

**Statement of Peter W. Jackson
Before the
Anesthetic and Life Support Drugs Advisory Committee**

March 29, 2007

Introduction

Distinguished members of the Anesthetic and Life Support Drugs Advisory Committee, thank you for the opportunity to speak to you today regarding the problem of prescription opioid drug abuse. My name is Peter W. Jackson. I am a biologist with the U.S. Environmental Protection Agency in Chicago. My wife and I reside in Arlington Heights, Illinois where we have raised two children, one boy and one girl. During the week of August 13, 2006, our daughter Emily, only eighteen years of age and days from her first day in college, was staying with relatives to console the family as they had just lost their father and husband to cancer. On August 18th Emily was killed accidentally when she consumed a pain killer that had been prescribed for her late uncle. The coroner conducted an inquest and concluded that Emily died from a combination of this drug, **OxyContin**, and other things in her system, which included alcohol and her own prescribed medication. While this combination presumably enhanced the toxic effect of the OxyContin, if you take away the OxyContin Emily would likely not have died. Emily was not a drug addict, she clearly did not know what she was getting involved with, and she made a simple but tragic mistake.

So, what is to be done to address this tragedy? Do we just blame Emily for using poor judgment? Do we wash our hands because the drug should have been immediately discarded after her uncle's death? Unfortunately, these viewpoints ignore the reality that the circumstances of Emily's tragedy – ready access to a dangerous prescription drug and a lack of knowledge about its true danger - are very common elements of a growing problem of prescription drug abuse in this country. Without question personal responsibility and drug safety awareness are important aspects to this problem, but if we do nothing more than preach the importance of personal responsibility, young people will continue to die in increasing numbers.

In the time since Emily's death I have done a lot of reading. I have learned a great deal regarding OxyContin, its manufacturer, Purdue Pharma, the wide popularity and rapid expansion of this drug throughout the United States, the extremely aggressive manner in which the drug was marketed for a variety of indications including moderate pain, and the high rates of diversion, abuse, addiction, and death resulting from this drug since it came on the market only eleven years ago. I have also learned that OxyContin is not the only opioid drug that is being seriously abused. Recent news accounts and national surveys highlight the growing problem with prescription opioid drug abuse in general, with OxyContin one of the most abused and most deadly [1, 2, 3]. My statement is

intended to underscore the urgent need for FDA to take bold action to control the escalating and deadly abuse of prescription opioid drugs, beginning with OxyContin.

OxyContin – History of Abuse and Death

OxyContin is continually overprescribed by doctors for people with many types of moderate pain who should never have been given this drug in the first place; this widened use can be directly traced to the marketing campaign of Purdue Pharma, which chose to expand the use of OxyContin for profit in spite of the absence of studies showing that the long-term use of this drug for chronic non-cancer pain is both safe and effective. As a result of this extremely aggressive marketing campaign implemented by Purdue Pharma, which has been cited as excessive by both FDA and the Drug Enforcement Administration (DEA) on several occasions, OxyContin soon became the top-selling brand-name narcotic pain reliever [4]. Given the widespread availability of the drug, the drug's potency, the ease of controlled-release bypass, and the often fatal effect when consumed with alcohol, OxyContin abuse and associated deaths have skyrocketed and have been well-documented across the United States. For example, according to the 2004 National Survey on Drug Use and Health, lifetime non-medical use of OxyContin increased from 400,000 people in 1999 to 2.8 million people in 2003, a seven-fold increase, and DAWN survey data indicate that emergency department mentions of oxycodone sustained release products increased from 1,178 in 1999 to 14,087 in 2002 [5]. These shocking statistics are consistent with the results of a 2002 DEA national survey of state medical examiner autopsy data which revealed that of 946 reports received, OxyContin was a contributing factor in half of these deaths [6].

Robert J. Meyer, M.D., Director of FDA's Office of Drug Evaluation II in the Center for Drug Evaluation and Research, is on record as stating that at the time of OxyContin's approval FDA believed that the controlled-release feature made the drug less prone to abuse and diversion [5]; FDA thus approved the drug for moderate pain. Unfortunately, as Dr. Meyer acknowledged, the controlled-release formulation is easily bypassed by crushing the timed-release capsule and then injecting or snorting it, which has led to a "widespread and high level of abuse" [5].

You need to be aware that OxyContin is killing our children *without being crushed*. A relative who saw Emily take the OxyContin said she took it like aspirin. My daughter was not an experienced drug abuser; she did not know anything about crushing the pill. Her tragedy proves an important point: OxyContin is extremely dangerous even when the pill is taken orally with water, like any pill. I have spoken with other bereaved parents who each said the same thing: witnesses said their kids just took them with liquid, like aspirin.

The consumption of OxyContin while drinking alcohol is another common element in many OxyContin deaths. In our daughter's case, we believe that it may have been alcohol that triggered the fatal effect by dissolving the coating on the pill. If Palladone was taken off the market because of the discovery that it has a life-threatening interaction with alcohol as indicated by Dr. Meyer (5), then why is OxyContin left ON the market in

its current formulation when the same effect has been documented? FDA needs to rethink how OxyContin is prescribed in a manner that reflects two realities: OxyContin can be fatal without being crushed, and the likelihood of a fatal overdose is increased substantially when the pill is consumed with alcohol.

We are concerned that Purdue Pharma will continue to run from its responsibility as a manufacturer of a dangerous narcotic and hide behind excuses. One excuse is that many who die with OxyContin in their systems also had consumed alcohol or other drugs. This ignores the obvious reality that the OxyContin is the common denominator – the substance with which these other elements react so adversely. As stated by Stephen G. Gelfand, MD of Myrtle Beach, South Carolina in comments to the FDA dated June 20, 2005: “The presence of multiple drugs in addition to oxycodone [the active drug in OxyContin] found in autopsy reports does not exclude the role of OxyContin in causing these deaths. It only indicates the extreme danger and additive effects of combining OxyContin with other psychoactive drugs and/or alcohol in a susceptible group...” Another excuse is that drug abuse is criminal behavior, and that such behavior is not a reasonable basis upon which to formulate policy. This ignores the fact that people who make one mistake like my daughter do not deserve to die. It also ignores the fact that multiple studies have documented a high rate of drug abuse in patients receiving opioids for chronic pain [7].

Part of a Bigger Problem (Opioid Drug Abuse)

As reported in the CDC Morbidity and Mortality Weekly Report for February 9, 2007, in 2004 poisoning was second only to motor-vehicle crashes as a cause of death from unintentional injury in the United States [8]. Rates for drug poisoning deaths increased 68.3% between 1999 and 2004; this increase was “attributed primarily to increasing numbers of deaths associated with prescription opioid analgesics (e.g. oxycodone)...”

We believe that Emily may have assumed that a prescribed medication for her uncle would not be any more dangerous than the prescribed medications she was taking for her own health problems. She may have been reassured by the fact that her uncle’s OxyContin had been prescribed by a doctor, and that it would thus be safe. We believe this demonstrates how easily and innocently this widely-distributed drug may be consumed by an unsuspecting person. We have learned of many similar OxyContin-related deaths that were preceded by assurances that the drug was “FDA-approved”, or that the drug was prescribed by a doctor, etc. Kids have been led to a false sense of security about OxyContin since it is so widely prescribed without adequate warnings to the public about its dangers. We were unfamiliar with this opiate drug until this incident, and we are shocked that such a powerful killer could be provided to patients in need in such a way as to be freely accessible for abuse by other family members. If this is a Class II substance, with a documented history of abuse that has been acknowledged by the FDA, why is it so unrestricted? *It is like leaving a loaded gun on the kitchen table.* As confirmed in the national media recently [1,3], this is a problem that applies to other widely-abused opioid drugs as well.

What we are looking for – Possible Actions

FDA's responsibility is to ensure that all new drugs are safe and effective. This responsibility for ensuring safety does not end once a drug has been approved. Dr. Meyer has acknowledged that FDA approved OxyContin based on incorrect information and that a "widespread and high level of abuse" has been the result. This record of abuse and the resulting death toll demonstrates that OxyContin is not safe. According to the U.S. Department of Health and Human Services, Center for Disease Control, "Effective response to increasing fatal drug overdoses requires strengthening regulatory measures to reduce unsafe use of drugs, increasing physician awareness regarding appropriate pharmacologic treatment of pain and psychiatric problems, supporting best practices for treating drug dependence, and potentially modifying prescription drugs to reduce their potential for abuse." [8] In light of the mounting information that FDA now has available to it, it is time for the FDA to do its job of ensuring the safety of American citizens.

We call on the FDA to schedule a special public meeting to explicitly address the problem of OxyContin abuse, along with other opioids with a high documented rate of abuse or which the FDA believes may have the potential for such abuse. The goal of this meeting should be to develop a comprehensive policy designed to substantially limit abuse potential of OxyContin and other widely-abused prescription opioids. Following are several strongly-recommended strategies for FDA's consideration insofar as OxyContin is concerned.

On February 1, 2005 bereaved parent Barbara Van Rooyan and her husband submitted FDA Citizen Petition 2005P-0076. Regarding OxyContin, this petition seeks to: 1) require FDA to temporarily recall OxyContin from the market until the drug can be reformulated to minimize abuse potential, and 2) make a label change that would limit the use of OxyContin to "severe chronic pain from documented peripheral tissue disease processes". We urge FDA to give serious consideration to these actions.

In addition to reformulation and restricting use to severe pain cases only, we are also interested in seeing additional controls placed on OxyContin so that individual prescriptions are more carefully issued and monitored. We would also like to see mandatory, specialized pain and addiction training of all doctors who are authorized to prescribe the drug, and long-term studies of addiction risks and the relative effectiveness of different dosages and other therapeutic options. In short, we would like to see OxyContin administered to patients in need in a manner that reflects the documented threat to public safety posed by this drug. We do not wish to restrict the drug from patients who need relief from severe chronic pain associated with peripheral tissue diseases. But too many kids are dying *even when* the drug is appropriately prescribed for someone such as Emily's uncle. The most effective policy will require a number of these regulatory actions to complement other initiatives outside of FDA's domain, such as education programs, that by themselves are clearly not working.

Conclusion

Emily was a compassionate, friendly, and loving person who cared more about the people around her than herself. She suffered from thyroid cancer and went through three major surgeries in her last four years of life, and despite the challenges she faced as a young teenager with cancer, *she* was the person who supported the people all around *her*. In her last week on this earth, she was staying with relatives to comfort them as they had lost their father and husband to cancer. The last time I had a good talk with her, she told me how good it made her feel to be able to support the family in their time of need. Since Emily died, several of her best friends have told me that she was the only person they felt they could confide in about the things that mattered most to them, because they knew she cared and would always say the right things to make them feel better. A trademark of Emily's was to always say "I love you mom", or "I love you dad" whenever she was going somewhere, even if she was coming right back. She never took her family or friends for granted. Emily was just three days from her first day in college and she was very excited about her life. The reason I tell you about Emily is that I want you to understand how vital she was in the lives of many people, and how much passion she had for life. There could not be a greater loss than hers.

She was truly one of a kind, and now she is gone. Our lives will never be the same. What we have experienced no family should ever have to experience. In my daughter's name, I beg of you to please address this issue, so that other families may be spared this tragedy and other young people may live full and happy lives. Thank you.

Sincerely,

Peter W. Jackson

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