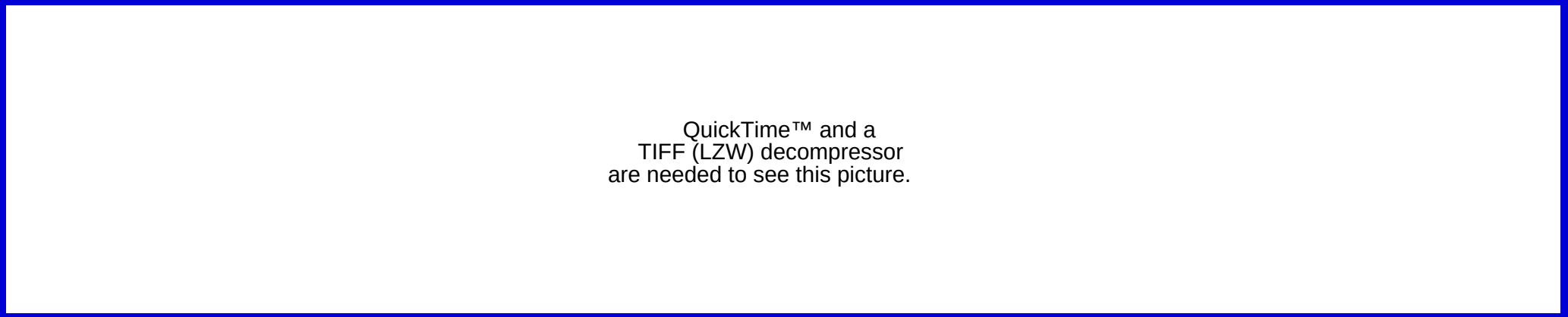
Privacy and Health Care

Bernard Lo, M.D.

February 23, 2004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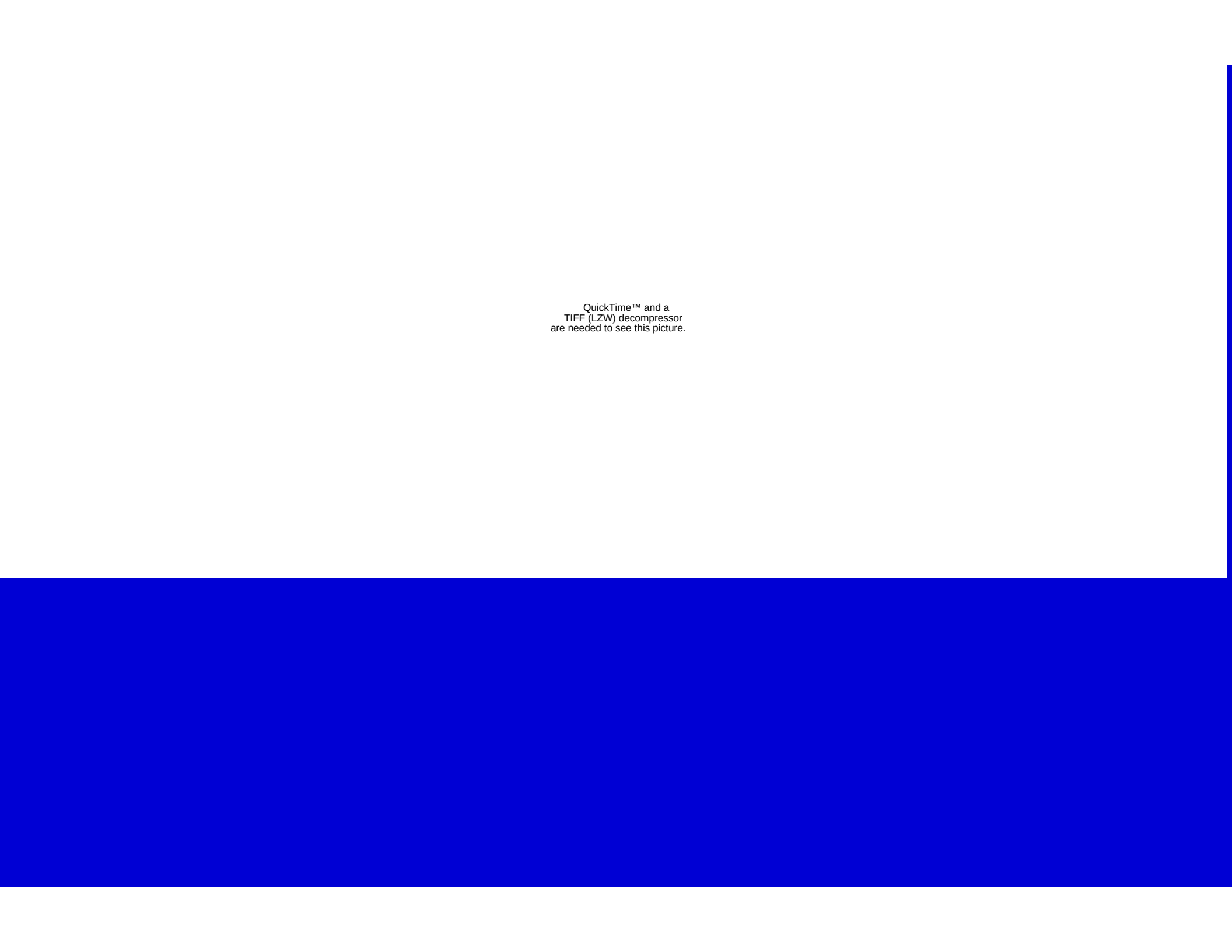
Withdrawal of Celebrex

- Notify patients by mail within 24 hours
- Withdraw from pharmacy
- Notify providers
- Alert MD when access EMR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Annals of Internal Medicine

Responding to the Rofecoxib Withdrawal Crisis: A New Model for Notifying Patients at Risk and Their Health Care Providers

Anil Jain, MD; Ashish Atreja, MD, MPH; C. Martin Harris, MD, MBA; Meghan Lehmann, PharmD; Jon Burns, BS; and James Young, MD

1 February 2005 | Volume 142 Issue 3 | Pages 182-186

THE LANCET

Risk of acute myocardial infarction and sudden cardiac death in patients treated with cyclo-oxygenase 2 selective and non-selective non-steroidal anti-inflammatory drugs: nested case-control study

David J Graham, David Campen, Rita Hui, Michele Spence, Craig Cheetham, Gerald Levy, Stanford Shoor, Wayne A Ray

Lancet 2005; 365: 475–81

Published online

Limitations of randomized trials

- Design: not long-term
- Power: need more subjects
- Turn to databases for retrospective cohort studies

Database studies

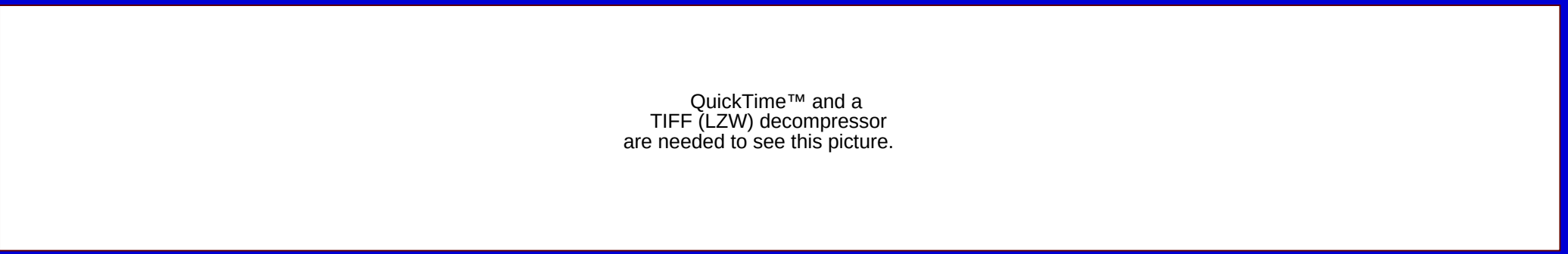
- **Need comprehensive data**
  - Pharmacy
  - Outpatient visits
  - Hospitalizations
  - Laboratory tests
  - Deaths
  - Need to maintain identifiers

Database studies

- **Need complete follow-up**
  - Care outside of system
  - No refusals or drop outs
    - Lose power
    - Selection bias

Other uses of EMR: Quality improvement

- Alert MDs prescribing above recommended dosage
- Require documentation of gastrointestinal problems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EMR with sensitive conditions? Potential for benefit

- Database research
- Inform patients and MD of concerns
- Quality control in prescribing

EMR with sensitive conditions? Concerns about confidentiality

- Mental health records may have special protection
- Separate psychiatric and medical providers and records

Reasons for confidentiality

- Encourages patients to seek medical care and disclose sensitive information
- Prevents stigma and discrimination
- Respects patients as persons

Dual policy goals

- Protect confidentiality
- Access to information for clinical care, public health, research

Database research: technical issues

- Compatibility between organizations with different data formats
- How to protect identifying links

Database research: patient authorization

- Patients consider permission important
- 1/2 of patients not give permission
- Selection bias: sickest, most complicated do not agree
- Incomplete data may be misleading

Database research: Oversight and regulations

- **Implementation of regulations**
  - De-identified data not be sufficient
  - Waiver of authorization
- **Guidance for IRBs and privacy boards**
- **Providers reluctant to release information to approved studies**

Suggestions for NCVHS

- **Public education about**
  - Value of database research
  - Tradeoffs between confidentiality and patient benefit

Suggestions for NCVHS

- **Some database research similar to public health**
  - Notification, rather than consent or authorization may be appropriate
- **Focus on confidentiality as well as privacy**
  - How to protect personal health information