



Policy and New Drug Development

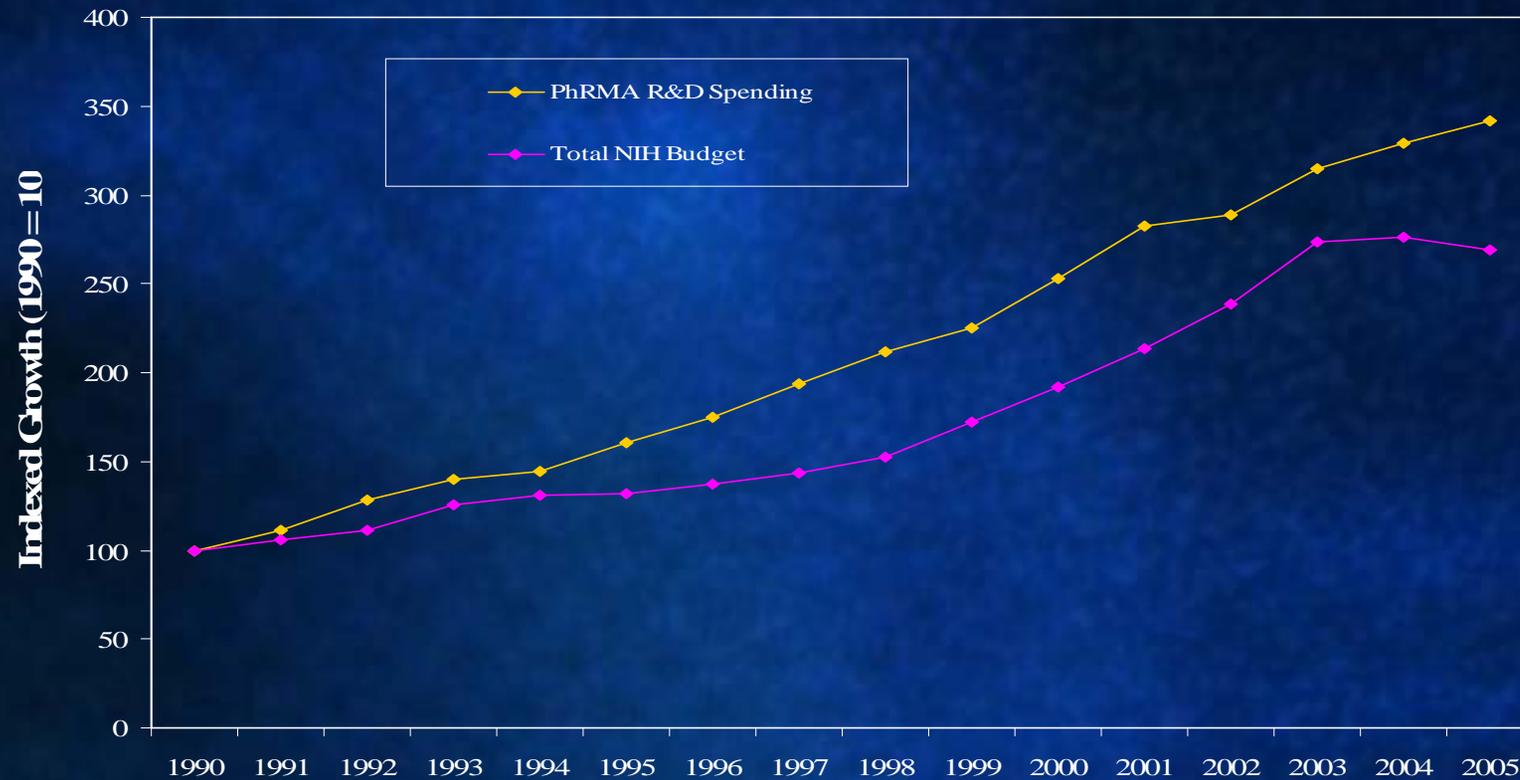
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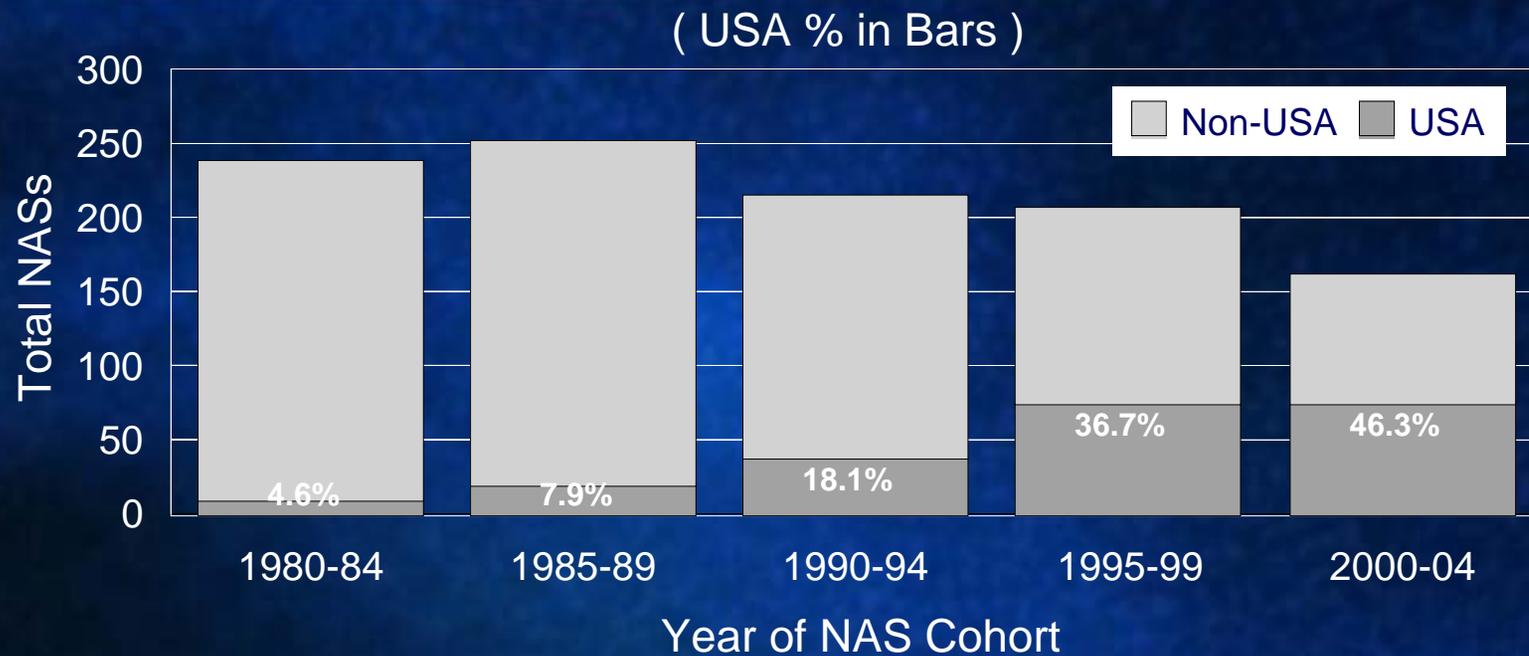
What is the Problem?

R&D Spending Has Accelerated Since 1990

Trends in Biomedical Research Spending

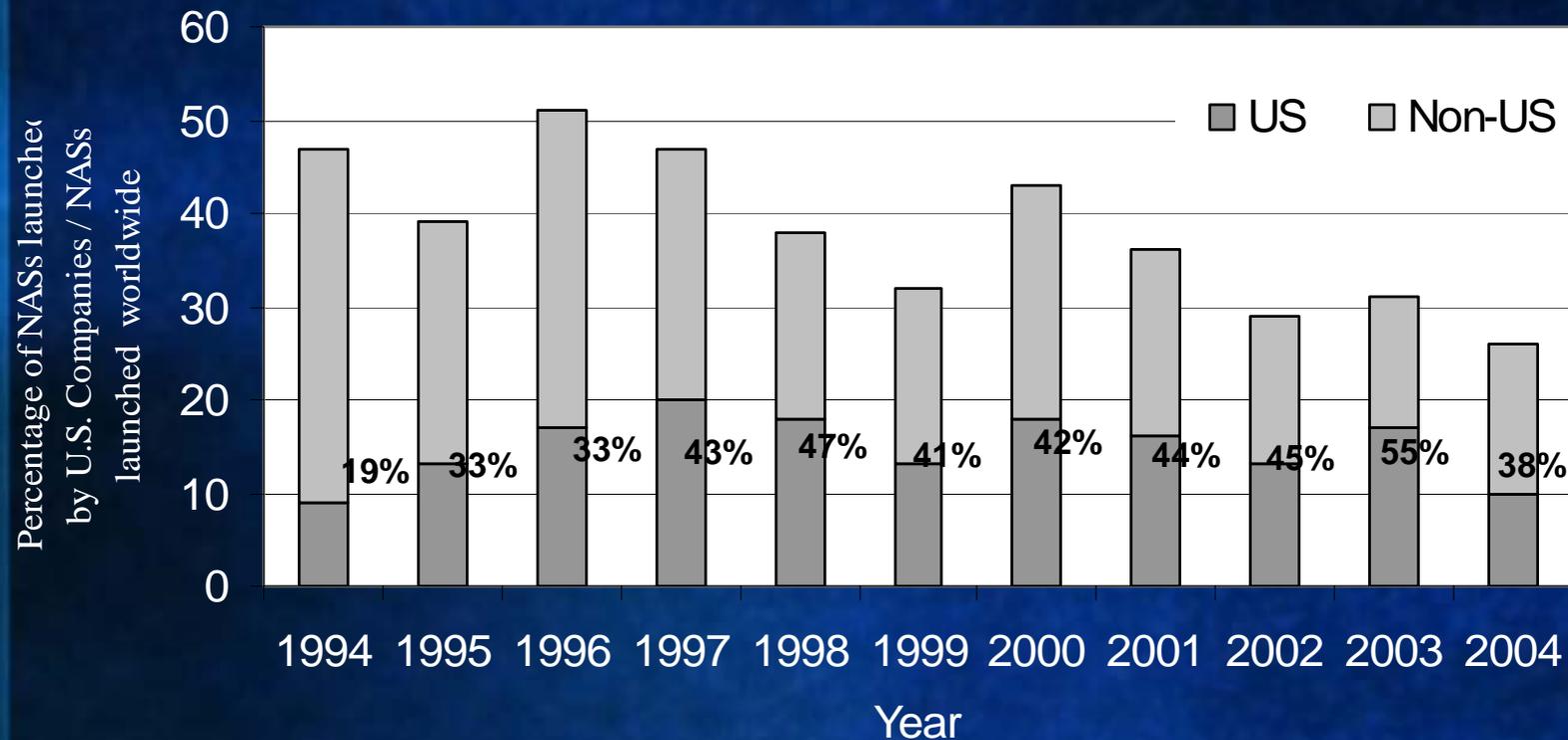


NASs First Launched in World Markets



Data source: Scrip World Pharmaceutical News & Scrip Magazine

NASs First Launched in World Markets by U.S. Companies Since 1994

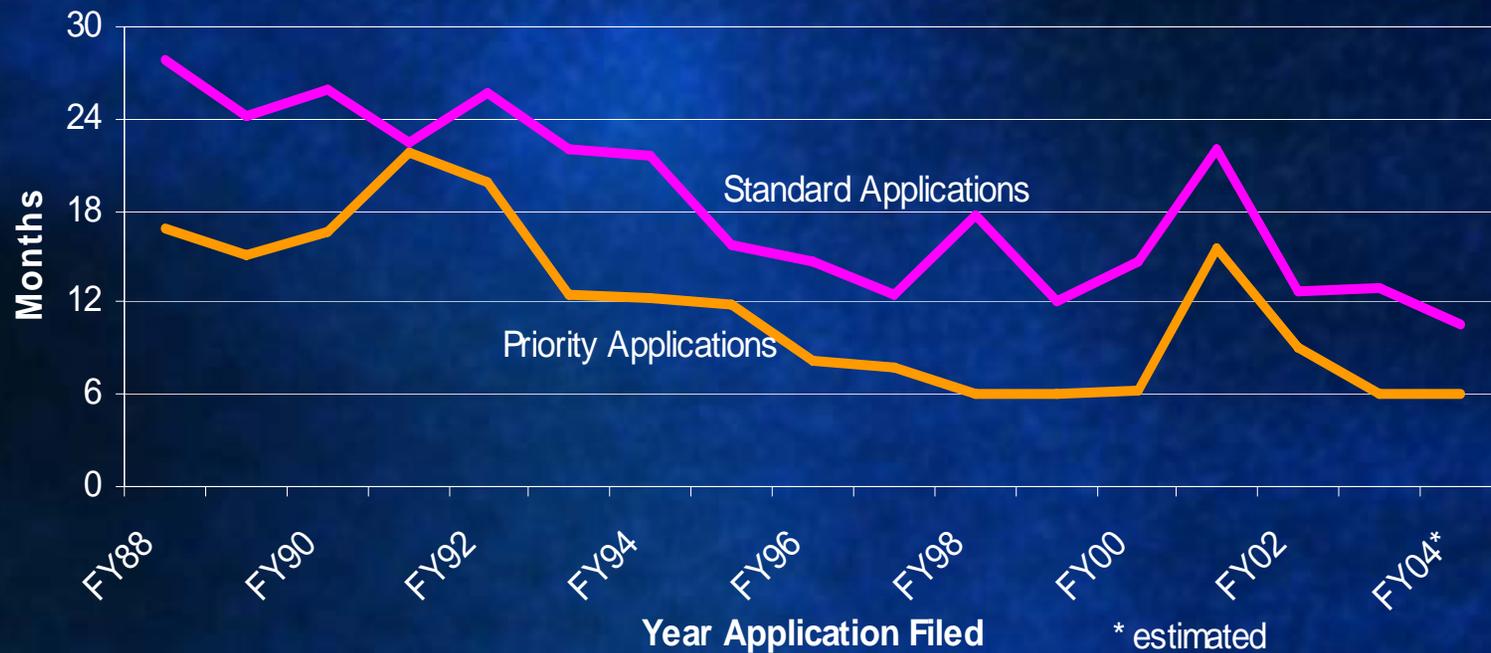


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Examples of FDA's Public Health Impact

- Greater patient access to new therapies

Median Total Approval Times for New Drugs

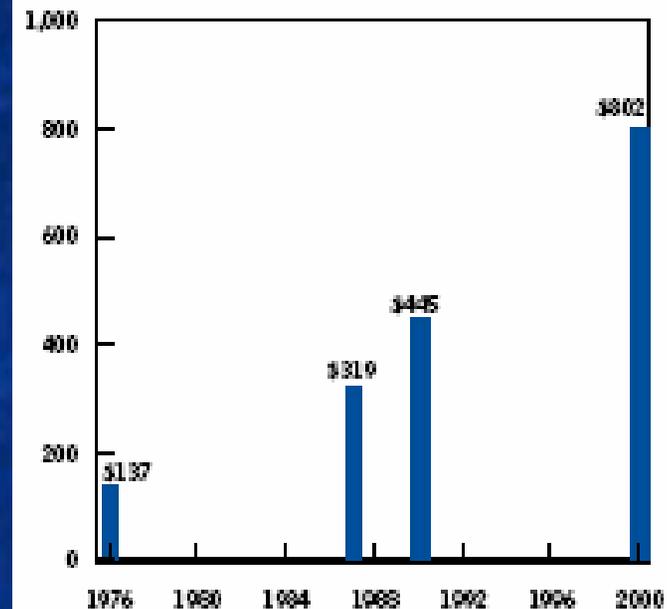


The Cost of Drug Development

- Estimated an average cost of \$802 million (in 2000 dollars) per investigational, self-originated therapeutic compound reaching the U.S. market. (DiMasi et al.)
 - This estimate may be high relative to the cost of developing all new drugs, because it applies only to self-originated new drugs marketed by large multinational pharmaceutical companies. (HHS Taskforce Report on Drug Importation)
 - The DiMasi estimate does not apply to all new drugs (NMEs and biologics) approved by FDA. (HHS Taskforce Report on Drug Importation)
 - Many of the kinds of compounds excluded from the DiMasi analysis are orphan drugs and/or drugs developed by relatively small entities. (HHS Taskforce Report on Drug Importation)
 - But the DiMasi estimate is credible enough to provide useful insights (HHS Taskforce Report on Drug Importation)

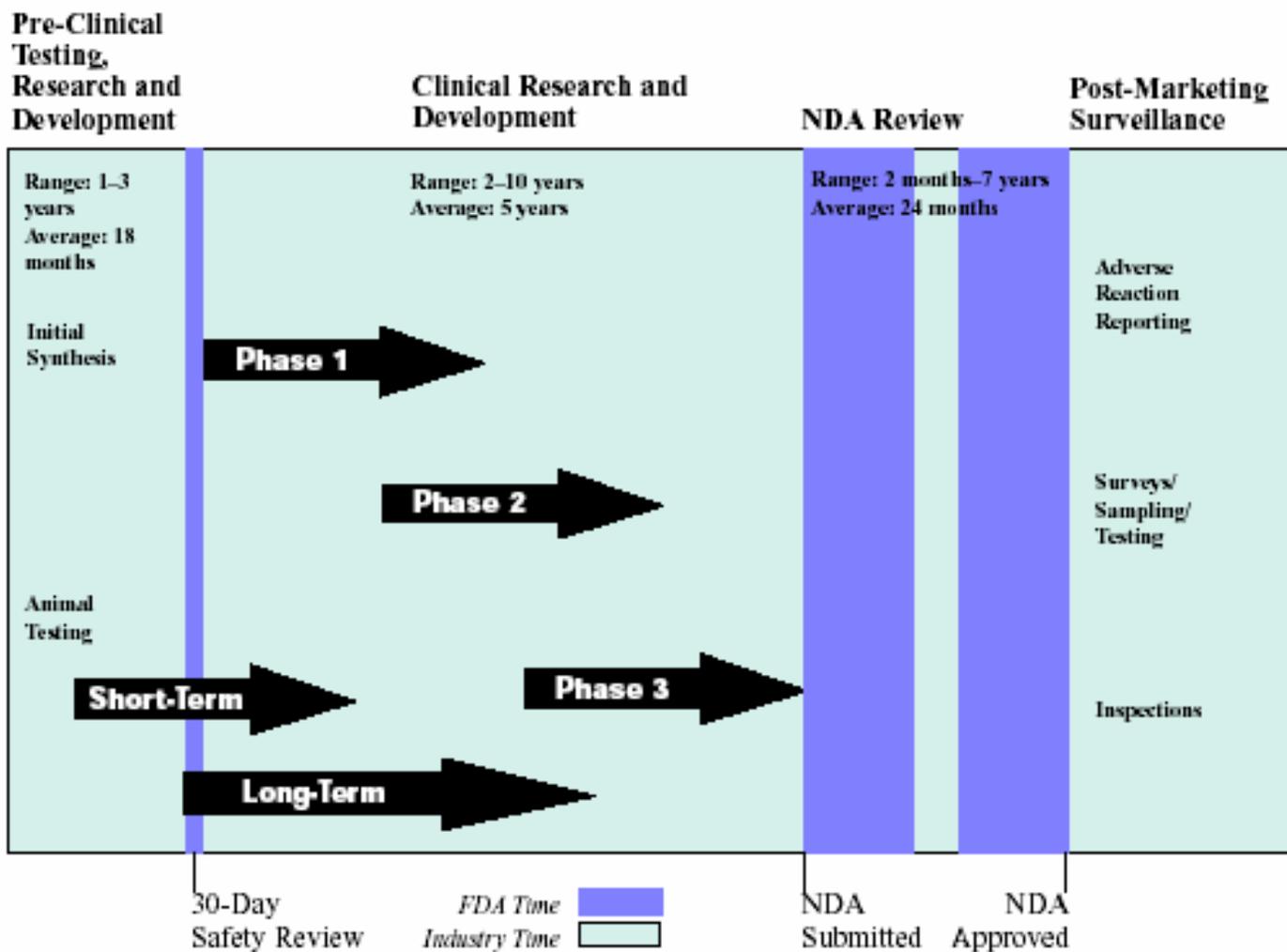
Various Estimates of the Average R&D Cost of a Successfully Developed New Molecular Entity

(Millions of 2000 dollars)



(See CBO October 2006 Study)

New Drug Development Timeline



Long-Term Payoff of Critical Path Efforts

- More informative development programs: lower failure rates, higher productivity, also better evidence base for marketing review and reimbursement decisions.
- Help select or rule out therapy for patients with marker, or be used as a treatment response measure -- advancing individualized medicine.
- Use new scientific tests and methods to modernize FDA review — to keep pace with the evolving science.
- Improve ROI from discovery science investments – more new products for patients.

CP Activities Benefit Patients and Sponsors

- New tools will provide patients with access to better products faster.
- New tools will directly benefit medical product industry
 - Increase quality and efficiency of product development
 - Lead to faster, less costly development of safer new drugs
- Make application review process more effective and efficient – moving products to patients faster.
- Results will support clinical use
 - Better targeted patient therapies
 - Improved safety
 - Enhanced effectiveness

Critical Path Example: Warfarin

- Warfarin helps prevent blood clots
 - Reduces risk of stroke but leads to increased risk of severe bleeding in some patients
- Genetic testing can identify patients with higher risk of bleeding
 - Reduced dose in sensitive patient population reduces bleeding events
 - Increased dose in non-sensitive patient population reduces strokes
- Genetic testing integrated with warfarin dosing may save over \$1 billion in healthcare costs (Mitchell K. Higashi et al 2002 & Joyce H. S. You et al 2004)