

# INTEREST IN PRODUCT SAFETY IS INCREASING

- Side effects
  - Drugs
  - Vaccines
  - Medical devices
- Medical errors
- Device malfunctions

# CONTRIBUTING FACTORS

- Emergence of many new products
- Speedier FDA processes
- Aging population
- The internet

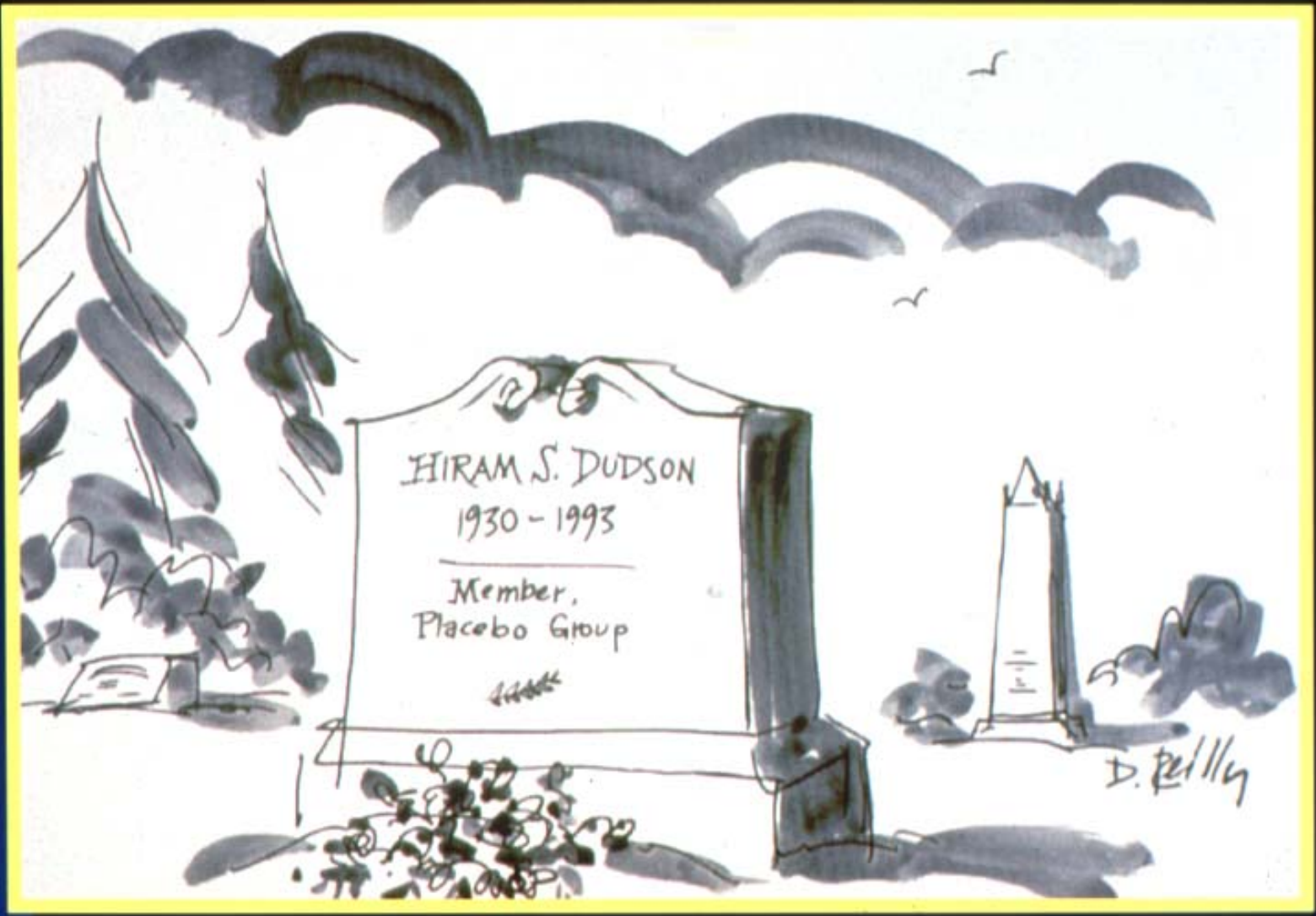
# APPROACHES TO STUDYING SAFETY OF MEDICAL TREATMENTS

- Monitoring spontaneous reports to FDA and/or product manufacturer
- Studying drug-outcome associations in existing cohorts
  - Claims data bases
  - Large research cohorts with ongoing follow-up
  - General Practice Research Database (UK)
- Formal studies
  - Observational study of those using treatment
  - Case-control study
  - Randomized comparison of two treatments
  - Meta-analysis of previously conducted studies

# WHAT ARE WE DOING AND HOW CAN WE DO BETTER?

- Surveillance of medical products in use
  - Less methods work in this area
  - Much more needing to be done
- Pre-marketing research
  - Pre-clinical and early phase development
  - Phase 3 studies

# SHIFTING PERCEPTIONS OF NEW DRUGS



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WOULD YOU LIKE TO VOLUNTEER  
TO TEST A NEW MEDICATION?

ONLY IF  
I GET THE  
PLACEBO

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