



Tufts Center for the Study of Drug Development

Impact REPORT

ANALYSIS AND INSIGHT INTO CRITICAL DRUG DEVELOPMENT ISSUES

Pharmaceutical industry innovation is more dispersed despite M&A activity

Technological opportunities spurred new drug approvals—and new entrants

- Pharmaceutical innovation has become increasingly diffuse across firms.
- Turnover has been substantial in company rankings, based on the number of new drug introductions.
- Wide diversification across therapeutic categories exists among leading firms.
- Top firms depend more on their own R&D rather than on licensing or acquisition.
- Technical and commercial productivity has varied substantially across the industry.

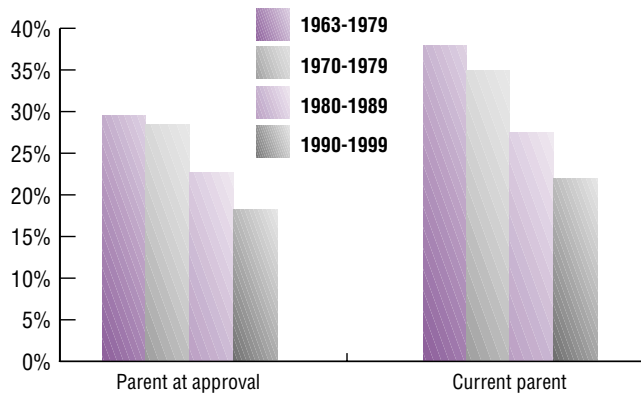
Logic and experience suggest that increased merger and acquisition activity within the pharmaceutical industry should lead to a greater concentration of drug development activity. The opposite has occurred. According to new research by the Tufts Center for the Study of Drug Development, highlighted in this Impact Report, concentration of new drug development has declined.

A full accounting of industry innovation requires an analysis of firm-specific factors, such as individual organizational structures and how effectively a firm reacts to changes in its environment, as well as an assessment of the impacts of regulation, trends in R&D costs, scientific opportunities, and knowledge spillovers.

Success, however, is often fleeting. The true leaders are those organizations that seek to compete more effectively within therapeutic areas. Typically, they do this by strengthening internal capabilities on their own or through mergers and acquisitions.

Despite M&A activity, concentration of new drug output among firms has declined

Share of NCE Approvals by Top 4 Firms



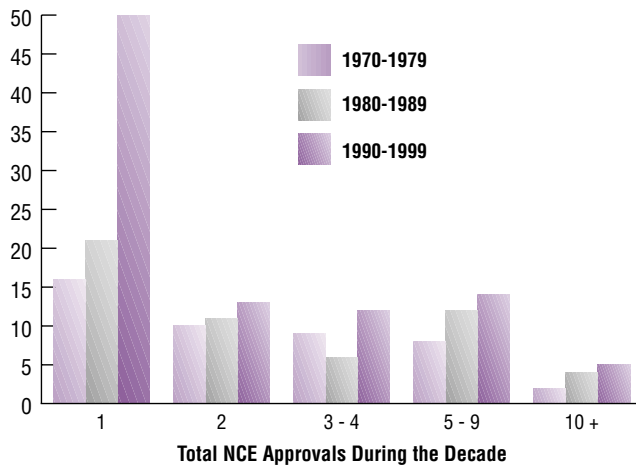
Source: Tufts Center for the Study of Drug Development

- Whether examining NCE (new chemical entity) approvals by company at the time of approval or by current parent, the share of approvals by the top four firms in the industry has declined since the 1960s.
- The same trend exists when analyzing by the top eight firms or by therapeutic class.
- Advances in biomedical science may have fostered deconcentration in new drug development among existing firms and stimulated new entry.

Ranks of the research-based pharmaceutical industry expanded markedly during the '90s

Number of firms with NCE Approvals in the US

(By parent company at time of approval)



Source: Tufts Center for the Study of Drug Development

- The number of firms with NCE approvals increased 84% from 1970-1979 to 1990-1999.
- Of the 50 firms that had one approval during 1990-1999, 41 of them had their first ever NCE approval in this period.
- On average, pharmaceutical firms obtained more NCE approvals during the 1990s vs. the 1980s.
- While some firms have maintained relatively high levels of innovation over long periods, a firm's success in developing new drugs in one period is no guarantor of its future success.

Substantial diversification across therapeutic categories exists among leading firms

- The number of categories in which a firm has obtained approvals does not necessarily indicate how concentrated its output is in those categories.
- Diversification generally has increased over time.
 - Eleven of 15 leading firms with the most approvals in 1982-1999 had a higher diversification index in 1982-1999 compared to 1963-1980.
 - Twelve of the firms had approvals in more therapeutic categories in 1982-1999 than in 1963-1980, while none had approvals in fewer categories.
- The increased diversification in approvals may be a result of greater diversification in discovery programs.

Top firms are more reliant on internal development than the industry as a whole

- Firms that were dominant within a therapeutic class in terms of total NCE approvals tended to have a relatively large number of the self-originated approvals in the class.
- Of the 691 NCEs approved in the United States from 1963 to 1999, 61.8% were self-originated.
- Eight of the top 11 firms ranked by the number of self-originated NCE approvals were in the top 10 for the total NCE count during the 1963-1999 period.
- The proportion of NCE approvals that were self-originated has declined from 71.6% for NCEs approved from 1963 to 1969 to 60.9% for NCEs approved in the 1990s.

Technical and commercial productivity vary widely across the industry

- Six of 15 leading firms had above average commercial productivity, with the results ranging from 53% below the industry average to 116% above the industry average.
- Five of the 15 firms were above-average technical performers, with performance ranging from 67% below average to 107% above average.
- Differences in clinical success reflect either heterogeneous firm capabilities and performance in drug discovery or the efficiency of clinical development programs.

Technical and Commercial Productivity for Leading Pharmaceutical Firms

Company	Current Success Rate ^a (%)	Predicted Final Success Rate ^b (%)	Technical Productivity Index ^c	Company	Mean Clinical Time (years) ^d	Commercial Productivity Index ^e
A	41.9	49.3	2.07	C	4.18	2.16
B	43.9	43.9	1.76	D	3.52	1.51
C	41.7	41.7	1.75	B	4.34	1.31
D	31.7	31.7	1.42	A	6.01	1.12
E	18.6	23.3	1.02	H	4.00	1.08
F	21.4	21.4	0.90	E	5.52	1.05
G	20.0	22.0	0.85	M	4.86	0.96
H	15.2	16.7	0.83	F	4.64	0.91
I	17.8	19.9	0.80	L	5.46	0.86
J	15.1	16.3	0.72	G	4.32	0.77
K	13.2	13.2	0.63	J	4.36	0.76
L	10.9	13.4	0.62	I	4.25	0.69
M	11.5	13.9	0.53	N	4.40	0.61
N	11.9	11.9	0.48	K	4.69	0.60
O	8.0	8.0	0.33	O	4.01	0.47

Source: Tufts Center for the Study of Drug Development

^a Percent of NCEs with INDs first filed during 1980-1989 that have been approved by the FDA through December 1999.

^b Percent of NCEs with INDs first filed during 1980-1989 that are predicted will ultimately be approved by the FDA. Predictions for NCEs that were still active as of the end of 1999 are estimated from a probit regression.

^c Ratio of the predicted final success rate for a company to the success rate the company would, given the make-up of its portfolio of investigational NCEs by therapeutic class and compound source, be expected to have if it were as technically successful as the industry as a whole.

^d Mean time from first IND filing to either a decision to abandon development or to NDA submission.

^e Ratio of 1998 company pharmaceutical sales per NCE-year (product of the number of NCEs with an IND first filed during 1980-1989 and mean clinical time) to 1998 industry pharmaceutical sales per NCE-year.

The full study on which this Tufts CSDD Impact Report is based—"New Drug Innovation and Pharmaceutical Industry Structure: Trends in the Output of Pharmaceutical Firms" by Joseph A. DiMasi, Ph.D.—will be published in the *Drug Information Journal* (Volume 34, issue 4) and will be available on the Drug Information Association website (www.diahome.org) in November 2000.

About the Tufts Center for the Study of Drug Development

The Tufts Center for the Study of Drug Development, affiliated with Tufts University, provides strategic information to help drug developers, regulators, and policy makers improve the quality and efficiency of pharmaceutical development, review, and utilization. The Tufts Center conducts a wide range of in-depth analyses on pharmaceutical issues and, in addition, hosts symposia, workshops, and public forums on related topics throughout the year.

Tufts Center for the Study of Drug Development
Tufts University
192 South Street, Suite 550
Boston, MA 02111 USA

Tel 617-636-2170

Fax 617-636-2425

Email tufts_csdd@infonet.tufts.edu

Web <http://www.tufts.edu/med/research/csdd>

© 2000 Tufts Center for the Study of Drug Development. All rights reserved.