

*Worldwide Trends in New Product Introductions –
Economic and Policy Issues*

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*The Quantity and Quality of Worldwide New Drug Introductions 1982-2003**

Analysis of trends for

- Global and first-in-class drugs
- Biotech and orphan drugs
- National origin of new drugs
- Country of first launch

* Co-authored with Y. Richard Wang, in *Health Affairs*, 25(2) March/April 2006

Motivation for Our Analysis

- Significant structural changes
- Important policy developments
- Many outstanding economic issues

Structural Changes: The Drug Industry of the Early 1980s

- Chemistry based discovery
- Multinational vertically integrated firms
- Infant biotech industry
- Fringe generic industry
- Physician driven Rxs

Structural Changes: The Drug Industry of the Early 2000s

- Biology based discovery
- Drug industry consolidation
- Growth of biotech sector
- Significant generic industry
- Very cost-conscious payors

Important U.S. Policy Developments

- Bayh-Dole Act (1980)
- Orphan Drug Act (1983)
- Hatch-Waxman Act (1984)
- Prescription Drug User Fee Act (1992)
- Medicare Part D (2005)

U.S. Policy Toward Pharma Industry Appears to be the Most “Innovation-friendly”

- Biomedical research support
- Technology transfer
- IP protection
- Regulatory reform
- Generic utilization
- Formularies

Key Conjectures About Trends Between 1982-2003

- Innovative and higher quality NCEs will increase relative to NCE introductions
- The United States should be the leading source of innovative new drugs
- After 1992, the United States also should be the preferred country of launch for important new drug introductions

Sample Characteristics

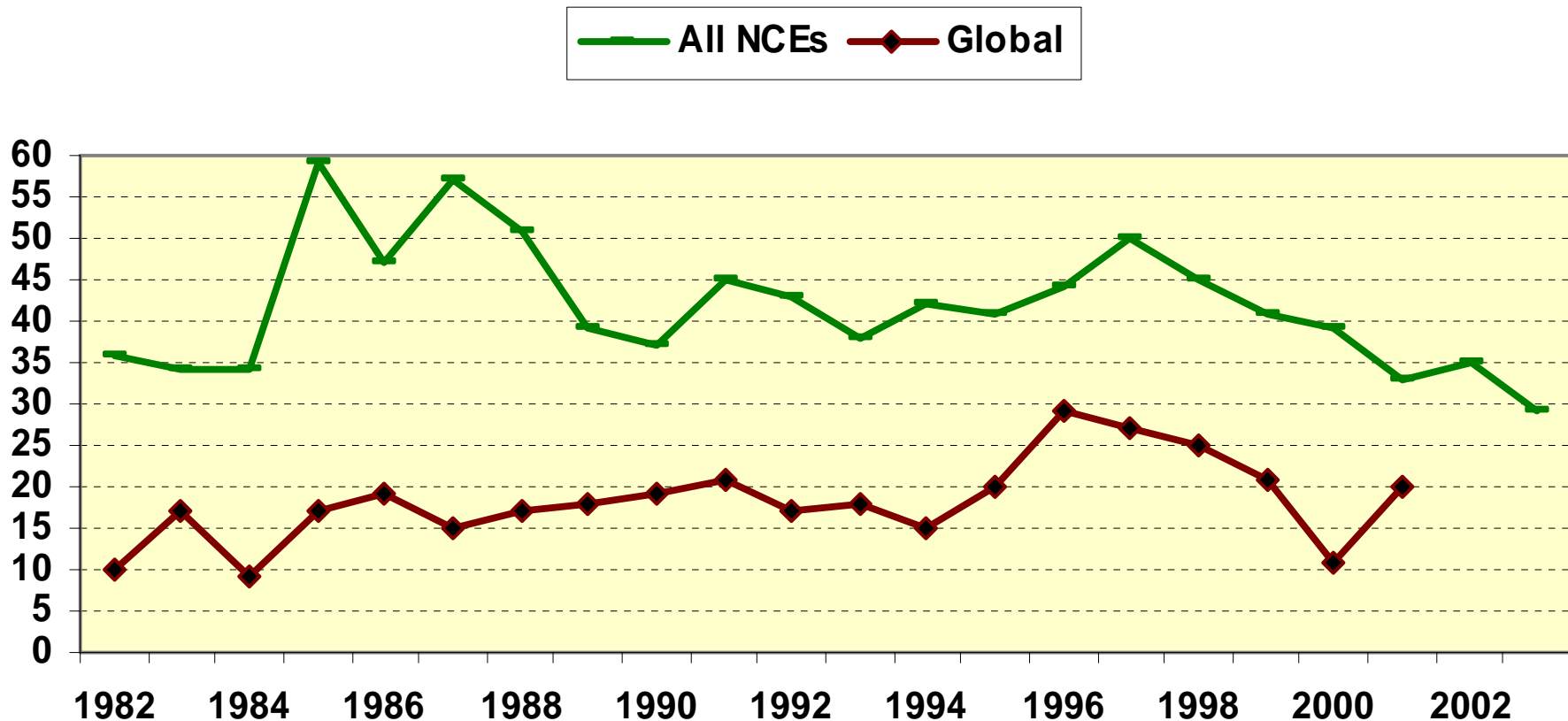
919 NCEs were first introduced worldwide between 1982 – 2003 including

- a) 385 global drugs
- b) 115 first-in-class drugs
- c) 90 biotech drugs
- d) 69 orphan drugs

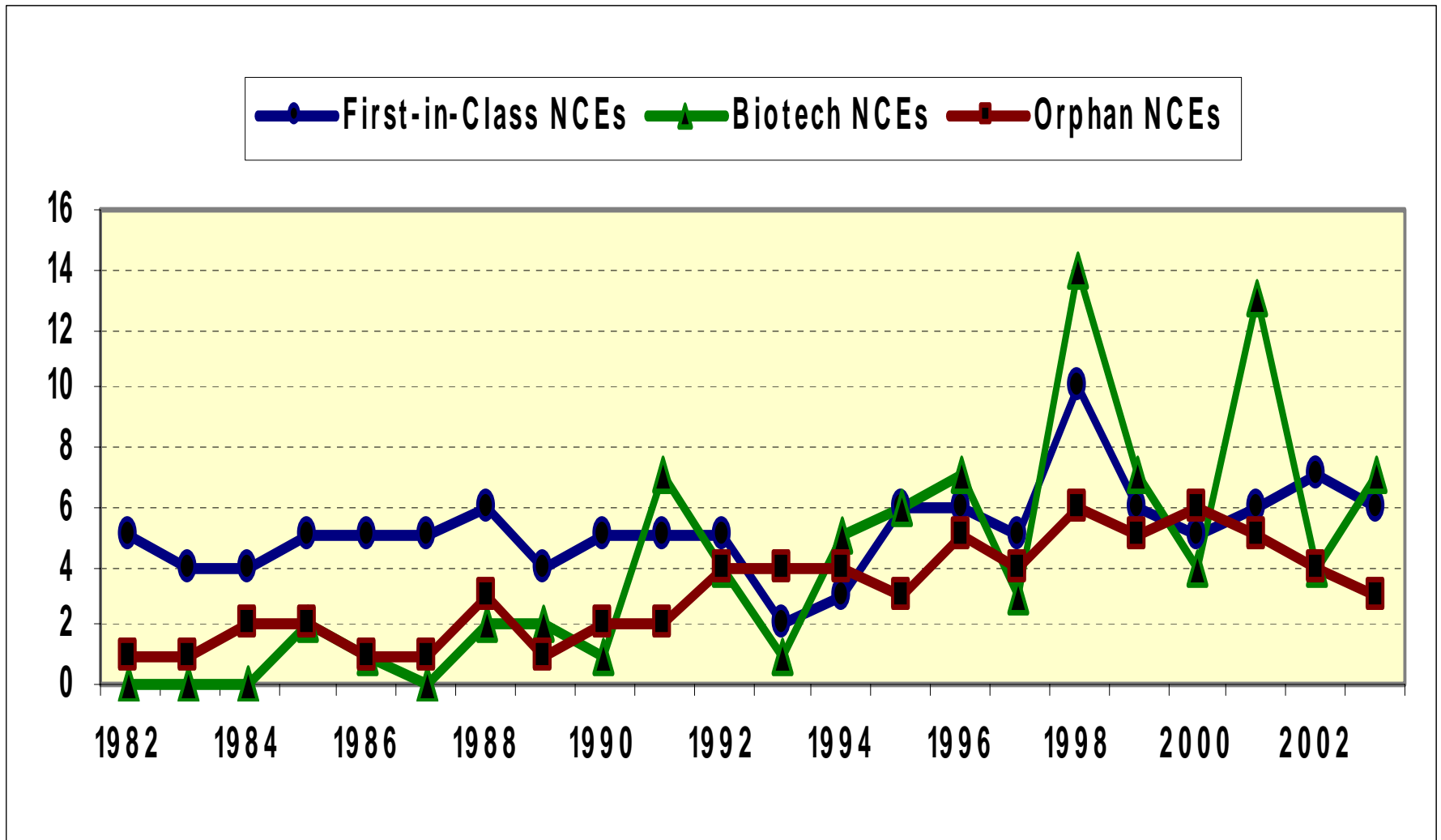
Definition of Terms

- A global NCE is a drug introduced into a majority of the G7 countries (US, Japan, Germany, France, UK, Italy, Canada)
- A first-in-class NCE is the first drug introduction in a particular 5 digit USC drug category (or 4 digit ATC)
- The national origin of an NCE is based on the nationality of the corporation that first introduced it worldwide
- Orphan drug classification is based on FDA designation at time of initial introduction

Annual Introductions of Total and Global NCEs, 1982-2002



Annual Introduction of First-in-Class, Biotech and Orphan Drugs 1982-2003



Some Important New Drug Classes Introduced Between 1982-2003

Statins (cholesterol reduction)

SSRIs (depression)

Proton pump inhibitors (ulcers)

Triptans (migraine)

Taxanes (cancer)

Macrolides (infections)

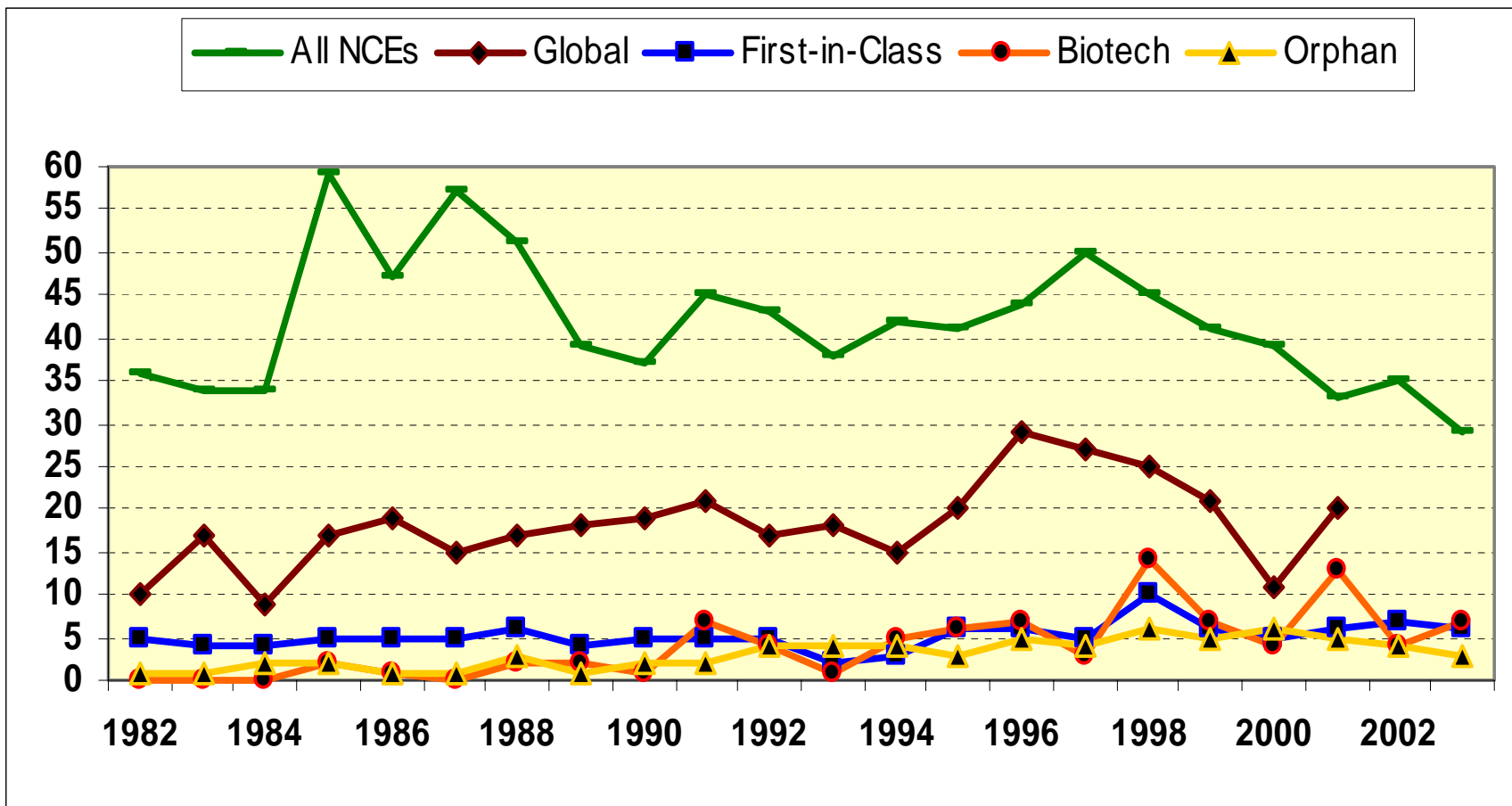
Atypical anti-psychotics (schizophrenia)

Protease inhibitors (AIDS)

Neutrophil growth factors (neutropenia)

SERMs (osteoporosis)

Annual Introduction of NCEs for Different Drug Categories, 1982-2003



Importance of Biotech Industry

- Biotech drugs grew from 4% of NCEs in 1982-1992 to 16% of NCEs in 1993-2002
- A key focus of biotech R&D and new drug introductions is the oncology area.
- Oncology category also had the highest number of first-in-class and orphan drugs

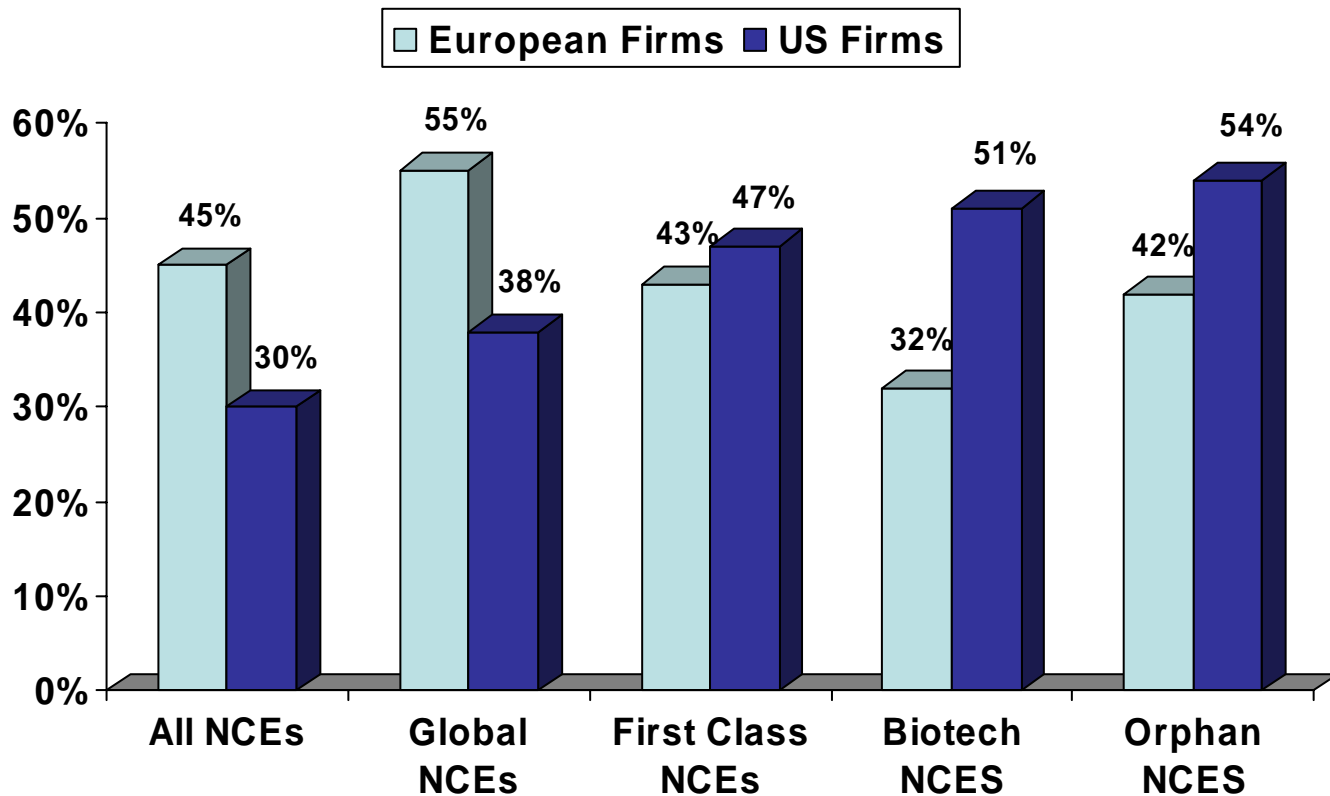
Therapeutic Focus By Regions

- Therapeutic area concentrations for global NCEs differ significantly across countries and regions
- Japanese firms focused particularly on antibiotics and respiratory drugs, rather than oncology or CNS
- By contrast, US and European firms had strong concentrations in oncology and CNS drugs
- Also significant areas of concentration in these two regions were anti-virals (US) and cardiovasculars (EU)

Innovative Performance Across Regions

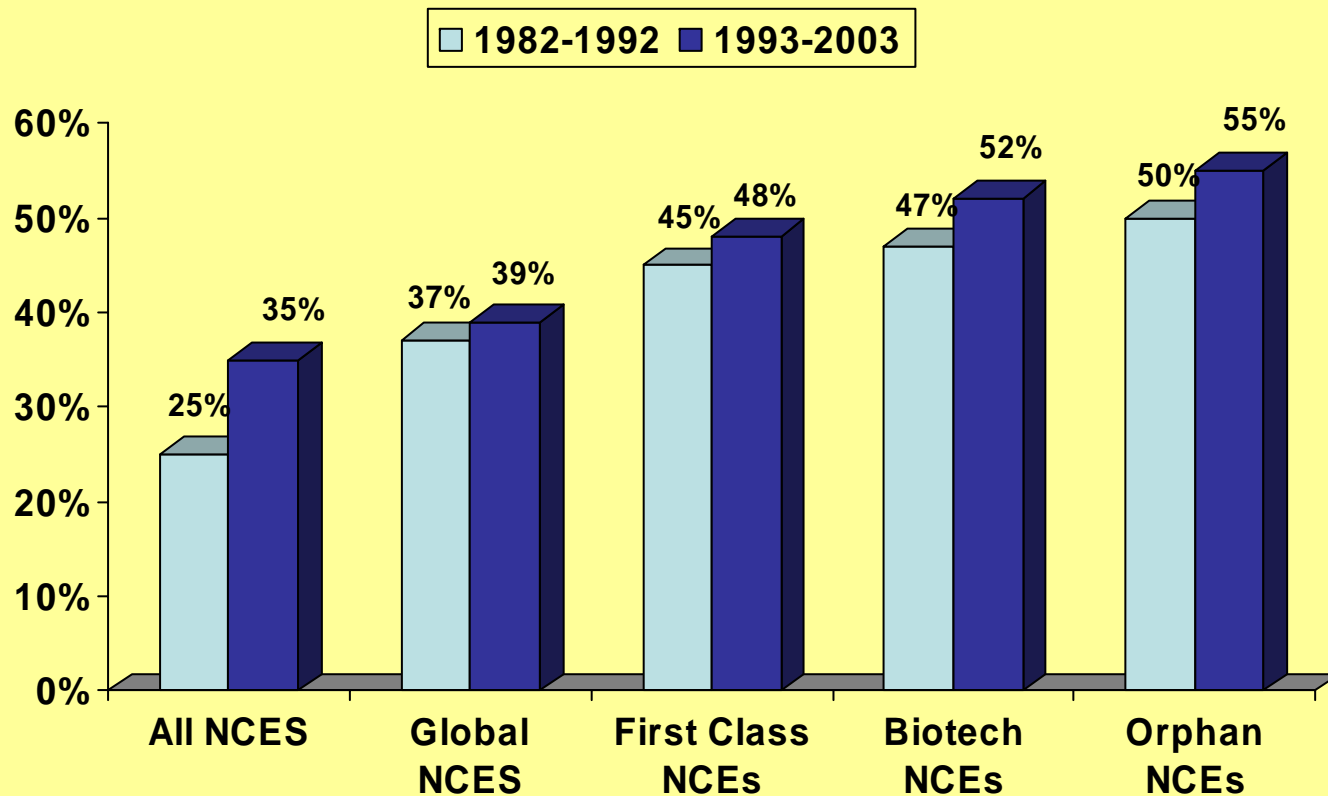
- European firms collectively accounted for the most total and global new drug introductions
- US firms were the leaders in first-in-class, biotech and orphan new drug introductions
- The United States lead in introducing innovative drug introductions increased in the 1990s
- Japanese firms and the rest of the world introduced relatively few innovative new drugs

Percentage of NCEs Originating in European Versus US Firms 1982-2003

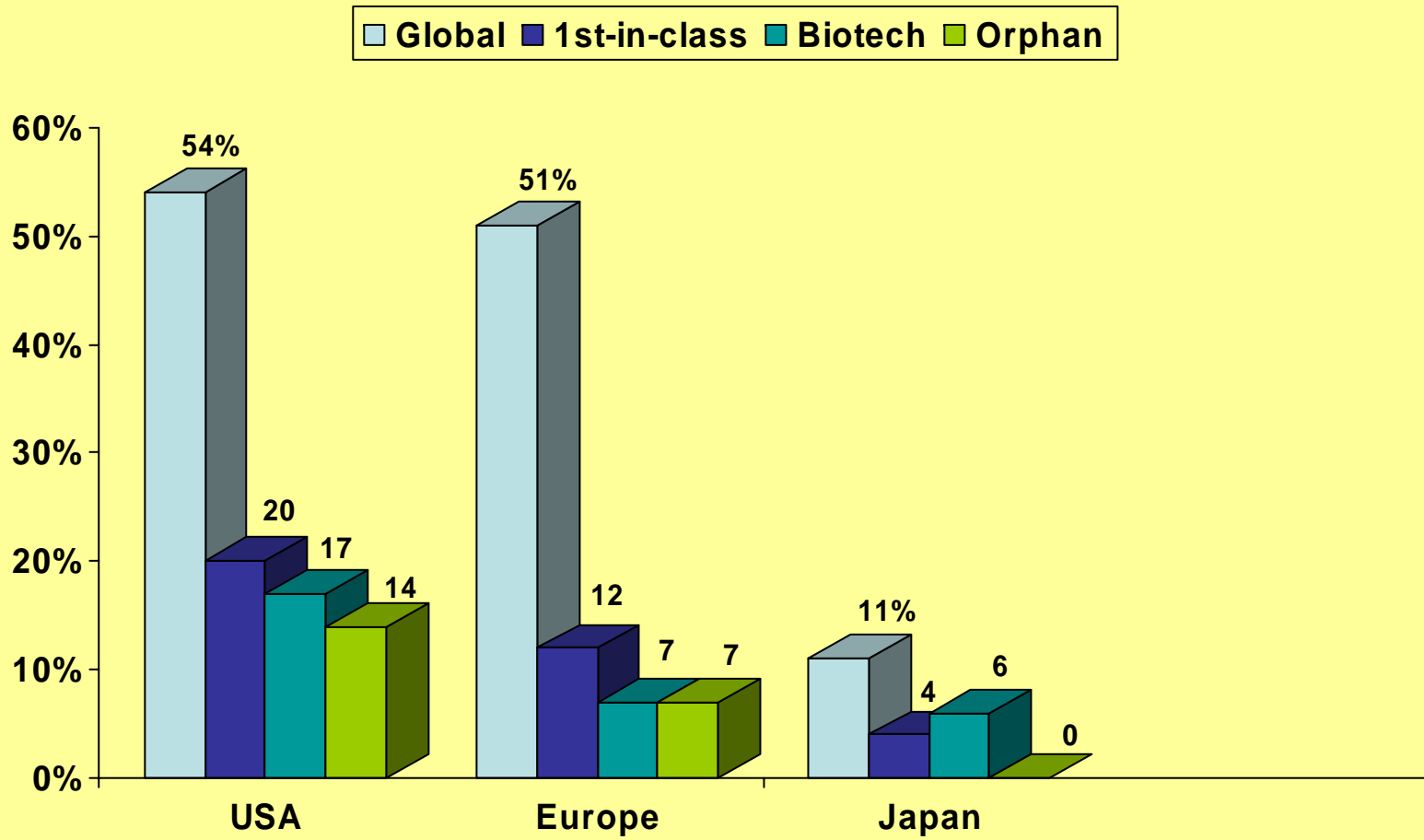


Note: Classification based on headquarters of firm making first worldwide introduction

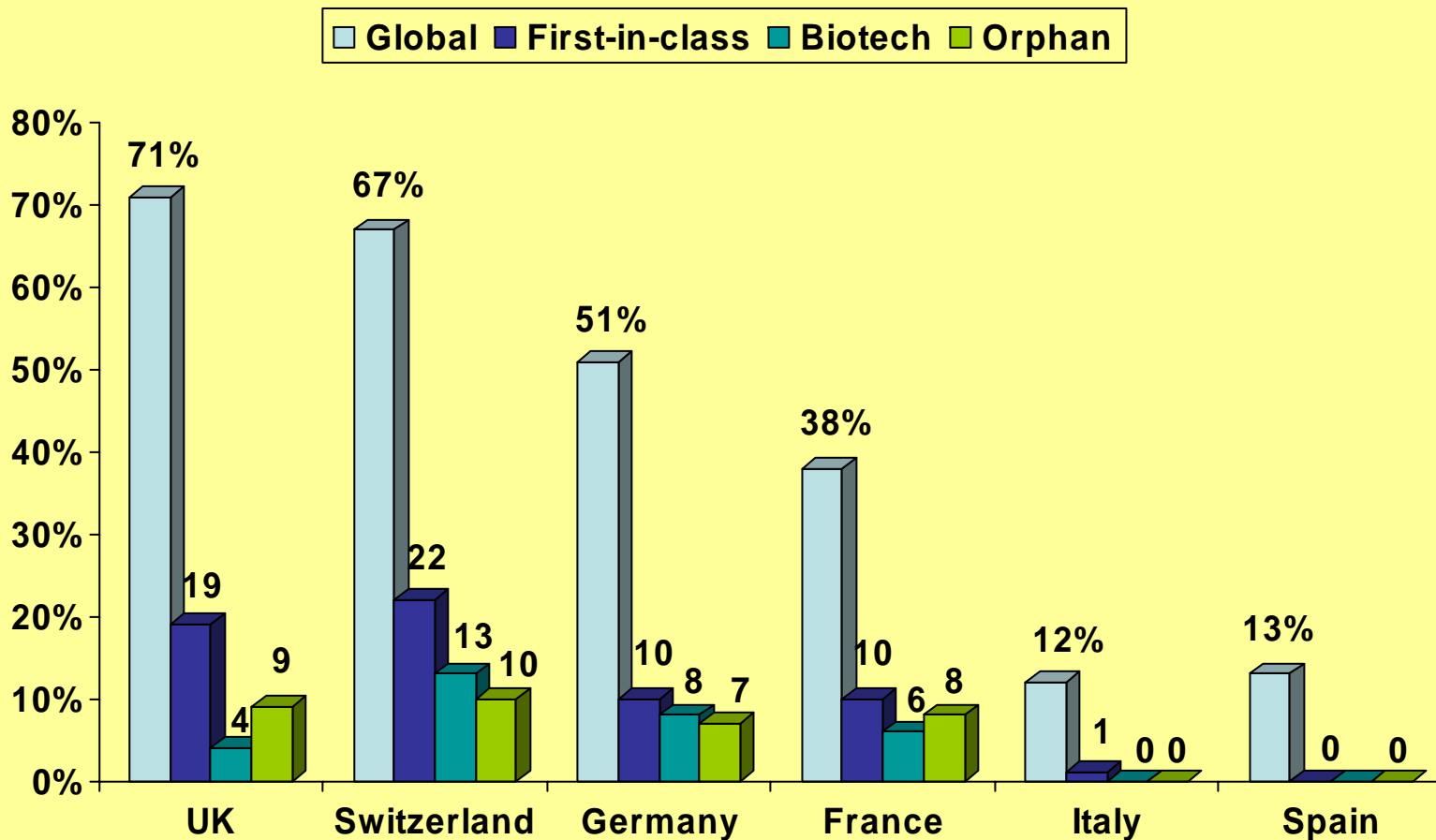
Percentage of NCEs Originating in US Firms 1982-1992 Versus 1993-2003



Characteristics of NCEs Originating From Different National Industries



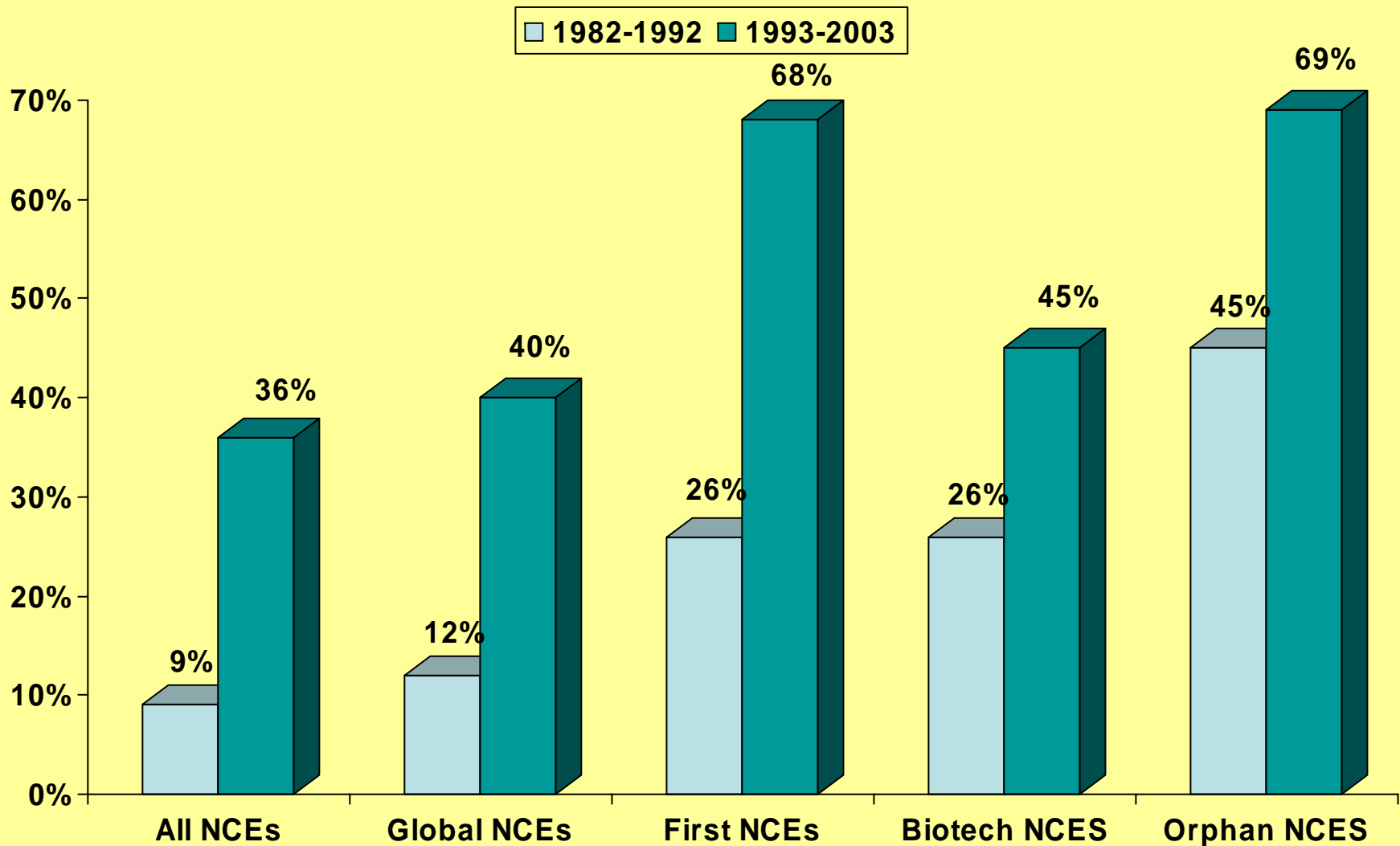
Characteristics of NCEs Originating From Different European Industries



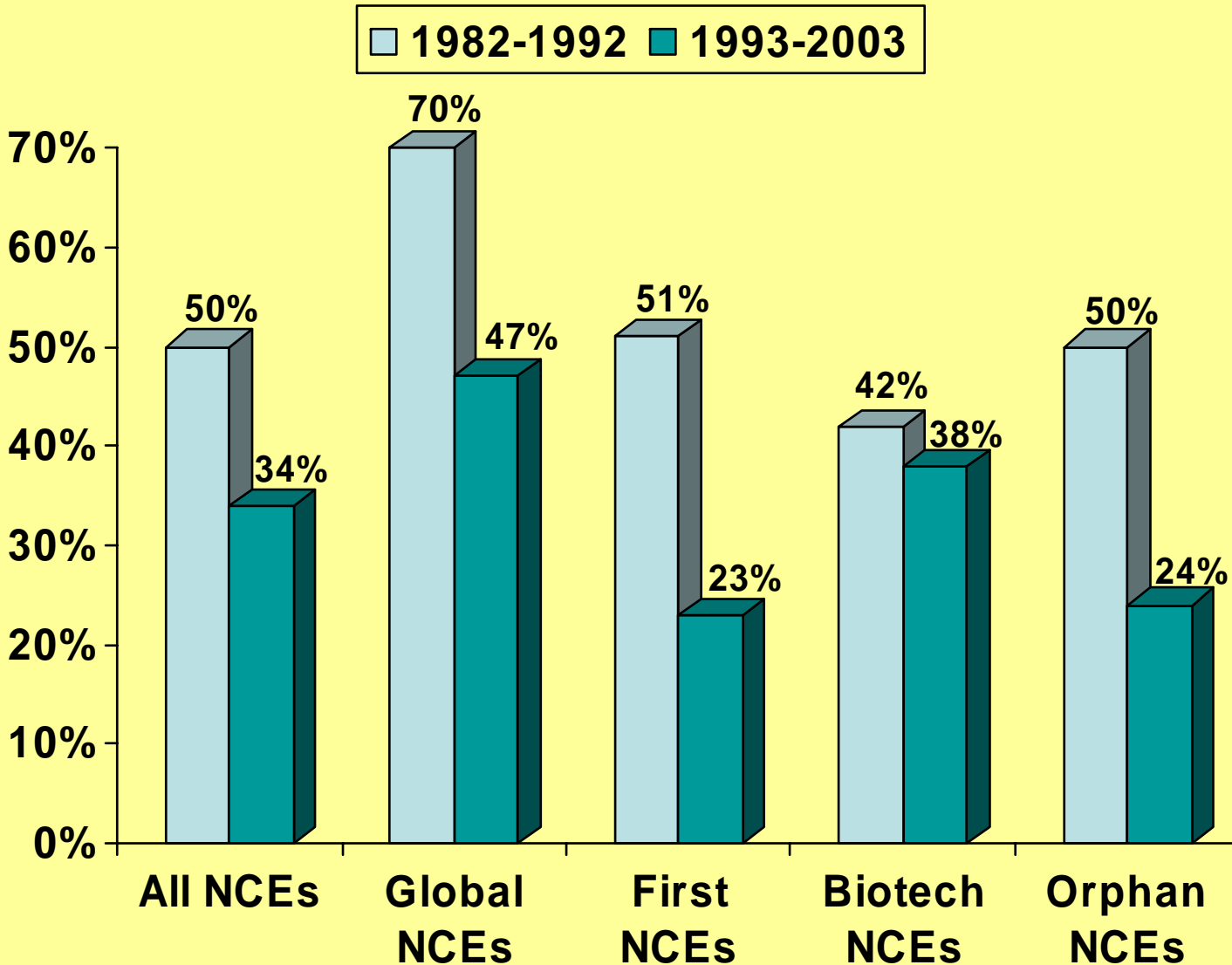
Country of First Worldwide Launch

- The United States was rarely the country of first launch in the 1982-92 period, confirming early “drug lag” studies
- The situation completely changed after 1992 as FDA review times significantly decreased
- The US then became the preferred country of first launch, especially for important NCEs

US as Country of First Worldwide Introduction



Europe as Region of First Worldwide Introduction



Discussion of Findings

The number of important new drug introductions has increased relative to total introductions

- Innovative products with few close substitutes are able to earn premium prices
- Products with close substitutes are subject to significant price pressures by insurers
- The evolving pattern is a rational economic response to demand and supply side changes

US Leadership in Important NCEs Reflects Its More Favorable Innovation Environment

- US research support and tech transfer policies have spawned many new firms
- US market oriented policies encourage risk taking by new and established entities
- US and foreign firms can benefit from this environment, but arguably US firms have been the greatest beneficiaries

The United States Is Now the Preferred Country to Launch Important NCEs

- US patients receive obvious benefits from timely access to innovative therapies
- But Mary Olson has found that innovative new drugs are subject to above average risks
- Post-marketing surveillance is especially important for novel new compounds

FDA Safety Policies Under Review

- The Institute of Medicine is investigating FDA policies in wake of Vioxx and other recalls
- Some industry critics advocate the end of user fees and a return to longer FDA review times
- This would delay patient access to new drugs and have adverse incentives for R&D
- Would it improve drug safety?

Do Faster Reviews Increase Safety Risks?

- In a new paper, we analyze how FDA review time and other variables affect drug safety
- More novel drugs and shorter US launch lags result in increased serious adverse event reports
- But no relation between FDA review times and serious ADRs after controlling for other factors
- No evidence that FDA officials are taking additional risks to meet review time targets

Other Evolving Policy Issues That Could Adversely Affect US Environment

- Current ban on NIH for research utilizing new stem cell lines
- Changes in Medicaid and Medicare reimbursement policies
- Increased litigation from early patent challenges by generic firms