U.S. Department of Justice
Office of Legislative Affairs

Office of the Assistant Attorney General

Washington, D.C. 20530

May 24, 2004

The Honorable Mark Souder
Chairman
Subcommittee on Criminal Justice, Drug Policy
and Human Resources
Committee on Government Reform
U.S. House of Representatives
Washington, DC 20515

Dear Mr. Chairman:

Enclosed please find responses to questions posed to Mr. Thomas W. Raffanello, Special Agent in Charge of the Miami Division of the Drug Enforcement Administration, following Mr. Raffenello's appearance before the Subcommittee on February 9, 2004. The subject of the hearing was: "To Do No Harm: Strategies For Preventing Prescription Drug Abuse."

We hope that you will find this information helpful. If we may be of additional assistance, we trust that you will not hesitate to call upon us.

Sincerely,

William E. Moschella
Assistant Attorney General

Enclosure

cc: The Honorable Elijah Cummings
Ranking Minority Member

COMMITTEE ON GOVERNMENT REFORM
SUBCOMMITTEE ON CRIMINAL JUSTICE, DRUG POLICY & HUMAN RESOURCES

"TO DO NO HARM: STRATEGIES FOR PREVENTING PRESCRIPTION DRUG ABUSE"

FEBRUARY 9, 2004

FOLLOW-UP QUESTIONS FOR THE RECORD FOR
MR. THOMAS W. RAFFANELLO
SPECIAL AGENT IN CHARGE, MIAMI DIVISION
DRUG ENFORCEMENT ADMINISTRATION

1. During the hearing you testified that the laws against illegal distribution of controlled substances over the Internet are very vague. What changes in the current federal laws would DEA like to see made? What new steps can Congress take to assist your law enforcement efforts to combat the illegal distribution and use of prescription drugs?

DEA is moving aggressively to enforce existing prohibitions against the illegal dispensation of controlled substances. At the same time, DEA and the Justice Department have been reviewing Federal law to determine whether changes need to be made. We look forward to working with the Congress on this issue.

2. From newspaper reports discussed at the hearing, it is clear that a relatively small number of doctors are prescribing very large amounts of oxycodone and other controlled substances in Florida. This information was based on data maintained by the Medicare/Medicaid system. Does the DEA monitor Medicare/Medicaid information and if so, how? How is this information used for law enforcement purposes?

Although the DEA does not monitor Medicare or Medicaid databases, information is routinely exchanged among the agencies. In Florida for example, DEA Special Agents and Investigators exchanged case related information directly with the Medicaid Fraud Control Unit.

3. What other kinds of information does DEA keep track of in its efforts to stop illegal diversion of prescription drugs? What factors go into a decision by DEA to open investigations into illegal use or distribution of prescription drugs?

The DEA monitors emerging drug trends through the Automation of Reports & Consolidated Orders System (ARCOS), an electronic reporting system for all manufacturers and distributors of Schedule II and Schedule III narcotic controlled substances. DEA is able to analyze the reported transactions and determine unusual purchasing patterns. DEA investigations focus on large scale trafficking organizations of pharmaceutical controlled substances that have a significant international, national, or regional impact.

4. Does the number of conditions for which a drug is approved by the US Food and Drug Administration impact the illegal use of the drug? In other words, if the number of approved uses increases, does that increase the potential for the drug to be diverted or misused? Should drugs like OxyContin be approved for use in treating moderate or even lesser levels of pain? Does the number of conditions for which a drug is approved by the FDA impact the illegal use of drugs?

The more approved uses there are for a particular drug results in more prescriptions written, which often equates to a higher frequency of diversion. For example, stocks in pharmacies are larger so robberies will cull a greater amount of a particular drug to be used illicitly. High-dose, single entity products like OxyContin® are ideal for patients who are or become opiate tolerant and need 24-hour coverage for an extended period of time for severe pain management. For moderate pain, other immediate release products will alleviate the pain. High-dose products are highly desirable for use as a heroin substitute by narcotic addicts. As has been publicly stated in the past, the DEA believes OxyContin® should only be used for severe pain management.

5. On February 15, 2004, the Washington Post reported that "top officials" at DEA were working to reclassify hydrocodone combination products (i.e., drugs that are made up of hydrocodone and another medicine, as opposed to pure hydrocodone) as Schedule II drugs). What is the status of this reclassification effort? What potential impact would it have on DEA's ability to combat the diversion and abuse of these drugs?

The DEA has received a petition to reschedule hydrocodone combination products, such as Vicodin® and Lortab® from Schedule III to Schedule II of the CSA. We are currently in the initial phase of gathering available data to be forwarded to the Department of Health and Human Services for review. We do not anticipate imminent action to reschedule hydrocodone products. Schedule II controls would prohibit prescription refills, eliminate call-in prescriptions, and provide greater security and oversight of these drugs. It also would put doctors on notice that these products have been extensively abused and more careful prescribing is needed.

6. During the hearing, the Subcommittee discussed several proposals for the creation of a database or databases to monitor the distribution and prescription of controlled substances. What form should such a database take, and who should create and maintain it? Should a single federal database be created? Or should each state create its own database? If the latter, how would we ensure that they would be linked and capable of sharing information with each other?

The Prescription Monitoring Programs (PMPs) offer the best approach to monitoring prescription use and abuse. Federal funding has been available for the states to initiate and improve PMPs through a grant program known as the Harold Rogers Prescription Drug Monitoring Program. Since fiscal year 2002, Congress has appropriated $16.5 million to the Department of Justice for PMPs. Twenty-two states, representing approximately 50 percent of the practitioners and

pharmacists registered with the DEA, currently operate PMPs.

A state by state approach to developing these programs provides the states with a high degree of flexibility in the design and implementation of the programs. The DEA and the National Association of State Controlled Substance Agencies are coordinating their approaches in order to capture basic data from each PMP in an effort to develop procedures for State officials to identify and track questionable substances between states.

7. Approximately what percentage of DEA's time and resources is expended in connection with illegal distribution of prescription drugs? How does that compare to the agency's efforts with respect to illegal drugs such as marijuana, cocaine and heroin?

Last year, the DEA expended 5.4% of its total work hours in connection with the illegal distribution and use of prescription drugs and 83.6% of total work hours combating illegal opiates, cocaine, cannabis, and other dangerous drugs.