

Successful Campaigning: Collaborations with Industry

Jessica Federer, MPH, Global Advocacy,
Bayer Schering Pharma

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Overview: Successful Campaigning

- This presentation will discuss how to best partner with industry for success in campaigns and provide information to facilitate an informed and compliant partnership.
- Outline:
 - Why Collaborate with Industry for Campaigns?
 - How to Collaborate with Industry?

Why do you want to work with industry for campaigns?

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Share a common goal of helping patients.
Industry can also provide...



Access to Funding

- Companies gave \$3.83 billion in cash donations in 2008
- And an additional \$3.23 billion in product in 2008

- *The 2008 Corporate Contributions Report



Global network of experts

- Top researchers and physicians
- non-medical experts in policy, communication, government, etc.



Development Focused

- Dedicated to progress
- Clinical trials for new therapy
- Ability to take risks

Why does industry want to work with patient organizations for campaigns?

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Share a common goal of helping patients.
Patient/Advocacy groups can also provide...



Independent Voice

- Advisors to authorities and payers on what patients want
- Expert voice to impact public perception
- Education and Information dissemination



Political Influence

- Impact the access environment to help patients and caregivers
- Unite industry and patient groups for common causes



Support to Patients

- Know what patients want and need.
- Know what is important to caregivers and families
- Share information and support

Industry Basics

- What should I know about industry so I can be an informed partner?

Industry needs to work with you!

Drug development is a “high risk” investment



Increasing: costs, regulatory requirements, reimbursement hurdles



Decreasing: budgets, approvals of new drugs

Quick Numbers

- Pharmaceutical companies invest an average of \$500-2,000m per new drug depending on company and therapy area.
- Development costs in AD field are among the highest.
- FDA 2009: 19 New Molecular Entities were approved
- EMA 2009: 29 CHMP positive recommendations for marketing authorization

1. Hughes, B. 2009 FDA drug approvals. *Nature Rev. Drug Discov.* 9, 89–92 (2010).

2. Adams C, Brantner V (2006). "Estimating the cost of new drug development: is it really 802 million dollars?". *Health Aff (Millwood)* 25 (2): 420–8. [doi:10.1377/hlthaff.25.2.420](https://doi.org/10.1377/hlthaff.25.2.420). [PMID 16522582](https://pubmed.ncbi.nlm.nih.gov/16522582/).

Working with organizations can help improve development and reduce risk

Organizations are not to be seen as “beneficiaries” or “recipients” but rather as



Equal Partners

Steps for a successful partnership

- Know the Rules
- Choose the right partners
- Get it in writing
- Mutual respect

Key Regulations

- Pharmaceutical Research and Manufacturers of America (PhRMA)
www.phrma.org
- European Federation of Pharmaceutical Industries and Associations (EFPIA) www.efpia.org
- Association of the British Pharmaceutical Industry (ABPI) www.abpi.org.uk
- International alliance of patients' organizations (IAPO)
www.patientsorganizations.org
- National Health Council (NHC) www.nationalhealthcouncil.org
- National Commission of Medical Arbitration
(www.conamed.gob.mx/index.php)
- International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) (www.ifpma.org)
- National Chamber of Pharmaceutical Industry guidelines
(www.canifarma.org.mx)

EFPIA Code Overview

- Article 1 Non-promotion of Prescription-Only Medicines
- Article 2 Written Agreements
- Article 3 Use of Logos and Proprietary Materials
- Article 4 Editorial Control
- Article 5 Transparency
- Article 6 Single Company Funding
- Article 7 Events and Hospitality
- Article 8 Enforcement

Know your own “Rules” and principles

- Include your own principles:
 - Integrity
 - Independence
 - Equity
 - Mutual benefit
 - Transparency

How to choose the right industry partners

- Read websites, annual reports, shareholder reports, etc. to know what they are working to develop.
- Ask your colleagues and other organizations for names to help identify the right contact in a company
- Call and “interview” potential industry partners
- Meet the people you would be working with at the company.
- Lay the foundation for a long-term relationship – don’t start by asking for money.

Steps for Developing an Agreement

- Identify your campaign goals clearly - what is success?
- Identify areas of mutual interest with potential industry partners – look for win-wins
- Develop a proposal together – don't distribute a menu with projects and prices.
- Ensure full legal and compliance review – don't risk your reputation.
- Continue to nurture the relationship- think long term.

Moving Forward Together

- We are members of the same team.
- Industry can share your passion and be a dedicated partner.
- We are people, not bank accounts – our families have diseases also, and we care about making a difference in their lives with new therapies.
- Together we can have successful campaigns with lasting impacts.

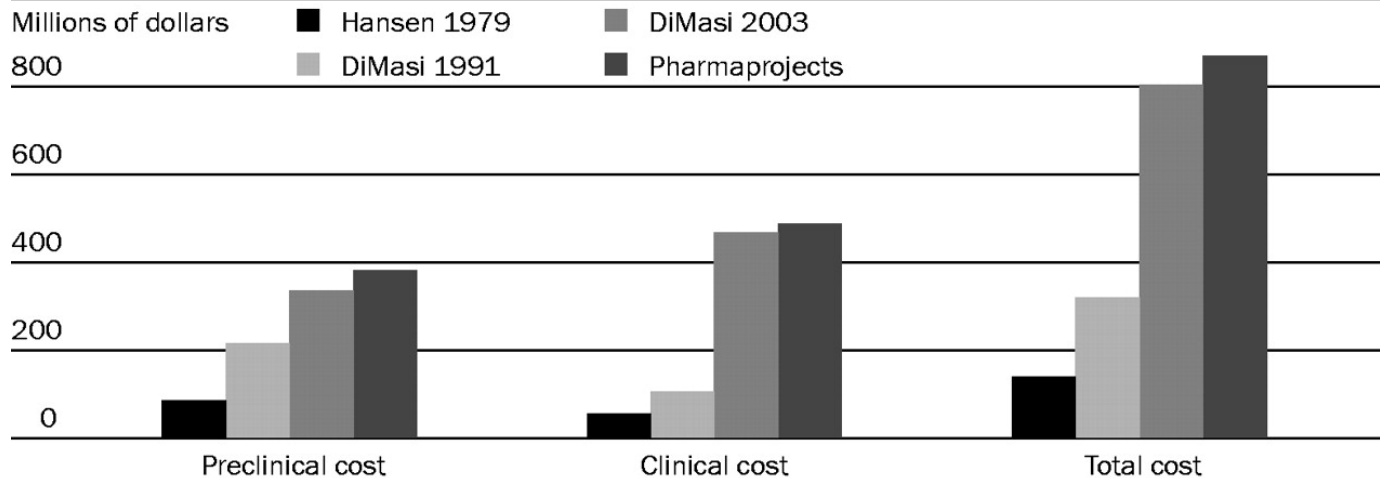
Thank you for the work you are doing to help improve the lives of patients and their families.

Back Up Slides

Total cost per new drug around 800million

EXHIBIT 3

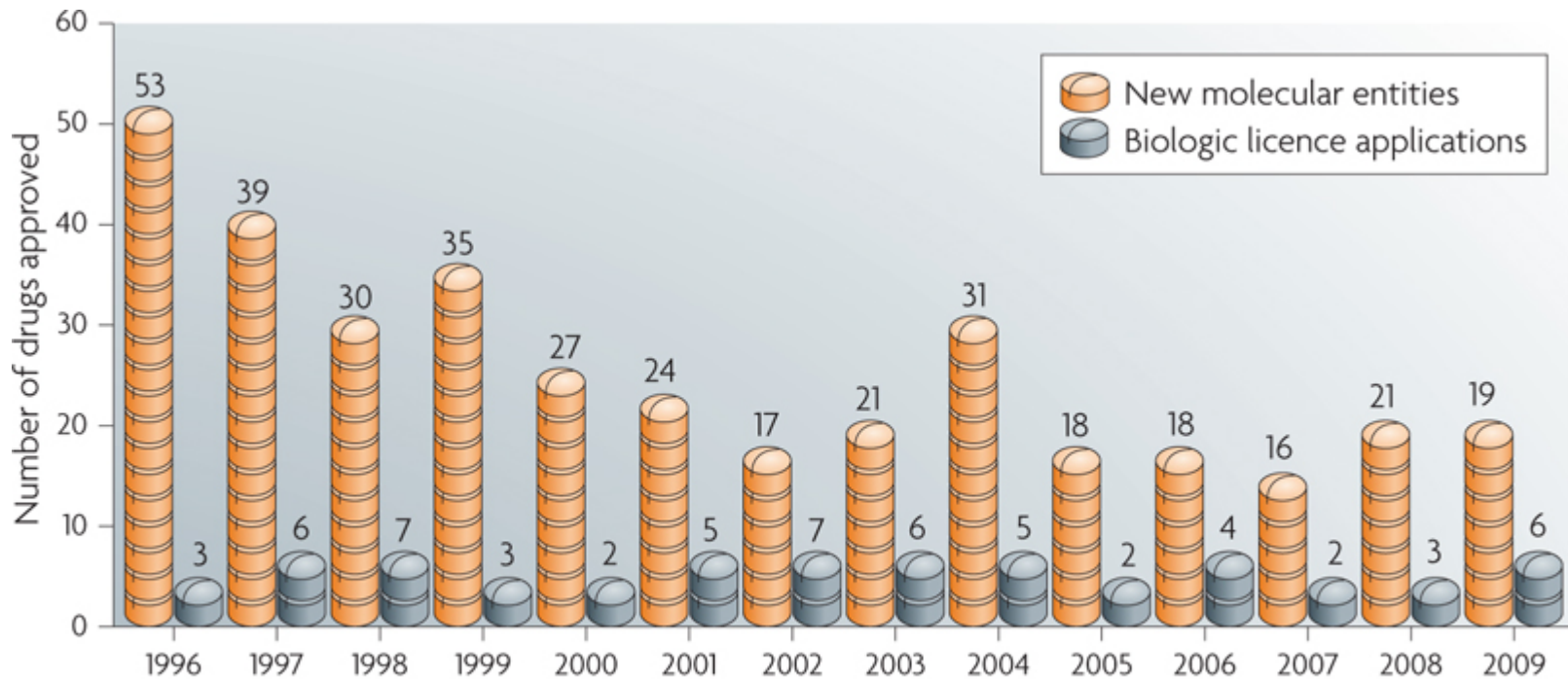
Capitalized Preclinical, Clinical, And Total Cost Per New Drug, In Millions Of 2000 Dollars



SOURCES: R.W. Hansen, "The Pharmaceutical Development Process: Estimates of Current Development Costs and Times and the Effects of Regulatory Changes," in *Issues in Pharmaceutical Economics*, ed. R.I. Chien (Lexington, Mass.: Lexington Books, 1979), 151-187; J.A. DiMasi et al., "Cost of Innovation in the Pharmaceutical Industry," *Journal of Health Economics* 10, no. 2 (1991): 107-142; J.A. DiMasi, R.W. Hansen, and H.G. Grabowski, "The Price of Innovation: New Estimates of Drug Development Costs," *Journal of Health Economics* 22, no. 2 (2003): 151-185; and data from Pharmaprojects.

Christopher P. Adams and Van V. Brantner,
Estimating The Cost Of New Drug Development: Is It Really \$802 Million?,
Health Affairs, Vol 25, Issue 2, 420-428

Fewer new drugs are being approved



Nature Reviews | Drug Discovery

2009 FDA Drug Approvals, *Nature Reviews Drug Discovery* 9, 89-92 (February 2010), doi:10.1038/nrd3101

Alzheimer's disease indication development costs are among highest

EXHIBIT 5

Probability Of Market Entry, Durations, And Costs For New Drugs, By Disorder And Primary Indication

Disorder	N	Entry probability (%)			Duration (months)			Cost (\$)
		Phase II	Phase III	Approval	Phase I	Phase II	Phase III	
Blood	163	60	57	25	18	32	33	906
Cardiovascular	280	69	42	22	14	35	30	887
Dermatological	122	84	44	29	13	29	24	677
Genitourinary	120	92	58	37	21	28	25	635
HIV/AIDS	108	75	50	36	19	23	19	540
Cancer	681	78	46	20	21	30	29	1,042
Musculoskeletal	134	73	41	22	19	39	30	946
Neurological	192	73	47	22	20	39	32	1,016
Antiparasitic	20	100	67	53	18	33	13	454
Respiratory	165	68	31	16	18	30	36	1,134
Sensory	53	88	60	40	11	44	30	648
Primary indication								
Alzheimer's disease	46	65	46	25	17	37	18	903
Rheumatoid arthritis	51	91	33	23	18	36	39	936
Asthma	74	81	36	26	18	33	31	740
Breast cancer	54	96	58	44	17	37	37	610
HIV/AIDS	89	83	56	44	22	22	19	479

SOURCE: Authors' calculations.

NOTES: Phases are for human clinical trials. New drug application (NDA) durations are as for the average drug. Cost is the total expected capitalized cost per new drug (in millions of 2000 dollars).

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