

Opening Statement
Chairman Mark Souder

“To Do No Harm: Strategies For Preventing
Prescription Drug Abuse”

Subcommittee on Criminal Justice, Drug Policy,
and Human Resources
Committee on Government Reform

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Good morning, and thank you all for coming. This hearing focuses on a very old and very widespread problem: the abuse of prescription drugs. Prescription drug abuse itself is nothing new, but recently a new generation of morphine-based pain killers has caused a wave of addiction and overdoses throughout the U.S. The drug OxyContin has produced the greatest amount of publicity, but numerous similar drugs – such as Percocet, Percodan and Tylox – have also been abused.

Prescription drug abuse presents special problems for government, the medical community, and the pharmaceutical industry. On the one hand, these are powerful and dangerous drugs, with as great a capacity for addiction and abuse as heroin and cocaine. There are many ways for these drugs to fall into the wrong hands: supplies of the drugs can be stolen from pharmacies and manufacturers and then sold on the black market; doctors may intentionally or unintentionally overprescribe the drugs to patients, leading to addiction and abuse; or patients themselves may obtain illegal quantities of the drugs by shopping for multiple prescriptions, and filling them at multiple pharmacies.

On the other hand, these drugs have legitimate medical uses, and may give the only possibility of relief for patients suffering from chronic pain. Many cancer patients, for example, rely on OxyContin

and similar drugs to combat crippling pain, while other individuals suffering from severe injuries may need similar treatment. Any regulatory plan must balance these competing concerns.

Two federal agencies are primarily responsible for the regulation of prescription drugs: the U.S. Food and Drug Administration, and the Drug Enforcement Administration. FDA has the job of testing new drugs, and specifying how the drug may be marketed, prescribed and used, while DEA is responsible for monitoring the distribution and prescription of these drugs to prevent their illegal use. In addition to investigating illegal trafficking of prescription drugs, DEA also controls the licenses that every physician must have in order to prescribe controlled substances.

FDA and DEA have been criticized both for being too lenient *and* for being too strict in their regulation of prescription drugs. Former addicts, relatives of those who have died of overdoses, and many media commentators have argued that FDA has failed to safeguard the public from dangerous drugs by sufficiently regulating their marketing and distribution. These critics (some of whom, it must be noted, have filed lawsuits) have accused manufacturers of overmarketing pain killers and failing to warn doctors of the real risks of addiction and abuse. By contrast, some doctors, patients, and other advocates for pain treatment have accused DEA of carrying out a virtual “war” against physicians by aggressively prosecuting those who willfully overprescribe pain killers.

While the specific actions of FDA, DEA and the pharmaceutical companies may be debated, it is clear that the federal government needs to explore new approaches to these problems. Congress and the executive branch need to re-examine the approval and marketing process, and determine how best to monitor the distribution and sale of pain killers. Several new proposals are already being debated. For example, a number of states are exploring the concept of setting up computerized databases that would track the sale and prescription of controlled substances, to enable law enforcement officials to determine when a doctor is prescribing, a pharmacist is dispensing, or an individual is receiving suspiciously large amounts of a drug. Many states are also attempting to combat the illegal distribution of these drugs over the internet – an issue that Government Reform

Committee Chairman Tom Davis is working to address. Other proposals focus on what warnings pharmaceutical manufacturers are required to give to doctors and patients, and providing information on addiction and how to treat it.

This hearing will allow the Subcommittee to hear from governmental, medical, and other witnesses to testify about the costs of prescription drug abuse, the benefits afforded by these drugs, and how best to balance these two. I first want to thank Congressman John Mica for proposing this hearing, and for the assistance that he and his staff provided in setting it up. We also welcome three witnesses who have joined us to discuss the federal government's response to this problem: Mr. William T. Fernandez, Director of the Central Florida High Intensity Drug Trafficking Area, or HIDTA, a program administered by the White House Office of National Drug Control Policy; Dr. Robert J. Meyer, Director of the U.S. Food and Drug Administration's Office of Drug Evaluation II at the Center for Drug Evaluation and Research; and Mr. Tom Raffanello, Special Agent in Charge of the Drug Enforcement Administration's Miami Division.

We are also pleased to be joined by two representatives of the Florida state government, who have taken a lead role in the fight against prescription drug abuse: Mr. James R. McDonough, Director of the Florida Office of Drug Control; and State Senator Burt L. Saunders, the Chairman of the Florida Senate Committee on Health, Aging and Long-Term Care. We also welcome Dr. Stacy Berckes, a Board Member of the Lake Sumter Medical Society; Mr. Jack E. Henningfield, of Pinney Associates, who is testifying on behalf of Purdue Pharma; and Ms. Theresa Tolle, President of the Florida Pharmacy Association.

We also welcome several witnesses who can discuss the importance of these issues to patients and individuals. In particular, we welcome Mr. Frederick Pauzar, who lost a son to an OxyContin overdose, and who has taken a leadership role in addressing the problem of prescription drug abuse. We are especially pleased to be joined by a specialist in the treatment of prescription drug addiction, Dr. Douglas Davies, Medical Director of the Stewart-Marchman Center. We also welcome Professor Paul L. Doering of the University

of Florida's College of Pharmacy; Ms. Karen O. Kaplan, President and CEO of Last Acts Partnership; and Dr. Chad D. Kollas, Medical Director for Palliative Medicine at the M.D. Anderson Cancer Center Orlando. We thank everyone for taking the time to join us this morning, and look forward to your testimony.