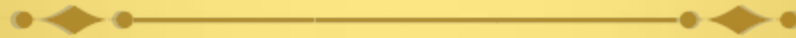


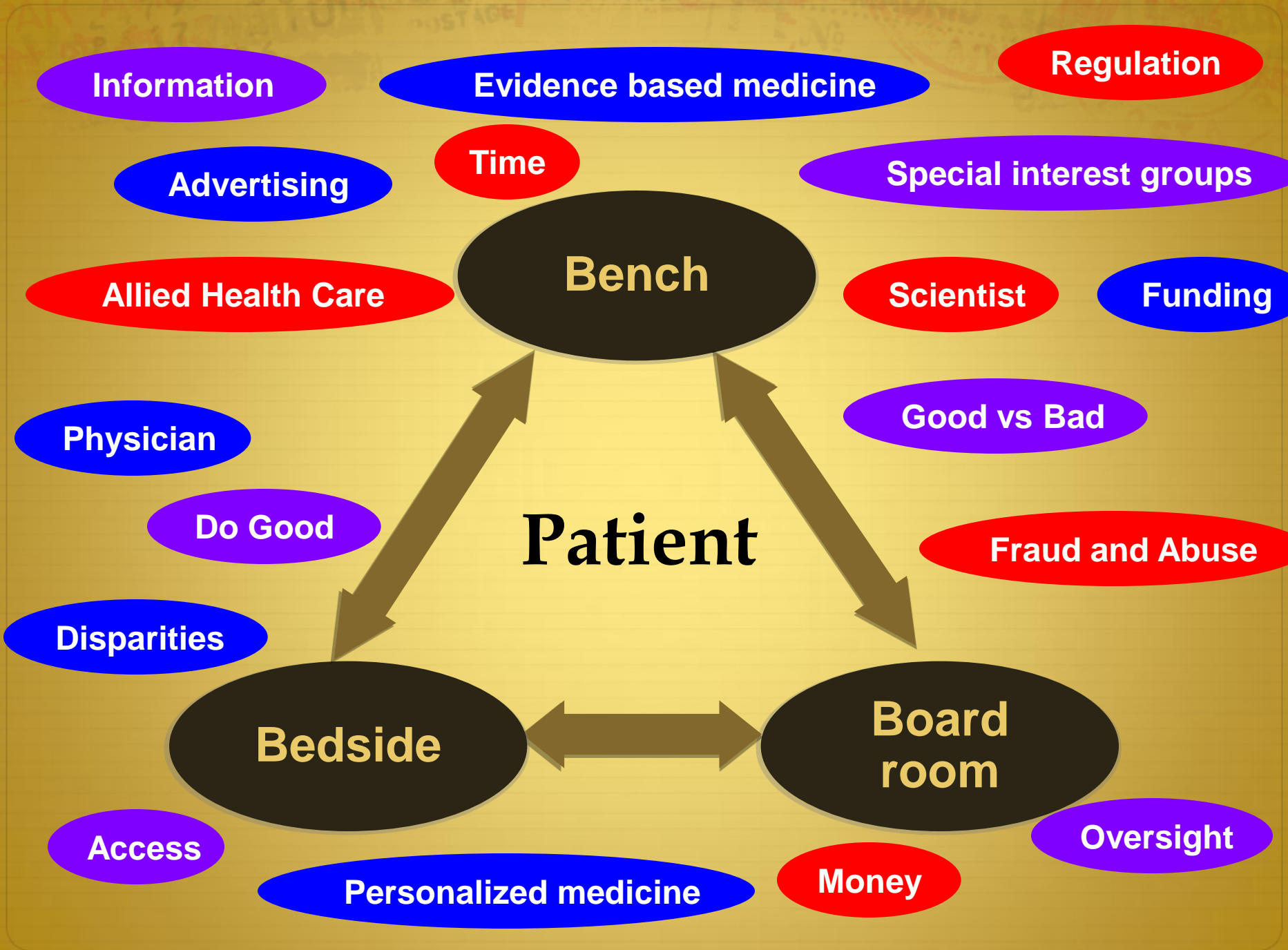




1945

Ideas





Information

Evidence based medicine

Regulation

Advertising

Time

Special interest groups

Allied Health Care

Bench

Scientist

Funding

Physician

Good vs Bad

Do Good

Fraud and Abuse

Disparities

Patient

Bedside

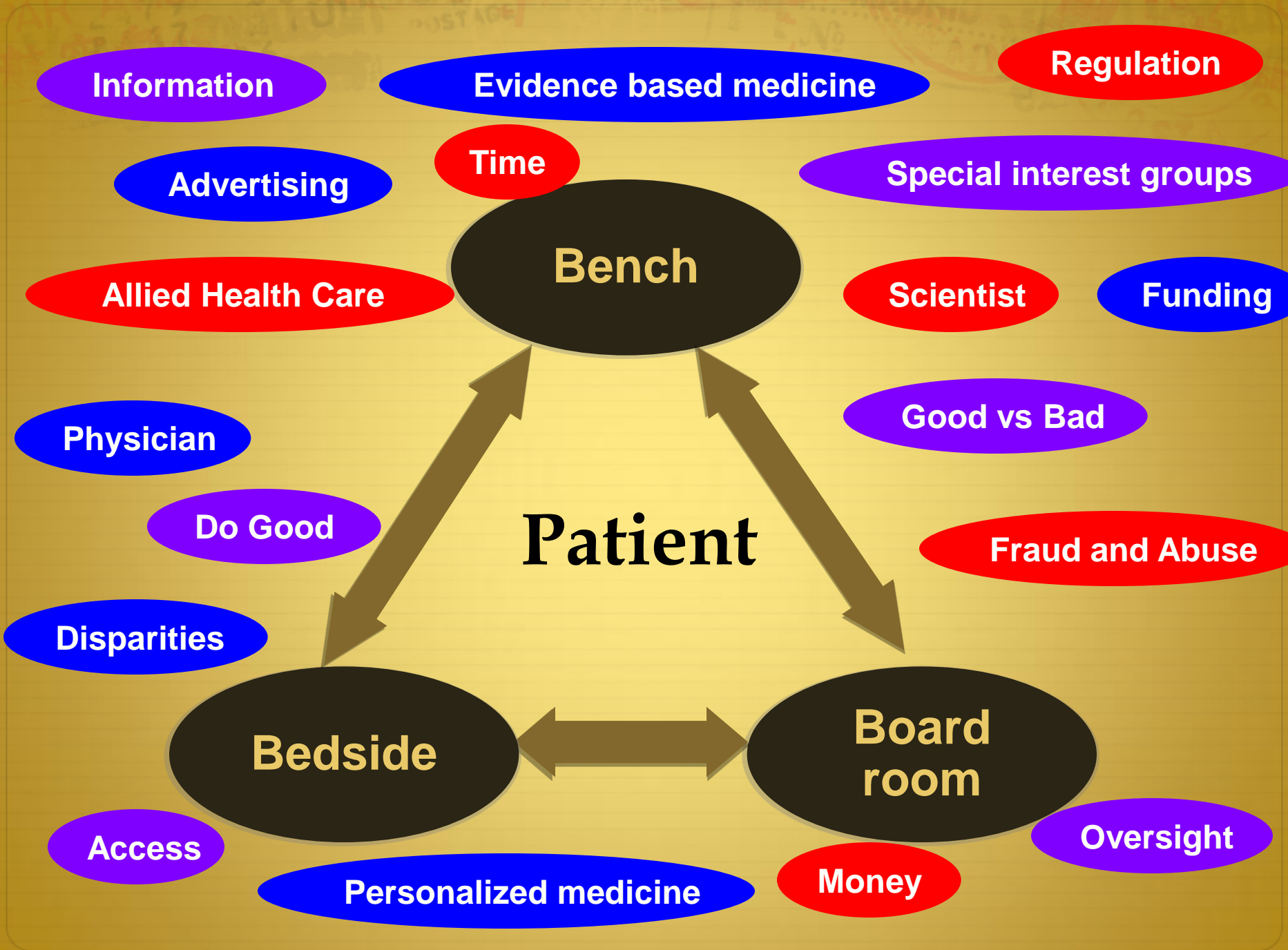
Board room

Access

Personalized medicine

Money

Oversight



Questions vs Answers





Do Good



About the World

✦ 7 billion people

✦ 195 official countries



Defining World Pain Statistics USA



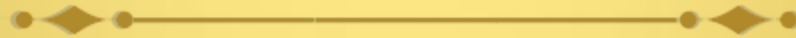
- ✦ **312 million USA population**
 - **25 million Texas population**
- ✦ **116 million chronic pain (37%)**
- ✦ **Will double by 2030**

Defining World Pain Statistics

(Extrapolated from USA)

✦ 2.6 billion with chronic pain

Personalized Medicine



DEMAND



- ✦ **Huge unmet medical need**
- ✦ **Commercially attractive market**

Unmet Medical Need



Therapeutic approaches not fully efficacious

- eg neuropathic pain - 40% overall effective
- pain in terminal cancer - 50-70% ineffective
- Side effects limit dose
 - eg 70% adverse effect on daily living and emotional well-being
- Major segments
 - Arthritis, neuropathic, cancer
 - Increase in aging population

Translational Medicine-Use-inspired basic research

✦ **Bench to the Bedside**

✦ **Pasteur's Quadrant 19th Century**

Bench to Bedside



- ✦ Former NIH head Elias Zerhouni pushed for translational research - findings from basic lab research would be used to develop medicines and other applications that would help patients directly.
- ✦ Now the head of R&D at Sanofi, Zerhouni says that such “*bench to bedside*” research is **more difficult than he thought.**



The Patient



There is *nothing men will not do*, there is *nothing they have not done*, to recover their health...

They have submitted to be *half-drowned* in water, and *half-choked* with gases, to be *buried* up to their chins in earth, to be *seared* with hot irons like galley-slaves, to be *crimped* with knives, like codfish, to have *needles thrust into* their flesh, and *bonfires kindled* on their skin, to *swallow* all sorts of abominations, and to *pay for all this*, as if to be singed and *scalded* were *costly privileges*, as if *blisters* were a blessing, and leeches were a *luxury*.

Oliver Wendell Holmes, 1871

The background features a collage of various postage stamps and currency notes. Visible stamps include 'PARIS AVION', 'MADRID', 'COSTA RICA', and 'PURCHASE'. Currency notes include '100.00' and '100.00'. The overall theme is money and international travel.

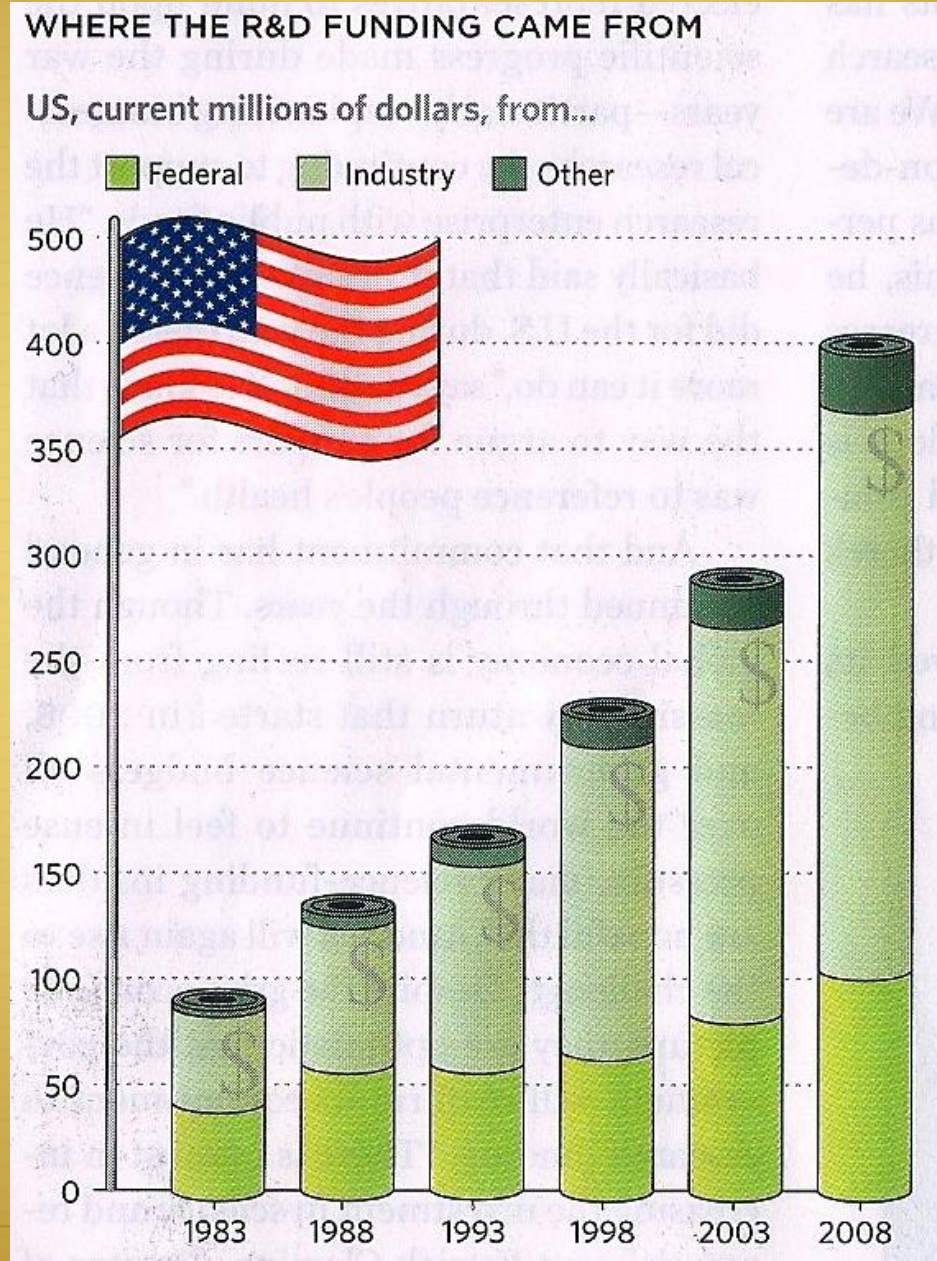
Money

A decorative horizontal line with diamond shapes at both ends, positioned below the title.

There does not exist a category of science to which one can give the name applied science. There are sciences and the applications of science, bound together as the fruit of the tree which bears it.

~Pasteur

Who Pays for R & D?



Funding Research?



- ✦ *... the pressures and temptations of closer connections with commerce have introduced policy issues that are testing the fabric of these institutions.*

~Rosenzweig

- **Massive economic cost of chronic pain to society**
 - **UK - 206 million working days/yr lost**
 - **USA - \$100 billion annual cost**
- **Commercially attractive market**
 - **\$20 billion currently**
 - **\$40 billion by 2020**
- **Over 500 companies involved in developing or marketing pain therapeutics**

Impediments

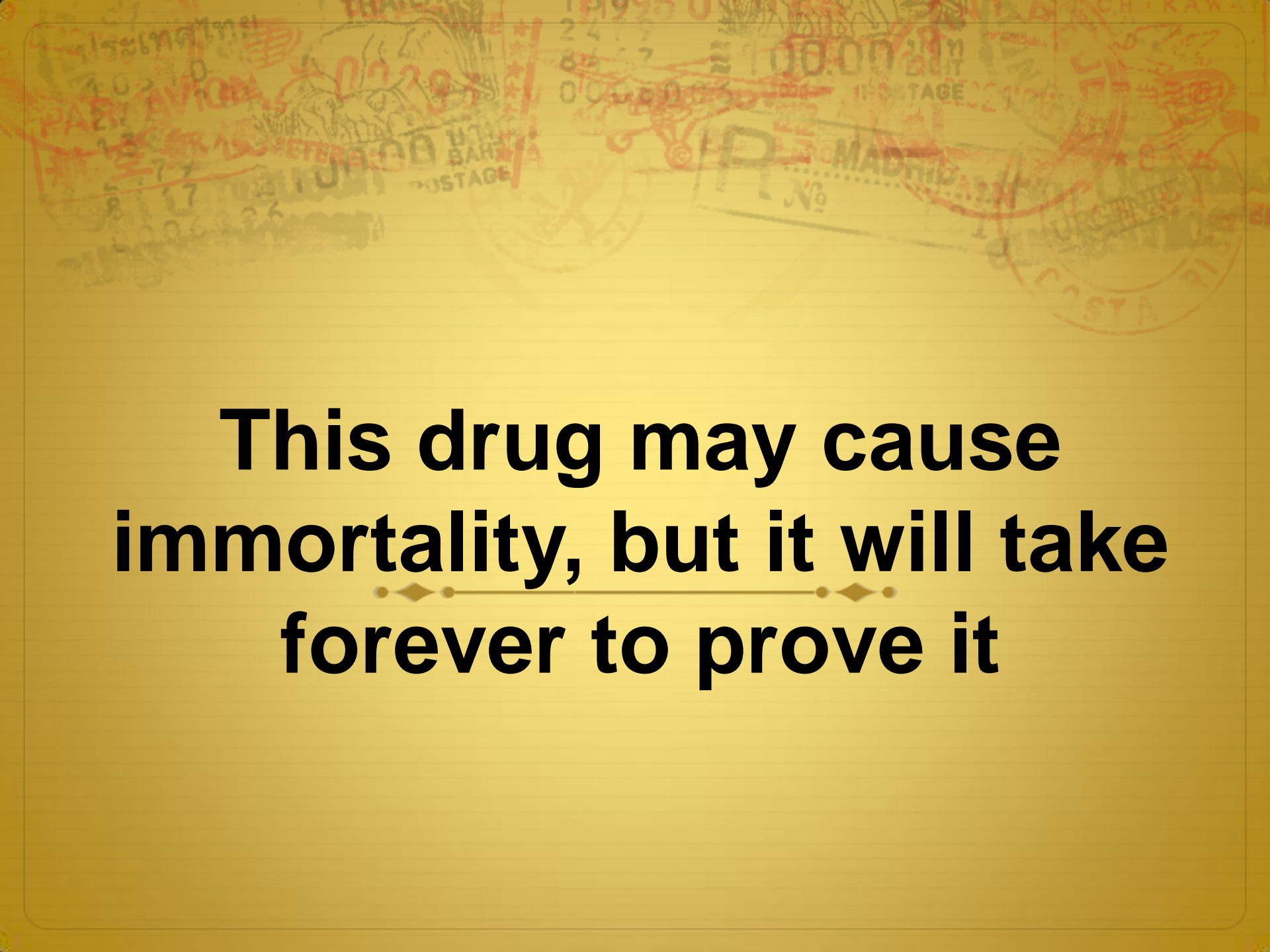


✦ **Discovery to patient application**

Ten Commandments

✦ We are being over regulated!



The background features a collage of various postage stamps and postmarks. Visible text includes 'PARAVION', 'PETERSEN', 'POSTAGE', '100.00', 'MADRID', 'PURCHASE', and 'COSTA RICA'. There are also some numbers and dates scattered throughout.

**This drug may cause
immortality, but it will take
forever to prove it**

Problems



- Failure in early clinical trial - lack of efficacy and/or poor tolerability
- 50% of late-stage projects fail



Diversion

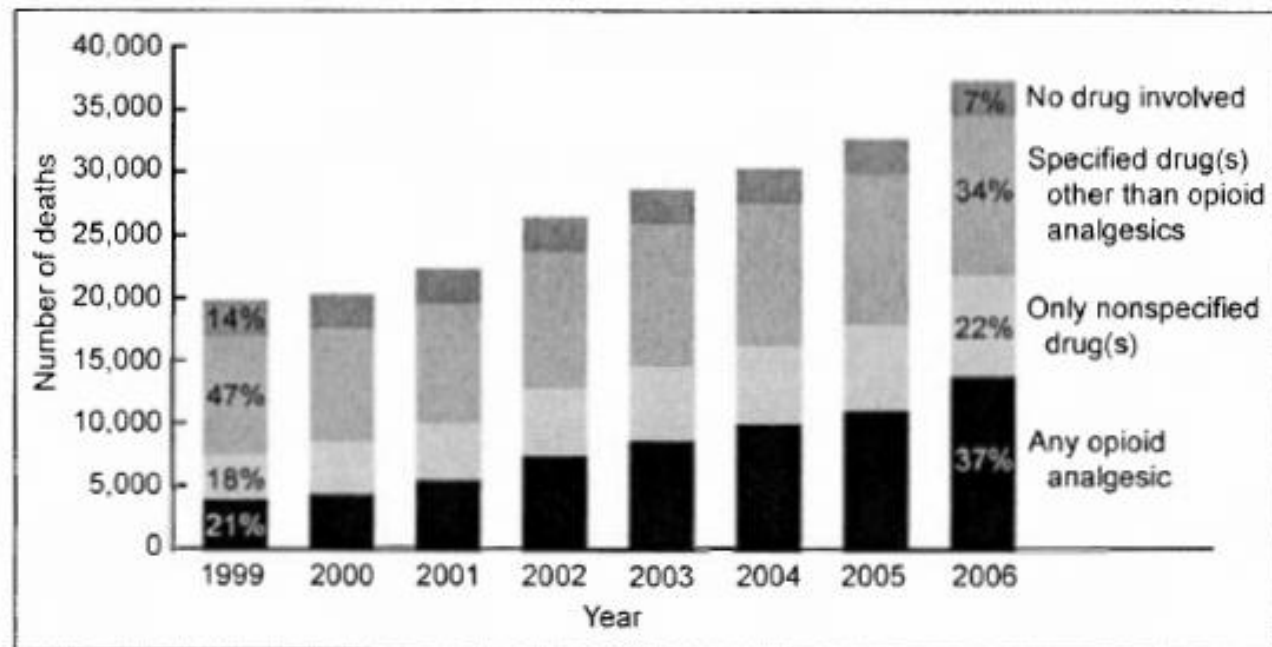


Increase in Fatal Poisonings Involving Opioid Analgesics in the United States, 1999–2006

Margaret Warner, Ph.D.; Li Hui Chen, M.S., Ph.D.; and Diane M. Makuc, Dr.P.H.

The number of poisoning deaths and the percentage of these deaths involving opioid analgesics increased each year from 1999 through 2006.

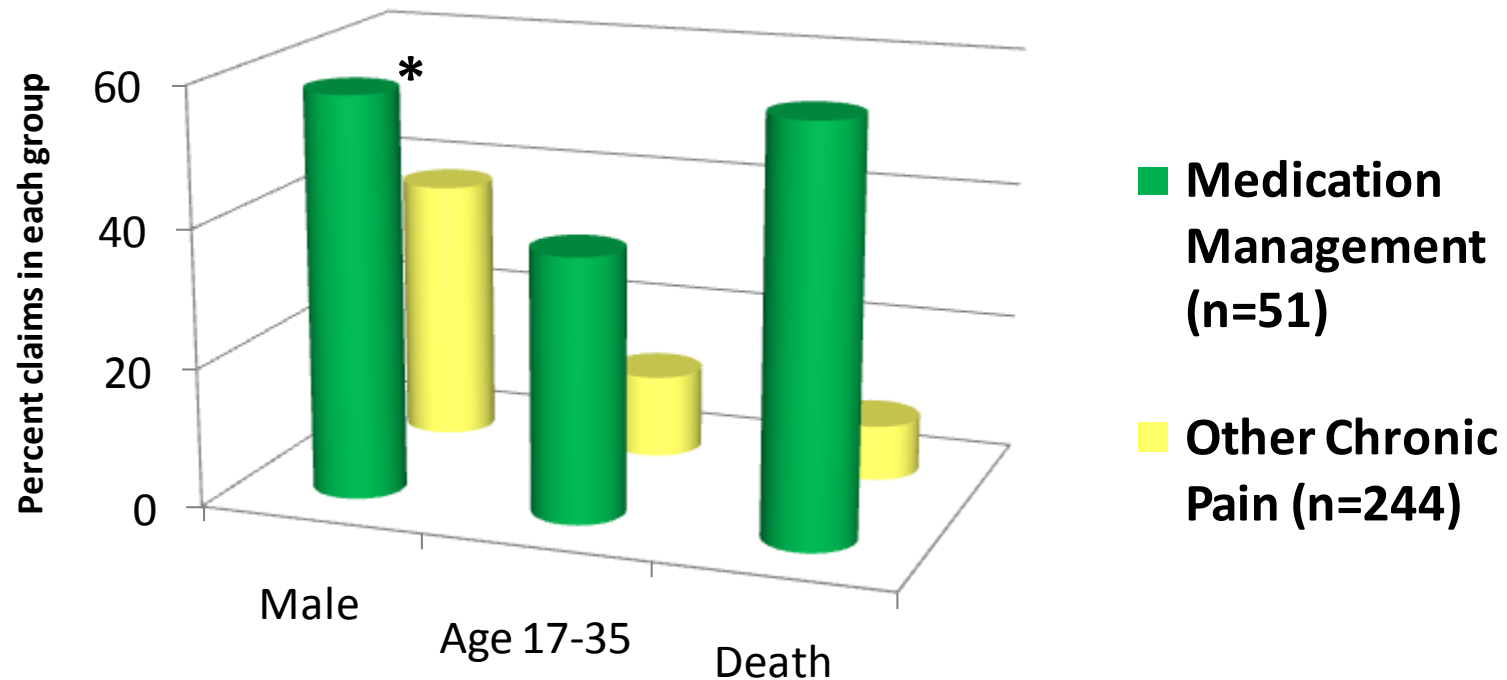
Figure 1. Poisoning deaths involving opioid analgesics, other drugs, and no drugs: United States, 1999–2006



NOTE: Access data table for Figure 1 at ftp.cdc.gov/pub/Health_Statistics/NCHS/Publications/Data_Briefs/db022/fig01.xls.
SOURCE: CDC/NCHS, National Vital Statistics System.

Chronic Pain Medication Management Liability Reflected by Lawsuits in US

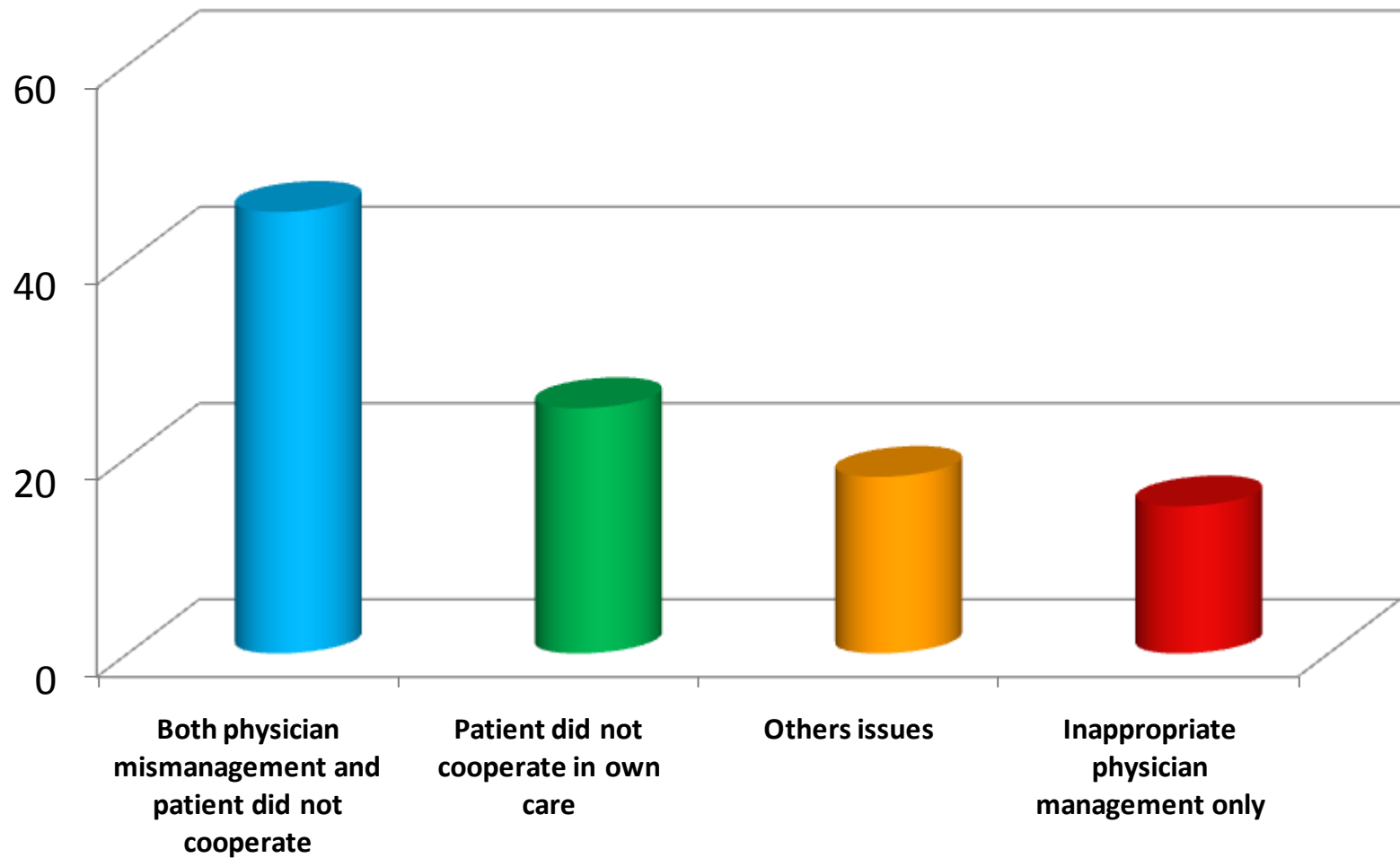
(17% of 295 chronic non-cancer claims collected 2005-2009)



* $p < 0.01$ medication management vs. other chronic pain

Issues in Medication Management (n=51)

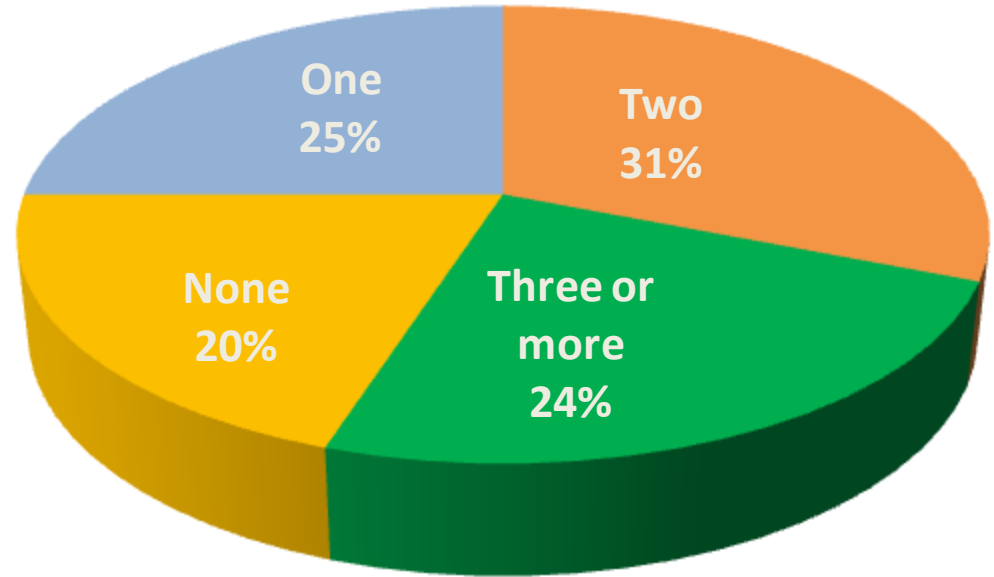
Percent claims in each group



Patient Factors Associated with Medication Misuse or Addiction

*Indicates the most common factors

- History of depression,* suicide attempt, or drug/alcohol problems*
- Medications from multiple providers*
- Failed screening tests
- Early refill requests
- Losing prescriptions
- Concurrent use of illicit drugs/alcohol
- Escalating doses without prescription
- Taking medications prescribed for others



- **New and improved delivery of existing drugs**
 - **Pumps for intrathecal delivery**
 - **Transcutaneous delivery**
 - **Nasal/oral mucosa**
- **Break through pain**
- **Prevent abuse**
 - **Mix opioid agonist and antagonist**
- **Pharmogenetics/ pharmacogenomics**
- **New targets**



Age of Machines



The background features a collage of various postage stamps and postmarks. Visible text includes 'PARAVION', '100.00', 'POSTAGE', 'MADRID', 'COSTA RICA', and 'PURCHASE'. There are also some numbers and dates like '1995' and '24'.

Special Interest Groups



Information





“I think the dosage needs adjusting. I’m not nearly as happy as the people in the ads.”

Perhaps the only thing that saves science from *invalid conventional wisdom* that becomes effectively permanent is the *presence of mavericks* in every generation—people who *keep challenging convention and thinking up new ideas* for the sheer hell of it or from an innate curiosity.

✦ **Do good**

✦ **Enjoy life**

✦ **Do not waste time**



THE BEGINNING

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