

Summary/Conclusions

Arthur Lipman, PharmD

PLAINTIFF TRIAL
EXHIBIT
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**Empowering Us and Our Patients
to Improve Pain Management**

**Pain Management Speakers Training
Program for Nurses and Pharmacists**

St. Petersburg, Florida
March 4, 2000

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**We are appalled by the needless pain
that plagues the people of the world -
in rich and poor nations alike. By any
reasonable code, freedom from pain
should be a basic human right limited
only by our ability to achieve it.**

Liebeskind J, Melzack R. Pain 1987;30:1

Pharmaceutical Care

- ◆ Pain is the single most common reason that patients visit physicians, clinical facilities, and pharmacies
Lipman AG. J Pharm Care Pain Sympt Control 1993;1:1-3
- ◆ The responsible provision of drug therapy for the purpose of achieving definite outcomes that improve a patient's quality of life.
Hepler CD, Strand LM. Am J Hosp Pharm 1990;47:533-43

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Acute Pain Management

- ◆ Opioids are commonly used too infrequently and at insufficient doses
- ◆ Federal Clinical Practice Guideline. Acute Pain Management: Operative or Medical Procedures and Trauma

Agency for Health Care Policy and Research
www.AHCPR.gov/clinic

Chronic Malignant Pain Management

- ◆ Opioids are commonly used too infrequently and at insufficient doses
- ◆ Federal Clinical Practice Guideline. Management of Cancer Pain

Available from the National Cancer Institute
1-800 4 CANCER

Opioid Concerns

- ◆ physical dependence
- ◆ psychological dependence
- ◆ addiction
- ◆ tolerance
- ◆ CNS depression
 - respiration
 - cognition
- ◆ legal sanction risks

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Myth: Opioids Cause Addiction, Dependence and Tolerance

- ◆ These effects can occur
- ◆ They are rare in patients who have pain due to physiological causes
- ◆ They are seriously overestimated in American society and most of the world
- ◆ They should not be impediments to good analgesic therapy

Addiction

- compulsive use of a substance resulting in physical, psychological, or social harm to the user
and
- continued use despite of that harm
Rinaldi R et al. JAMA 1988;259:555-7.

Opioid Addiction

Addiction in the context of pain treatment with opioids is characterized by a consistent pattern of dysfunctional opioid use that may involve: adverse consequences associated with the use of opioids

- loss of control over the use of opioids
- preoccupation with obtaining opioids despite the presence of adequate analgesia

American Society of Addiction Medicine
Public Policy Statement, April, 1997

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**American Society of Addiction
Medicine Public Policy Statement**

“...Individuals who have severe, unrelieved pain may become intensely focused on finding relief for their pain. Sometimes, such patients may appear to observers to be preoccupied with obtaining opioids, but the preoccupation is with finding relief of pain, rather than using opioids, *per se*. This phenomenon has been termed ‘pseudoaddiction’...”

April, 1997

Pseudoaddiction

- ◆ appropriate drug seeking behavior
 - demanding doses before they are scheduled
 - viscous cycle of anger, isolation, and avoidance leading to complete distrust
- Weissman DE, Haddox DJ. Pain 1989;36:363-6
- ◆ increase the opioid dose by 50%
 - assure that breakthrough doses are available
 - ◆ complaints resolve when analgesia is established

Prevalence of Iatrogenic Addiction

- ◆ Porter J, Jick H. Addiction rare in patients treated with narcotics. NEJM (letter) 1980;302:123.
4 of 11,882 0.03%
- ◆ Perry S, Heidrich G. Management of pain during debridement:
a survey of U.S. pain units. Pain 1982;13:267-80.
0 of >10,000 0%
- ◆ Medina JL, Diamond S. Drug-dependency in patients with chronic headache. Headache 1977;17:12-14.
3 of 2,369 0.12%

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Pharmacological/Physiological Dependence

A physiological phenomenon characterized by:

- ◆ abstinence syndrome upon
 - abrupt discontinuation
 - substantial dose reduction
 - administration of an antagonist
- ◆ Rinaldi R et al. JAMA 1988;259:555-7
- ◆ occurs with steroids and many other drugs
 - nearly universal with regularly scheduled opioids

Myth: Tolerance to Opioids Occurs Predictably

- ◆ Clinicians and patients commonly believe that ever increasing doses of opioid are needed to maintain analgesia
- ◆ It may take several days to titrate a patients to the opioid dose needed to provide comfort
- ◆ Once an effective dose is found, dose increases are rarely needed unless pathology increases or another variable occurs

Distinct Types of Opioid Tolerance

- ◆ Tolerance to Analgesia
 - may occur in first days to weeks of therapy; rare after pain relief achieved with consistent dosing without increasing or new pathology.
- ◆ Tolerance to Respiratory Depression and Sedation
 - occurs predictably after 5-7 days of consistent opioid administration
- ◆ Tolerance to Constipation
 - does not occur; scheduled stimulating laxatives are indicated with regularly scheduled opioids

Lipman AG, Jackson KC. Opioid. In Warfield C and Bajwa Z, eds. Principles and Practice of Pain Management, McGraw-Hill, 2000

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Pseudotolerance

- ◆ progressive disease
- ◆ new pathology
- ◆ excessive activity
- ◆ noncompliance
- ◆ drug interaction
- ◆ drug diversion
- ◆ addiction

Pappagallo M. J Pharm Care Pain Sympt Control 1998; 6(2):95-98

Myth: If Used Early in Progressive Disease, Opioids May Work Later

- ◆ There is no ceiling effect for mu opioids
Doses can be increased over a large range
- ◆ Tolerance to analgesia is rare
- ◆ Failure to treat pain may result in adverse sequelae of undertreated pain
- ◆ Treat pain whenever it occurs in the course of the disease

Myth: Opioids Always Depress Respiration

- ◆ Acutely, opioids can be profound respiratory depressants
opioid-naïve patients
- ◆ After 5-7 days of continuous opioids, patients predictably become tolerant to respiratory effects
opioid-tolerant patients
- ◆ pain is a powerful analeptic in awake patients

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Myth: Patients in Pain Don't Skip Analgesic Doses

- ◆ Once pain is controlled for a few days, patient often try to skip doses of short acting opioids
 - fear of adverse drug effects
 - family and friends who fear drug effects
- ◆ Long term compliance is greatly aided with less frequent dosing

Myth: Patients Taking Opioids Cannot Drive Safely

- ◆ Opioids impair cognition and psychomotor coordination initially
 - patients should not drive for 5-7 days after starting opioids or a dose increase
 - ◆ After 5-7 days of continuous opioids, tolerance to these effects develops
 - studies show no increase in MVA in patient taking chronic opioids
- Vainio A et al. Lancet 1995;346:667-70

Myth: Opioids Cause End Organ Toxicity

- ◆ Respiratory and CNS toxicity have occurred with high opioid doses in opioid-naïve patients
- ◆ Long term opioid therapy does not produce reported end-organ toxicity in patients who are titrated to response and monitored correctly
 - Long term NSAIDs may cause GI and renal toxicity
 - High acetaminophen doses can cause hepatotoxicity


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**Report of the Institute of Medicine
Committee on Care at the End of Life**



Field MJ, Cassel CK, Editors
 Division of Health Care Services
 Institute of Medicine
 National Academy of Sciences

National Academy Press
 Washington DC
 1997

**Institute of Medicine Committee for
Care at the End-of-Life Conclusions**

Emphasis on high-tech cures has caused us to neglect pain management and palliative care for the dying. In trying so hard to save lives, we have become less skilled at helping people as they approach death.

More medical training in palliative care is necessary

- Changes are needed in laws regulating prescription narcotics and in our attitudes toward narcotic use for pain control.
- One attitude that especially needs changing is our unreasonable fear about addiction at life's end.

Cassel C, Field M, editors. Approaching Death: Improving Care at the End of Life. National Academy Press, 1997

Why Patients Seek to End their Lives

- ◆ pain and other physical symptoms
- ◆ depression
 - loneliness
 - sense of desolation and desertion
- ◆ not wanting to be a burden
 - fear of draining family resources
- ◆ existential issues
 - concern about the value of remaining life

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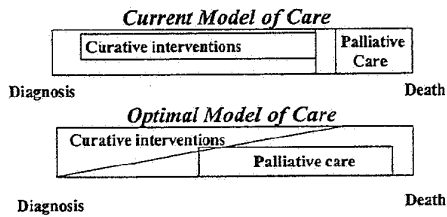
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**World Health Organization
Definition of Palliative Care**

Active total care of patients whose disease is not responsive to curative treatment. Control of pain, of other symptoms, of psychological, social and spiritual problem is paramount. The goal of palliative care is the achievement of the best quality of life for patients and their families.

Initiation of Palliative Care



Adapted from Cancer Pain and Palliative Care. W.H.O., 1990.

Curative v. Palliative Care

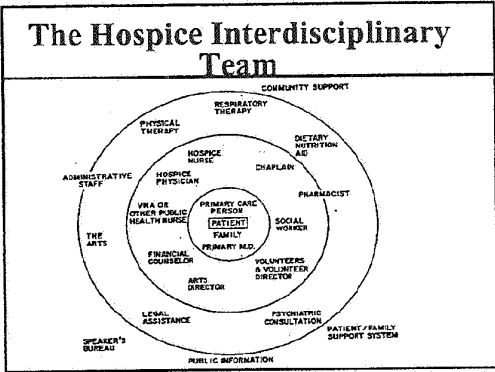
- ◆ Cure is the goal
- ◆ Analytical and rationalistic
- ◆ Based on diagnoses
- ◆ Scientific and biomedical
- ◆ Aimed at disease process
- ◆ Views patients as parts
- ◆ Based on "hard" sciences
- ◆ Impersonal care
- ◆ Hierarchical
- ◆ Death is seen as failure
- ◆ Symptom control is the goal
- ◆ Subjective
- ◆ Based on symptoms
- ◆ Humanistic and interpersonal
- ◆ Aimed at comfort
- ◆ Views patient as a whole
- ◆ Based on "soft" social sciences
- ◆ Individualized care
- ◆ Interdisciplinary
- ◆ Death is accepted as normal

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- ### Common Symptoms in Palliative Care Requiring Drug Therapy
- ◆ pain
 - ◆ weakness
 - ◆ nausea/vomiting
 - ◆ anorexia
 - ◆ constipation
 - ◆ anxiety
 - ◆ depression
 - ◆ insomnia
 - ◆ dyspnea

- ### Pharmacists' Roles in Palliative Care
- ◆ assure availability of needed drugs
 - maintain inventories
 - compound needed dosage forms
 - dispense appropriate quantities
 - oppose regulatory barriers
 - ◆ monitor patients' drug therapy outcomes
 - ◆ take detailed patient medication histories
 - ◆ provide patient and professional education
 - ◆ participate in interdisciplinary care teams
 - ◆ provide volunteer and community education

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We all must die!

But that I can save (a person) from days of torture, that is what I feel is my great and ever new privilege.

Pain is an even more terrible lord of mankind than death itself.

Albert Schweitzer

Interdisciplinary Pain Team

- ◆ **Physicians**
 - anesthesiologists psychiatrists
 - physiatrists neurologists
- ◆ **Mental Health Professionals**
 - psychologists - behavioral medicine
 - social workers
 - psychologists
- ◆ **Nurses**
 - patient educators case managers

Interdisciplinary Pain Team

- ◆ **Rehabilitation Professionals**
 - physical therapists occupational therapists
 - vocational counselors recreational therapists
 - drug therapy managers
- ◆ **Pharmacists**
 - detoxification
 - pharmaceutical care plans
 - patient education
 - drug information resource

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Barriers to Pain Management

- ◆ Attitudes
 - no one every died from pain
 - patients will tell me if they hurt
- ◆ Knowledge
 - opioid doses and pharmacokinetics
 - risk:benefit ratio of using analgesics appropriately
- ◆ Practices
 - discouraging opioid use
 - avoiding patients who seek opioids
 - using nonopioids in favor of opioids

Barriers to Pain Management

- ◆ Health Care Providers
 - fear of addiction, tolerance and respiratory depression
 - fear of regulatory sanctions
- ◆ Patients
 - fear of addiction and adverse effects
 - concern that drugs should be saved until needed
- ◆ The Health Care System
 - multiple copy prescription forms
 - overly zealous regulators
 - the "just say no" mentality

Overcoming the Barriers

- ◆ Get involved! *Gain Knowledge-Change practices*
 - State cancer pain initiatives
 - Local Unit/Division of the American Cancer Society
 - Assure that your alma mater teaches pain well
 - Involve your professional societies
 - » APhA, ASHP, ASCP, ANA, ONS, AHPN; local affiliates
 - Join a pain society
 - » American Pain Society 847 375-4715
 - » International Association for the Study of Pain 206 547-6409
 - Read the pain-related literature

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Some Published Pain Management Guidelines and Statements

- ◆ AHCPR Acute Pain Guideline 1992
 - ◆ AHCPR Cancer Pain Guideline 1994
 - ◆ ASA Cancer Pain Guidelines 1996
 - ◆ AAPM-APS Opioids in Chronic Pain 1997
 - ◆ ASAM Public Policy Statement 1997
 - ◆ AGS Chronic Elderly Pain Guidelines 1998
 - ◆ Federation of State Medical Boards 1998
 - ◆ APS Acute and Cancer Principles 1997
 - ◆ APS Sickle Cell Pain Guidelines 1999
 - ◆ APS RA and OA Pain Guidelines 2000
- www.ampainsoc.org

Refute Myths About Opioids

- ◆ Addiction is exquisitely rare
Don't confuse pain patients with opioid addicts
- ◆ Dependence is nearly universal
Not a problem, drugs can be tapered over ~7 days
- ◆ End organ damage very rare with chronic use
- ◆ Tolerance to analgesia is not common
- ◆ Opioids do not produce functional deterioration



All this needless pain and suffering impoverishes the quality of life of those afflicted and their families; it may even shorten life by impairing recovery from surgery or disease. People suffering severe or unrelenting pain become depressed. They may lose their will to live and fail to take normal health preserving measures; some commit suicide.

Liebeskind J, Melzack R. Pain 1987;30:1

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