

Drug Development Timelines and the Prescription Drug User Fee Act



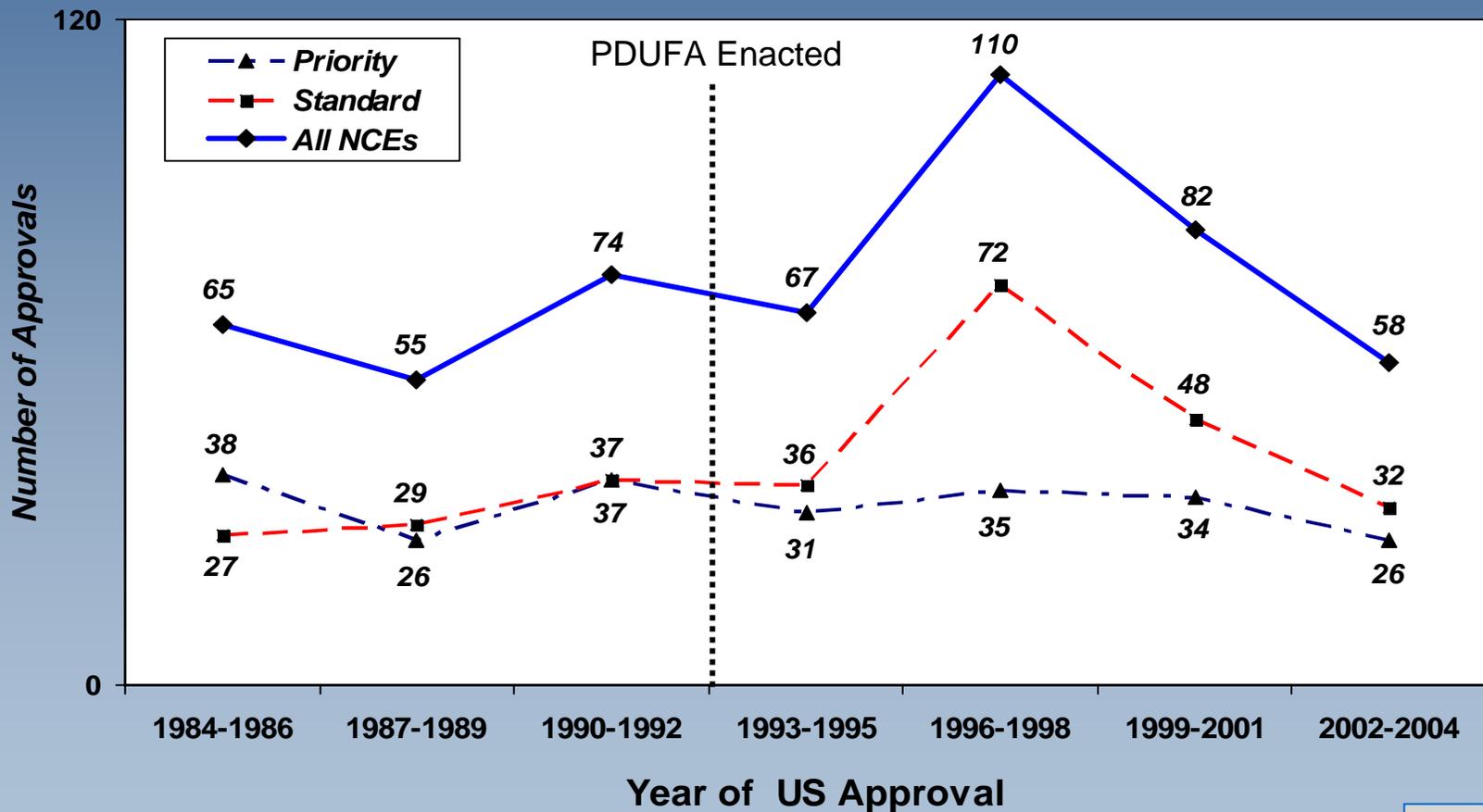
Tufts CSDD
Tufts University

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FDA Public Hearing on PDUFA
Rockville, MD, November 14, 2005

*Theme 1:
Declining NME output*

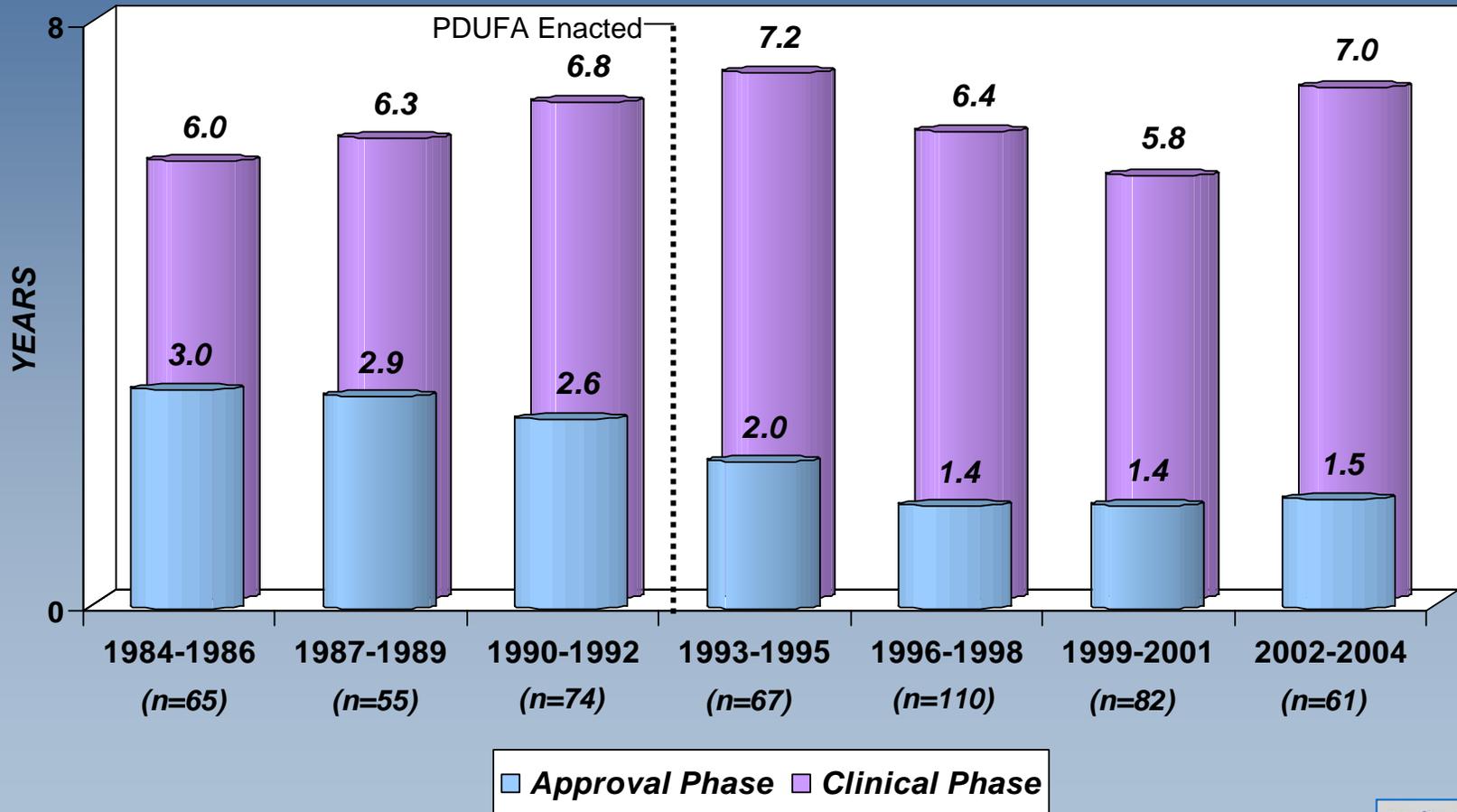
Total Drug Approvals Declined 47% Between 1996-98 and 2002-04



Source: Tufts CSDD, 2005

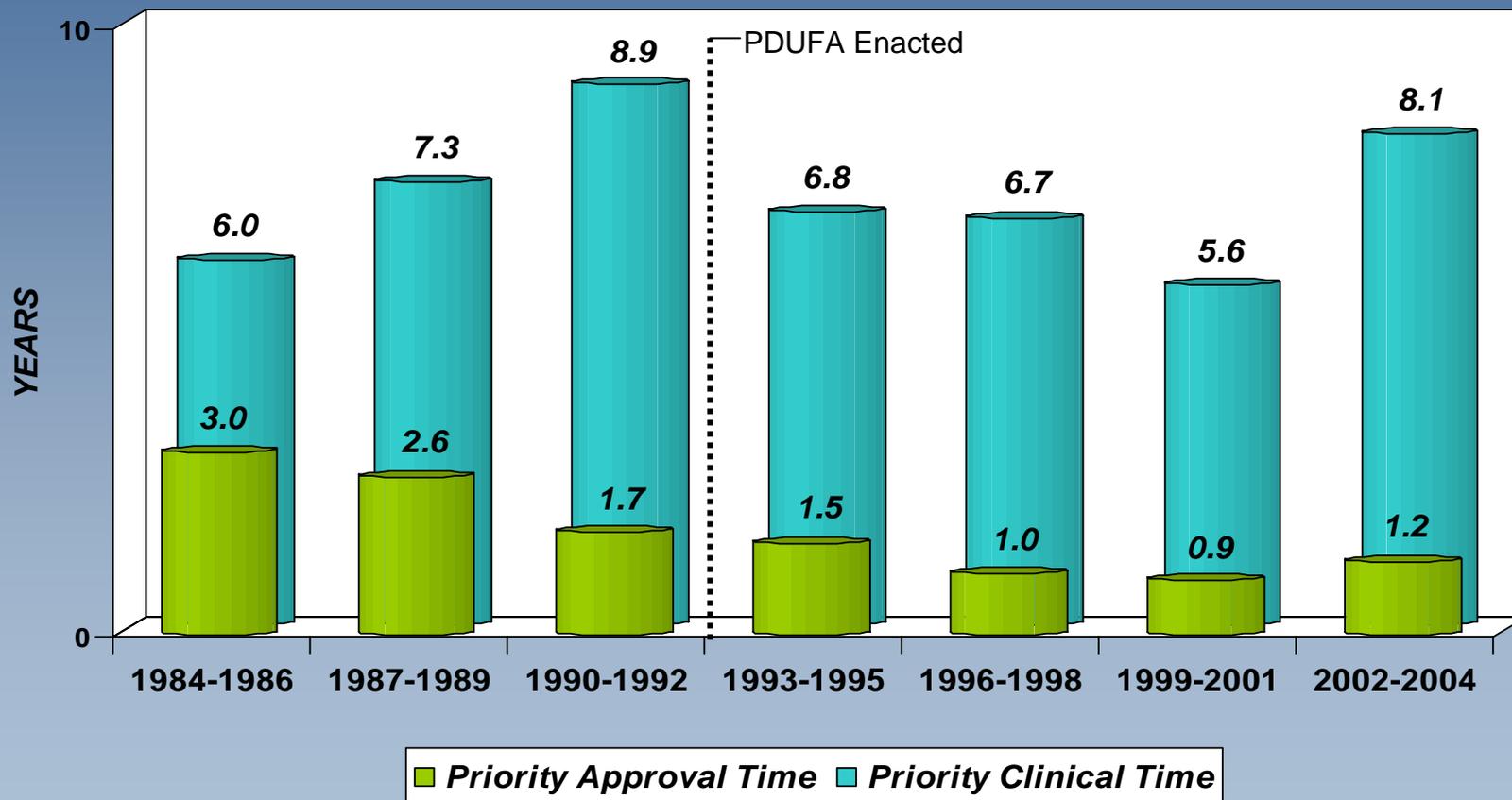
*Theme 2:
Rising Clinical Development Times*

Clinical and Approval Times over Two Decades: Clinical Times are Rising



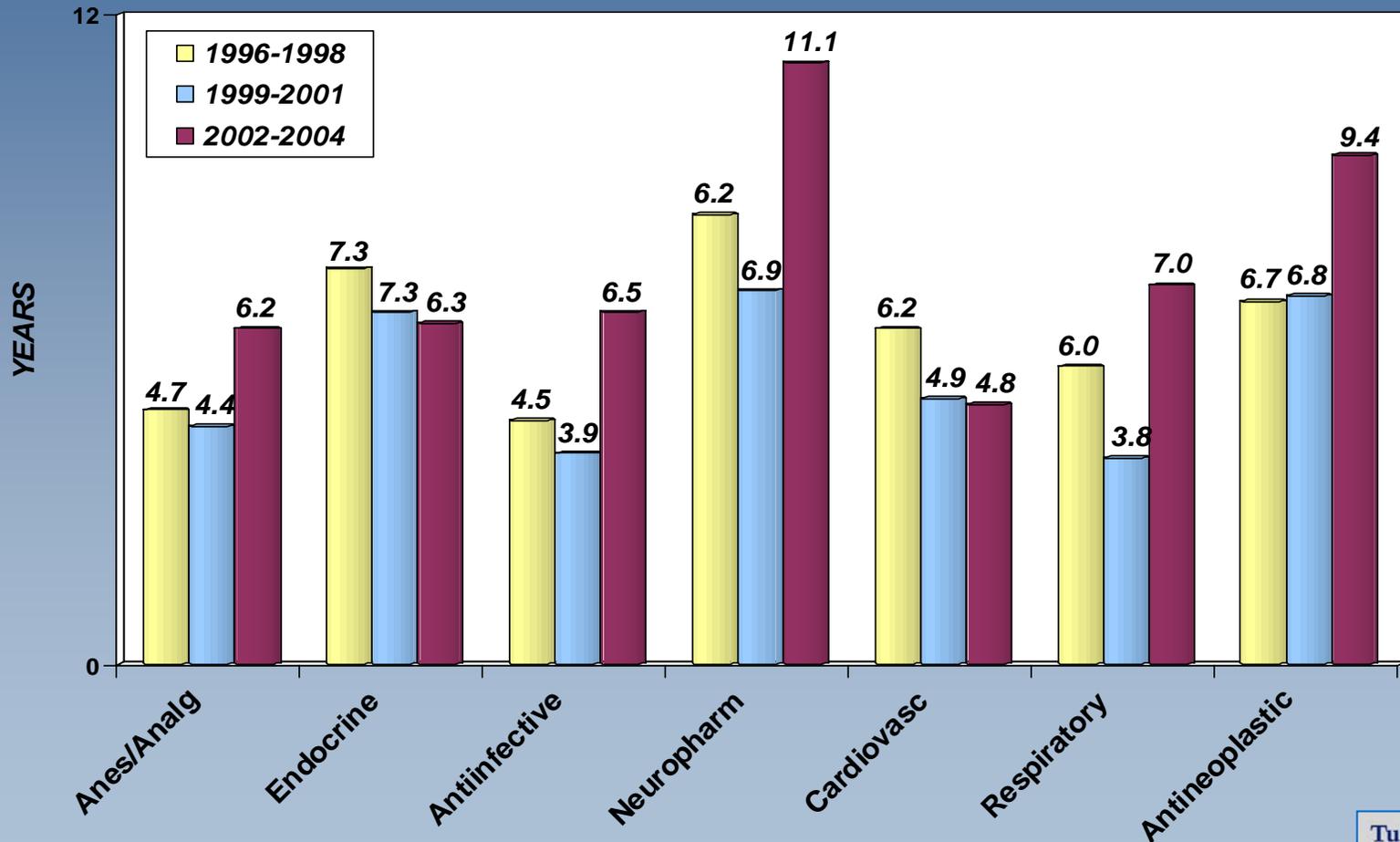
Source: Tufts CSDD, 2005

Clinical Times for Priority Drugs are at their Longest since PDUFA Enactment



Source: Tufts CSDD, 2005

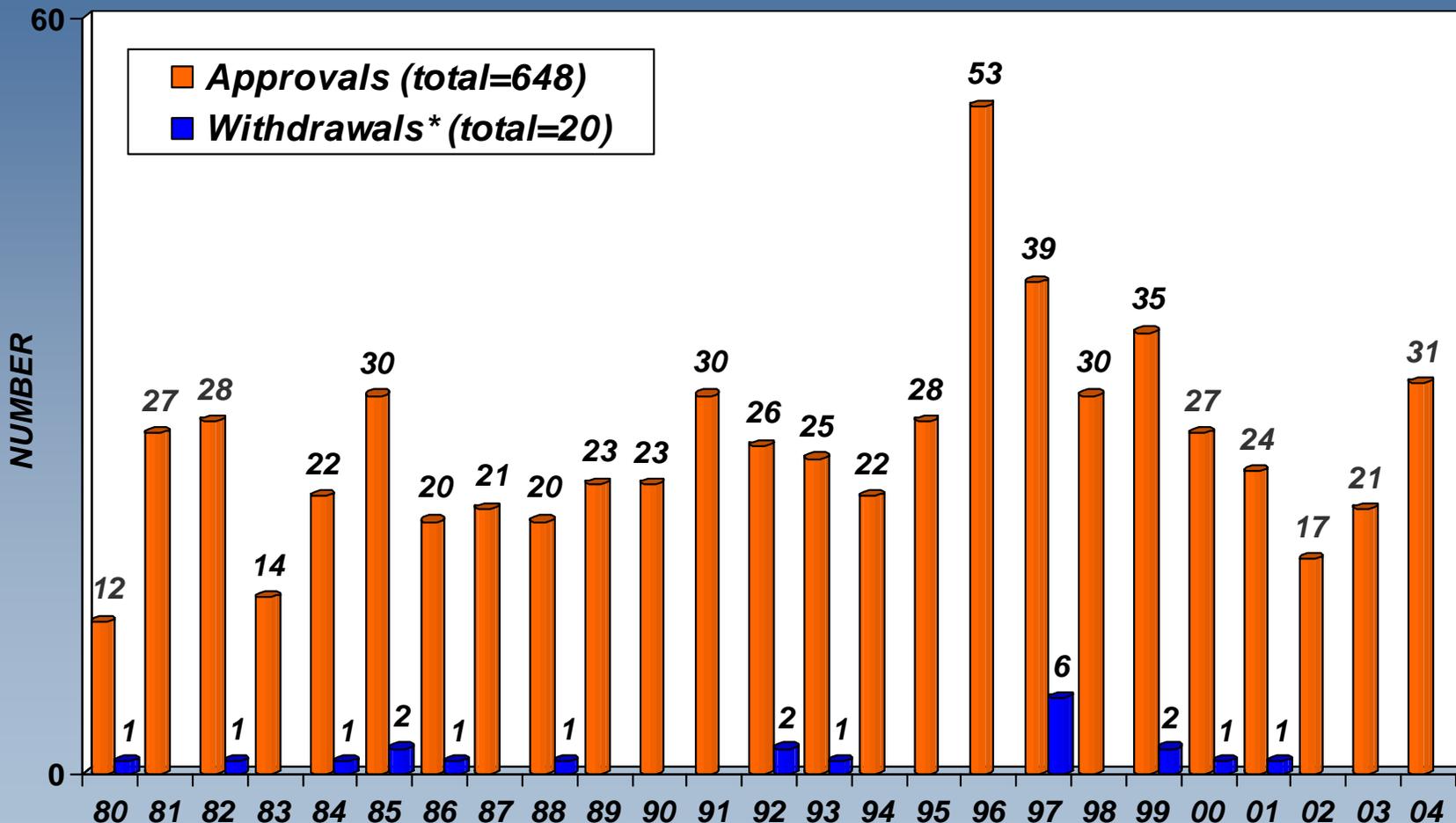
Clinical Phases Have Increased in Nearly All Therapeutic Classes



Source: Tufts CSDD, 2005

*Theme 3:
Drug Safety*

Rates of New Drug Approvals and Withdrawals 1980-2004



* Withdrawals listed by year of product approval

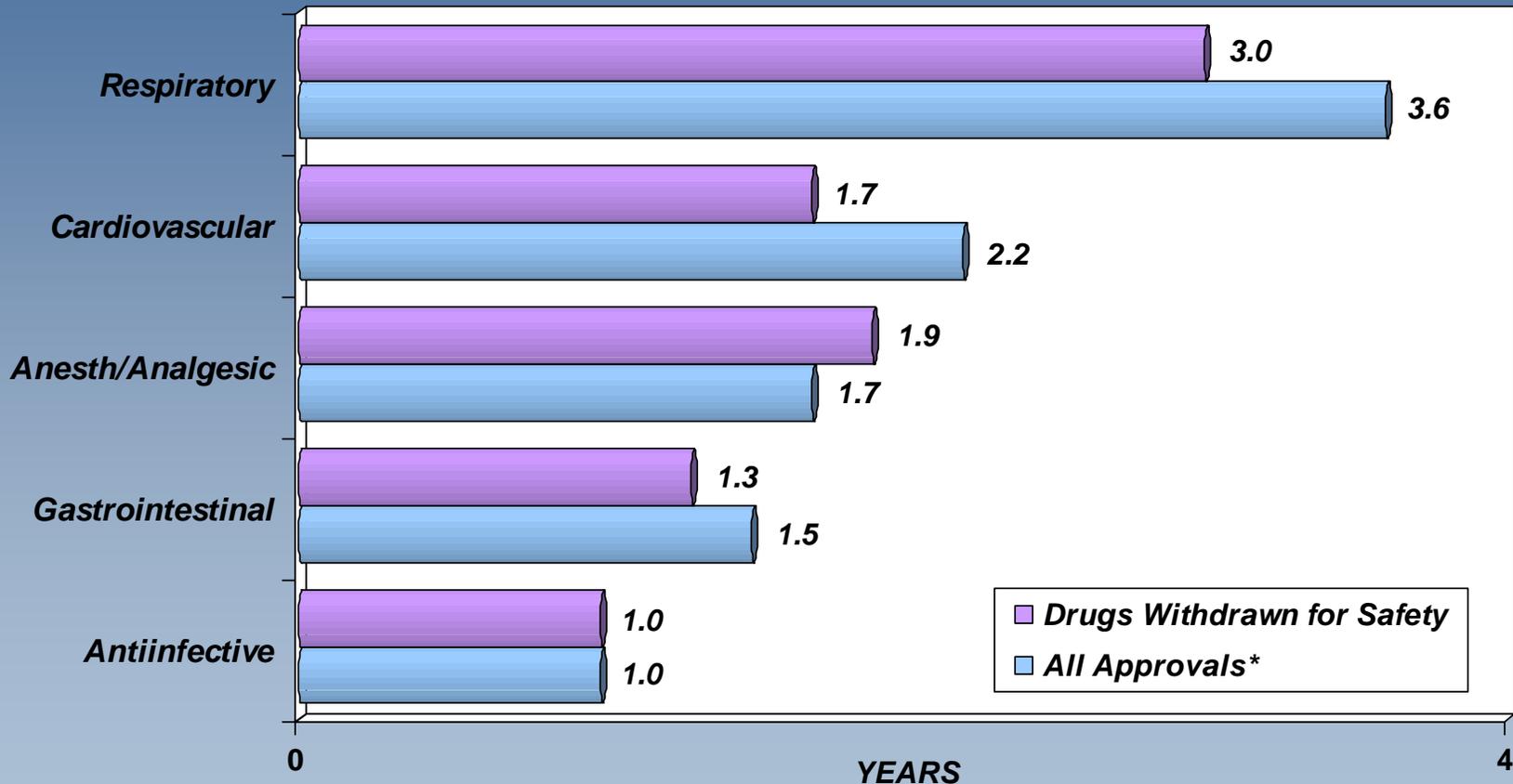
Source: Tufts CSDD, 2005

Percentage of Products Withdrawn for Safety Reasons Has Increased Slightly

<i>Year of Approval</i>	<i>Total NME Approvals</i>	<i>Total Safety Withdrawals</i>	<i>%</i>
<i>1981-1992</i>	284	8	2.8%
<i>1993-2004</i>	352	11	3.1%

Source: Tufts CSDD, 2005

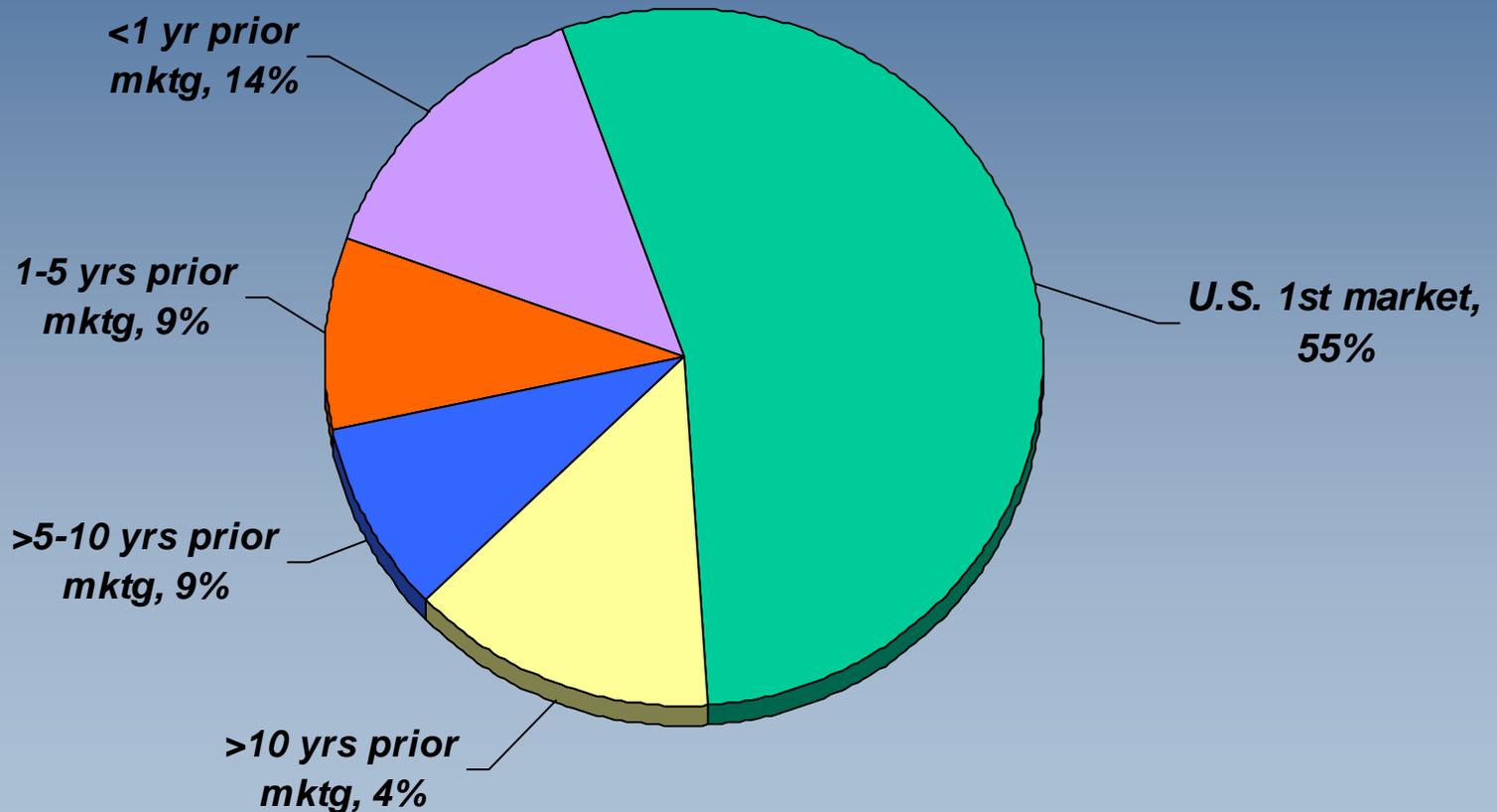
Median Approval Times for Safety Withdrawals vs All Drugs—by Class



* Median values for all approvals are for range of years of safety withdrawals
Source: Tufts CSDD, 2005

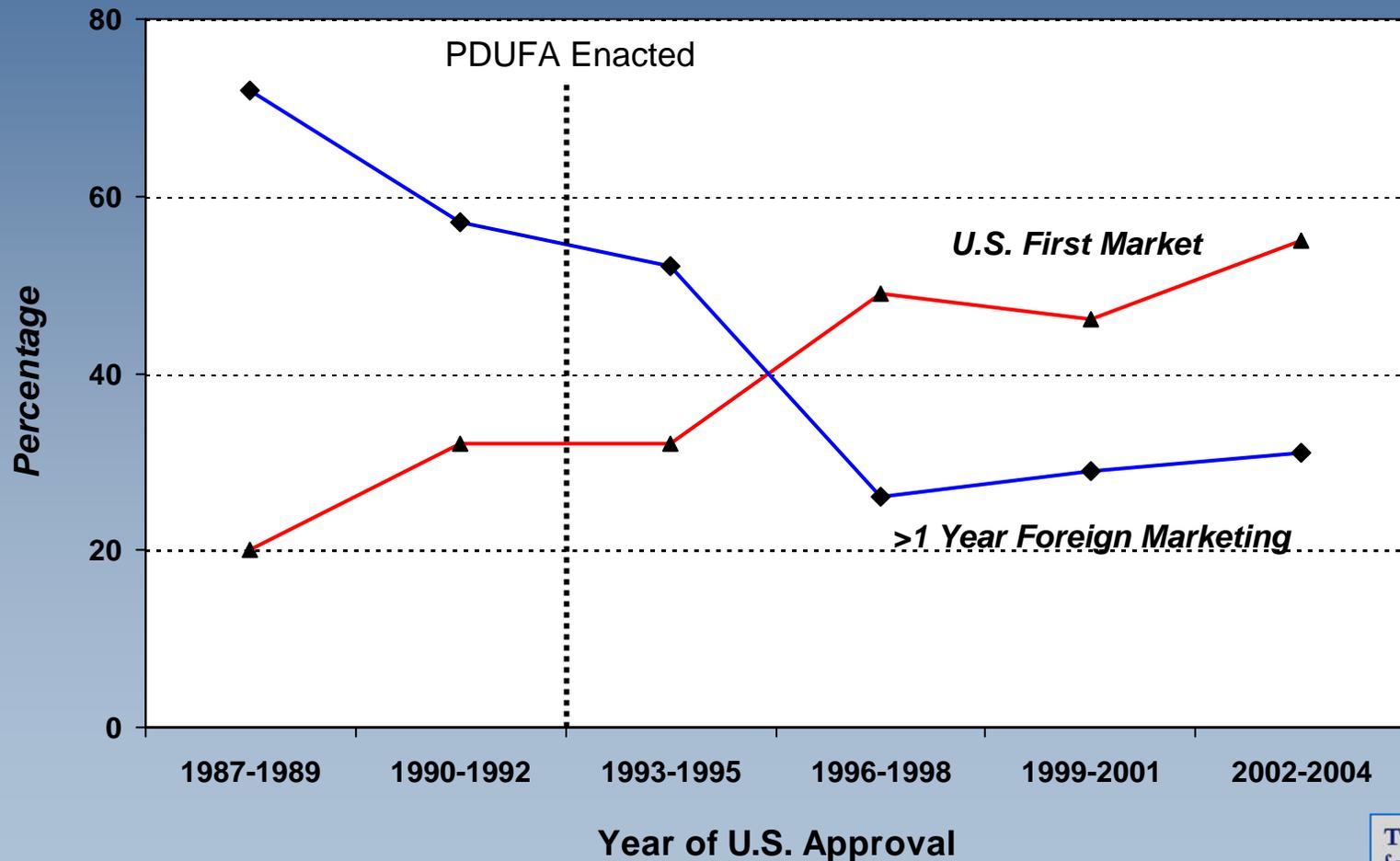
Theme 4:
Attractiveness of US Market

Prior, Foreign Marketing of New Drugs Approved in the US, 2002-04



Source: Tufts CSDD, 2005

Incentives for Developers to Market NCEs first in the US Continue to Grow



Source: Tufts CSDD, 2005

Conclusions

- ◆ NME output has declined in PDUFA era.
- ◆ Increase in clinical development times has offset reduction in NDA approval times and delayed time to market.
- ◆ Despite slight rise in percent of products withdrawn for safety reasons after 1993, there is no correlation between approval time and likelihood of safety withdrawal.
- ◆ The US remains an attractive market for first launch of new prescription drugs.

Moving Forward

- ◆ **FDA should work with industry to identify and address regulation-related causes of lengthening clinical development times.**
- ◆ **FDA should focus on understanding the assessment of post approval drug risks and improving the process of identifying and responding to drug safety problems.**