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Dear Dr. Reedt:

Thank you for the opportunity to express our opinion on the "Revised Proposed Amendment: Oxycodone" (hereafter, Proposal, Appendix I) to amend the United States Sentencing Guidelines (USSG) for crimes involving oxycodone. Purdue Pharma L.P., the distributor of OxyContin[®] (oxycodone hydrochloride controlled-release) Tablets, is very concerned that persons with legitimate medical need have access to OxyContin and other controlled opioids, when indicated, and that persons engaged in criminal activities involving OxyContin, or any other prescription medication, be punished in a manner that is equitable within the federal sentencing schema.

The Proposal would change the USSG that currently equate one gram of oxycodone to 500 grams of marijuana (Drug Equivalency Tables). Under the current USSG, "oxycodone" is construed to mean a mixture containing oxycodone and other ingredients. The Proposal would have sentences involving oxycodone formulations calculated on the basis of the nominal weight of the oxycodone salts, as opposed to the weight of the oxycodone mixture, similar to the manner of calculation under the existing USSG for phencyclidine, amphetamine and methamphetamine.

To achieve the stated Congressional goals of honesty, uniformity and proportionality in sentencing, we agree with the intent and rationale of the Proposal. Our rationale for this decision is explained in Appendix II.

We fully understand the utility of using nominal weights of oxycodone in licit pharmaceutical formulations, as opposed to the precise weight of the oxycodone itself, since a 10 MG OxyContin tablet contains slightly less than 10 MG of oxycodone and a 5 MG tablet of Percocet contains slightly less than 5 MG of oxycodone. Acceptance of this convention will save time for the courts and will not, if applied uniformly, create any disparity in sentencing.

We would, however, like to raise an issue for consideration by the Commission. The language in the Proposal does not consider any licit formulation of oxycodone other than tablets or capsules. Oxycodone is available as an oral solution in the US and is available in an injectable formulation in other countries. These, and other as yet unmarketed novel formulations, could conceivably be involved in sentencing decisions. Likewise, if a crime involved trafficking in or possession of powdered oxycodone salts, the language of the Proposal might be unclear. There also exists the possibility of illegal manufacture of oxycodone for trafficking, as has occurred with fentanyl. We would suggest, therefore, that the language in the Proposal might be unnecessarily limiting. Contemplating these issues, and borrowing language from 21CFR 1300.01(b)(5)(i), we propose you consider modifying the Proposal by replacing the paragraph that reads:

The term "Oxycodone (actual)" refers to the weight of the controlled substance, itself, contained in the pill or capsule.

with:

The term "Oxycodone (actual)" refers to the total nominal weight of the controlled substance, its salts, esters, ethers, isomers and salts of isomers, esters and ethers contained in a licitly manufactured pharmaceutical formulation (including, but not limited to, solutions, tablets or capsules). In the case of oxycodone in any form that is not licitly manufactured for legitimate medical or scientific purposes, the term "Oxycodone (actual)" shall refer to the total actual weight of the oxycodone salts, esters, ethers, isomers and salts of isomers, esters, ethers contained in the mixture.

In reviewing the USSG, there are several other areas involving licitly manufactured opioids that also should be revised to adhere to the intent of Congress. If the Commission is to consider parity amendments for other forms of marketed opioids in the future, we would like to participate in those discussions.

I understand from our telephone call yesterday that there will be no opportunity for oral testimony on this issue at the hearings later this month. If testimony on these issues will occur at future hearings, I am willing to appear on behalf of Purdue.

Again, you have our thanks for being consulted on this important and timely issue.

Sincerely,



J. David Haddox, DDS, MD
Vice President, Health Policy

Appendix I

REVISED PROPOSED AMENDMENT: OXYCODONE

Synopsis of Proposed Amendment: This proposed amendment responds to proportionality issues in the sentencing of oxycodone trafficking. Oxycodone is an opium alkaloid found in certain prescription pain relievers such as Percocet and Oxycontin. This prescription drug is generally sold in pill form and the sentencing guidelines currently establish penalties for oxycodone trafficking based on the entire weight of the pill. The proportionality issues arise (1) because of the formulations of the different medicines and (2) because different amounts of oxycodone are found in pills of identical weight.

As an example of the first issue, the drug Percocet contains, in addition to the oxycodone, the non-prescription pain reliever acetaminophen. The weight of the oxycodone component accounts for a very small proportion of the total weight of the pill. This is in contrast to Oxycontin in which the weight of the oxycodone accounts for a substantially greater proportion of the weight of the pill. For example, a Percocet pill containing five milligrams (mg) of oxycodone weighs approximately 550 mg (oxycodone accounting for 0.9 percent of the total weight of the pill) while the weight of an Oxycontin pill containing 10 mg of oxycodone is approximately 135 mg (oxycodone accounting for 7.4 percent of the total weight). Consequently at sentencing, the same five year sentence results from the trafficking of 364 Percocet pills or 1,481 Oxycontin pills. Additionally, the total amount of the narcotic oxycodone involved in this example is vastly different depending on the drug. The 364 Percocets produce 1.6 grams of actual oxycodone while the 1,481 Oxycontin pills produce 14.8 grams of oxycodone.

The second issue results from differences in the formulation of Oxycontin. Three different amounts of oxycodone (10, 20, and 40 mg) are contained in pills of identical weight (135 mg). As a result, an individual trafficking in a particular number of Oxycontin pills would receive the same sentence regardless of the amount of oxycodone contained in the pills.

To remedy these proportionality issues it is proposed that sentences for oxycodone offenses be calculated using the weight of the actual oxycodone instead of the current mechanism of calculating the weight of the entire pill. Currently the Drug Equivalency Tables in '2D1.1 equates 1 gram of oxycodone ~~mixture~~ to 500 grams of marijuana. The proposal would equate 1 gram of **actual** oxycodone to 6,700 grams of marijuana. This equivalency would keep penalties for offenses involving 10 mg Oxycontin identical to current levels but would increase penalties for all other doses of Oxycontin. At the same time, penalties for Percocet would be substantially reduced.

Proposed Amendment:

2D1.1. Unlawful Manufacturing, Importing, Exporting, or Trafficking (Including Possession with Intent to Commit These Offenses); Attempt or Conspiracy

*Notes to Drug Quantity Table:

(A) Unless otherwise specified, the weight of a controlled substance set forth in the table refers to the entire weight of any mixture or substance containing a detectable amount of the controlled substance. If a mixture or substance contains more than one controlled substance, the weight of the entire mixture or substance is assigned to the controlled substance that results in the greater offense level.

(B) The terms "PCP (actual)", "Amphetamine (actual)", and "Methamphetamine (actual)" refer to the weight of the controlled substance, itself, contained in the mixture or substance. For example, a mixture weighing 10 grams containing PCP at 50% purity contains 5 grams of PCP (actual). In the case of a mixture or substance containing PCP, amphetamine, or methamphetamine, use the offense level determined by the entire weight of the mixture or substance, or the offense level determined by the weight of the PCP (actual), amphetamine (actual), or methamphetamine (actual), whichever is greater.

The term "Oxycodone (actual)" refers to the weight of the controlled substance, itself, contained in the pill or capsule.

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Commentary

Application Notes:

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9. *Trafficking in controlled substances, compounds, or mixtures of unusually high purity may warrant an upward departure, except in the case of PCP, amphetamine, ~~or~~ methamphetamine, or oxycodone for which the guideline itself provides for the consideration of purity (see the footnote to the Drug Quantity Table). The purity of the controlled substance, particularly in the case of heroin, may be relevant in the sentencing process because it is probative of the defendant's role or position in the chain of distribution. Since controlled substances are often diluted and combined with other substances as they pass down the chain of distribution, the fact that a defendant is in possession of unusually pure narcotics may indicate a prominent role in the criminal enterprise and proximity to the source of the drugs. As large quantities are normally associated with high purities, this factor is particularly relevant where smaller quantities are involved.*

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10.

DRUG EQUIVALENCY TABLES

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Schedule I or II Opiates*

1 gm of Morphine =

500 gm of marihuana

~~1 gm of Oxycodone =~~ ~~500 gm of marihuana~~

1 gm of Oxycodone (actual) = 6700 gm of marihuana

Appendix II

Our reasoning for endorsing the "Revised Proposed Amendment: Oxycodone" to the USSG is as follows:

The USSG currently states that offenses involving at least 100 KG, but not more than 400 KG of marihuana, deserve a five-year sentence (sentencing level 26), assuming no other factors are in evidence to warrant adjusting the sentence. The amount of "oxycodone" (mixture) currently needed to equal 100 KG of marihuana is 200 G, so applying the factor of 200 to the "oxycodone" (mixture) equivalent yields 200 G, or 200,000 milligrams.) Thus, under current sentencing USSG, it requires only about 364 Percocet[®] tablets (containing nominally 5 MG of oxycodone and weighing 550 MG per tablet), but it takes 1481 OxyContin[®] (oxycodone hydrochloride controlled-release) Tablets 10 MG (weighing 135 MG per tablet) to yield 200,000 MG of total mixture weight, an amount that warrants a five-year sentence, without applying any adjustments.

This schema under-penalizes the illegal possession of oxycodone in the form of OxyContin and over-penalizes the illegal possession of oxycodone in the form of Percocet or similar formulations, since in the latter cases, a large part of the sentencing is due to the weight of non-opioid tablet constituents, the bulk of which is often acetaminophen, a medicine not controlled under the Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 USC 801, et seq.).

The current scheme does not take into account the fact that tablets of OxyContin containing 10, 20 and 40 MG all weigh 135 MG, so sentencing under the current USSG would be equivalent for the same number of tablets, despite the potential of a four-fold difference in the amount of oxycodone illegally possessed.

To establish proportionality in sentencing, if one begins with the amount of OxyContin 10 MG tablets as a constant, that is, 1481 tablets ($1481 \times 135 \text{ MG per tablet} = 199,935 \text{ MG}$ or about 200 G), then the amount of "oxycodone (actual)", or oxycodone salt, required for a 5-year sentence is 14.8 grams.

If one then divides the amount of marihuana required for a 5-year sentence (100,000 G or 100 KG) by the amount of oxycodone required for a 5-year sentence (14.8 G), this yields 6756 G (rounded to 6700 G) of marihuana equivalent to one G of "oxycodone (actual)".