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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, Faruqui, 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 =24	20 + 2 for interactive computer service, § 2D1.1(b)(6) - 2 for safety valve +2 for use of special skill, § 3B1.3 - 3 for acceptance = 19

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 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

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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 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).

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 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.

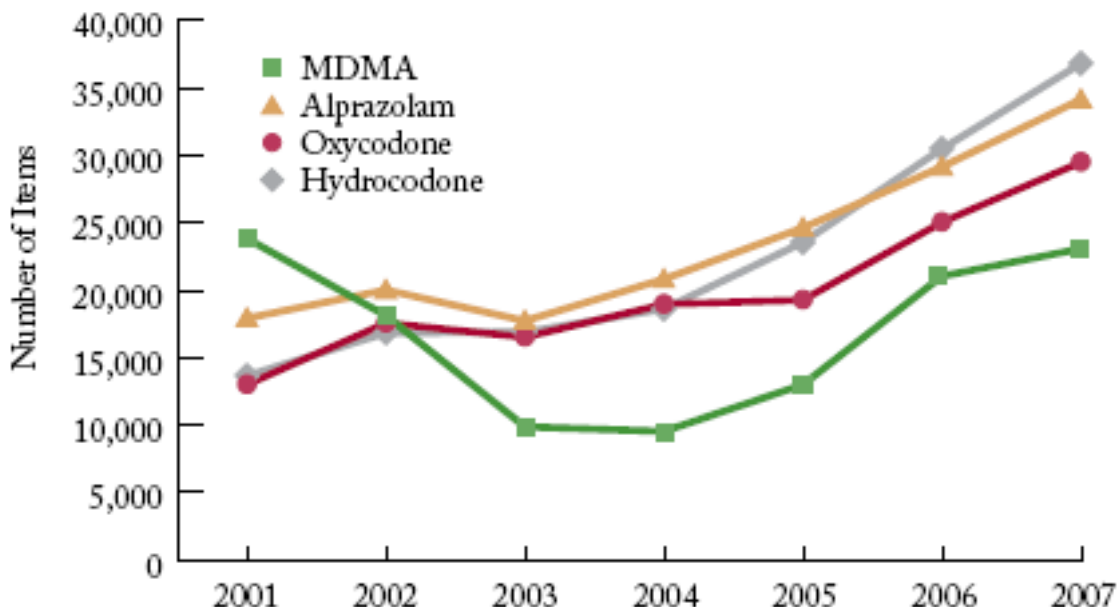
	Annual																2006- 2007	
	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000	2001	2002	2003	2004	2005	2006	2007	change
OxyContin <sup>m,t</sup>																		
8th Grade	—	—	—	—	—	—	—	—	—	—	—	1.3	1.7	1.7	1.8	2.6	1.8	-0.7
10th Grade	—	—	—	—	—	—	—	—	—	—	—	3.0	3.6	3.5	3.2	3.8	3.9	+0.1
12th Grade	—	—	—	—	—	—	—	—	—	—	—	4.0	4.5	5.0	5.5	4.3	5.2	+0.9
Vicodin <sup>m,t</sup>																		
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 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

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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.

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

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 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.

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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. §

§ 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.

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.

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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).

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

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 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.

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

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



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 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

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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

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 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  
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