PDUFA Reauthorization: Past Successes -- Outlook for the Future

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FDA Public Hearing on PDUFA
Washington, D.C., December 7, 2001

PDUFA I Intent

Companies:	more predictable & faster reviews
Patients:	faster access to needed medicines
Congress:	improved product review system without additional appropriations
FDA:	resources for review divisions to do job more efficiently and effectively

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PDUFA II Intent

- Continue PDUFA I success
- Improve FDA's responsiveness to industry sponsors
- Enhance communication with industry sponsors
- Reduce clinical drug development time

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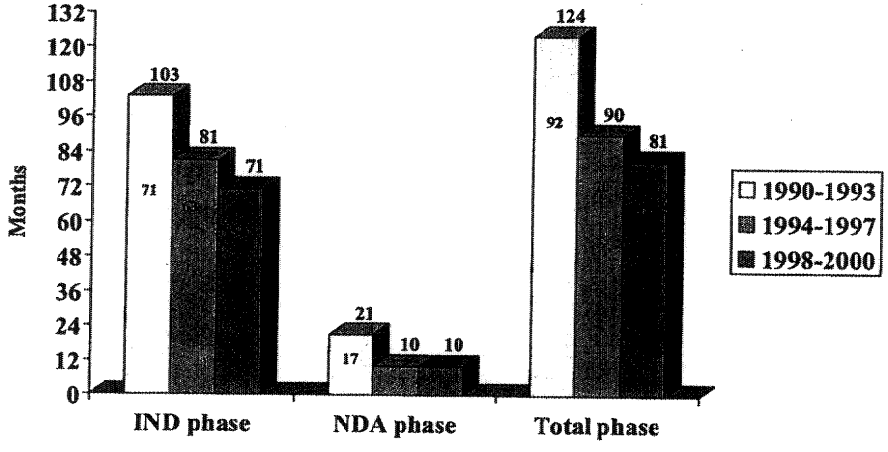
Development Times for CDER User Fee Approvals: 1990-2000 Priority Review Drugs



N.B. Mean times denoted on top of columns and median times denoted inside columns

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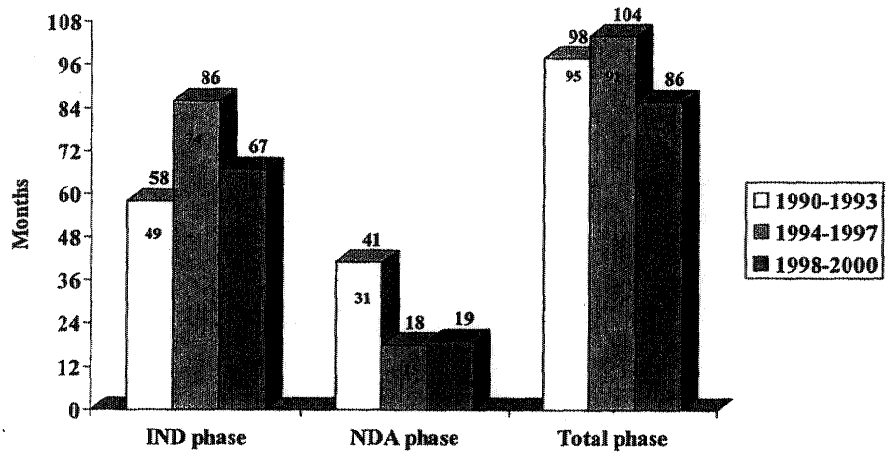
Development Times for CDER User Fee Approvals: 1990-2000 Standard Review Drugs



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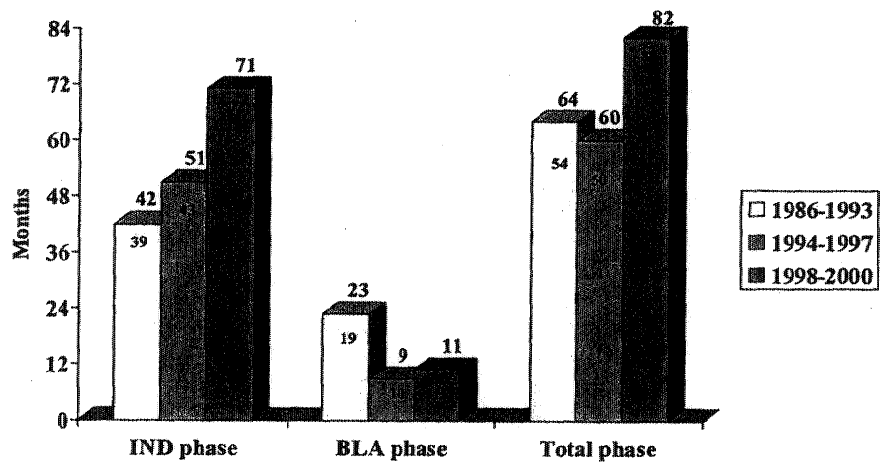
Development Times for CBER User Fee Approvals: 1986-2000 Priority Review Biologics



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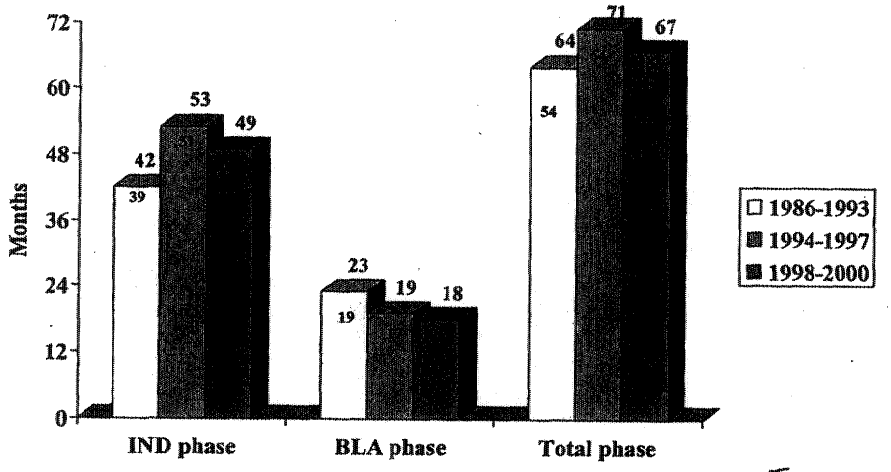

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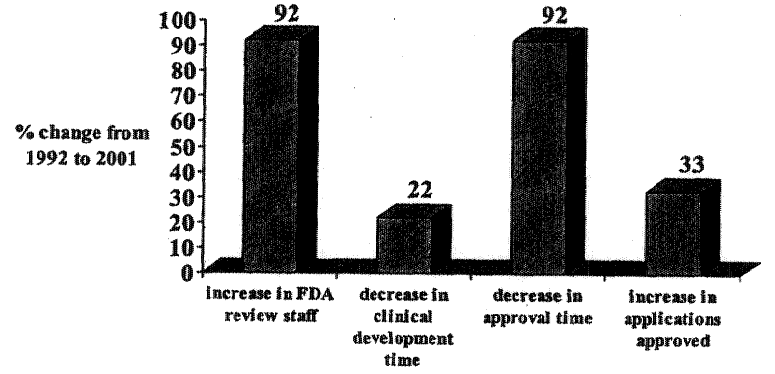
Impact of PDUFA: ⇧ Staff + Performance Goals = ⇩Total Development Time + ⇧Approval Rate



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PDUFA II/FDAMA Demands on FDA Resources

- Additional emphasis on reducing clinical phase of drug development
- More guidance documents and FDA-sponsor conferences
- Performance goals for accelerated consultations, dispute resolution, and clinical holds
- New programs for pediatric studies and serious and life-threatening illnesses

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Pediatric Studies Program: Benefits

- 20 active moieties labeled; 1/3 with significant dosing and adverse event information
- Over 70 diseases and conditions being studied
- Over 400 studies in progress, 32% in neonates and infants
- Dozens of formulation, sampling technique, and clinical endpoint innovations and improvements expand pediatric R&D infrastructure and information

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Pediatric Studies Program: Resource Demands

- 65 FDA staff spread over 13 new pediatric studies activities
- New Office of Pediatric Drug Development and Program Initiatives formed
- 3-fold increase in number of pediatric trials, involving 45,000 children
- Doubling of pediatric supplements

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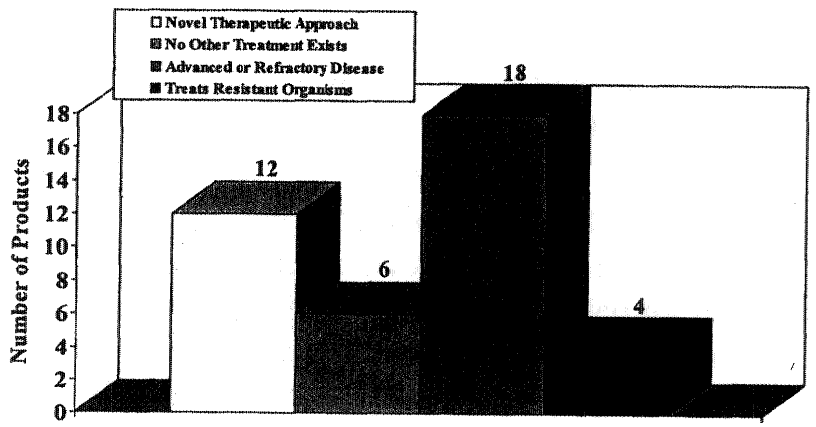
Fast Track Development Program Benefits: Expanding the Frontiers of Medical Science



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Conclusions

- Overall intent of PDUFA I & II has been fulfilled
- Resource demands of PDUFA II improvements and FDAMA programs may be impacting approval times
- Perspective on safety depends on how you look at data:
  - for drugs approved from 1980-1993, there was a 3.2% withdrawal rate with 4.6 years before withdrawal occurred
  - for drugs approved from 1994-2000, there was a 3.4% withdrawal rate, with 1.7 years before withdrawal occurred

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