to 2007. *Id.*, Part 7.1. In 2007, during their most recent treatment in the past year, 2.5 million people aged 12 or older received treatment for alcohol; 936,000 for marijuana; 809,000 for cocaine; 558,000 for pain relievers of any type; 335,000 for heroin; 311,000 for stimulants; and 303,000 for hallucinogens. *Id.*, Figure. 7.6.

According to SAMHSA’s most recent report on drug-related emergency department visits, the number of such visits attributable to all drug misuse and abuse was stable from 2004 to 2006. SAMHSA, *Drug Abuse Warning Network, 2006: National Estimates of Drug-Related Emergency Department Visits* at 41.<sup>7</sup> There was no significant increase in emergency department visits for hydrocodone from 2004 to 2005, or from 2005 to 2006, but there was a 44% increase from 2004

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<sup>6</sup> Available at <http://www.oas.samhsa.gov/NSDUH/2k7NSDUH/2k7results.cfm>.

<sup>7</sup> Available at <http://dawninfo.samhsa.gov/files/ED2006/DAWN2k6ED.pdf>.

to 2006. *Id.* at 46; SAMHSA, *Drug Abuse Warning Network, 2005: National Estimates of Drug-Related Emergency Department Visits* at 43.<sup>8</sup> It is important to note, however, that this increase is in absolute numbers and does not account for the population growth or the increase in the dispensation of pharmaceuticals for legitimate purposes during that period. SAMHSA, *Drug Abuse Warning Network, 2006: National Estimates of Drug-Related Emergency Department Visits* at 41. Nor does it differentiate between Schedule II and Schedule III hydrocodone.

The increase in emergency department visits for oxycodone from 2004 to 2006, abuse of which DEA claims was curtailed by higher guideline ranges, was 56%. SAMHSA, *Drug Abuse Warning Network, 2006: National Estimates of Drug-Related Emergency Department Visits* at 46. The increase for alprazolam, a Schedule IV substance sold as Xanax, was 40%. *Id.* at 45.

None of this data provides support for increasing guideline ranges for Schedule III hydrocodone. Moreover, the number of emergency department visits for hydrocodone pales in comparison to those for alcohol and street drugs including marijuana, and is considerably less than that for oxycodone:

<b>Emergency Department Visits 2006</b>	
Cocaine	548,608
Heroin	189,780
Marijuana	290,563
Stimulants	107,575
Alcohol Alone	126,704
Alcohol in Combination; drugs most frequently combined with alcohol do not include any type of pain reliever	450,817
Oxycodone	64,888
Hydrocodone	57,550

SAMHSA, *Drug Abuse Warning Network, 2006: National Estimates of Drug-Related Emergency Department Visits* at 29, 43, 44, 46.

If death or serious bodily injury results from the use of hydrocodone, the guidelines invite upward departure. *See* USSG §§ 5K2.1, 5K2.2; *see also* Part C, *infra*.

As with other drugs, the surest and possibly only way to successfully combat illegal drug trafficking is to decrease demand. More than 50% of the prescription opioid analgesic abusers surveyed for the journal article in *Pain* obtained their drugs from doctors. Because it was unlikely that there were dozens or hundreds of corrupt doctors in the region examined, most of this was attributed to doctor shopping and scams by patients. The authors noted that doctors are poorly

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<sup>8</sup> Available at <http://dawninfo.samhsa.gov/files/DAWN-ED-2005-Web.pdf>.

equipped to recognize substance abuse, apparently because they are trained to credit patient accounts of their symptoms, and may find it difficult to achieve the right balance between ensuring that patients receive adequate analgesia and denying access to clever and deceptive abusers. *See Theodore J. Cicero, et al. Source of Drugs for Prescription Opioid Analgesic Abusers: A Role for the Internet?* 9 *Pain Medicine* 718 (2008). Doctors may need more training in this regard, and public education regarding the potential harms of prescription drugs may help. What is most lacking is treatment: 20 million people who needed treatment for a drug or alcohol problem in 2007 did not receive it. *2007 National Survey*, Table G.32. If the Commission does anything to amend the guidelines, it should make drug treatment an alternative to incarceration.

**3. Neither the Need for Incapacitation Nor the Need for Treatment or Training Provide a Reason to Increase Guideline Ranges.**

Guideline increases to protect the public from further crimes of the defendant are clearly not needed. The doctors and pharmacists who are integral to these crimes can be incapacitated in many ways short of imprisonment, including loss of licensure. Nor is lengthier imprisonment needed or appropriate for purposes of treatment or training. Even for those offenders who are themselves drug abusers, prison is not to be used for the purpose of treatment if the other purposes of sentencing do not require incarceration. *See* 28 U.S.C. § 994(k); 18 U.S.C. § 3582(a); S. Rep. 98-225 at 119, 176 (1983). Moreover, as a practical matter, very few defendants receive drug treatment in prison. Court-mandated treatment during pretrial supervision and residential community treatment facilities are all available without the need to burden the taxpayers with lengthier terms of imprisonment.

**C. Death or Serious Bodily Injury Resulting from Use of a Schedule III Prescription Drug**

The Act raises the statutory maximum by 10 years if death or serious bodily injury resulted from the use of a Schedule III substance. *See* 21 U.S.C. § 841(b)(1)(E)(i), (ii).

Existing policy statements invite upward departure for death, USSG § 5K2.1, and for physical injury whether serious and intended or less serious and merely negligent, USSG § 5K2.2. Departure is the appropriate way to deal with death or serious bodily injury from the use of Schedule III substances because it is infrequent.

Westlaw research produced only an extremely small number of cases involving prosecutions for Schedule III substances (whether online prescribing was involved or not), and only one case involved evidence of injury or death. In that case, the defendant advertised ketamine, a Schedule III substance, for sale over the Internet, and a college student ordered several bottles. He injected heroin, then inhaled 200 mg. of ketamine an hour later. His mother found him in a barely responsive state and took him to the hospital, from which he checked out against

medical advice. *See United States v. Pacheco*, 489 F.3d 40 (1st Cir. 2007). The court departed upward from the advisory guideline range of 18-24 month to 36 months under USSG § 5K2.2. The court of appeals rejected the defendant’s argument that he should not have received the departure because there was no proof that the ketamine rather than the heroin caused the death, holding that § 5K2.2 required “proof of a but-for causal connection,” but did not require proof that the substance was the sole or direct cause. *Id.* at 46-47.

Of all the federal cases posted on the DEA’s website entitled “Cases Against Doctors,” [http://www.deadiversion.usdoj.gov/crim\\_admin\\_actions/index.html](http://www.deadiversion.usdoj.gov/crim_admin_actions/index.html), six cases are reported as involving death or serious bodily injury, but none resulted from the use of Schedule III substances.<sup>9</sup> The website reports 12 cases involving Internet prescribing, but none are reported as involving death or injury, nor do the case files contain any such allegations. *See* Chart of Online Pharmacy Prosecutions (Baron, Barrera, Bethencourt, Diaz, Dominique, Gonzalez, Hanny, Mach, McNeil, Millette, Nyamekye, Schwab).

In the other cases we reviewed, none involved allegations of bodily injury and three involved allegations of death. In the case involving Ryan Haight’s death, the government did not seek an upward departure for the doctor who prescribed the hydrocodone found by his parents, and the judge also agreed not to consider the death because Mr. Haight had ingested numerous other drugs before his death. The owner/operator in that case received a sentence of 240 months. *See* Chart of Online Pharmacy Prosecutions (Fuchs, Ogle). In another case, where an online pharmacy distributed primarily diet pills and some Ambien (not hydrocodone), a connection to two deaths was mentioned at some point, but the government either could not prove it or did not pursue it. In fact, the government entered into an 11(c)(1)(C) plea with the owner/operator for a sentence of 33 months and does not appear to have sought an upward departure for anyone based

Case	Charges	Substance that caused death (from indictment or appeals decision)	Sentence
Loxley, Sidney S., 2:04-cr-00236 (E.D. Va.)	846 drug conspiracy	methadone, dilaudid, oxycontin, percocet	87 months
Martinez, Jorge A., 4:04-cr-00430 (N.D. Oh.)	“Healthcare fraud resulting in death”; Distribution of Schedule II	oxycontin	Life
McIver, Ronald Allen, 8:04-cr-00745 (D.S.C.)	841, 846 & death resulted	oxycontin, dilaudid, morphine, methadone	360 months
Merrill, Thomas, 5:05-cr-00023 (N.D. Fla.)	Unlawful dispensing of Schedule II resulting in death; fraud	oxycodone, morphine, fentanyl	Life
Wexler, David, 1:03-cr-01150 (S.D.N.Y.)	841, 846 (Sch II, III, IV)	dilaudid	20 years
Williams, Freddy J., 5:03-cr-00059 (N.D. Fla.)	Wire fraud; health care fraud; 841, 846	oxydodone, oxycontin	Life

on death. *Id.* (Chhabra). In the third case involving an allegation of death, the owner/operator received a two-level enhancement for risk of death under § 2B1.1 and was sentenced under that guideline to 30 years. *Id.* (Smith).

Given the above, the “sole reason” for adding any provision for death or serious bodily injury resulting from the use of a Schedule III substance would be the increased statutory maximum, and so would violate the directive. That should end the matter, but we also note that options other than departure do not make sense. Section 2D1.1 uses an alternative base offense level for death or serious bodily injury for offenses under 21 U.S.C. § 841(b)(1)(A), (B) or (C) in order to match the mandatory minimums that apply to those offenses, but offenses under new 21 U.S.C. § 841(b)(1)(E) are not subject to a mandatory minimum. If an alternative base offense level was used, it would have to be established by the offense of conviction in order to be consistent with the base offense levels for Schedule I and II, yet the rationale for requiring establishment by the offense of conviction for those offenses, *i.e.*, a mandatory minimum, does not exist with respect to Schedule III offenses. A specific offense characteristic would be too rigid to account for warranted differences. For example, it would not advance any purpose of sentencing, and would constitute unwarranted uniformity, for a website designer or shipping clerk with no medical or pharmaceutical training to receive the same increase as the owner/operator, prescribing doctor, or pharmacist.

We hope that these comments are helpful, and look forward to working with the Commission and submitting further comment as the amendment process unfolds.

Very truly yours,

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On Behalf of the Federal Public and Community Defenders  
and the Federal Defender Sentencing Guidelines Committee

cc: Hon. Ruben Castillo, Vice Chair  
Hon. William K. Sessions III, Vice Chair  
Commissioner Michael E. Horowitz  
Commissioner Beryl A. Howell  
Commissioner Dabney Friedrich  
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