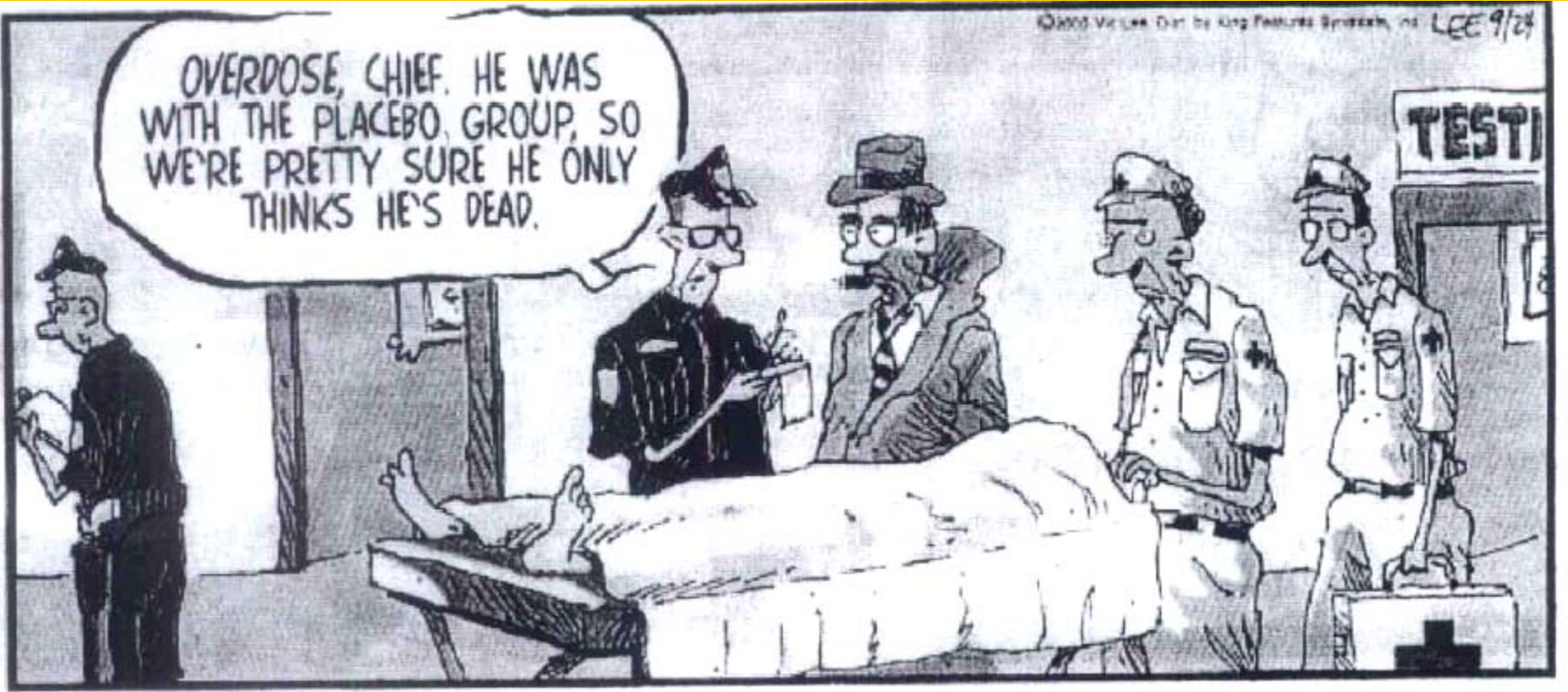


# **Long-Term Evaluation of Psychotropic Drugs in Major Psychiatric Disorders**

**Outcome Measures and Statistical  
Approaches**

OVERDOSE, CHIEF. HE WAS WITH THE PLACEBO GROUP, SO WE'RE PRETTY SURE HE ONLY THINKS HE'S DEAD.



# Outcome Parameters in Major Psychiatric Disorders

- Consensus on short-term outcomes in psychiatric diagnoses – How good are they?
- No widely used outcomes specific to long-term treatment
  - Main outcome used is relapse
  - Majority of relapses occur within the first 4-6 weeks

# Outcome Parameters in Major Psychiatric Disorders

- Need for outcomes relevant for long-term use of psychotropic NCEs
  - QoL, functioning, social interaction
  - Patient- versus Clinician reported outcomes
  - Subsyndromal morbidity
  - Composite outcomes – burden of illness
  - Others, time to/in remission, AUC...
  - Logistical and statistical implications

# Session III: Outcome measures and Statistical Approaches

1.30 – 1.40 Introduction

1.40 – 2.20 Investigator and patient based outcomes – J Endicott

2.20 – 3.00 Overview, trial design and analyses – A Leon

*3.00 - 3.15 Coffee break*

3.15 – 3:45 Industry perspective - L Alphs

3:45 – 4:15 Regulatory comments

4:15 – 4:45 General discussion