

CONGRESS OF THE UNITED STATES
CONGRESSIONAL BUDGET OFFICE

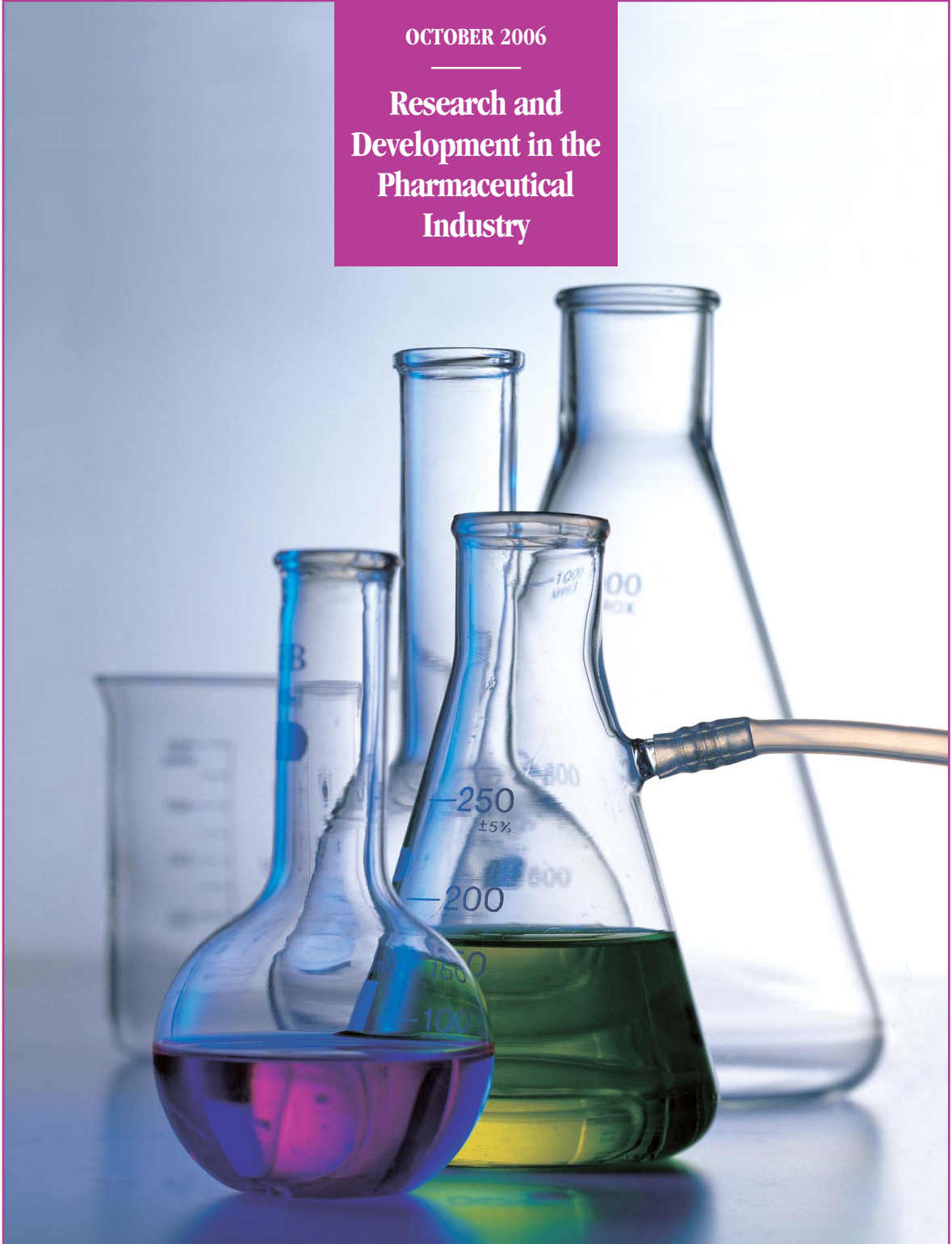
A

CBO

STUDY

OCTOBER 2006

Research and
Development in the
Pharmaceutical
Industry

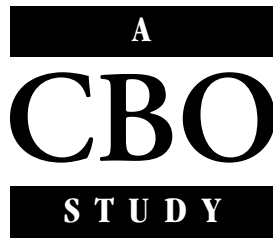


© Unistad Images, Inc.

DOCKET
ALARM

Find authenticated court documents without watermarks at docketalarm.com.

Pub. No. 2589



Research and Development in the Pharmaceutical Industry

October 2006

The Congress of the United States ■ Congressional Budget Office



Preface

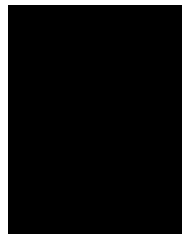
Perceptions that the pace of new-drug development has slowed and that the pharmaceutical industry is highly profitable have sparked concerns that significant problems loom for future drug development. This Congressional Budget Office (CBO) study—prepared at the request of the Senate Majority Leader—reviews basic facts about the drug industry’s recent spending on research and development (R&D) and its output of new drugs. The study also examines issues relating to the costs of R&D, the federal government’s role in pharmaceutical research, the performance of the pharmaceutical industry in developing innovative drugs, and the role of expected profits in private firms’ decisions about investing in drug R&D. In keeping with CBO’s mandate to provide objective, impartial analysis, the study makes no recommendations.

David H. Austin prepared this report under the supervision of Joseph Kile and David Moore. Colin Baker provided valuable consultation. Jim Baumgardner, Anna Cook, Doug Hamilton, and Dennis Zimmerman of CBO provided comments, as did Iain Cockburn of Boston University, Mark Duggan of the University of Maryland, and Judith Wagner of the Institute of Medicine. (The assistance of external reviewers implies no responsibility for the final product, which rests solely with CBO.)

Christian Howlett edited the study, and Kate Kelly proofread it. Angela Z. McCollough prepared drafts of the manuscript. Maureen Costantino prepared the report for publication, with assistance from Allan Keaton, and designed the cover. Lenny Skutnik printed the initial copies, and Simone Thomas prepared the electronic version for CBO’s Web site (www.cbo.gov).

Donald B. Marron
Acting Director

October 2006



Contents

1	Introduction and Summary 1
	The Cost of Developing a New Drug 1
	The Role of Federal Research and Development 2
	Assessing the Drug Industry's R&D Performance 3
	The Drug Industry's Profits and R&D Investment 4
2	Trends in R&D Spending and Output of New Drugs 7
	Spending for Research and Development 7
	R&D Intensity 9
	Output of Innovative New Drugs 11
	Leading Therapeutic Classes 12
	Modifications and Approved New Uses of Drugs 14
3	What Does It Cost to Develop a New Drug? 19
	Primary Determinants of R&D Costs 19
	Why Have R&D Costs Risen for Innovative New Drugs? 21
4	Does Federal R&D Spending Stimulate or Substitute for Private-Sector Spending? 27
	Public and Private R&D Spending 27
	Does Government R&D Crowd Out Private R&D? 29
	A Changing Role for Public-Sector Research 33
5	Has the Drug Industry's Innovative Performance Declined? 35
	Recent Innovative Performance 35
	Did Changes in the Size of Drug Companies Affect Research Productivity? 39

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.