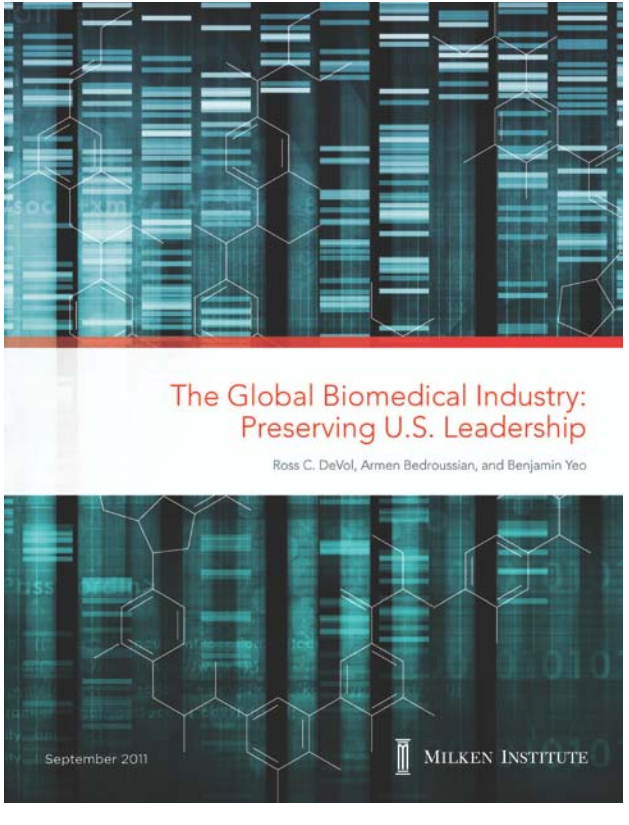

Milken Institute

COUNCIL FOR AMERICAN MEDICAL INNOVATION

Breakfast briefing:
Ross DeVol
Chief Research Officer
Milken Institute
September 22, 2011
The Phoenix Park Hotel
Washington, DC

Study overview

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- **Part 1: The Global Biomedical Industry: Understanding the Factors that Led to U.S. Dominance**
- **Part 2: The Changing Global Landscape**
- **Part 3: Recommendations to Retain U.S. Leadership**

Size of biomedical industry

2009

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Industry	Employment	Wages, US$B	Output, US$B
Biopharmaceuticals	283,700	$29.0	$82.4
Medical devices and equipment	409,200	$26.5	$59.4
Research, testing and medical labs	526,300	$40.3	$64.5
Total Biomedical	1,219,200	$95.9	$213.2

Sources: Bureau of Labor Statistics, Moody's Analytics, Milken Institute.

Four largest European countries comprised more than half of all NCEs produced during 1970s….

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NCEs =New chemical entities by headquarter country of inventing firm

	1971-1980	
Country	**NCEs**	**% total**
U.S.	157	31
France	98	19
Germany	96	20
Japan	75	15
Switzerland	53	10
U.K.	29	6
Total NCEs	508	

Sources: Arthur Daemmrich, "Where Is the Pharmacy to the World? International Variation and Pharmaceutical Industry Location," Harvard Business School Working Paper, 2009; Milken Institute.

….but in the previous decade, the U.S. share jumped to 57 percent

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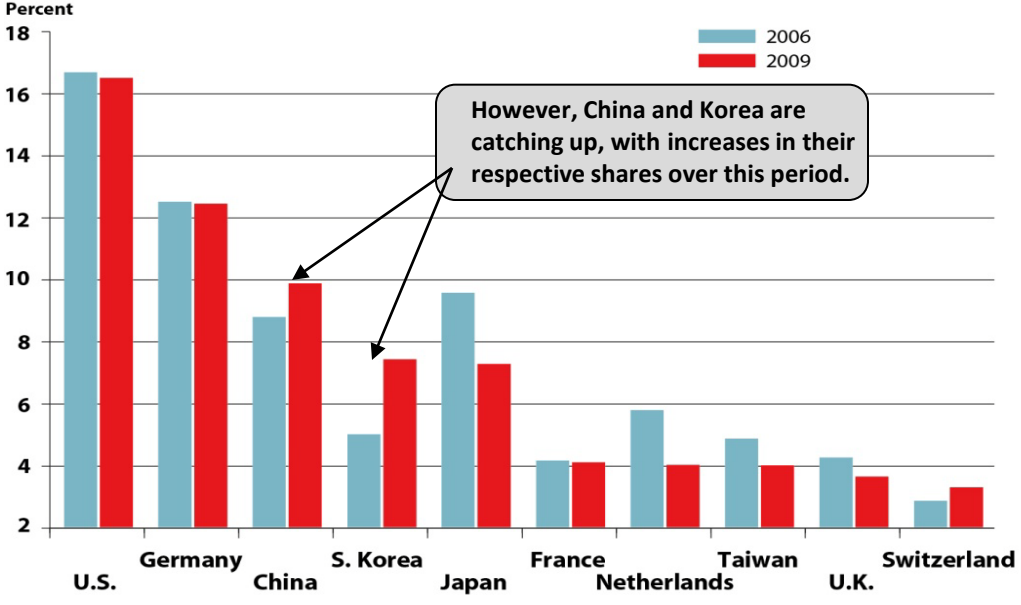
NCEs =New chemical entities by headquarter country of inventing firm

	2001-2010	
Country	**NCEs**	**% total**
U.S.	111	57
France	11	6
Germany	12	6
Japan	18	9
Switzerland	26	13
U.K.	16	8
Total NCEs	194	

Sources: Arthur Daemmrich, "Where Is the Pharmacy to the World? International Variation and Pharmaceutical Industry Location," Harvard Business School Working Paper, 2009; Milken Institute.

U.S. accounts for 16 percent of world's medical device exports

Percent share of global medical device exports, 2006 and 2009



Source: ITC.

U.S. accounts for 41.5 percent of all biotech patent applications

Top 10 regions, 2004 -2006

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Region	Country	Biotechnology patents	Share (%) in total
San Jose-San Francisco-Oakland	U.S.	1,510	5.5
Boston-Worcester-Manchester	U.S.	1,422	5.2
New York-Newark-Bridgeport	U.S.	1,090	4.0
Washington-Baltimore-Northern Virginia	U.S.	811	3.0
Tokyo	Japan	729	2.9
San Diego-Carlsbad-San Marcos	U.S.	782	2.9
Los Angeles-Long Beach-Riverside	U.S.	613	2.2
Philadelphia-Camden-Vineland	U.S.	587	2.2
Nordrhein-Westfalen	Germany	506	1.9
Hovedstadsregionen DK	Denmark	454	1.7

Sources: OECD, Patent and REGPAT databases (2009); EPO Worldwide Statistical Patent Database (2008).

California: A hotbed of biotech

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Boston: A hub of medical innovation

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2010 QS World University rankings

Life Sciences & Medicine

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Rank 2010	School	Country	Score
1	Harvard University	U.S.	100
2	University of Cambridge	U.K.	92
3	University of Oxford	U.K.	82
4	Stanford University	U.S.	75
5	University of California, Berkeley	U.S.	70
6	University of Tokyo, The	Japan	66
7	Johns Hopkins University	U.S.	66
8	Massachusetts Institute of Technology	U.S.	64
9	Yale University	U.S.	63
10	University of California, Los Angeles	U.S.	60

Rank 2010	School	Country	Score
11	Imperial College London	U.K.	58
12	University of California, San Diego	U.S.	57
13	National University of Singapore	Singapore	54
14	University of Melbourne	Australia	53
15	University College London	U.K.	53
16	University of Toronto	Canada	52
17	University of Edinburgh	U.K.	50
18	Kyoto University	Japan	50
19	University of Sydney	Australia	49
20	University of British Columbia	Canada	49

Sources: Quacquarelli Symonds, Times Higher Education.

U.S. share of foreign students declining

Global destinations for international students at the post secondary level

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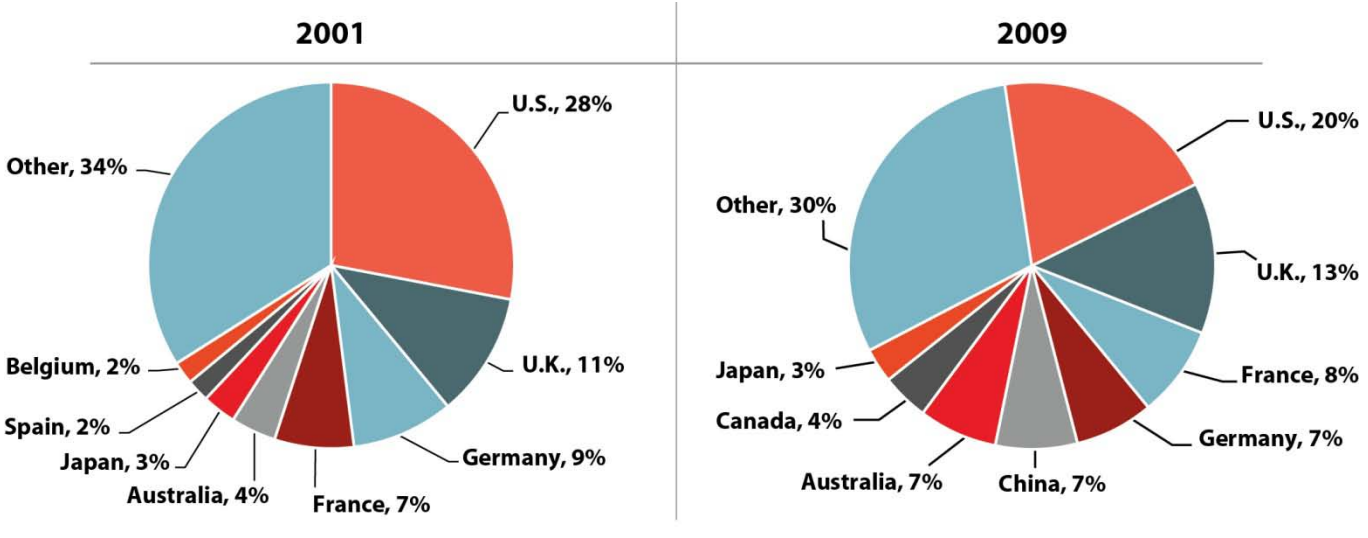

Sources: OECD; Atlas of Student Mobility, Institute of International Education.

Developing a new medicine takes an average of 10 -15 years

Pharmaceutical R&D process

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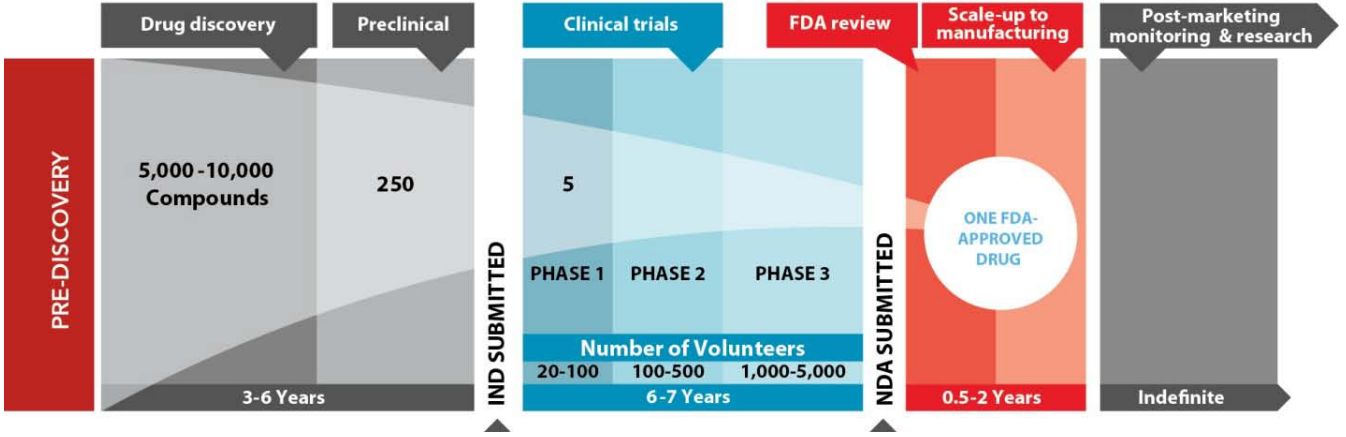
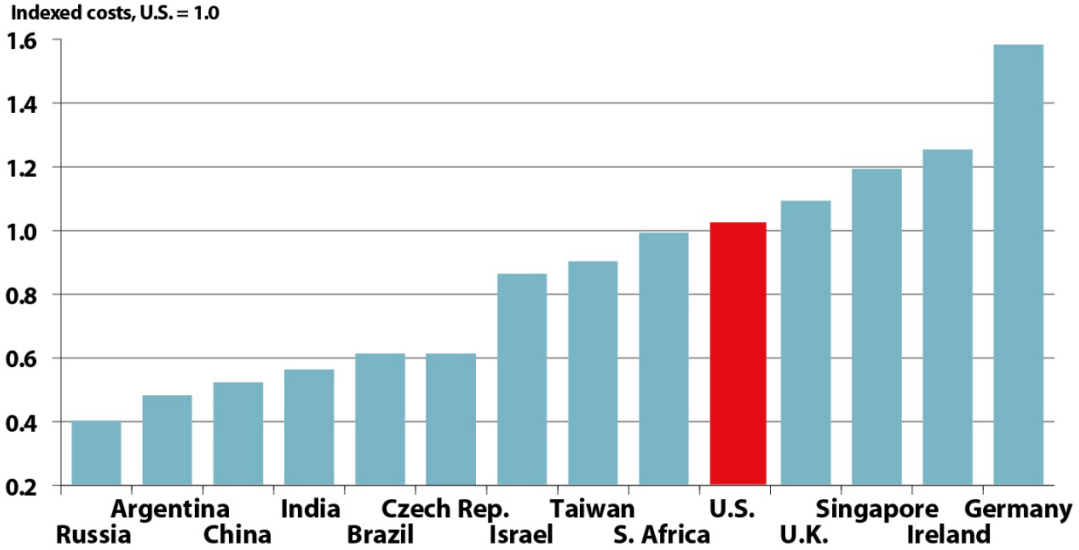


Source: Pharmaceutical Research and Manufacturers of America.

U.S. clinical trial costs are non-competitive



Sources: Salary Expert.com; WDI Database; Economist Intelligence Unit; CBRE Global Markets Rent 2005; A.T. Kearney; Clinical Trial Offshoring.

Average time for 510(k) products and PMAs has risen by 45 and 75 percent, respectively, since 2007

Medical devices approval process

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Device class	Application	Clinical requirements	Approval type	Mean time to approval
Class I (Low risk)	510(k)	Preclinical – *Proof of good manufacturing standards, correct branding and labeling*	Clearance	3-6 months
Class II (Medium risk)	510(k)	Preclinical – *In addition to Class I requirements, mandatory performance standards, and post market surveillance*	Clearance	3-6 months
Class III (High risk)	PMA	Preclinical, Pilot trial, Pivotal trial – *PMA submitted to CDRH for scientific and clinical review. CDRH determines endpoint of clinical testing and makes recommendation to FDA for final approval decision*	Approval	12-24 months

Sources: FDA Devices Program, Boston Consulting Program Group Analysis.

Singapore: Innovation as national priority

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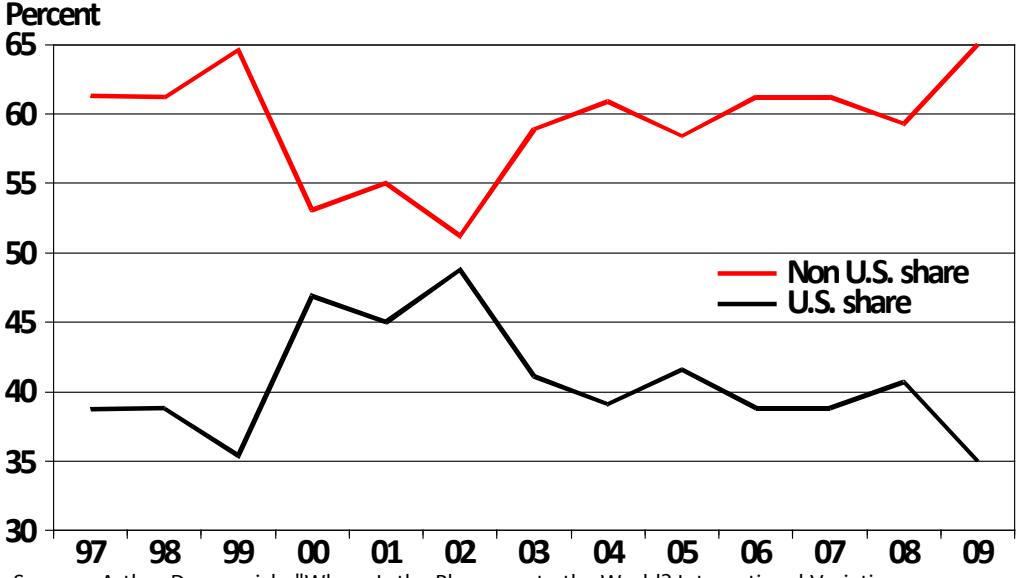
E.U.-based firms recapturing innovation position

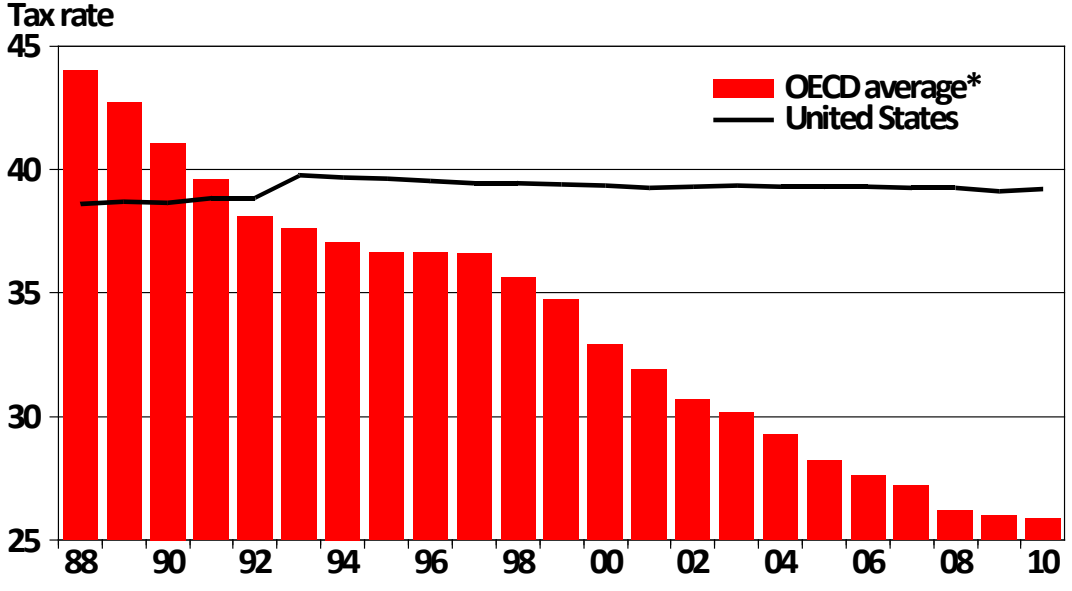
New drug approvals in the E.U. by headquarters of sponsoring company



Sources: Arthur Daemmrich, "Where Is the Pharmacy to the World? International Variation and Pharmaceutical Industry Location," Harvard Business School Working Paper, 2009; Milken Institute.

U.S. has second-highest corporate tax among OECD countries

Statutory corporate income tax rates, OECD average vs. United States



Sources: OECD, Milken Institute.

*OECD average includes Chile from 2000 onward

Recommendations on how U.S could retain and bolster its leadership in biomedical innovation

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- Increase R&D tax incentives and them permanent
- Cut corporate tax rates to match the OECD average
- Extend support for emerging biomedical research fields
- Provide adequate resources for the FDA and the NIH to expedite regulatory reviews and clinical trials
- Leverage existing strengths in medical devices
- Build human capital for biomedical innovation
- Promote and expand role of universities by adopting best practices in tech transfer and commercialization