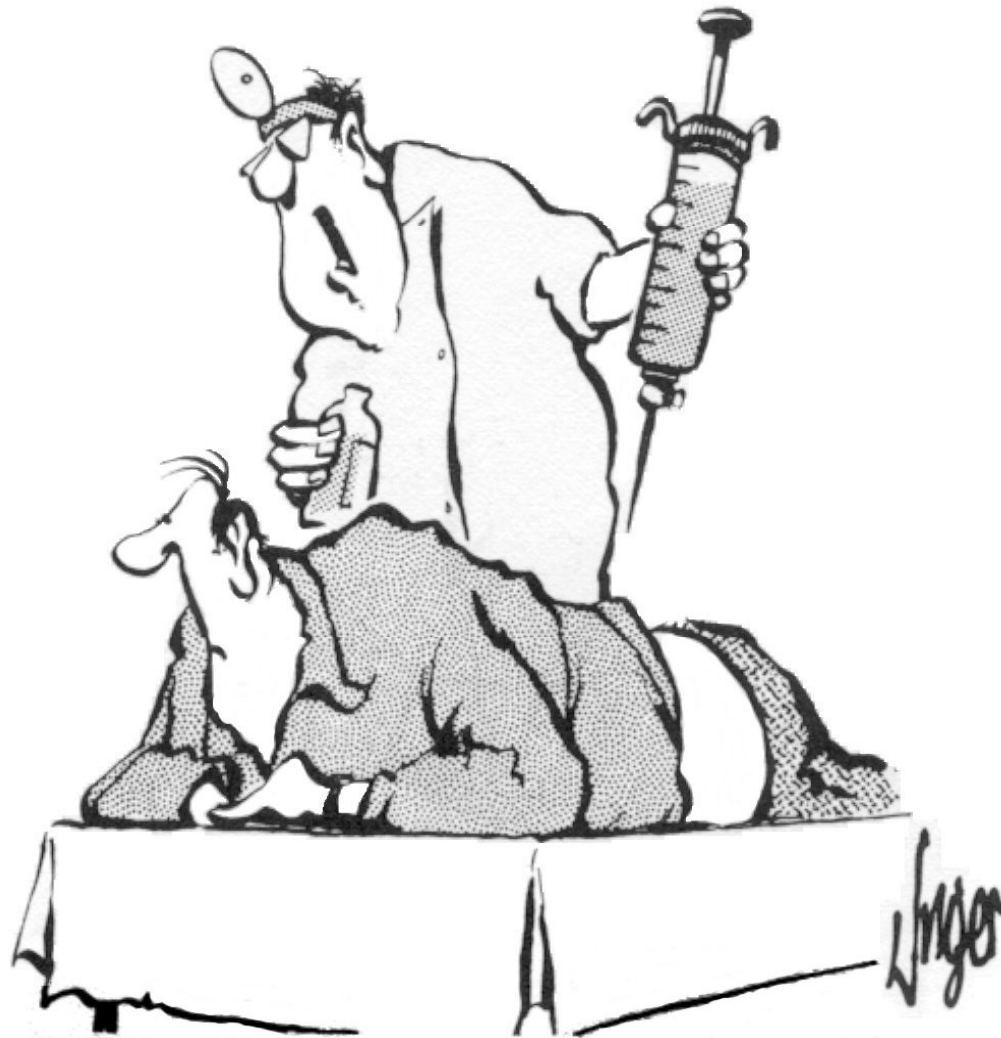




Opioids: Slippery Slope in the Management of Non-Malignant Chronic Pain



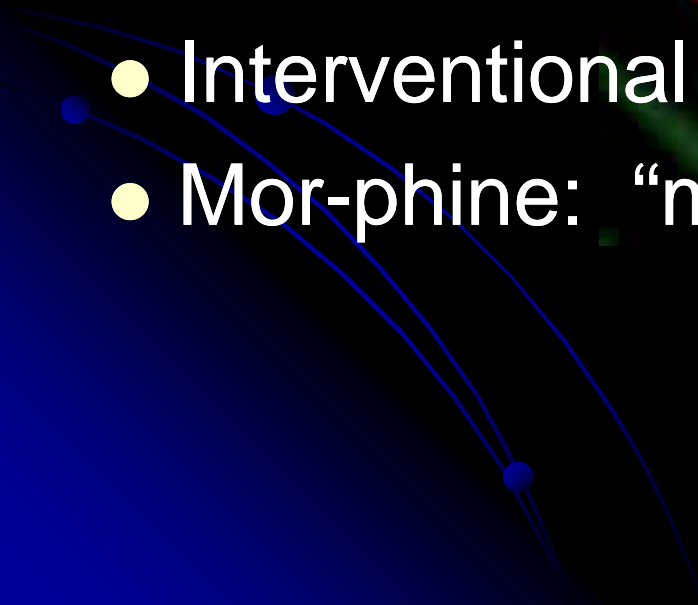
Michael Gofeld MD
Center for Pain Relief
University of Washington
Seattle, WA



"I'll give you something to ease the pain."

DISCLOSURE:



- No pharma stocks, agreements or grants
 - Member of initiative group WSORI (Washington State Opioid Reduction Initiative)
 - Interventional physician: oxymoron ?
 - Mor-phine: “more fun” or “mort + fin”
- 

Road Blocks in Chronic Opioid Therapy



Opioids – Why Not?

- Society perspective:
 - efficacy
 - potential for addiction
 - morbidity and mortality
- Doctors' perspective:
 - limited evidence
 - medicolegal issues
 - additional and unnecessary workload



Ideal patient: “Doctor, since I’ve been taking these pinkish pills I feel great!!!”

Lack of Efficacy



- 15 randomized placebo controlled trials
- 11/15 po meds, 1-8 weeks trial, 6-24 mos. Open label f/u; Mean reduction pain 30%

Conclusions:

- Short-term efficacy good for musculoskeletal and neuropathic pain
- Inconclusive regarding long term efficacy, tolerance, addiction

Kalso E et al. Opioids in chronic non-cancer pain: Systemic review of efficacy and safety. *Pain* 2004;112:372-80.

Efficacy and Safety of Opioid Agonists in the Treatment of Neuropathic Pain of Nonmalignant Origin

Systematic Review and Meta-analysis
of Randomized Controlled Trials

Elon Eisenberg, MD

Ewan D. McNicol, RPh

Daniel B. Carr, MD

JAMA 2005;293:3043-52

- Intermediate-term studies (up to 8 weeks) demonstrate significant efficacy of opioids over placebo for neuropathic pain.
- No evidence of long-term efficacy
- No change in QoL

Opioids and Disability

- Odds of chronic work loss were 11-14 times greater for claimants with opioid prescriptions of any type [compared with reference group]
- Costs of claimants with schedule II opioids averaged \$19,453 higher than reference group
- Opioid therapy did not arrest the cycle of work loss and pain

Volinn E, Fargo JD, Fine PG. Opioid therapy for nonspecific low back pain and the outcome of chronic work loss. Pain 2009; 142:194-201.



Pain 125 (2006) 172–179

PAIN

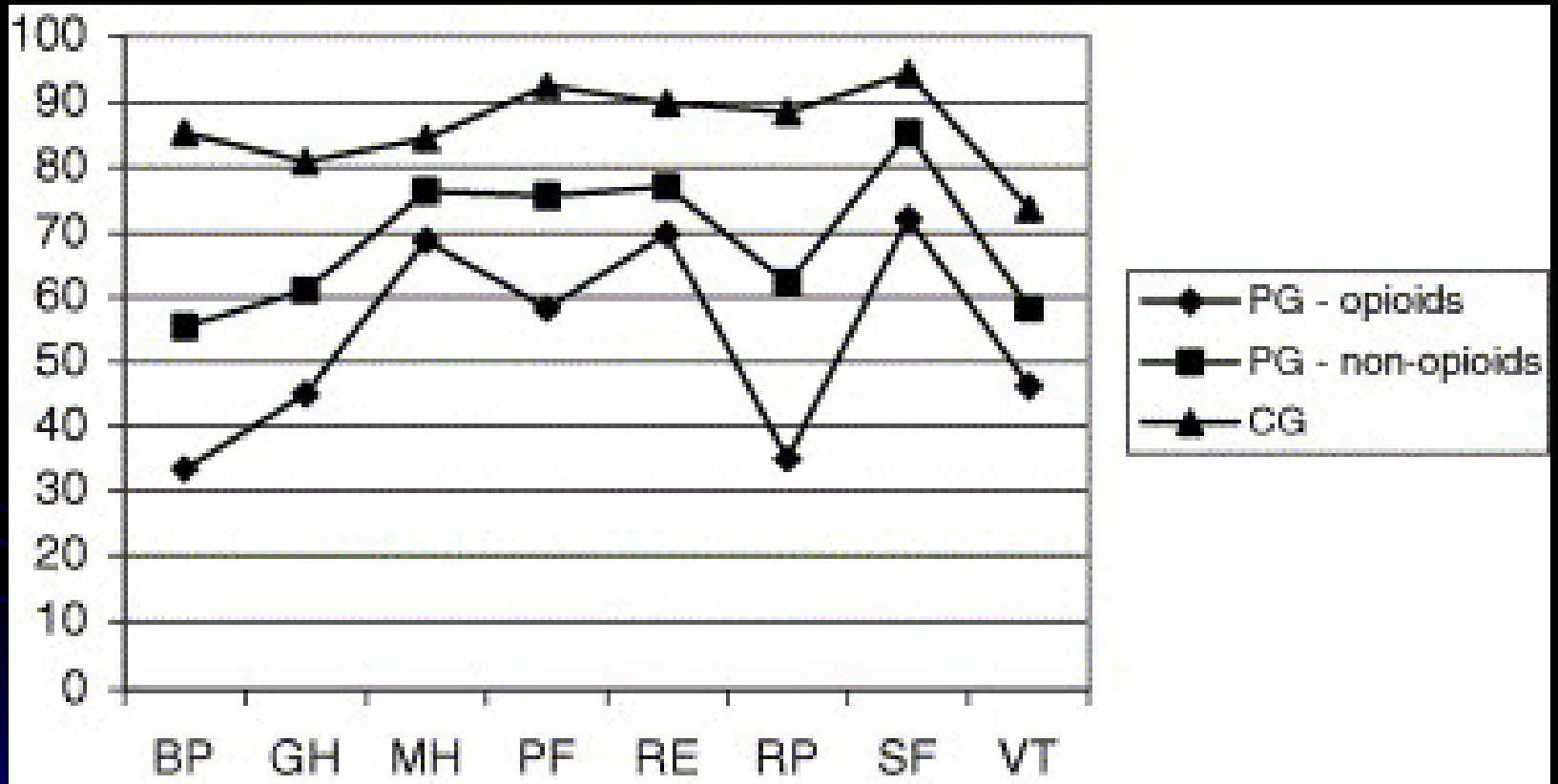
www.elsevier.com/locate/pain

Critical issues on opioids in chronic non-cancer pain:
An epidemiological study

Jørgen Eriksen ^a, Per Sjøgren ^{a,*}, Eduardo Bruera ^b, Ola Ekholm ^c, Niels K. Rasmussen ^c

“...opioid treatment of chronic non-cancer pain does not seem to fulfill any of the key outcome goals: pain relief, improved quality of life and improved functional capacity.

One can argue that these outcomes would have been even poorer without opioids, but another plausible explanation may be that opioids are not very helpful or even deleterious in the long-run...”





Pain 125 (2006) 3–4

PAIN

www.elsevier.com/locate/pain

Editorial

Opioids for chronic pain: Taking stock

... The Eriksen study provides compelling evidence that opioids are not a panacea for chronic pain.

JC Ballantyne

Systematic Review: Opioid Treatment for Chronic Back Pain: Prevalence, Efficacy, and Association with Addiction

Bridget A. Martell, MD, MA; Patrick G. O'Connor, MD, MPH; Robert D. Kems, PhD; William C. Becker, MD; Knashawn H. Morales, ScD; Thomas R. Kosten, MD; and David A. Fiellin, MD

Ann Intern Med. 2007;146:116-127.

- Meta-analysis of the 4 studies assessing the efficacy of opioids compared with placebo or a nonopioid control did not show reduced pain with opioids
- the estimates of the prevalence of current substance use disorders were as high as 43%. Aberrant medication-taking behaviors ranged from 5% to 24%.

Addiction

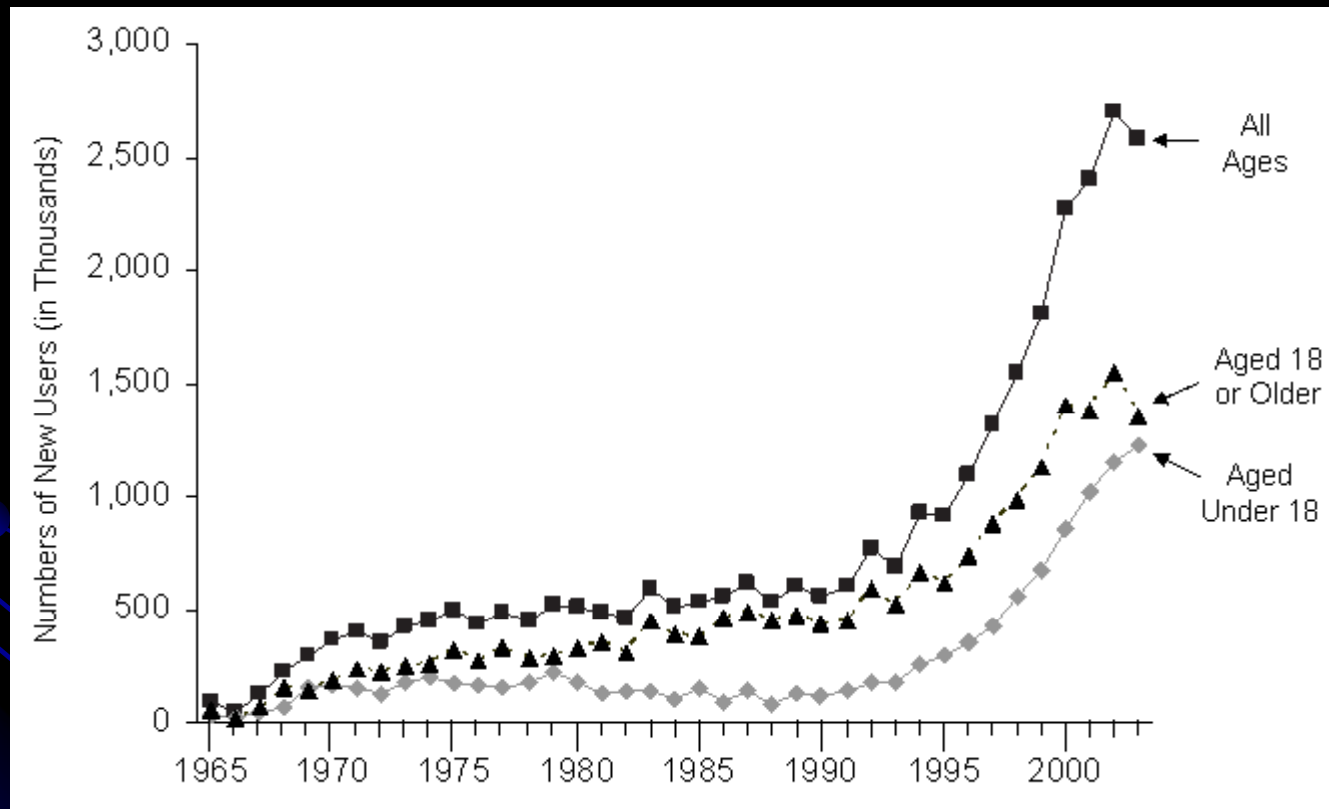


What is the Risk of Medication Misuse?

- 7% of population uses/abuses illegal drugs¹
- Random surveillance urine tox n=400 patients in KY pain practice²:
 - 17% + screen (Comm. Ins)
 - 10% + screen (Medicare)
 - 39% + screen (Medicaid)
- Random surveillance urine tox n = 470 BWH Pain Clinic³:
 - 45% abnormal screen
 - 22% showed illegal drug (14% cannabis, 7% cocaine)
 - 14% showed prescription drug (not prescribed)
 - 10% missing drugs

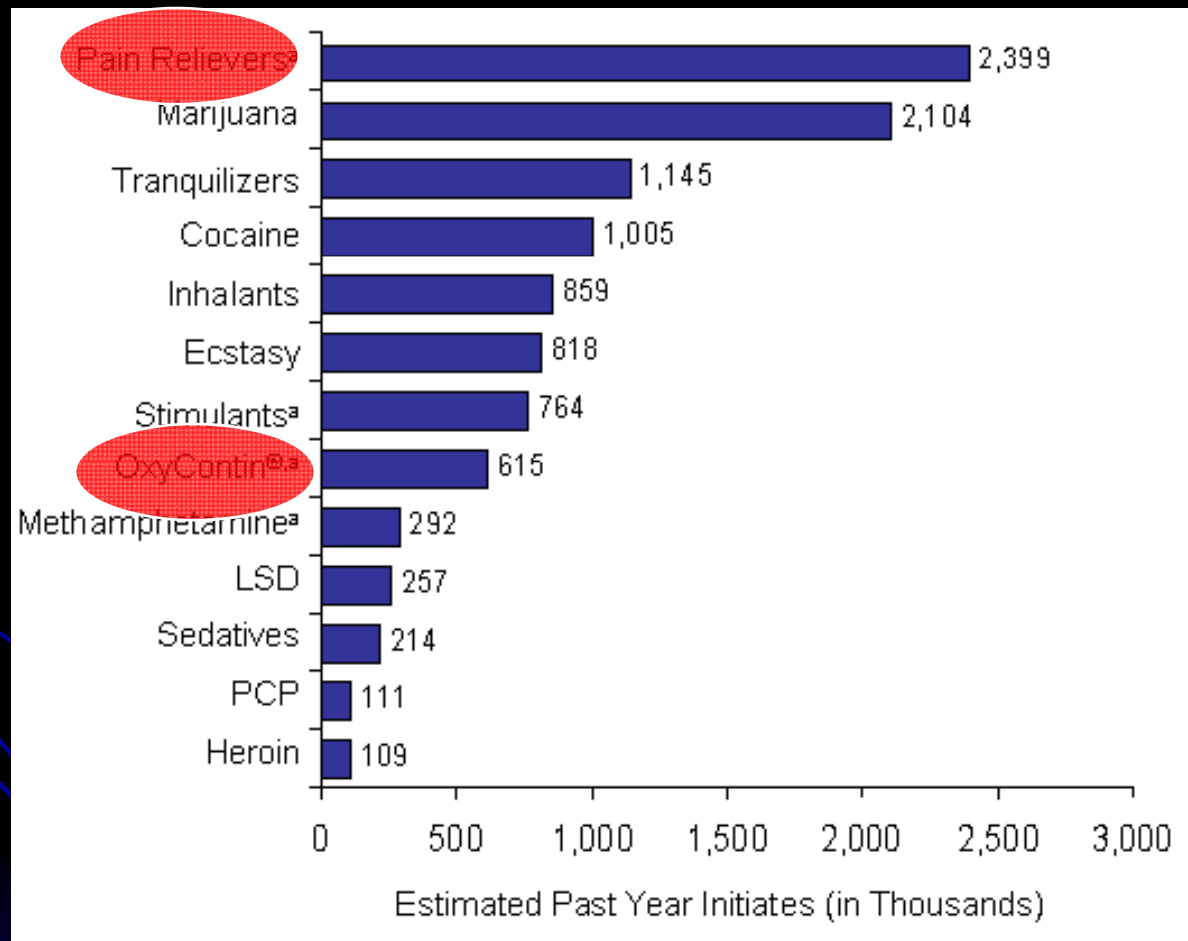
1. Lussier D, Pappagallo M. The Neurologist 2004;10:221-4
2. Manchakanti L, et al. J Ky Med Assoc 2005;103(2):55-62
3. Michna E, et al. Clin J Pain 2007

Annual Numbers of New Nonmedical Users of Pain Relievers, by Age at Initiation: 1965-2003



Source: SAMHSA, Office of Applied Studies, National Survey on Drug Use and Health, 2002, 2003, and 2004.

Initiates of Illicit Drug Use, by Drug: Annual Averages Based on 2002- 2004



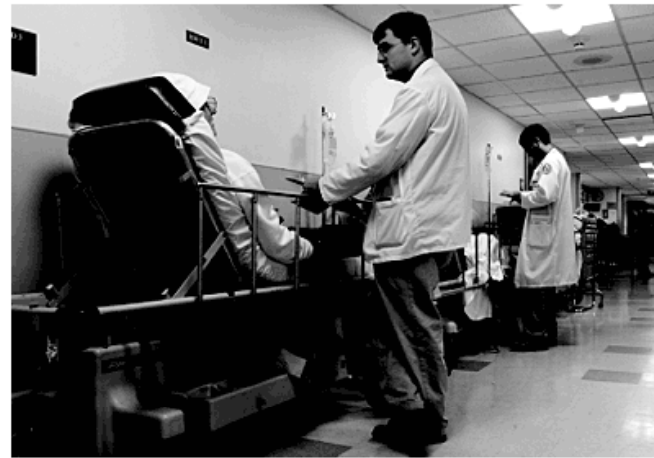
Source: SAMHSA, Office of Applied Studies, National Survey on Drug Use and Health, 2002, 2003, and 2004.

Where do they get prescription opiates?

- 56% get free from friend or family member
 - 19% from a doctor
 - 9% bought them from friend or family
 - 4% from a drug dealer
 - 0.1% purchasing them from the internet
- Punch line - 84% got drugs from US**

Top emergency-room users

Low-income Washington residents covered by Medicaid are visiting hospital emergency rooms more often. The vast majority seek treatment once or twice a year. But the state says nearly 2,400 Medicaid patients went to the emergency room a dozen or more times last year. And a small group of patients sought ER care far more often than that.



TOM REESE / THE SEATTLE TIMES

Top Medicaid emergency-room patients in 2003*

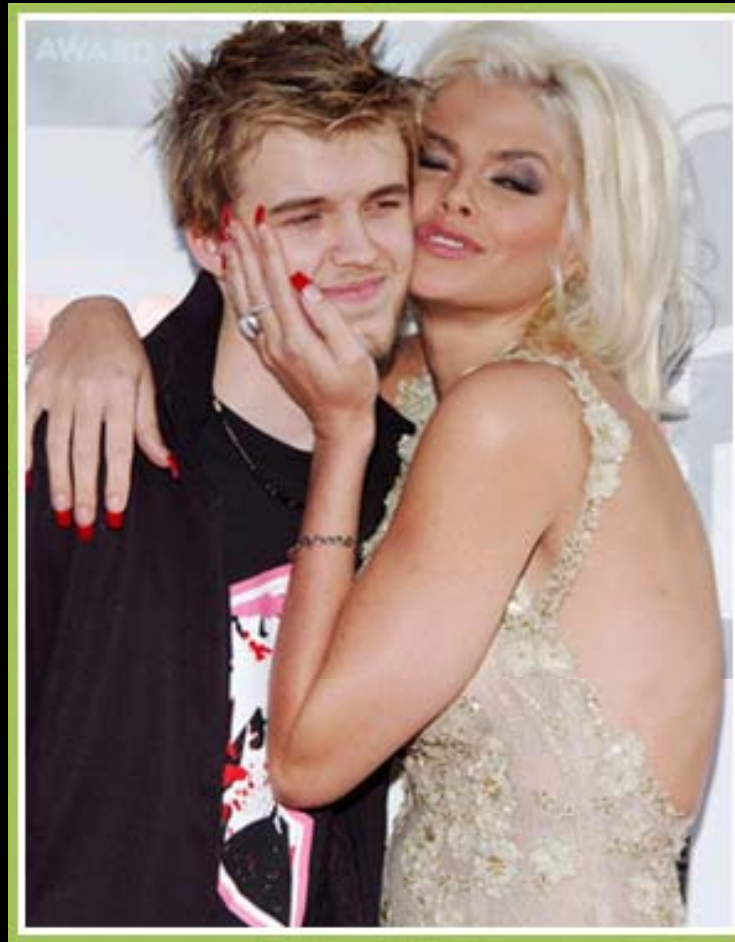
Rank (by number of ER visits)	Patient, county	Number of ER visits Number of hospitals Number of prescriptions	ER costs	Prescription costs	Most common complaints/number
1.	47-year-old female: Snohomish	131 29 164	\$21,461	\$7,097	Headache 43 Backache 34 Migraine 13
2.	27-year-old, female: King	127 12 207	\$29,667	\$6,648	Abdominal pain 32 Sprain, lumbar region 18 Dental disorder 11
3.	57-year-old, male Thurston	126 59 181	\$22,684	\$8,691	Backache 34 Sciatica (leg pain) 16 Contusion of upper limb 9
4.	43-year-old, male: Thurston	122 28 214	\$35,833	\$4,264	Contusion of chest wall 27 Painful respiration 22 Swollen testicle and epididymis 21
5.	46-year-old, female: Spokane	119 5 392	\$27,575	\$18,154	Abdominal pain 36 Urinary-tract infection 9 Depressive disorder 9
6.	27-year-old, female: Pierce	117 32 165	\$44,380	\$1,919	Dislocated elbow 23 Sprained elbow/forearm 11 Migraine 10
7.	50-year-old, male: Snohomish	117 1 101	\$11,519	\$1,150	Abdominal pain 38 Abdominal pain in left upper side 17 Headache 7
8.	42-year-old, female: Snohomish	114 5 208	\$36,951	\$4,457	Abdominal pain 48 Headache 11 Migraine 6
9.	43-year-old, female: Yakima	112 9 40	\$9,007	\$676	Shoulder joint pain 30 Backache 13 Back sprain 9
10.	47-year-old, male: Grant	106 28 32	\$174,156	\$1,005	Heart failure 64 Chest pain 15 Painful respiration 7

* Does not include patients covered under Medicaid's HMO plan called Healthy Options

2006 Healthy Youth Survey

In Past 30 Days:	10 th Grade	12 th Grade
Used a pain killer to get high , like Vicodin, Oxycontin or Percocet?	10%	12%
Smoked cigarettes?	15%	20%

Opioid Related Deaths



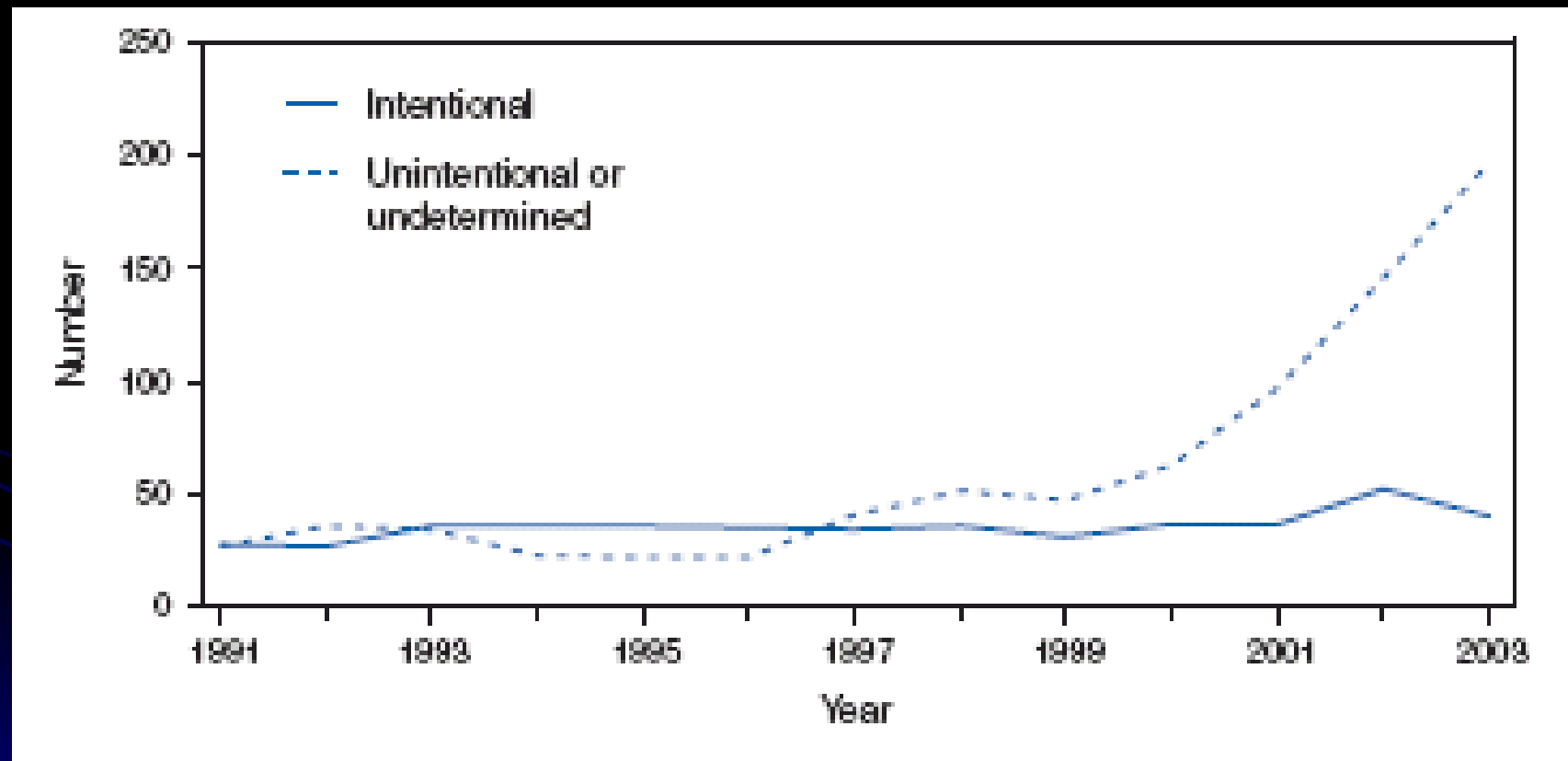
“Mortality from opioid analgesics must not be ignored”

- “Concern for mortality more important than concern about addiction”
- CDC data “opioid analgesic poisoning” n = 5528 (2002 data)
- Mortality must enter into risk/benefit discussions about chronic opioid therapy

Methadone and FDA Box Warning

- 1999-2004 Methadone related deaths 786 > 3849 (390% increase)*
- All poisoning deaths up 54% over same period.*
- SAMHSA 2004 consensus report > increase in deaths related to pain prescribing

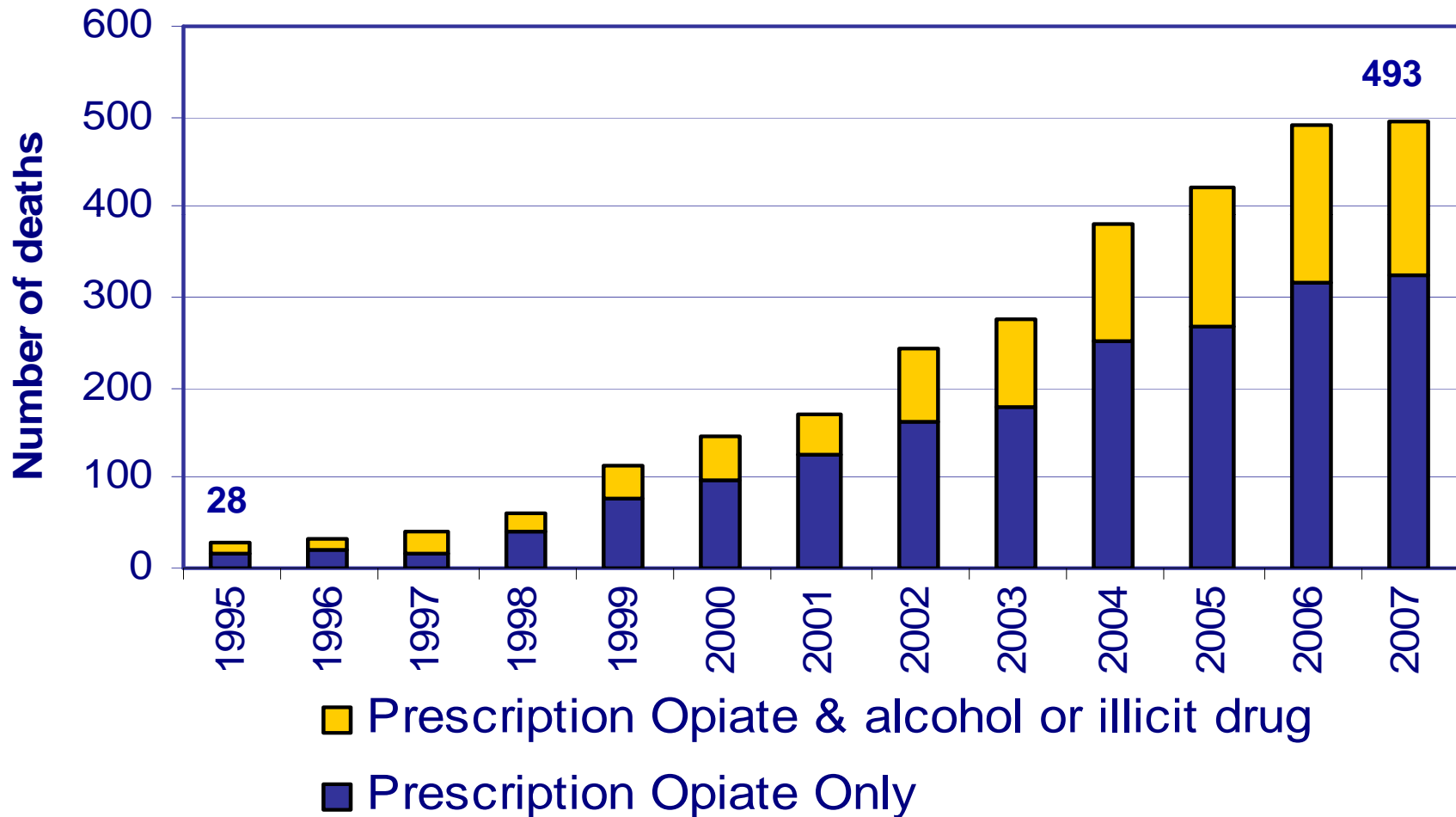
UT: Number of Non-Illicit Drug-Poisoning Deaths, by Intent & Year (1991-2003)



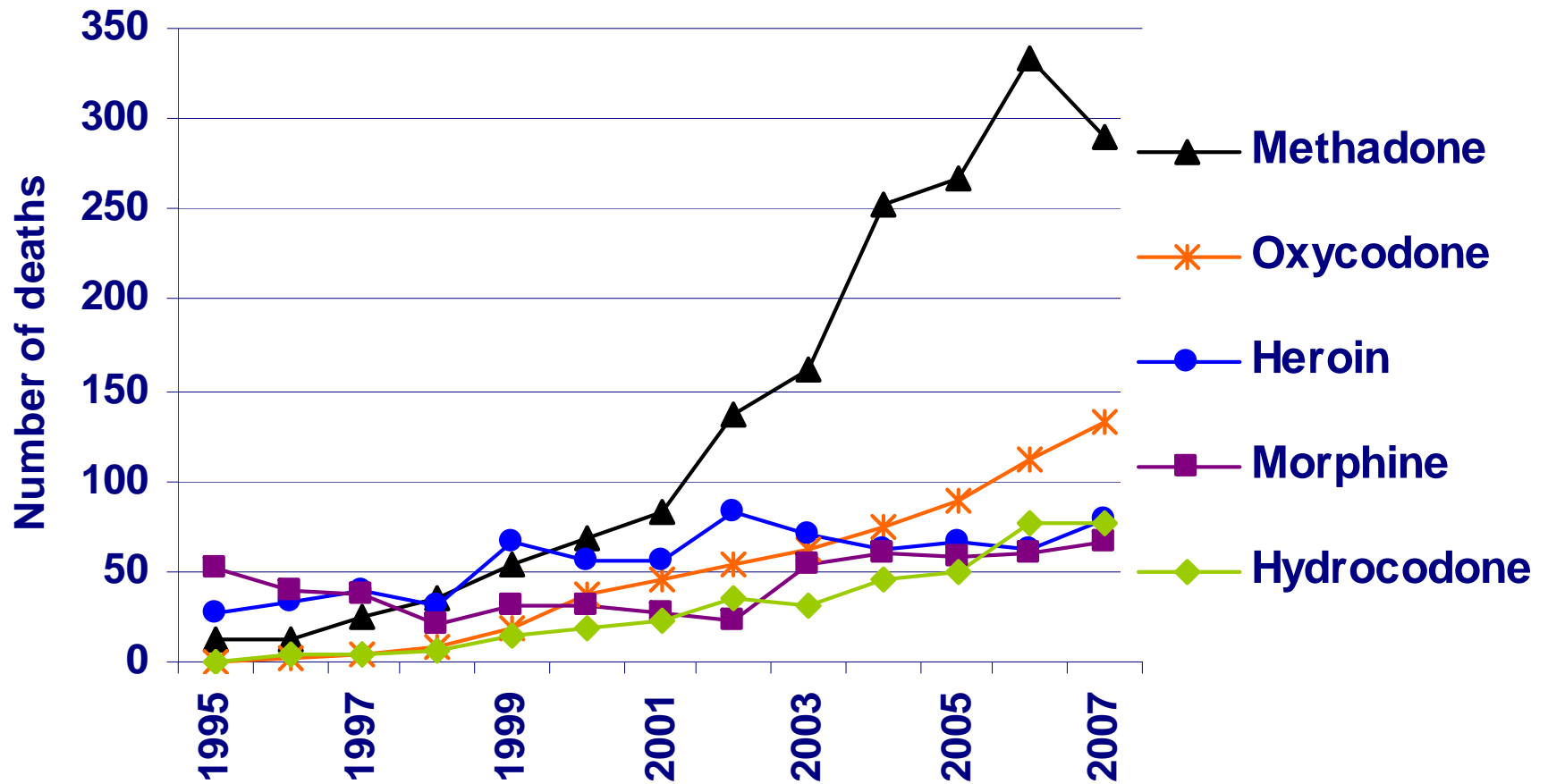
Source: EM Caravati, T Grey, B Nangle, RT Rolfs, CA Peterson-Porucznik. Increase in Poisoning Deaths Caused by Non-Illicit Drugs — Utah, 1991-2003.

<http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5402a1.htm>

Prescription Opiate Deaths Washington 1995-2007



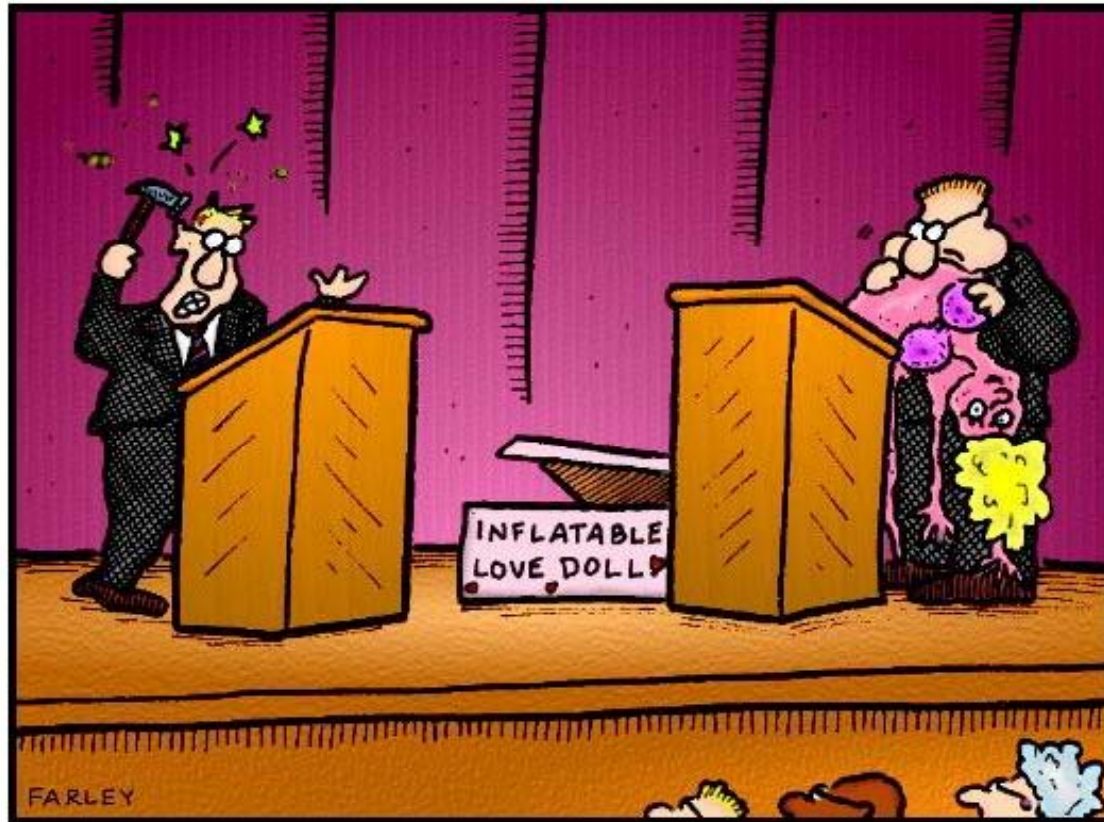
Trends for Specific Opiates Washington 1995-2007



Should WE Prescribe?

DOCTOR FUN

02-11-94



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dgfl@midway.uchicago.edu
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At the Pain Versus Pleasure Debates

Evidence

Current level of evidence of efficacy and safety of opioids for nonmalignant pain should be defined as indeterminate

Recent literature does not support opioid therapy, especially for a long-term administration



Medicolegal Issues



- Are we (doctors) exposed to potential lawsuits (iatrogenic addiction, opioid-related death, dementia, impotence)?
- Are we (doctors) fully protected by our insurers in view of the newest data questioning efficacy and safety of chronic opioid administration?



Opioids and Law

- A survey of prosecutors in four states found that many would recommend a police investigation when given a scenario of a patient with nonmalignant pain treated with opioids

Ziegler SJ et al. J Law, Med Ethics 2003

- In several high-profile prosecutions of physicians for prescribing opioids, prosecutors claimed that the doctors should have known the individuals were feigning pain solely to obtain the prescriptions

Jung, Reidenberg. Pain Medicine 2007

Additional Practice Burden

If we take the prescribing business seriously we need:

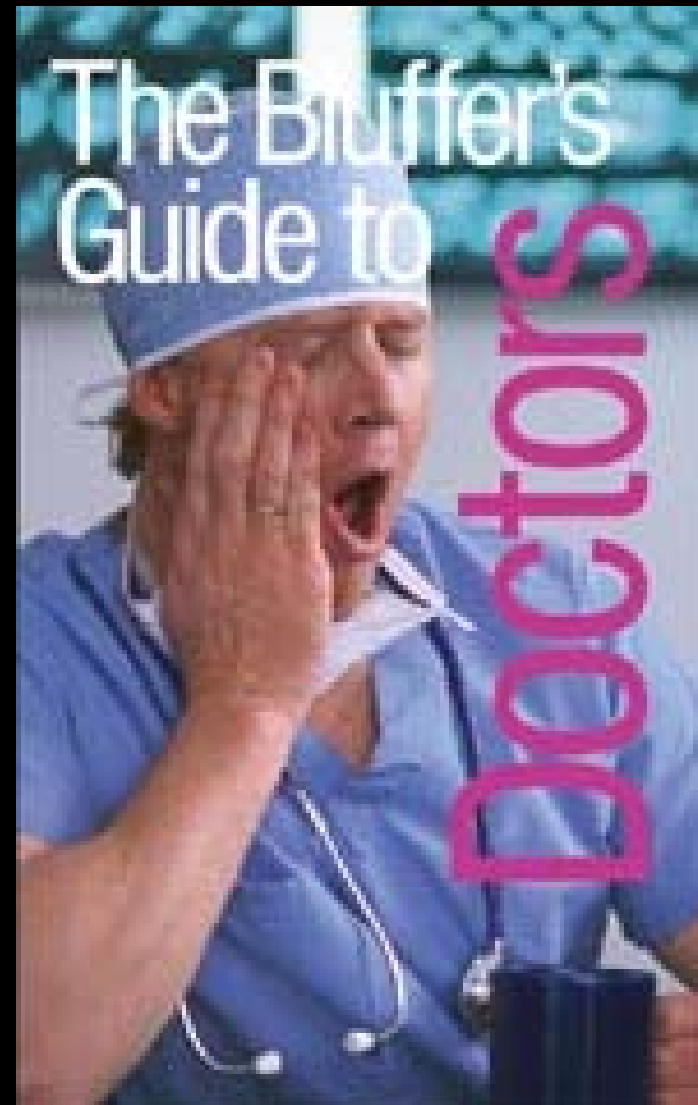
1. Adhere to National and Institutional Policies for prescribing controlled substances
2. Sign Treatment Agreement with a patient
3. Initiate so called “opioid trial”
4. Monitor 4-6 A’s
5. Order random UDT
6. Deal with ‘problematic patients’ (MMTP, stolen prescriptions, abusive personalities)

Who's Supposed to be the Guard?



“The doctor ... is expected to examine, diagnose and treat more patients per hour than the average person serving in McDonald's. At the end of eight hours of this you feel like walking into moving traffic”

By Patrick Keating



Usually chronic opioid management is initiated in a solo-practice, although “when a patient is managed by a multidisciplinary team, the compliance is better and risk of loss of control and complications are less than when a single doctor is managing the patient”.



Breivik H. Opioids in chronic non-cancer pain, indications and controversies. *Eur J Pain* 2005;9:127-30.

Conclusion

- Though long-term opioid therapy can be a valuable option for selected patients in a specific setting of multidisciplinary pain management, their routine administration should be discouraged
- Practice of amateur prescribing should be discontinued until firm evidence of efficacy and safety is established for the long-term use



Kill Poppy-Bill 2