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The Role of Postmarketing Surveillance

- We don't know everything about drugs or vaccines at approval
- Unexpected findings emerge after widespread use
  - Rare side effects
  - Use in different populations or under different conditions
  - Drug interactions

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FDA's Drug/Biologic Surveillance System is Severely Challenged

- Found inadequate in 1980 (Report to Senator Kennedy)
- Numerous studies/editorials since then have reconfirmed
- Calls for additional oversight
- Growth of reports

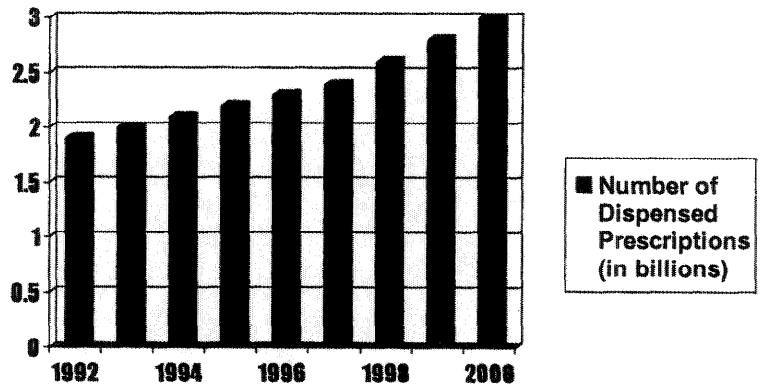
Current Status of System

- Foundation is "spontaneous reports" - voluntary reporting by health professionals
- Manufacturer reporting mandatory
- Major effort in mid-late 1990's to modernize database was successful
- Funding for work with healthcare databases severely limited
- Lack enough safety evaluator, epidemiologist & other scientific staff

Stresses on System

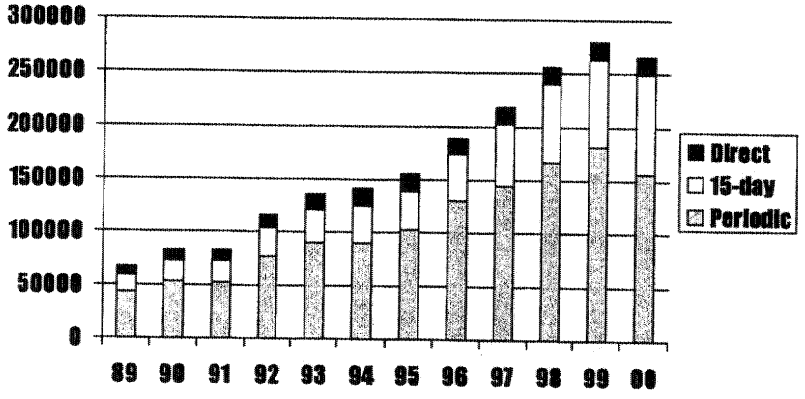
- Increases in number of drugs/biologics approved
- PDUFA has led to U.S. being "first in the world"
- Increases in drug utilization

Prescription Drugs Emerging With a Central Role in US Health Care



Sources:
Prescription Drug Trends: A Chartbook, Kaiser Family Foundation, 2000
Pharmacy Times, 2001

AERS Reporting to FDA
1989 to 2000



Stresses on System: Public Expectations

- In the past: risk management by medical community - "learned intermediary"
- New: The Public & Congress expect FDA to take an active role

Role of Pharmaceuticals in Medical Errors

- Estimated 50-100,000 hospital fatalities/year due to errors
- Medications involved in 25%
- FDA postmarketing programs aimed at preventing errors in use of products
  - Packaging
  - Labels
  - Risk Management

How does this relate to PDUFA?

- Rapid premarket review process predicated on robust postmarket surveillance.
- U.S. "first in world" means our population at greater risk - speed of discovery is important.
- Effective drugs may be removed from market if risk management not done properly.
- Public confidence in drug regulatory system must be maintained.