

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

Congress of the United States, House of Representatives

Committee on Government Reform

Subcommittee on Criminal Justice, Drug Policy and Human Resources

-- Testimony by --

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Introduction

On behalf of M. D. Anderson Cancer Center Orlando and Orlando Regional Healthcare, I would like to thank Chairman Mark E. Souder and the Subcommittee on Criminal Justice, Drug Policy and Human Resources for inviting me to testify at this hearing. I would also extend special thanks to Representative John Mica of Winter Park, Florida, and his office for their gracious assistance and support.

I would also like to acknowledge the support and efforts of those who contributed to the research that led to this testimony, particularly the work of Susan Dempsey-Walls, RN, MN, Mary Ella Mahoney, PharmD, Pam Nicolenco, RN, Jeanne Adam, and the Orlando Regional Healthcare Market Research. I thank as well Beth Boyer Kollas, MS,

MDiv, PhD, for her assistance with scientific review and editing. I also would like to thank each of the patients who returned completed surveys, thereby giving me the opportunity and privilege to bring the voice of cancer patients to the important discussions that will characterize this hearing.

My testimony will focus on conveying the views of central Florida's cancer patients regarding their unique experiences with prescription pain medications, an issue that has received substantial attention in the news media in Orlando over the last four months. I hope that I am able to faithfully express their practical and valuable insights at this hearing to help in this subcommittee's worthwhile effort to reduce prescription drug diversion and misuse, while protecting the interests of patients with legitimate needs for pain management.

Background

In the fall of 2003, the misuse and diversion of the prescription opiate analgesic, OxyContin® (sustained-release oxycodone), received intense media coverage in central Florida following national reports of alleged OxyContin® abuse by a prominent talk-radio personality. In my palliative medicine outpatient practice at M. D. Anderson Cancer Center Orlando (MDACCO), several patients described difficulty obtaining prescription pain medications and shared that their friends and families had expressed increased concerns about addiction to pain medications. A few expressed specific concerns that OxyContin® would be "pulled from the market," causing them fear about the potential to suffer from increased cancer pain. Many patients expressed specific concerns that the

newsprint media did not address adequately or fairly issues related to cancer pain. They also expressed frustration about the lack of a widely visible forum in which they could voice their concerns about the media's lack of attention to their pain issues.

In November 2003, the news media announced the plan to convene this congressional subcommittee's congressional hearing, thereby providing a unique and powerful opportunity for cancer patients to voice their concerns and opinions about prescription pain medication issues. After meeting with other interested MDACCO and Orlando Regional Healthcare (ORH) providers, we began efforts to objectively characterize our patients' opinions about the issues related to management of their pain with prescription medications, including OxyContin®. Our goal was to better serve our patients by giving them a voice in the important discussions that will arise in this subcommittee hearing. To achieve this goal, we developed a survey designed to examine the experiences of cancer patients with prescription pain medications, including their perceptions of news media coverage of pain, their physicians' pain management, and the characteristics of their pain experience.

Survey Design

Before distributing surveys, we obtained approval from the MDACCO Institutional Research Board to conduct the study with a waiver of consent, as participant's consent would be implied by survey completion and return. Given the sensitive nature of the study issue, we did not collect information that would allow identification of any participants. All survey costs were funded by MDACCO and ORH.

The study group included 1,200 randomly identified patients who had received care at MDACCO between August and November 2003. Each of these patients received a survey and explanatory cover letter dated December 30, 2003. We asked them to complete the survey and return it using the U. S. Postal Service in an enclosed, self-addressed, stamped envelope by January 16, 2004. The cover letter emphasized that the intent of the study was to collect information for presentation at this committee hearing. We also explained that the survey did not represent an effort to identify patients who misused their medications, nor were we seeking information on behalf of a pharmaceutical company or other interest.

ORH Market Research collected surveys, entered and analyzed data preliminarily, then created a summary database spreadsheet with a report containing descriptive statistics. The study's principal investigator subsequently analyzed selected data to uncover comparative relationships, using SPSS 11.0 for Windows [SPSS, Inc., 2001]. For the purpose of this subcommittee hearing and related to the limited amount of time available to testify, I will report the study's main results with a brief interpretation of their meaning. We plan to formally publish more detailed results in a peer-reviewed medical journal at a later date.

Main Results and Discussion

Response Rate and Demographics.

The response rate for the survey was 16.7% (190 surveys returned), and 69.4% of respondents were female. The age distribution of respondents was as follows:

18-35 years:	2%
36-50 years:	30%
51-64 years:	12%
65-80 years:	45%
81 years or older:	12%

Pain Experience in Cancer Patients.

Just over half (52%) of the cancer patients who responded to the survey reported that they experienced pain *daily*, and 41% agreed that pain interfered with their ability to work and be productive. One-fifth of respondents agreed that they could not perform routine activities -- getting dressed, driving the car, shopping for groceries -- due to pain. About 27% of respondents felt that pain had adversely affected relationships with loved ones and friends. Furthermore, 43% of respondents expressed concern about asking for or using pain medication because of its potential for addiction. Of particular note, patients with concerns about addiction reported pain twice as often as those without concerns (statistically significant difference; $p = 0.01$). Additionally, although 80% of respondents agreed that their healthcare providers took their pain complaints seriously, fewer (68%) reported that they were satisfied with their current pain management overall.

These results confirm that cancer patients suffer from a significant amount of pain on a daily basis, and that their pain affects their ability to live their lives in a free, productive manner. Cancer patients expressed concerns about addiction, although they are part of a group suffering from a type of pain that has traditionally received more social acceptance than other types of pain, such as chronic, musculoskeletal pain, for

example. Furthermore, although two-thirds of cancer patients were satisfied with their pain management, medical research suggests that patients can achieve better results through the efforts of well-trained pain management providers (see Rich B; Wm Mitchell L. Rev., 2000].

OxyContin® and the Pain Experience.

About 41% of respondents currently used or had used OxyContin® to manage their pain, while 59% currently used or had used other opiate analgesics for their pain. In the first group, 82% reported that OxyContin® relieved their pain, but fewer respondents in the second group (72%) reported pain relief with other opiates. Furthermore, over 87% of the responding cancer patients who currently use or have used other opiates agreed that they would not take opiates if they had no pain compared to 91% in the subgroup taking OxyContin®. Both of these differences between groups were statistically significant. Both groups reported the similar levels of satisfaction (70%) with how they felt when taking pain medication, and both groups reported no difficulty with side effects at an equal rate (about 70%). Additionally, 53% of those taking *any* opiates either now or in the past agreed that opiates analgesics were the *only* medications that helped their pain.

These results suggest that opiate analgesics offer effective relief for cancer pain, often in cases in which other analgesics have failed. The results also suggest that OxyContin® *may* produce higher success rates in the control of cancer pain than other opiates, although we would strongly caution the subcommittee the study was not intended as a formal comparison of pain medications. Our main point of emphasis would be, rather, that OxyContin® clearly has a legitimate use in the treatment of pain in cancer

patients, and may – in certain cases – offer more favorable analgesia than other opiate medications.

The Media and OxyContin®.

About two-thirds of respondents agreed they followed most of the television and newspaper coverage of OxyContin®. About 30% agreed the coverage of OxyContin® was fair and balanced, but 27% disagreed and 43% were neutral or unsure. In contrast to this, however, 43% disagreed that the media adequately addressed the issue of cancer pain, while 16% agreed and 40% were neutral or unsure. Of greatest interest to the study investigators, however, we found no relationship between concerns about addiction and attention to media coverage.

These results show that although most of the cancer patients who responded to our study followed the media coverage of OxyContin®, it did not significantly increase their fears of addiction. Many cancer patients agree, however, that the recent newspaper and television media coverage of OxyContin® did not adequately address cancer pain. Based upon these observations, we suspect that cancer patients value the personal, experiential lessons of the cancer pain and their own experiences with opiate analgesia more than what they read, hear or view in the media. We also believe that this confirms that fear of addiction to OxyContin® or other opiate analgesics is a complex, multi-factorial phenomenon, rather than the result of intense media coverage [for a comprehensive discussion, see Weinmann BP; J. Legal Med., 2003].

Conclusion

The Subcommittee on Criminal Justice, Drug Policy and Human Resources has accepted the difficult task of preventing diversion and abuse of prescription medications, while preserving access to pain medications for patients with legitimate needs. Our survey of cancer patients in central Florida reaffirms that opiate analgesics, including OxyContin®, offer relief from cancer pain, in most cases more effectively than non-opiate analgesics. Although a great deal of media attention has focused on the addictive nature of opiates, particularly OxyContin®, cancer patients seem to base their opinions of opiate analgesia on their own experiences, a practical approach that reflects – at least in my opinion – a good bit of wisdom. Although the media effect upon our patients was relatively weak, and in spite of the clear benefits that they receive from opiate analgesia, some cancer patients continue to express concerns about addiction to OxyContin® and other pain medications. This suggests that concerns about addiction arise from many causes, including personal and societal attitudes about pain and analgesics, physicians’ values, attitudes and practices, and governmental policy regarding prescription drugs [see Weinmann, 2003].

In light of our patients’ views, we offer several guiding recommendations to the subcommittee regarding its approach to developing strategies to prevent prescription drug abuse and diversion. Because they legitimately need pain medications, we would discourage regulatory efforts that would reduce cancer patients’ access to opiate analgesics, including sustained-release oxycodone. In the past, some regulations have limited patients’ access to pain medications, including multi-copy prescription programs, laws that failed to define “inappropriate or excessive use” of opiates, and programs that

limited opiate dosages and/or dosing frequency without attention to tolerance and differences in pain perception [see Weinmann, 2003]. At the same time, we recognize our government's clear obligation to protect the lives of those who suffer due to the diversion and abuse of prescription analgesics, and we applaud this subcommittee's earnest efforts to develop regulatory mechanisms that would protect these people. We also remind those involved in this hearing that people who misuse prescription medications often suffer from underlying untreated psychiatric illnesses that influence their drug abuse. Successful solutions to the problem of diversion and abuse should take this phenomenon into account. Lastly, we would encourage the subcommittee to challenge medical professionals to help create new policy through frank discussions and the continued pursuit of clinical excellence in pain management for all patients with legitimate pain issues. In our experience, specialized education in pain management helps physicians to recognize and avoid diversion or misuse of prescription drugs. We encourage the development of strategies that emphasize this educational approach, such as House Resolution 1863, the National Pain Care Policy Act of 2003.

Although this subcommittee faces formidable challenges, I conclude my testimony on a positive note. When we mailed our surveys, we hoped that our patients would entrust their voice to us. They did so, embracing the belief that their views and concerns would reach your ears -- as they now have. Although you face a difficult task, we have chosen to face it together -- patients, physicians, pharmacists, politicians -- openly and with resolve to succeed. Because of this, I have renewed hope for a better future for all patients in pain.