



U. S. Department of Justice
Drug Enforcement Administration

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Springfield, Virginia 22152

MAR 18 2015

The Honorable Patti B. Saris, Chair
United States Sentencing Commission
One Columbus Circle, NE
Suite 2-500, South Lobby
Washington, D.C. 20002

Dear Chief Judge Saris and members of the United States Sentencing Commission:

I thank you for the opportunity to not only testify before you on March 12, 2015 concerning the proposed amendment to the federal sentencing guidelines for hydrocodone but to submit this response to the Federal Defender's March 13, 2015 letter and attachments. The two studies attached to Ms. Meyers' March 13, 2015 letter were previously addressed in Federal Public Defender Lex Coleman's written statement. The lead author of both studies is Theodore Cicero, Ph.D. (hereinafter "Cicero"). DEA respectfully reminds This Honorable Commission that Dr. Sharon Walsh briefly and generally addressed the same studies, and we would further respond to them as follows:

On page 13 of his written statement, Mr. Coleman wrote:

Research also shows that fewer opioid dependent individuals preferred hydrocodone (29.4%) than oxycodone (44.7%) "because the quality of the high was viewed to be much better by 54% of the sample, compared to just 20% in hydrocodone users, who cited acetaminophen as a deterrent to dose escalation to get high and hence, its low euphoric rating,"

citing the two Cicero studies since sent to you by Ms. Meyers.

It is DEA's position, based on investigative experience as well as scientific analysis that the conclusions reached by these studies were predicated on inaccurate or incomplete studies. The above statement, made in the abstract, cannot be verified by reliable data. The responses gathered to make these findings came from user surveys as opposed to controlled clinical studies. The determination of diversion of hydrocodone as compared with oxycodone comes from user surveys but does not include law enforcement data about which I testified before you on March 12, 2015 that evidenced similar diversion patterns based on geographical locations.

Equally as significant, the comparison made in the Cicero studies did not compare hydrocodone single entity products to oxycodone single entity products. Instead, they compared hydrocodone combination products to oxycodone single entity products, a factor that skews the analysis and was repeatedly addressed during the testimony of multiple witnesses before you on March 12, 2015. Yet, even to the extent that any or all of the study is deemed significantly reliable, interestingly, the

2013 Cicero study provided by Ms. Meyers and referenced by Mr. Coleman (Factors influencing the selection of hydrocodone and oxycodone as primary opioids in substance abusers seeking treatment in the United States) reflects that 70% of the users surveyed indicated they would be more likely to use a single entity hydrocodone.

Both Cicero studies were published before any single entity hydrocodone product was approved for marketing by the FDA (Zohydro ER was the first single entity hydrocodone product approved in October 2013 and first marketed in March 2014). Therefore, the comparisons in prescription drug likability were made between oxycodone products - including single-entity immediate release, extended release products, and combination (oxycodone in combination with other nonnarcotic pain reliever drugs) products - versus hydrocodone combination products. As you heard through the witness testimony on March 12, 2015, the appropriate comparison is between oxycodone combination products and hydrocodone combination products.

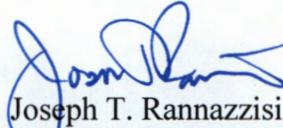
It is also important to note that the dependence (addiction) producing property of a given opioid analgesic drug is a function of dose. Each unit (tablet or capsule) of oxycodone single entity products contains large amounts of “actual” oxycodone (up to 80 mg oxycodone in OxyContin®) as compared to hydrocodone combination products (up to a maximum of 10 mg of hydrocodone). In fact as a part of efforts to reschedule hydrocodone combination products, DEA conducted an extensive analysis of drug dependence data obtained from the National Survey on Drug Use and Health (NSDUH). The DEA found that the incidence of substance use disorder is higher among lifetime users of OxyContin®, a high strength extended-release product, as compared to the corresponding data among lifetime users of other oxycodone products (excluding OxyContin® lifetime users) and hydrocodone combination products (DEA (2014) Schedules of Controlled Substances: Placement of Hydrocodone Combination Products into Schedule II: Background, Data, and Analysis: Eight Factors Determinative of Control and Findings Pursuant to 21 U.S.C.812(b)). Therefore although the study by Cicero and his associates was informative, there was no actual comparison of hydrocodone combination products versus oxycodone combination products containing acetaminophen. To that end, the statement that acetaminophen is likely to counter the abuse potential of hydrocodone is not based on reliable scientific data, but it is an assumption. Cicero and his associates did concede that the decision to choose one drug over another is a complex one and depends on many factors, a point raised by Dr. Walsh and me at the March 12, 2015 hearing.

In scientifically reliable studies where oxycodone combination products and hydrocodone combination products were compared (Stoops et al. 2010; Walsh et al., 2008), subjects were blinded to the drug. In both studies, the authors reported that the psychoactive and analgesic effects were similar.

Dr. Walsh’s testimony highlighted the crucial disconnect of the Cicero studies – addicts surveyed who have advanced to ingestion beyond the intended oral method (i.e., injecting or snorting) preferred oxycodone because abusers recognize that the acetaminophen contained in hydrocodone products is dangerous thereby preventing them from escalating their abuse of hydrocodone. At the time, single-entity hydrocodone was not available, and today, it is.

I hope that this submission further clarifies the testimony you heard on March 12, 2015, sufficiently rebuts any conclusions set forth in the two Cicero studies relied upon by the Federal Defenders' Office, and supports the position of the Department of Justice that the marijuana drug equivalency of 6,700 grams to one gram of "actual" hydrocodone is appropriate.

Sincerely,



Joseph T. Rannazzisi
Deputy Assistant Administrator
Office of Diversion Control